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WHEN: Tuesday, February 7, 2006
9:00 a.m.–Noon

WHERE: Office of the Federal Register
Conference Room, Suite 700
800 North Capitol Street, NW.
Washington, DC 20002

RESERVATIONS: (202) 741–6008

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CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

Rules and Regulations

Federal Register
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Friday, January 27, 2006

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Parts 301, 305, 318, and 319

[Docket No. 03–077–2]

Treatments for Fruits and Vegetables

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations by revising the approved doses for irradiation treatment of imported fruits and vegetables. This rule will establish a new minimum generic dose of irradiation for most plant pests of the class *Insecta*, establish a new minimum generic dose for the fruit fly family, reduce the minimum dose of irradiation for some specific fruit fly species, add 10 pests to the list of pests for which irradiation is an approved treatment at less than the generic dose, and provide for the use of irradiation as a treatment for cut flowers and foliage. These actions will allow the use of irradiation to neutralize more pests and to neutralize some pests at lower doses. Furthermore, we are providing for the irradiation of fruits and vegetables moved interstate from Hawaii at the pest-specific irradiation doses that are now approved for imported fruits and vegetables. We are also providing for the use of irradiation to treat fruits and vegetables moved interstate from Puerto Rico and the U.S. Virgin Islands. These actions will allow irradiation to serve as an alternative to other approved treatments for additional commodities moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. Finally, we are adding irradiation as a treatment for bananas from Hawaii and adding vapor-heat treatment as an optional treatment for sweetpotatoes from Hawaii. These actions will provide an alternative to the currently approved treatments for those commodities while continuing to provide protection against the spread of plant pests from Hawaii into the continental United States.

EFFECTIVE DATE: February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Dr. Inder P.S. Gadh, Senior Risk Manager, Commodity Import Analysis & Operations, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236; (301) 734–8758.

SUPPLEMENTARY INFORMATION:

Background

The phytosanitary treatments regulations contained in 7 CFR part 305 set out standards and schedules for treatments required in 7 CFR parts 301, 318, and 319 for fruits, vegetables, and other articles to prevent the introduction or dissemination of plant pests or noxious weeds into or through the United States. Within 7 CFR part 305, the irradiation treatments subpart (§§ 305.31 through 305.34, referred to below as the regulations) sets out standards and minimum doses for irradiation treatment for imported fruits and vegetables and for regulated articles moved interstate from quarantined areas within the United States, along with other requirements for performing irradiation treatments.

On June 10, 2005, we published in the **Federal Register** (70 FR 33857–33873, Docket No. 03–077–1) a proposal to amend the regulations by making several amendments to the irradiation treatment regulations for imported fruits and vegetables, for fruits and vegetables moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands, and for regulated articles moved interstate from areas quarantined for Mexican fruit fly or Mediterranean fruit fly. We also proposed to provide for the use of irradiation treatment for bananas moved interstate from Hawaii and to provide for the use of a vapor heat treatment for sweetpotatoes moved interstate from Hawaii.

On June 20, 2005, the **Federal Register** published a correction (70 FR 35500) to the table in § 305.31(a) of our proposal in which the generic dose for all pests of the phylum *Arthropoda*, excluding adults and pupae of the order *Lepidoptera*, was corrected to read 400 gray.

We solicited comments concerning our proposal for 60 days ending August 9, 2005. We received 13 comments by that date. They were from producers, researchers, representatives of State and foreign agricultural departments, an international industry organization, a public interest organization, and a private citizen. The comments are discussed below by topic.

Issue Outside the Scope of APHIS' Authority

One commenter raised an issue that concerns a matter under the regulatory authority of the Food and Drug Administration (FDA), not the Animal and Plant Health Inspection Service (APHIS). Specifically, the commenter expressed concern that irradiation will make foods unsafe to eat. The commenter stated that irradiation produced 2-alkylcyclobutanones, which she contended is a dangerous residue chemical present in irradiated fruits and vegetables.

The FDA has primary regulatory responsibility for ensuring that approved irradiation doses do not render foods unsafe to eat. FDA regulations (21 CFR 179.26) establish a limit of 1.0 kilogray for disinfestation of arthropod pests in fresh fruits and vegetables. All of the irradiation doses contained in this rule are significantly less than this approved safe dose limit.

Use of Irradiation to Treat Cut Flowers and Foliage

One commenter requested that we also provide for the use of irradiation to treat cut flowers and foliage that are subject to treatment requirements in the regulations.

We agree that cut flowers and foliage that are hosts of pests for which irradiation is an approved treatment can be treated at the pest-specific doses provided in this final rule. Therefore, in this final rule we have amended the phytosanitary treatment regulations as well as the Hawaiian and territorial quarantine regulations to provide for the use of irradiation to treat cut flowers and foliage. Specifically, we have amended paragraph (a) of § 305.31 to provide that irradiation at the pest-specific doses may be used to treat cut flowers and foliage. We have also amended § 305.31 by replacing the words ''fruits and vegetables'' with the word ''article'' each time they occur. Sections 305.34, 318.13–4f, and 318.58–4b provide administrative instructions for irradiation treatment of certain fruits

and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands, respectively. We have amended these sections by replacing the words ''fruits and vegetables'' with the word ''article'' each time they occur. Finally, we have amended the cut flowers regulations in § 319.74–2 by adding a new paragraph (d) to indicate that cut flowers may be treated at the pest-specific irradiation doses listed in § 305.31(a). Cut flowers and foliage are also subject to the packaging requirements provided in §§ 305.31 and 305.34 of the regulations.

Irradiation may have negative effects on the quality of cut flowers, and the shipper and facility operator are responsible for determining tolerance of cut flowers to treatment. APHIS assumes no responsibility for any loss or damage that may result in the use of irradiation.

Use of Irradiation To Control Pests

Two commenters objected to the use of irradiation to treat imported fruits and vegetables. One commenter stated that food in the United States has been altered so much that it has become inferior to food in Europe. A second commenter stated that APHIS should not employ irradiation as a treatment but should instead use other treatments and procedures to prevent the introduction of dangerous plant pests associated with imported fruits and vegetables. This second commenter added that irradiation has not been shown to be a safe, effective, or viable means to eradicate invasive pests and that the U.S. Department of Agriculture should cease pursuing irradiation as a treatment for plant pests.

We have not made any changes to the rule in response to these comments. Importers are free to choose other treatments authorized by the regulations in lieu of irradiation. The reason that irradiation may be attractive to certain importers, particularly those importing fresh tropical fruits from fruit fly-infested regions, is that irradiation allows fruits of higher quality to be imported. Alternative heat, cold, and fumigation treatments can cause unacceptable phytotoxicity (damage to the fruits). Also, these alternative treatments often must be used on fruit harvested before it is fully ripe. The irradiation alternative allows importers to sell riper, more valuable fruit, with less damage.

In authorizing irradiation treatments, we have considered both the efficacy and the environmental effects of irradiation compared to other treatments already authorized by our regulations. The irradiation treatments in the final rule are effective against the listed plant pests. It is true that several technologies under development may also provide effective treatments for various plant pests (*e.g.*, pressure treatments, controlled atmosphere, and laser ultraviolet light pulses). To date, we have not seen conclusive scientific documentation that establishes standard methodologies for these treatments, or that demonstrates that these treatments effectively control pests of concern in fruits and vegetables subject to APHIS regulations. APHIS is always willing to evaluate petitions to add new treatments to our import regulations. Petitioners should submit a detailed description of the methodology and standards of the treatment to be evaluated, and should include any scientific studies that document the effectiveness of the treatment and related issues (*e.g.*, quality effects on treated articles).

One commenter stated that the proposed rule could stimulate the construction of more irradiation facilities, some of which could use radioactive cobalt-60 or cesium-137, which Federal regulations permit. The commenter stated that these facilities will pose serious risks to the communities where they are built.

We are not making any changes in response to this comment. The safety of operations of irradiation facilities is regulated by the Nuclear Regulatory Commission (NRC). NRC ensures that such facilities are built and operated according to Federal regulations. To be licensed, the facility must have been designed with multiple fail-safe measures, and must establish extensive and well-documented safety procedures and worker training. With proper design and operating procedures, commercial irradiation facilities can be operated safely and without posing any significant radiation risk to workers or the public.

Recommended Doses

One commenter presented two studies [1] which demonstrated that Mexican fruit fly (Mexfly) is more radiotolerant than West Indian fruit fly, but noted that we proposed an irradiation dose of 100 Gy for West Indian fruit fly and only 70 Gy for Mexfly. The commenter recommended lowering the dose for West Indian fruit fly to 70 Gy.

We have reviewed the research submitted by the commenter and agree that the dose for West Indian fruit fly (*Anastrepha obliqua*) should be lowered to 70 Gy and have done so in this final rule.

Two commenters stated that it was unnecessary to list green scale in the pest table in § 305.31 because it requires the generic dose (400 Gy). One commenter noted that this implied that 400 Gy was the lowest possible dose that can control green scale. The second commenter added that there has been no large-scale research done on this dose, but that preliminary research at the University of Hawaii suggested 250 Gy would control green scale.

We agree with these commenters and have amended the table in § 305.31(a) by removing the entry for *Coccus viridis*, green scale.

One commenter recommended adding a statement in the final rule that lower irradiation doses might be sufficient for the plant pests being added in this rule in order to encourage more research on minimum irradiation levels.

We are not making any changes as a result of this comment. As stated previously in this document, APHIS is always willing to evaluate research that supports new treatments or changes to existing treatments such as lowering the required doses for irradiation. Petitioners should submit any scientific studies that document the effectiveness of the dose, and APHIS will consider each request as it is presented.

One commenter recommended rounding irradiation doses to the nearest 10 Gy increment because dosimeters can vary by 1 to 2 percent in their accuracy. The commenter added that it is difficult during research to accurately apply doses in less than 10 Gy increments due to variability in the density and consistency of the infested fruit or vegetable.

We are not making any changes in response to this comment. We believe that the measures we have in place to monitor and administer irradiation treatment will ensure that at least the appropriate minimum dose is administered. When applying irradiation treatment, several factors are taken into account, including geometry of the source, the dimensions of the irradiation container, as well as the bulk-density of the load and its distribution. Recording of process parameters and dosimetry is required to ensure that the treatments applied are within the limits established by APHIS. Further, the available data indicate that the doses we proposed are the lowest

[1] Bustos, M.E., Enkerlin, W., Reyes, J., and Toledo, J. 2004. Irradiation of mangoes as a postharvest quarantine treatment for fruit flies (Diptera: Tephritidae). J. Econ. Entomol. 97: 286–292.

Hallman, G.J. and Worley, J.W. 1999. Gamma radiation doses to prevent adult emergence from immatures of Mexican and West Indian fruit flies (Diptera: Tephritidae). J. Econ. Entomol. 92: 967–973.

effective doses necessary to achieve phytosanitary security; thus, rounding a dose up to the nearest 10 Gy increment would have the effect of requiring more than the minimum dose and would be contrary to our World Trade Organization (WTO) agreements.

Safeguards on Commodity Movement

Two commenters noted that we should put in place safeguards, such as sealed containers, against plant pest spread for untreated commodities that are moved to the mainland United States for treatment. One of the commenters suggested prohibiting movement of untreated commodities with pretreated commodities and adding protocols for transport and containment upon arrival.

Section 305.34 of the regulations sets forth instructions for fruits and vegetables shipped from Hawaii to the mainland United States, including safeguards for untreated commodities being shipped to the mainland United States for treatment. For imported fruits and vegetables, § 305.31, paragraph (g)(1) prohibits packaging irradiated fruits and vegetables with nonirradiated fruits and vegetables and paragraph (g)(2) provides packaging provisions for fruits and vegetables irradiated prior to entering the United States to prevent the entry of fruit flies. However, § 305.31 does not contain packaging provisions for imported fruits and vegetables to be irradiated upon arrival in the United States. Therefore, we are amending § 305.31(g) in this final rule by adding a new paragraph that requires cartons of untreated regulated articles being imported into the United States for treatment to be shipped in shipping containers sealed prior to importation with seals that will visually indicate if the shipping containers have been opened. These provisions we have added regarding imported articles mirror those in § 305.34 for untreated articles moved from Hawaii to the mainland United States for treatment.

Bananas from Hawaii

One commenter stated that the configuration of bananas on the stalk make visual inspections an ineffective detection method. The commenter added that the lethal dose for banana moth should be determined before including this commodity in the regulations.

We have determined that the generic dose of 400 Gy would be sufficient for banana moth larvae; however inspection is necessary for pupae and adults of this pest. Bananas may also undergo irradiation treatment at a dose of 150 Gy for fruit flies, which would require inspection for banana moth and green scale as an additional mitigation measure. We agree with this commenter that the configuration of bananas on the stalk makes visual inspection more difficult. Therefore, we have amended § 318.13–4i, paragraphs (b)(1) and (b)(2), in this final rule to specify that bananas must be removed from the stalk during inspection.

One commenter suggested that we allow green bananas from Hawaii grown under the systems approach to be irradiated at 400 Gy if found to be infested with green scale or to have certain defects that would otherwise trigger rejection upon inspection.

We agree with this commenter and have amended § 318.13–4i in this final rule by revising paragraph (b), introductory text, to state that ''Bananas of any cultivar or ripeness that do not meet the conditions of paragraph (a) of this section may also be moved interstate from Hawaii with irradiation in accordance with the following conditions.''

Sweetpotatoes

One commenter questioned whether early stages of Kona coffee root-knot nematode could be found by visual inspection.

We have found inspection to be very effective at detecting nematodes of all stages.

One commenter suggested that the regulations should provide that the required probes be placed in the largest roots when applying heat treatment to sweetpotatoes.

We agree that inspectors should locate temperature probes in the largest potatoes when applying heat treatment. Therefore, we have amended § 305.24(k)(1) in this final rule to provide that temperature probes must be placed in the approximate center of the ''largest individual sweetpotato roots.''

One commenter stated that recent research [2] indicates that sweetpotato weevil, West Indian sweetpotato weevil, and sweetpotato vine borer can all be neutralized with a dose of 150 Gy. The commenter asked that we add West Indian sweetpotato weevil and sweetpotato vine borer with a dose of 150 Gy and that we change the dose for sweetpotato weevil to 150 Gy.

After reviewing the research provided by the commenter, we have amended the table in § 305.31(a) in this final rule by adding entries for West Indian sweetpotato weevil and sweetpotato vine borer and specifying a minimum irradiation dose of 150 Gy for both pests. We have also reduced the minimum irradiation dose for sweetpotato weevil from 165 Gy to 150 Gy.

With these changes, all but one of the pests of concern for sweetpotatoes from Hawaii for which irradiation is an authorized treatment may be treated with a minimum irradiation dose of 150 Gy. The exception is the ginger weevil (*Elytrotreinus subtruncatus*), which requires a minimum irradiation dose of 400 Gy. (The regulations also require inspection for two other pests for which irradiation is not an authorized treatment, *i.e.*, the gray pineapple mealybug [*Dysmicoccus neobrevipes*] and the Kona coffee-root knot nematode [*Meloidogyne konaensis*]). In the proposed rule, we proposed to add a vapor heat treatment option for sweetpotato from Hawaii that included provisions for the sampling, cutting, and inspection of sweetpotatoes for the ginger weevil, and we are adopting those proposed provisions in this final rule (see § 318.13–4d in the regulatory text at the end of this document). To harmonize the irradiation treatment provisions for sweetpotatoes from Hawaii with those new vapor heat provisions, we have amended the regulations in § 305.34 in this final rule to offer two irradiation treatment options: The existing 400 Gy dose or a 150 Gy dose supplemented by sampling, cutting, and inspection for the ginger weevil, with the sampling, cutting, and inspection requirements being the same as those found in the vapor heat provisions in § 318.13–4d. The inspection requirements for the gray pineapple mealybug and the Kona root-knot nematode will continue to apply to sweetpotatoes treated at both the 400 Gy and 150 Gy dose. To effect this change, we have amended § 305.34(b)(7)(i) and (ii) in this final rule to reflect the new inspection requirement for ginger weevil if sweetpotatoes are to be irradiated at 150 Gy; a new footnote in the entry for sweetpotato in the table in paragraph (a)(1) of that section directs the reader to § 305.34(b)(7)(i) and (ii). Because litchi from Hawaii is also subject to additional inspection requirements in § 305.34(b)(7), the entry for litchi in the table has also been annotated with a reference to that footnote.

Pineapples From Hawaii

One commenter asked that we delete the reference to ''other than smooth Cayenne'' in the entry for pineapples in § 305.34, paragraph (a)(1). The commenter noted that this would allow

[2] Follett, Peter A. Irradiation for postharvest control of Omphisa anastomosalis (Lepidoptera: Pyralidae), Euscepes postfaciatus and Cylas formicarius elegantulus (Coleoptera: Curculionidae) in sweetpotatoes.

all varieties of pineapple to be treated by irradiation for plant pests in accordance with § 305.31(a) and § 305.34(a)(2).

The commenter is correct. We mistakenly included the reference to ''other than smooth Cayenne'' when in fact, all varieties of pineapple are eligible for irradiation. We have amended the entries for pineapple in § 305.34(a)(1) and § 318.13–4f by removing the words ''(other than smooth Cayenne).''

General Comments

In the supplementary information of our proposed rule, we stated that mites are not arthropod plant pests. Two commenters noted that mites are arthropod plant pests and that we should not use the term ''arthropod.''

We agree with the commenters have amended the last row in the table in § 305.31 by changing the words ''phylum *Arthropoda*'' to ''class *Insecta*.''

One commenter suggested that we should explain to inspectors what they can expect to find with properly irradiated commodities (*e.g.*, live fruit flies and perhaps eggs, but no further development from either).

Customs and Border Protection and APHIS inspectors are trained as to what they might specifically find in commodities treated by irradiation and have been inspecting irradiated fruit moved interstate for more than a decade. Therefore, it is unnecessary to include such information in this final rule.

One commenter suggested that we include a provision to prohibit irradiation of low-oxygen-stored produce until research on the effectiveness of irradiation on such produce can be completed. The commenter stated that a recent study showed that four pests showed an increase in radiotolerance when stored in such conditions.

We have no evidence to either support or refute the commenter's concern with the response of pests in low-oxygen-stored produce to irradiation, but agree that irradiation should be only applied to articles that have been stored under certain conditions. Because these conditions may vary based on the specific commodity, pest of concern, or country of origin, we will address specific storage conditions in the operational work plan or the compliance agreement with plant health officials in the areas where commodities are produced, packed, and treated.

One commenter stated that we incorrectly classified the dose ranges for plant pests in the International Plant Protection Convention Guidelines for the Use of Irradiation as a Phytosanitary Measure (ISPM Publication No. 18) as recommended minimum dose ranges. The commenter stated that these doses are only estimates.

We acknowledge that we incorrectly characterized the estimates as recommended minimum doses. That statement appeared in the supplementary information of the proposed rule, however, so there is no need to make any changes to the regulations in this document.

Two commenters stated that research did not demonstrate that all fruit flies of the family *Tephritidae* would be neutralized by a dose of 150 gray.

The commenters are correct in that, technically, all fruit flies of the family *Tephritidae* were not tested, but all of the fruit flies that were tested in this family were neutralized by this dose. Therefore, we consider the results from the fruit flies we tested to be applicable to the entire *Tephritidae* family. However, we agree that it would have been clearer to state that ''we consider all fruit flies of the family *Tephritidae* to be neutralized by a dose of 150 gray.''

In the supplementary information of the proposed rule, we stated that required irradiation doses were specific to plant pests rather than to the commodities with which they are associated, which reflects the fact that the effectiveness of irradiation treatment is dependent on the dose that is absorbed by the commodity. One commenter considered this statement misleading, noting that it suggests that the radiation is absorbed by the commodity thereby killing the insect. The commenter added that the doses are specific to the pest rather than commodity because the commodity provides limited shielding for the insect from the ionizing radiation.

We agree with this commenter, but because this statement appeared in the supplementary information of the proposed rule, there is no need to make any changes to the regulations in this document.

In the proposed rule, we referred to minimum doses as ''pest-specific.'' One commenter suggested that we use either ''pest species-specific'' or ''individual pest-specific.''

We are not making changes in response to this comment. We prefer the general term ''pest-specific'' which can apply to both individual pests or a pest group (*e.g.*, all fruit flies).

In the proposed rule, we stated that fruit quality problems associated with high irradiation doses prompted us to examine lowering doses. One commenter noted that we made no mention of any financial considerations taken into account.

While economic benefits result from our lowering of irradiation doses, they are not the reason for our doing so. Under WTO agreements, we are obliged to base our regulations on sound science; to ignore research that showed lower irradiation doses to be effective would be contrary to these agreements.

One commenter stated that the proposed rule would open up large parts of the United States to increased risks of infestation. The commenter stated that our reasoning that fruit flies would not survive irradiation treatment or weather conditions in many areas of the United States was faulty. The commenter added that while the rule only applies to 12 species of fruit flies, there are numerous hosts in the United States that would be susceptible to those fruit flies.

We agree that preventing the introduction of exotic fruit flies into the United States is of the utmost importance. According to ARS, 150 Gy will be sufficient to neutralize all fruit flies and that doses lower than 150 gray are sufficient to neutralize certain species of fruit flies. We believe that treatment of fruits, vegetables, cut flowers, and foliage at these doses, when properly administered, will be sufficient to prevent the introduction of fruit flies via commodities treated by irradiation.

Economic Analysis

One commenter suggested that our economic analysis should take note of some advantages to irradiation, such as the fact that fruit that is to be irradiated can be allowed to ripen longer on the tree, resulting in higher-quality fruit.

We have added a paragraph highlighting additional advantages of irradiation over some other treatments to the economic analysis in this final rule.

One commenter stated that it is naive to assume that there are markets for irradiated fruits and vegetables in the United States. The commenter noted that since the FDA legalized the irradiation of fruits and vegetables in 1986, very few types of irradiated produce have been sold in U.S. grocery stores. The commenter also cited the financial troubles of a company that stood to benefit from irradiation as an example of the lack of a market for irradiated fruit in the United States.

The proposed rule and this final rule are concerned with the phytosanitary security of fruits and vegetables and not their marketing. Our regulations offer various treatment options; whether or

not producers or distributors choose to use irradiation when it is available is up to them.

Miscellaneous

Two commenters pointed out several nonsubstantive editorial errors in the proposed rule. We appreciate the commenters bringing these errors to our attention and wherever appropriate, have made the corrections in this document.

Other Comments

One commenter suggested that in light of the availability of the generic irradiation dose, we reconsider our current pest risk analysis process and require evidence only that the few target pests that could not be treated effectively with irradiation are not present in a particular country or are not pests of concern for a particular commodity, rather than requiring that a list all possible pests be considered in the pest risk analysis.

We agree with this commenter that the availability of the generic irradiation dose may simplify the pest risk analysis process for commodities from countries where pests that can be targeted with the generic dose exist. We expect that a pest list would still have to assembled in most cases, but the risk management aspect of the risk analysis process could be abbreviated if the risks associated with all identified quarantine pests could be addressed through the application of the generic irradiation dose. If quarantine pests that could not be addressed using the generic dose were identified in the pest list, then the risk management analysis could be limited to examining mitigation measures for those pests alone.

The commenter also requested that we reconsider the requirement that every new commodity must be added to the regulations through rulemaking before being eligible for entry into the United States.

While we are unable to make any changes in this document in response to this comment, we are currently developing a proposed rule that would redesign the fruits and vegetables regulations to provide for the evaluation and approval or denial of new import requests in a more expeditious and effective manner.

One commenter asked that we postpone the comment period for the proposed rule because a request submitted by her organization under the Freedom of Information Act (FOIA) regarding another rulemaking related to irradiation had not yet been fulfilled.

We do not believe it is necessary or appropriate to delay this final rule pending the resolution of commenter's FOIA request concerning an entirely separate rulemaking. The APHIS FOIA staff is working to address the request referred to by the commenter.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review under Executive Order 12866.

This rule makes several amendments to the current provisions for the use of irradiation as a treatment for various plant pests, allows the use of irradiation and inspection as a treatment for bananas moved interstate from Hawaii as an alternative to the systems approach currently described in the regulations, and allows the use of a vapor heat treatment for sweetpotatoes moved interstate from Hawaii as an alternative to fumigation with methyl bromide and irradiation. The potential economic impacts of the changes are discussed below.

Irradiation Treatment for Fruits, Vegetables, Cut Flowers, and Foliage

The regulations in § 305.31 set out standards, minimum doses, and other requirements for performing irradiation treatments on imported fruits, vegetables, cut flowers, and foliage and set out minimum doses necessary to neutralize 11 fruit flies and the mango seed weevil. This rule adds minimum doses for more pests and lowers the minimum doses for others. Specifically, this rule establishes:

- A minimum generic dose of 400 Gy for all plant pests of the class *Insecta* other than pupae and adults of the order Lepidoptera;
- A minimum generic dose of 150 Gy for all fruit flies of the family *Tephritidae*;
- Lower minimum doses for certain fruit flies; and
- New approved minimum doses for 10 plant pests.

This rule also allows irradiation to serve as an alternative to other approved treatments for additional articles moved interstate from Hawaii, Puerto Rico, and the U.S. Virgin Islands. Articles from Hawaii, Puerto Rico, and the U.S. Virgin Islands that are required to be treated by other means for pests listed in § 305.31(a) prior to interstate movement will be allowed to be moved interstate if they are treated with irradiation at the doses listed in § 305.31(a) and in accordance with the other conditions specified in § 305.34.

Section 305.34 has only provided for irradiation treatment of fruits and vegetables from Hawaii; however, we have determined that irradiation treatment can be used effectively for commodities from Puerto Rico and the U.S. Virgin Islands if the safeguards in § 305.34 are implemented. Currently, no irradiation facilities exist in Puerto Rico or the U.S. Virgin Islands, and no requests have been received to approve the construction of such facilities. However, this rule provides for the option of moving the commodities under limited permit to an irradiation facility on the U.S. mainland for treatment prior to entering interstate commerce.

Economic Effects on Small Entities of Changes in Irradiation Treatment Provisions

The Regulatory Flexibility Act requires that agencies specifically consider the economic impact of their regulations on small entities. The Small Business Administration (SBA) has established size criteria using the North American Industry Classification System (NAICS) to determine which economic entities meet the definition of a small firm.

Irradiation facilities affected by this rule will belong to one of the following two NAICS categories: (1) Firms providing irradiation services for the treatment of fruits and vegetables, which would fall within NAICS category 115114, ''Postharvest Crop Activities (except Cotton Ginning)''; or (2) firms providing irradiation services for decontamination or sterilization purposes, which would fall within NAICS category 811219, ''Medical and surgical equipment repair and maintenance services.''

Most treatments of Hawaiian produce are likely to occur at an existing irradiation facility on the island of Hawaii. This facility is used to treat other fruits and vegetables for which irradiation is an approved treatment and can be classified under NAICS category 115114. The SBA criteria classify this facility as a small entity, since its annual sales are less than $6 million.

Another firm on the U.S. mainland operates two facilities in Illinois and one facility in New Jersey. Its primary service is to provide irradiation treatment for the sanitation of medical devices on contract. This firm is classified within NAICS category 811219. However, since it is part of a larger corporation for which annual receipts may exceed $6 million, this

firm is not classified as a small entity under the SBA criteria. Thus, at least one firm that could be affected by this rule is a small entity.

Irradiation facilities, whether large or small, will benefit from this rule. The range of commodities imported and moved interstate for which irradiation will be an approved treatment will increase. At the same time, dosage levels, and therefore operating costs, will decrease for many commodities. The changes to irradiation doses and provisions allowing the use of pest-specific doses to treat commodities for interstate movement will facilitate the importation of fruits, vegetables, cut flowers, and foliage and their interstate movement from Hawaii, Puerto Rico, and the U.S. Virgin Islands. For certain pests for which irradiation is already an approved treatment, required irradiation dosages will be lowered to the minimum level necessary. In other instances, irradiation will be newly allowed as an alternative phytosanitary treatment.

This rule will result in lower costs and increased flexibility for importers, gains that could be expected to be at least partly realized by U.S. consumers through lower prices, assuming competitive markets. For some commodities, irradiation may also provide quality advantages over other treatment methods in terms of increased shelf life. Irradiation allows fruits and vegetables of higher quality to be imported. Alternative heat, cold, and fumigation treatments can cause unacceptable damage to fruits, vegetables, cut flowers, and foliage. At this time, we are unsure as to the extent of damage the use of irradiation may cause to certain cut flowers and it is entirely the importer's or owner's responsibility to assess which treatment should be used with each variety of cut flowers. Also, these alternative treatments often must be used on fruit harvested before it is fully ripe. Irradiation allows importers to sell riper, more valuable fruit, with less damage. Choice of irradiation as a treatment alternative would rest upon its expected net returns relative to other treatment methods.

Because these changes will have the potential to affect the importation or interstate movement of a wide range of commodities, it is difficult to predict exactly what economic effects these changes will have. However, while affected irradiation firms, large and small, are expected to benefit, we do not expect the impacts to be significant.

Irradiation and Inspection for Bananas Moved Interstate from Hawaii

The regulations in § 318.13–4i have provided that green bananas (*Musa* spp.) of the cultivars ''Williams,'' ''Valery,'' ''Grand Nain,'' and standard dwarf ''Brazilian'' may be moved interstate from Hawaii under a systems approach. At this time, only green bananas of these specified cultivars have been eligible for interstate movement under those provisions.

We are adding two combinations of irradiation and inspection as treatments for bananas from Hawaii. Specifically, bananas, regardless of cultivar or ripeness, from Hawaii will be eligible for interstate movement if they have been inspected in Hawaii for adults and pupal stages of the banana moth *Opogona sacchari* (Bojen), and have undergone irradiation treatment with a minimum dose of 400 gray at an approved facility. Bananas from Hawaii will also be eligible for interstate movement if they have been inspected in Hawaii for the banana moth and the green scale, *Coccus viridis* (Green), and have undergone irradiation treatment with a minimum dose of 150 gray at an approved facility.

Cost of Irradiation Treatment

The cost of irradiation is estimated at 15 cents per pound.[3] We expect that most bananas moved interstate from Hawaii under this approach will be treated at the existing commercial irradiation facility on the island of Hawaii. However, the treatment could be performed at the irradiation facilities on the mainland United States as well.

Cost of APHIS Inspection

Monitoring of quarantine treatments conducted during standard business hours (weekdays between 8 a.m. and 4:30 p.m.) on the island of Hawaii comes at no cost to the facility. APHIS charges for the monitoring of treatments conducted before 8 a.m. and after 4:30 p.m. and on weekends at a time-and-a-half rate.

Benefits

The combination of irradiation treatment and inspection will offer an alternative to the systems approach for green fruit of the specified four banana cultivars, and will allow fruit of any ripeness or cultivar to be moved interstate from Hawaii. The approach described in this rule can be used to mitigate the pest risk associated with all Hawaiian bananas, regardless of cultivar or ripeness. This will allow banana producers and parties moving bananas interstate greater flexibility in operations, more choices with regard to the types of bananas moved interstate, a greater volume of bananas to ship, and less risk of facing rejections during inspection under the systems approach and Banana Compliance Agreement.

Growers have been reluctant to ship bananas to U.S. mainland markets under the systems approach because § 318.13–4i(c) of the regulations has required that bananas to be moved interstate be inspected by an inspector and found free of the following defects: Prematurely ripe fingers, fused fingers, or exposed flesh (not including fresh cuts made during the packing process). Bananas moved interstate from Hawaii under this systems approach are required to be free of these defects because they are conducive to fruit fly infestation. However, growers are concerned about the risk of having whole shipments of fruit prohibited from interstate movement as a result of a single fault detected when bananas in a random selection of boxes are inspected. No commercial container shipments of bananas have been made to U.S. mainland markets under the regulations in effect prior to this rule. Since the irradiation treatment options provided by this rule are sufficient to neutralize fruit flies and other pests of concern, irradiation will provide the Hawaiian banana industry with an alternative treatment for interstate movement and could open new marketing opportunities.

U.S. consumers will benefit from an increased supply of bananas. Growers in Hawaii believe that the U.S. mainland demand for bananas from Hawaii may be equivalent to (if not higher than) the existing demand for Hawaiian papaya. Hawaiian growers moved approximately 12 million pounds of papayas to U.S. mainland markets in 2003.[4] Demand may be especially high for the apple banana variety, which has a higher sugar content and more aromatic flavor than the standard commercial banana varieties currently available in U.S. mainland markets. Consumers will benefit from the availability of this specialty product.

Hawaii accounts for almost all U.S. banana production.[5] In 2002, there were 677 banana farms in Hawaii,[6] and the value of sales amounted to $ 8.6

[3] Source: Hawaii Department of Agriculture.

[4] Source: Hawaii Department of Agriculture.

[5] The Census of Agriculture (2002) reports minimal acreage in California, Florida, and Texas, which together account for only 131 acres.

[6] National Agricultural Statistics Service, 2002 Census of Agriculture.

million.[7] Table 1 summarizes production information for bananas and papayas in Hawaii. The utilized production of bananas amounted to 19.5 million pounds in 2002.

TABLE 1.—PRODUCTION STATISTICS FOR BANANAS AND PAPAYAS IN HAWAII (2002)

Item	Bananas	Papayas
Bearing acreage (acres)	1,300	1,720.
Utilized production (1,000 pounds)	19,500	45,900.
Price (per pound)	$0.430	$0.260.
Value of utilized production	$8.385 million	$11.924 million.
Movement to mainland U.S. markets (1,000 pounds)	None	12,000.

Sources: Hawaii Department of Agriculture (movement statistics) and National Agricultural Statistics Service.

The United States imported 7,883 million pounds (3,576 million kg) of fresh bananas in 2003, valued at $959 million.[8] Ecuador, Costa Rica, Guatemala, Colombia, and Honduras accounted for 97 percent of the quantity of imports (table 2). Compared to the 7,883 million pounds of bananas currently imported, Hawaii's total production of 20 million pounds is extremely small, and it is not likely that 100 percent of the State's production will be moved to the mainland United States. Thus, as long as phytosanitary mitigation by means of the approved treatments is maintained, the interstate movement of bananas from Hawaii is unlikely to significantly affect current U.S. trade in fresh bananas.

TABLE 2.—QUANTITY AND VALUE OF FRESH BANANAS IMPORTED INTO THE UNITED STATES FROM THE FIVE MAJOR EXPORTING COUNTRIES (2003)

Country	Quantity (million kg)	Value (million U.S. dollars)
Ecuador	902	237.8
Costa Rica	901	247.5
Guatemala	868	229.1
Colombia	429	117.7
Honduras	388	100.4
Total imports	3,576	959.3

Source: World Trade Atlas (2003).

Economic Effects on Small Entities of Irradiation and Inspection Provisions for Bananas

Most treatments of Hawaiian bananas are likely to occur at the existing irradiation facility on the island of Hawaii, which, as noted previously, is considered a small entity.

Banana farming is classified under NAICS category 111339 as ''Other Noncitrus Fruit Farming.'' The SBA considers entities in this category to be small if their average annual receipts are less than $750,000. The 677 banana farms in Hawaii accounted for annual sales of $8.6 million in total in 2002. Therefore, it is likely that most Hawaiian banana farms will be classified as small entities under the SBA criteria. The treatment monitoring program will be mainly operated by APHIS personnel, and no impact is anticipated on other small entities or government agencies.

Vapor Heat Treatment for Sweetpotatoes Moved Interstate From Hawaii

We are allowing vapor heat treatment, combined with tuber cutting and visual inspection, to be used as a treatment for sweetpotatoes moved interstate from Hawaii. We believe this treatment will be an effective alternative to the methyl bromide and irradiation treatments currently prescribed by the regulations to control pests of concern.

Cost of Vapor Heat Treatment

Hawaii has three packing plants on the Island of Hawaii that provide vapor heat treatment services. No other vapor heat treatment plants are currently in operation elsewhere in the State. Since APHIS has yet to certify a facility for the treatment of sweetpotato by vapor heat, the costs of treating this crop specifically cannot be determined with certainty at this time. However, one of the packinghouses estimated that vapor heat treatment costs could amount to 2 to 3 cents per pound for the required treatment protocol. This estimate considered the costs of labor, electricity, water, and sewer service. APHIS has traditionally certified vapor heat treatment chambers (for example, for papaya) in the ''fully loaded configuration.'' The costs of treating sweetpotato in smaller batch loads still have to be determined. This estimate of treatment cost also does not include a markup for the facility. The markup will be determined by the number of plants providing service and the demand for service.

Cost of APHIS Inspection for Vapor Heat Treatment or Irradiation

Monitoring of quarantine treatments conducted during standard business hours (weekdays between 8 a.m. and 4:30 p.m.) on the island of Hawaii comes at no cost to the facility. APHIS charges for the monitoring of treatments conducted before 8 a.m. and after 4:30 p.m. and on weekends at a time-and-a-half rate.

Comparison of Vapor Heat Treatment, Irradiation, and Methyl Bromide

Vapor heat treatment will provide the Hawaiian sweetpotato industry with an alternative treatment to irradiation or methyl bromide fumigation. If vapor heat treatment can be performed at 2 to 3 cents per pound, it will constitute the most cost-effective treatment, compared to irradiation at 15 cents per pound and fumigation costs ranging from 40.6 cents per pound for 1 pallet to 6.7 cents per pound for 12 pallets (table 3). (These are treatment costs only and do not include the costs of APHIS monitoring or inspection activities or inter-island transportation costs necessary to perform treatments.)

TABLE 3.—ESTIMATED PER-UNIT COST OF VAPOR HEAT TREATMENT, IRRADIATION, AND METHYL BROMIDE FUMIGATION

Treatment	Per unit cost (cents per pound)
Vapor heat treatment	2–3
Irradiation	15

[7] From *http://www.nass.usda.gov/hi/fruit/annban.htm.* Sales of Hawaiian bananas in 2003 were valued at $9.225 million.

[8] World Trade Atlas, 2003.

TABLE 3.—ESTIMATED PER-UNIT COST OF VAPOR HEAT TREATMENT, IRRADIATION, AND METHYL BROMIDE FUMIGATION—Continued

Treatment	Per unit cost (cents per pound)
Methyl bromide fumigation: [1]	
One pallet	40.6
Two pallets	20.3
Three pallets	13.5
Four pallets	10.1
Five pallets	8.1
Six pallets	6.7
Nine pallets	7.6
Twelve pallets	6.9

[1] One pallet contains 1,500 pounds of sweetpotatoes.

Sources: Packinghouse estimate (vapor heat treatment); Hawaii Department of Agriculture (irradiation and methyl bromide fumigation).

The availability of vapor heat treatment thus provides the Hawaiian sweetpotato industry with an alternative treatment option at a competitive cost. Furthermore, the vapor heat treatment plants in Hawaii will benefit if sweetpotatoes are included in the list of agricultural products to be treated. The availability of vapor heat treatment as an alternative to fumigation might become increasingly important in view of the global phaseout of methyl bromide under the Montreal Protocol. Irradiation may have positive effects on the quality and shelf life of the tubers, and allows flexibility since both small and large product lots can be staged for treatment to meet specific market demands. Vapor heat treatment is not known to offer quality or shelf-life benefits to the product, but some consumers may prefer this option above irradiation, especially in Japan, Canada, and Europe.

Impact on U.S. Sweetpotato Production

Commercial sweetpotato production in Hawaii occurs on the islands of Hawaii, Kauai, Maui, and Oahu. In 2002, there were 59 sweetpotato farms,[9] and the value of sales was $989,000.[10] The utilized production of sweetpotatoes in Hawaii was 1.8 million pounds in 2001 (table 4). The crop is in year-round production in Hawaii.

[9] National Agricultural Statistics Service, 2002 Census of Agriculture.

[10] From *http://www.nass.usda.gov/hi/vegetble/annveg.htm.*

TABLE 4.—PRODUCTION STATISTICS FOR HAWAIIAN SWEETPOTATOES (2001)

Item	Amount
Harvested acres	220
Yield per acre (1,000 pounds)	8.2
Production (1,000 pounds)	1,800
Farm price (cents per pound) [1]	50

[1] The 2001 farm price for sweetpotato was 47.3 cents per pound in Hawaii, Honolulu, and the Kauai Counties, and 60 cents per pound in the Maui County (Hawaiian Department of Agriculture).

Source: Hawaii Agricultural Statistics Service.

In the mainland United States, sweetpotato is grown commercially in Alabama, California, Georgia, Louisiana, Mississippi, New Jersey, North Carolina, South Carolina, Texas, and Virginia. North Carolina, Louisiana, Mississippi, and California account for the major proportion of production area by State (table 5). In total, the United States produced 1,355 million pounds of sweetpotatoes from 93,500 acres in 2003 (table 6). The Hawaiian sweetpotato production of 1.8 million pounds thus comprises a minor proportion of the total production of 1,355 million pounds in the United States.

TABLE 5.—ACRES OF SWEETPOTATOES PLANTED IN THE UNITED STATES (2003)

State	Acres planted
North Carolina	42,000
Louisiana	18,000
Mississippi	14,000
California	10,100
Texas	3,400
Alabama	2,900
Others [1]	3,100
Total	93,500

[1] Including Hawaii.

Source: Economic Research Service, USDA.

TABLE 6.—PRODUCTION AND UTILIZATION STATISTICS FOR SWEETPOTATOES IN THE UNITED STATES (2003) [1]

Item	Amount
Acres planted	93,500
Three-year average yield (cwt/acre)	150
Production (million pounds)	1,355
Imports (million pounds)	17.0
Exports (million pounds)	53.0
Total utilization (million pounds) [2]	1,148.3
Per capita use (pounds)	3.9
Three-year average per capita use (pounds)	4.0
Current dollars ($/cwt)	15.75
Constant 1996 dollars ($/cwt)	13.91

[1] Estimates are for the total United States, and therefore include Hawaii. Forecasted estimates are shown.

[2] Total utilization includes 103 million pounds used for seed and 67.8 million pounds accruing to feed use, shrink, and loss.

Source: Economic Research Service, United States Department of Agriculture. Acres were obtained from Lucier, G. ''Sweet potatoes—getting to the root of demand.'' Economic Research Service, USDA, 2002.

The Hawaiian sweetpotatoes intended for the U.S. mainland markets are of a special purple flesh variety, and they are therefore shipped to the mainland as a specialty product intended for niche markets. U.S. mainland consumers could, therefore, benefit from an increased supply of these specialty sweetpotatoes.

Interstate movement provides Hawaiian growers and shippers with increased marketing opportunities. Sweetpotatoes are in year-round production in Hawaii, but some seasonal variation in volume is expected. Out-shipment to U.S. mainland markets is estimated at 50,000 to 60,000 pounds per week. New plantings of the crop have increased on the island of Hawaii since irradiation was approved as an alternative to methyl bromide fumigation in June 2003. However, plantings are likely to increase each year if the market demand increases for Hawaiian sweetpotatoes regardless of whether the product is treated by methyl bromide fumigation, irradiation, or vapor heat treatment. Nevertheless, even if sweetpotato production increases in Hawaii, the relative volume of production (1.8 million pounds) remains extremely small in comparison to the volume of U.S. mainland sweetpotato production (1.36 billion pounds).

Thus, since Hawaiian production is so small in comparison to U.S. mainland production, and as long as phytosanitary mitigation by the approved treatments is maintained, sweetpotato shipments from Hawaii are unlikely to affect mainland producers. Consumers will benefit from the availability of the purple-fleshed specialty sweetpotato product, and the Hawaiian sweetpotato industry will gain opportunities to expand its mainland U.S. markets.

Vapor Heat Treatment of Sweetpotatoes Moved Interstate From Hawaii

The availability of vapor heat treatment at a competitive cost could divert some sweetpotatoes moved interstate from Hawaii from the existing irradiation facility in Hawaii to a vapor heat treatment facility. This will affect the existing irradiation facility in Hawaii, which is a small entity. However, it is not known at this time what proportion of Hawaiian sweetpotatoes moved interstate will be treated with vapor heat instead of irradiation.

On the other hand, vapor heat treatment facilities could benefit by the addition of vapor heat as an approved treatment for sweetpotatoes moved interstate from Hawaii. However, since facilities for the vapor heat treatment of Hawaiian sweetpotatoes have not been certified yet, the businesses cannot be conclusively categorized into small or large entities at this time.

Sweetpotato farming is classified under NAICS category 111219, ''Other Vegetables (except Potato) and Melon Farming.'' According to the SBA's criteria, an entity involved in crop production is considered small if it has average annual receipts of less than $750,000. The 59 sweetpotato farms in Hawaii accounted for annual sales of $989,000 in total in 2002. Therefore, it is likely that most of these farms would be considered small entities according to the SBA criteria. The monitoring and inspection program will be mainly operated by APHIS personnel, and no impact is anticipated on other small entities and government agencies.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0281.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects

7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

7 CFR Part 305

Irradiation, Phytosanitary treatment, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements.

7 CFR Part 318

Cotton, Cottonseeds, Fruits, Guam, Hawaii, Plant diseases and pests, Puerto Rico, Quarantine, Transportation, Vegetables, Virgin Islands.

7 CFR Part 319

Coffee, Cotton, Fruits, Imports, Logs, Nursery stock, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Rice, Vegetables.

■ Accordingly, we are amending 7 CFR parts 301, 305, 318, and 319 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

■ 1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

Section 301.75–15 also issued under Sec. 204, Title II, Pub. L. 106–113, 113 Stat. 1501A–293; sections 301.75–15 and 301.75–16 also issued under Sec. 203, Title II, Pub. L. 106–224, 114 Stat. 400 (7 U.S.C. 1421 note).

■ 2. In § 301.64–10, paragraph (g) introductory text and the OMB control number citation at the end of the section are revised to read as follows:

§ 301.64–10 Treatments.

* * * * *

(g) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any fruit listed as a regulated article in § 301.64–2(a).

* * * * *

(Approved by the Office of Management and Budget under control number 0579–0088)

■ 3. In § 301.78–10, paragraph (c) introductory text is revised to read as follows:

§ 301.78–10 Treatments.

* * * * *

(c) *Approved irradiation treatment.* Irradiation, carried out in accordance with the provisions of part 305 of this chapter, is approved as a treatment for any berry, fruit, nut, or vegetable listed as a regulated article in § 301.78–2(a) of this subpart.

* * * * *

PART 305—PHYTOSANITARY TREATMENTS

■ 4. The authority citation for part 305 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

■ 5. Section 305.2 is amended as follows:

■ a. By revising paragraph (h)(1) to read as set forth below.

■ b. In the table in paragraph (h)(2)(ii), under Hawaii, by adding a new entry, in alphabetical order, for ''Banana'' to read as set forth below.

■ c. In the table in paragraph (h)(2)(ii), under Hawaii, by removing the entry for ''Sweet potato'' and adding in its place a new entry for ''Sweetpotato'' to read as set forth below.

§ 305.2 Approved treatments.

* * * * *

(h) *Fruits and vegetables.* (1) Treatment of fruits and vegetables from foreign localities by irradiation in accordance with § 305.31 may be substituted for other approved treatments for any of the pests listed in § 305.31(a). Treatment of fruits and vegetables from Hawaii, Puerto Rico, and the U.S. Virgin Islands by irradiation at the minimum doses listed in § 305.31(a) and in accordance with § 305.34 may be substituted for other approved treatments for any of the pests listed in § 305.31(a).

(2) * * *

(ii) * * *

Location	Commodity	Pest	Treatment schedule
*	*	*	*
Hawaii			
*	*	*	*
	Banana	*Bactrocera curcurbitae, Bactrocera dorsalis, Ceratitis capitata, Coccus viridis.*	IR.
*	*	*	*
	Sweetpotato	*Euscepes postfasciatus, Omphisa anastomosalis, Elytrotreinus or subtruncatus.*	MB T101–b–3–1 or § 305.24(k) or IR.
*	*	*	*

* * * * *

■ 6. In § 305.24, a new paragraph (k) is added to read as follows:

§ 305.24 Vapor heat treatment schedules.

* * * * *

(k) *Vapor heat treatment for sweetpotatoes moved interstate from Hawaii.* (1) Temperature probes must be placed in the approximate center of the largest individual sweetpotato roots.

(2) The air surrounding the sweetpotato roots must be heated. After the temperature of the air surrounding the sweetpotato roots reaches 87.8 °F (31 °C), its temperature must be incrementally raised from 87.8 °F (31 °C) to 111.2 °F (44 °C) over a period of 240 minutes.

(3) Using saturated water vapor at 118.4 °F (48 °C), the core temperature of the individual sweetpotato roots must be raised to 116.6 °F (47 °C).

(4) After the core temperature of the sweetpotato roots reaches 116.6 °F (47 °C), the core temperature must then be held at 116.6 °F (47 °C) or higher for 190 minutes.

■ 7. Section 305.31 is amended as follows:

■ a. By revising the section heading to read as set forth below.

■ b. By revising paragraph (a), including the table, to read as set forth below.

■ c. By redesignating paragraph (g)(2) as paragraph (g)(3) and adding a new paragraph (g)(2) to read as set forth below.

■ d. In paragraphs (b), (e)(1), (e)(2), (f)(1)(i), (f)(1)(ii), (f)(1)(iii), (g) introductory text, (g)(1), and (n), and in newly redesignated paragraphs (g)(3) introductory text, (g)(3)(i) introductory text, and (g)(3)(ii) introductory text, by removing the words ''fruits and vegetables'' each time they appear and adding the word ''articles'' in their place.

■ e. In newly designated paragraph (g)(3)(i)(A), footnote 3, and in paragraph (l), by removing the words ''Inspection and'' and adding the words ''Science and'' in their place and by removing the words ''1017 Main Campus Drive, suite 2500'' and adding the words ''1730 Varsity Drive, Suite 400'' in their place.

The revisions and additions read as follows:

§ 305.31 Irradiation treatment of imported regulated articles for certain plant pests.

(a) *Approved doses.* Irradiation at the following doses for the specified plant pests, carried out in accordance with the provisions of this section, is approved as a treatment for all regulated articles (i.e., fruits, vegetables, cut flowers, and foliage):

IRRADIATION FOR CERTAIN PLANT PESTS IN IMPORTED REGULATED ARTICLES[1]

Scientific name	Common name	Dose (gray)
Anastrepha ludens	Mexican fruit fly	70
Anastrepha obliqua	West Indian fruit fly	70
Anastrepha serpentina	Sapote fruit fly	100
Anastrepha suspensa	Caribbean fruit fly	70
Bactrocera jarvisi	Jarvis fruit fly	100
Bactrocera tryoni	Queensland fruit fly	100
Brevipalpus chilensis	False red spider mite	300
Conotrachelus nenuphar	Plum curculio	92
Croptophlebia ombrodelta	Litchi fruit moth	250
Cryptophlebia illepida	Koa seedworm	250
Cylas formicarius elegantulus	Sweetpotato weevil	150
Cydia pomonella	Codling moth	200
Euscepes postfasciatus	West Indian sweetpotato weevil	150
Grapholita molesta	Oriental fruit moth	200
Omphisa anastomosalis	Sweetpotato vine borer	150
Rhagoletis pomonella	Apple maggot	60
Sternochetus mangiferae (Fabricus)	Mango seed weevil	300
Fruit flies of the family *Tephritidae* not listed above		150
Plant pests of the class *Insecta* not listed above, except pupae and adults of the order Lepidoptera		400

[1] There is a possibility that some cut flowers could be damaged by such irradiation. See paragraph (n) of this section.

* * * * *

(g) * * *

(2) For all articles to be irradiated upon arrival in the United States, the articles must be packed in cartons that have no openings that will allow the entry of fruit flies and that are sealed with seals that will visually indicate if

the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.

* * * * *

§ 305.32 [Amended]

■ 8. Section 305.32 is amended as follows:

■ a. In paragraphs (a)(1) and (d), by removing the words ''a minimum absorbed ionizing radiation dose of 150 Gray (15 krad)'' and adding the words ''the approved dose for Mexican fruit fly listed in § 305.31(a)'' in their place.

■ b. In paragraph (e)(2), by removing the words ''150 Gray (15 krad)'' and adding the words ''the approved dose for Mexican fruit fly listed in § 305.31(a)'' in their place.

■ c. In paragraph (g), by removing the words ''Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565'' and adding the words ''Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606'' in their place.

§ 305.33 [Amended]

■ 9. Section 305.33 is amended as follows:

■ a. In paragraphs (a)(1) and (d), by removing the words ''a minimum absorbed ionizing radiation dose of 225 Gray (22.5 krad)'' and adding the words ''the approved dose for Mediterranean fruit fly listed in § 305.31(a)'' in their place.

■ b. In paragraph (e)(2), by removing the words ''225 gray (22.5 krad)'' and adding the words ''the approved dose for Mediterranean fruit fly listed in § 305.31(a)'' in their place.

■ c. In paragraph (g), by removing the words ''Oxford Plant Protection Center, 901 Hillsboro St., Oxford, NC 27565'' and adding the words ''Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606'' in their place.

■ 10. Section 305.34 is amended as follows:

■ a. By revising the section heading to read as set forth below.

■ b. By revising paragraph (a), including the table, to read as set forth below.

■ c. In paragraphs (b) introductory text, (b)(1), (b)(2)(ii), and (b)(4), by adding the words '', Puerto Rico, or the U.S. Virgin Islands'' after the word ''Hawaii'' each time it occurs.

■ d. In paragraphs (b) introductory text, (b)(1), (b)(2)(i), (b)(2)(ii), (b)(4)(i), (b)(4)(ii), (b)(5), (b)(7)(i), (b)(7)(ii), and (e), by removing the words ''fruits and vegetables'' each time they appear and by adding the word ''articles'' in their place.

■ e. In paragraph (b)(7)(i), by adding two new sentences after the last sentence to read as set forth below.

■ f. In paragraph (b)(7)(ii), by adding two new sentences after the last sentence to read as set forth below.

■ g. In paragraph (c), by removing the words ''1017 Main Campus Drive, suite 2500'' and adding the words ''1730 Varsity Drive, Suite 400'' in their place.

■ h. By revising the OMB control number citation at the end of the section to read as set forth below.

The revisions and additions read as follows:

§ 305.34 Irradiation treatment of certain regulated articles from Hawaii, Puerto Rico, and the U.S. Virgin Islands.

(a) *Approved irradiation treatment.*

(1) *Commodity-specific doses.* Irradiation, carried out in accordance with the provisions of this section, is approved as a treatment for the following fruits and vegetables from Hawaii at the specified dose levels:

IRRADIATION FOR PLANT PESTS IN HAWAIIAN FRUITS AND VEGETABLES

Commodity	Dose (gray)
Abiu	150
Atemoya	150
Bell pepper	150
Carambola	150
Eggplant	150
Litchi[1]	150
Longan	150
Mango	300
Papaya	150
Pineapple	150
Rambutan	150
Sapodilla	150
Italian squash	150
Sweetpotato[1]	400 or 150
Tomato	150

(2) *Pest-specific doses.* Any articles from Puerto Rico or the U.S. Virgin Islands, as well as any articles from Hawaii not listed in paragraph (a)(1) of this section, that are required by part 318 of this chapter to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) may instead be treated with irradiation. Articles treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of this section.

* * * * *

(b) * * *

(7) * * *

(i) * * * In addition, sweetpotato from Hawaii to be treated with irradiation at a dose of 150 Gy must be sampled, cut, and inspected in Hawaii and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*) by an inspector before undergoing irradiation treatment in Hawaii. Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(ii) * * * In addition, sweetpotato from Hawaii to be treated with irradiation at a dose of 150 Gy must be sampled, cut, and inspected in Hawaii and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*) by an inspector. Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

* * * * *

(Approved by the Office of Management and Budget under control numbers 0579–0198 and 0579–0281)

[1] Litchi and sweetpotato are also subject to the additional inspection requirements in paragraph (b)(7) of this section.

PART 318—HAWAIIAN AND TERRITORIAL QUARANTINE NOTICES

■ 11. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 7 CFR 2.22, 2.80, and 371.3.

§ 318.13 [Amended]

■ 12. In § 318.13, paragraph (c) is amended by removing the words ''leaves in full force and effect § 318.30 which restricts the movement from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State or certain Territories or Districts of the United States of all varieties of sweetpotatoes (Ipomoea batatas Poir.). It also''.

■ 13. Section 318.13–1 is amended as follows:

■ a. In the definition of *compliance agreement,* by removing the words ''§ 318.13–3(b), § 318.13–4(b), or § 318.13–4f of this subpart'' and adding the words ''§ 318.13(b) or § 318.13–4(b) of this subpart or § 305.34 of this chapter'' in their place.

■ b. By revising the definition of *inspector* to read as set forth below.

§ 318.13–1 Definitions.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the

Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

§ 318.13–2 [Amended]

■ 14. In § 318.13–2, in paragraph (b), the list of articles is amended by adding, in alphabetical order, a new entry for ''Sweetpotato (Ipomoea batatas Poir.).''

■ 15. Section 318.13–3 is amended as follows:

■ a. By revising paragraph (b)(3) to read as set forth below.

■ b. By adding a new paragraph (b)(4) to read as set forth below.

§ 318.13–3 Conditions of movement.

* * * * *

(b) * * *

(3) Untreated regulated articles from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 305.34 of this chapter are met and if the articles are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). Untreated bananas from Hawaii may be moved interstate for irradiation treatment on the mainland United States if the provisions of § 318.13–4i(b) are met and if the bananas are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). The limited permit will be issued only if the inspector examines the shipment and determines that the shipment has been prepared in compliance with the provisions of this subpart.

(4) Untreated sweetpotatoes from Hawaii may be moved interstate for vapor heat treatment on the mainland United States if the provisions of § 318.13–4d are met and if the sweetpotatoes are accompanied by a limited permit issued by an inspector in accordance with § 318.13–4(c). The limited permit will be issued only if the inspector examines the shipment and determines that the shipment has been prepared in compliance with the provisions of this subpart.

* * * * *

§ 318.13–4b [Amended]

■ 16. Section 318.13–4b is amended as follows:

■ a. By adding the words ''or vegetables'' after the word ''fruits'' in the following places:

i. The section heading.

ii. Paragraph (a).

iii. Paragraph (b), in the paragraph heading and the first sentence.

iv. Paragraph (c).

v. Paragraph (e).

vi. Paragraph (f).

■ b. In paragraph (b), by removing the words ''fruit flies'' and adding the words ''plant pests'' in their place.

■ c. In paragraph (b), by adding the word ''sweetpotatoes,'' after the word ''rambutan,''.

■ 17. A new § 318.13–4d is added to read as follows:

§ 318.13–4d Vapor heat treatment of sweetpotatoes from Hawaii.

(a) Vapor heat treatment, carried out in accordance with the provisions of this section, is approved as a treatment for sweetpotato from Hawaii.

(b) Sweetpotatoes may be moved interstate from Hawaii in accordance with this section only if the following conditions are met: [2]

(1) The sweetpotatoes must be treated in accordance with the vapor heat treatment schedule specified in § 305.24.

(2) The sweetpotatoes must be sampled, cut, and inspected and found to be free of the ginger weevil (*Elytrotreinus subtruncatus*). Sampling, cutting, and inspection must be performed under conditions that will prevent any pests that may emerge from the sampled sweetpotatoes from infesting any other sweetpotatoes intended for interstate movement in accordance with this section.

(3) The sweetpotatoes must be inspected and found to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*) and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

(4)(i) Sweetpotatoes that are treated in Hawaii must be packaged in the following manner:

(A) The cartons must have no openings that will allow the entry of fruit flies and must be sealed with seals that will visually indicate if the cartons have been opened. They may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the fruit in the carton.[3]

(B) The pallet-load of cartons must be wrapped before it leaves the treatment facility in one of the following ways:

(*1*) With polyethylene sheet wrap;

(*2*) With net wrapping; or

(*3*) With strapping so that each carton on an outside row of the pallet load is constrained by a metal or plastic strap.

(C) Packaging must be labeled with treatment lot numbers, packing and treatment facility identification and location, and dates of packing and treatment.

(ii) Cartons of untreated sweetpotatoes that are moving to the mainland United States for treatment must be shipped in shipping containers sealed prior to interstate movement with seals that will visually indicate if the shipping containers have been opened.

(5)(i) *Certification on basis of treatment.* A certificate shall be issued by an inspector for the movement of sweetpotatoes from Hawaii that have been treated and handled in Hawaii in accordance with this section. To be certified for interstate movement under this section, sweetpotato from Hawaii must be sampled, cut, and inspected by an inspector and found by an inspector to be free of the ginger weevil (*Elytrotreinus subtruncatus*) and inspected and found by an inspector to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*), and the Kona coffee-root knot nematode (*Meloidogyne konaensis*) before undergoing vapor heat treatment in Hawaii.

(ii) *Limited permit.* A limited permit shall be issued by an inspector for the interstate movement of untreated sweetpotato from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this section, untreated sweetpotato from Hawaii must be sampled, cut, and inspected in Hawaii by an inspector and found by an inspector to be free of the ginger weevil (*Elytrotreinus subtruncatus*) and inspected and found by an inspector to be free of the gray pineapple mealybug (*Dysmicoccus neobrevipes*), and the Kona coffee-root knot nematode (*Meloidogyne konaensis*).

(Approved by the Office of Management and Budget under control number 0579–0281)

■ 18. Section 318.13–4f is revised to read as follows:

§ 318.13–4f Irradiation treatment of certain regulated articles from Hawaii.

Irradiation, carried out in accordance with the provisions in § 305.34 of this chapter, is approved as a treatment for the following fruits and vegetables: Abiu, atemoya, bell pepper, carambola, eggplant, litchi, longan, mango, papaya, pineapple, rambutan, sapodilla, Italian squash, sweetpotato, and tomato. Any

[2] Sweetpotatoes may also be moved interstate from Hawaii in accordance with § 305.34 of this chapter or after fumigation with methyl bromide according to treatment schedule T–101–b–3–1, as provided for in § 305.6(a) of this chapter.

[3] If there is a question as to the adequacy of a carton, send a request for approval of the carton, together with a sample carton, to the Animal and Plant Health Inspection Service, Plant Protection and Quarantine, Center for Plant Health Science and Technology, 1730 Varsity Drive, Suite 400, Raleigh, NC 27606.

other commodities that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Commodities treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

■ 19. Section 318.13–4i is amended as follows:

■ a. By revising the section heading to read as set forth below.

■ b. By redesignating paragraphs (a), (b), (c), and (d) as paragraphs (a)(1), (a)(2), (a)(3), and (a)(4), respectively, and by designating the introductory text of the section as paragraph (a), introductory text.

■ c. By adding a new paragraph (b) to read as set forth below.

§ 318.13–4i Conditions governing the movement of bananas from Hawaii.

* * * * *

(b) Bananas of any cultivar or ripeness that do not meet the conditions of paragraph (a) of this section may also be moved interstate from Hawaii in accordance with the following conditions:

(1) The bananas are irradiated at the minimum dose listed in § 305.31(a) of this chapter and in accordance with the other requirements in § 305.34 of this chapter for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), the Oriental fruit fly (*Bactrocera dorsalis*), and the green scale (*Coccus viridis*) and are inspected, after removal from the stalk, in Hawaii and found to be free of the banana moth (*Opogona sacchari* (Bojen)) by an inspector before or after undergoing irradiation treatment; or

(2) The bananas are irradiated at the minimum dose listed in §A305.31(a) of this chapter and in accordance with the other requirements in § 305.34 of this chapter for the Mediterranean fruit fly (*Ceratitis capitata*), the melon fruit fly (*Bactrocera curcurbitae*), and the Oriental fruit fly (*Bactrocera dorsalis*) and are inspected, after removal from the stalk, in Hawaii and found to be free of the green scale (*Coccus viridis*) and the banana moth (*Opogona sacchari* (Bojen)) before or after undergoing irradiation treatment.

(3)(i) A certificate shall be issued by an inspector for the movement of bananas from Hawaii that have been treated and inspected in Hawaii in accordance with this paragraph § 318.13–4i(b). To be certified for interstate movement under this paragraph, bananas from Hawaii must be treated, inspected, and, if necessary, culled in accordance with the requirements of this paragraph prior to interstate movement from Hawaii.

(ii) A limited permit shall be issued by an inspector for the interstate movement of untreated bananas from Hawaii for treatment on the mainland United States in accordance with this section. To be eligible for a limited permit under this paragraph § 318.13–4i(b), bananas from Hawaii must be inspected in accordance with the requirements of this paragraph prior to interstate movement from Hawaii.

§ 318.13–5 [Amended]

■ 20. In § 318.13–5, footnote 6 is redesignated as footnote 4.

§ 318.13–12 [Amended]

■ 21. In § 318.13–12, footnotes 7 and 8 are redesignated as footnotes 5 and 6, respectively.

§ 318.13–17 [Amended]

■ 22. In § 318.13–17, footnotes 9 and 10 are redesignated as footnotes 7 and 8, respectively.

Subpart—Sweetpotatoes [Removed]

■ 23. Subpart—Sweetpotatoes, consisting of §§ 318.30 and 318.30a, is removed.

§ 318.58 [Amended]

■ 24. In § 318.58, paragraph (d) is amended by removing the words ''leaves in full force and effect § 318.30 which restricts the movement from Hawaii, Puerto Rico, or the Virgin Islands of the United States into or through any other State or certain Territories or Districts of the United States of all varieties of sweetpotatoes (Ipomoea batatas Poir.). It also''.

■ 25. In § 318.58–1, the definition of *inspector* is revised to read as follows:

§ 318.58–1 Definitions.

* * * * *

Inspector. Any individual authorized by the Administrator of APHIS or the Commissioner of Customs and Border Protection, Department of Homeland Security, to enforce the regulations in this part.

* * * * *

§ 318.58–2 [Amended]

■ 26. In § 318.58–2, in paragraph (b)(2), the list of articles is amended by adding, in alphabetical order, a new entry for ''Sweetpotato (Ipomoea batatas Poir.).''

■ 27. A new section § 318.58–4b is added to read as follows:

§ 318.58–4b Irradiation treatment of regulated articles from Puerto Rico and the U.S. Virgin Islands.

Any regulated articles from Puerto Rico or the U.S. Virgin Islands that are required by this subpart to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Commodities treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34.

■ 28. A new section § 318.58–4c is added to read as follows.

§ 318.58–4c Movement of sweetpotatoes from Puerto Rico to certain ports.

Sweetpotatoes from Puerto Rico may be moved interstate to Atlantic Coast ports north of and including Baltimore, MD, if the following conditions are met:

(a) The sweetpotatoes must be certified by an inspector of the Commonwealth of Puerto Rico as having been grown under the following conditions:

(1) Fields in which the sweetpotatoes have been grown must have been given a preplanting treatment with an approved soil insecticide.

(2) Before planting in such treated fields, the sweetpotato draws and vine cuttings must have been dipped in an approved insecticidal solution.

(3) During the growing season an approved insecticide must have been applied to the vines at prescribed intervals.

(b) An inspector of the Commonwealth of Puerto Rico must certify that the sweetpotatoes have been washed.

(c) The sweetpotatoes must be graded by inspectors of the Commonwealth of Puerto Rico in accordance with Puerto Rican standards which do not provide a tolerance for insect infestation or evidence of insect injury and found by such inspectors to comply with such standards prior to movement from Puerto Rico.

(d) The sweetpotatoes must be inspected by an inspector and found to be free of the sweetpotato scarabee (*Euscepes postfasciatus* Fairm.).

PART 319—FOREIGN QUARANTINE NOTICES

■ 29. The authority citation for part 319 continues to read as follows:

Authority: 7 U.S.C. 450, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

§ 319.56–2 [Amended]

■ 30. In § 319.56–2, paragraph (k) is amended by removing the words ''11 species of fruit flies and one species of seed weevil'' and adding the words ''plant pests'' in their place.

■ 31. Section 319.74–2 is amended as follows by redesignating paragraph (d) as paragraph (e) and by adding a new paragraph (d) to read as follows:

§ 319.74–2 Conditions governing the entry of cut flowers.

* * * * *

(d) *Irradiation.* Cut flowers and foliage that are required under this part to be treated or subjected to inspection to control one or more of the plant pests listed in § 305.31(a) of this chapter may instead be treated with irradiation. Commodities treated with irradiation for plant pests listed in § 305.31(a) must be irradiated at the doses listed in § 305.31(a), and the irradiation treatment must be conducted in accordance with the other requirements of § 305.34 of this chapter. There is a possibility that some cut flowers could be damaged by such irradiation.

* * * * *

Done in Washington, DC, this 20th day of January 2006.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 06–746 Filed 1–26–06; 8:45 am]

BILLING CODE 3410–34–P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 52

RIN 3150–AH56

AP1000 Design Certification

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to certify the AP1000 standard plant design. This action is necessary so that applicants or licensees intending to construct and operate an AP1000 design may do so by referencing this regulation [AP1000 design certification rule (DCR)]. The applicant for certification of the AP1000 design was Westinghouse Electric Company, LLC (Westinghouse).

DATES: *Effective Date:* The effective date of this rule is February 27, 2006. The incorporation by reference of certain material specified in this regulation is approved by the Director of the Office of the Federal Register as of February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Lauren Quinones-Navarro or Jerry N. Wilson, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone (301) 415–2007 or (301) 415–3145; e-mail: *lnq@nrc.gov* or *jnw@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Subpart B of 10 CFR part 52 sets forth the process for obtaining standard design certifications. On March 28, 2002 (67 FR 20845; April 26, 2002), Westinghouse tendered its application for certification of the AP1000 standard plant design with the NRC. Westinghouse submitted this application in accordance with subpart B and appendix O of 10 CFR part 52. The NRC formally accepted the application as a docketed application for design certification (Docket No. 52–006) on June 25, 2002 (67 FR 43690; June 28, 2002). The pre-application information submitted before the NRC formally accepted the application can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) under Docket Number PROJ0711 (Project No. 711).

The NRC staff issued a final safety evaluation report (FSER) for the AP1000 design in September 2004 (NUREG–1793). The FSER provides the bases for issuance of a final design approval (FDA) under appendix O to part 52, which is a prerequisite to a design certification. The FDA for the AP1000 design was issued on September 13, 2004, and published in the **Federal Register** on September 17, 2004 (69 FR 56101). A proposed rule to certify the AP1000 was published on April 18, 2005 (70 FR 20062).

Subsequently, Westinghouse submitted editorial and minor technical changes and clarifications to the inspections, tests, analyses, and acceptance criteria (ITAAC) in revision 15 to the design control document (DCD). The NRC staff evaluated these changes in a supplement to the FSER (NUREG–1793, Supplement No. 1). Supplement No. 1 is being made available to the public as part of this rulemaking. The FSER and Supplement No. 1 provide the bases for the Commission's approval of the AP1000 standard plant design. An FDA, which incorporates the changes to the DCD, will be issued to supersede the current FDA after issuance of this final design certification rule.

II. Comment Analysis

The period for submitting comments on the proposed DCR, AP1000 DCD, or draft environmental assessment (EA) expired on July 5, 2005. The NRC received three letters from two private citizens and one letter from the Nuclear Energy Institute (NEI). The comments addressed three categories of information: Environmental Assessment (EA), Design Control Document, and Design Certification Rule. The responses to the comments on the EA are discussed in section 7.0 of the EA (ML053630176). Responses to the comments in the second and third categories are discussed below.

A. Design Control Document (DCD)

Comment summary. There is an over-reliance on passive systems in the AP1000.

Response. The NRC disagrees with this comment. The NRC required tests of the new passive safety systems to demonstrate that they will perform as predicted in the safety analysis (see Chapter 21 of the AP1000 FSER). The NRC also required higher availability for certain active backup systems to compensate for any remaining uncertainties in the performance of the passive safety systems (see Chapter 22 of the AP1000 FSER). As a result of these reviews, the NRC concluded that the use of passive safety systems in the AP1000 design is acceptable.

Comment Summary. The AP1000 is an unnecessary and unsafe variation on AP600.

Response. The NRC disagrees with the comment. The NRC has determined that the AP1000 design can be built and operated safely (see AP1000 FSER). The

NRC does not determine which designs are necessary for future deployment.

Comment Summary. The AP1000 DCD referenced in the proposed rule does not meet the requirement of 10 CFR part 52 that the plant design be complete except for site-specific elements and other specific exemptions.

Response. The NRC disagrees with this comment. The requirement for a complete scope of design [10 CFR 52.47(b)(2)(i)(A)(4)] was met by the applicant (see discussion in section 1.2.1 of AP1000 FSER). The comment appears to be directed at the requirement for an application to contain a sufficient level of design information for the Commission to reach a conclusion on all safety questions associated with the design [10 CFR 52.47(a)(2)], which was also met by the applicant (see discussion in section 1.5 of AP1000 FSER).

Comment Summary. The appropriateness of the process used to derive the AP1000 design from the AP600 design has not been given sufficient attention in the NRC's review.

Response. The NRC disagrees with this comment, which appears to apply to the NRC's review of the applicant's quality assurance (QA) program. In its application for design certification of the AP1000 plant, Westinghouse stated that a continuous QA program spanning the AP600 design and the AP1000 design has been used. Since March 31, 1996, activities affecting the quality of items and services for the AP1000 project during design, procurement, fabrication, inspection, and/or testing have been performed under the quality plan described in ''Westinghouse Energy Systems Business Unit—Quality Management System.'' The Quality Management System (QMS) establishes design control measures for preparing, reviewing, and approving design documentation for safety-related structures, systems, and components (SSCs). As documented in an NRC evaluation letter, dated February 23, 1996, from S. Black (NRC) to N.J. Liparulo, the Westinghouse QMS was reviewed by the NRC and found to meet the requirements of 10 CFR part 50, appendix B. Subsequent revisions to the QMS have also been reviewed by the NRC and found to be acceptable. To provide additional assurance that Westinghouse implemented the measures described in the QMS, the NRC staff performed a QA implementation inspection at the Westinghouse engineering offices in Monroeville, Pennsylvania, which was documented in NRC Inspection Report No. 99900404/03–01, dated November 4, 2003 (ADAMS Accession No. ML033090510). Therefore, the NRC concludes that the applicant's QA program for the AP1000 design was acceptable.

Comment Summary. The decision by the NRC not to require Westinghouse to build and test a prototype for the automatic depressurization system (ADS) 4th stage squib valve was made under pressure of the accelerated AP1000 schedule.

Response. The NRC disagrees that the AP1000 schedule affected the decision not to require Westinghouse to build and test a prototype for the ADS 4th stage squib valve. The need for a prototype test was evaluated by the NRC staff during the AP1000 design review. Also, the ability to design and build the ADS valve for AP1000 was discussed with the Advisory Committee on Reactor Safeguards (ACRS) at its future plant subcommittee meeting on July 17–18, 2003. In addition, in a letter to ACRS dated May 18, 2004, the NRC staff stated that the ADS–4 squib valves will be designed, constructed, and tested under Section III of the Boiler and Pressure Vessel Code promulgated by the American Society of Mechanical Engineers and are actuated by redundant and diverse instrumentation and control systems. The staff also performed a sensitivity study by increasing the failure probability and the common-cause failure probability of the ADS–4 squib valves by an order of magnitude. This sensitivity study indicated that the CDF increased by only a factor of three (to 6×10^{-7}/year)and was not large enough to impact the probabilistic risk assessment (PRA) conclusions and insights about the AP1000 design.

Comment Summary. The effect of heat of solar radiation on the performance of the AP1000 passive containment cooling system (PCS) has not been resolved, and geographical latitude ought to be a site parameter, unless it can be shown that the PCS is effective at all geographical latitudes, even when heat of solar radiation is taken into account.

Response. The NRC disagrees with these comments. The site parameters for the AP1000 design include minimum and maximum air temperatures (see DCD Table 2–1). The safety maximum temperature is 115 °F, which is based on historical site data and excludes peaks of less than 2-hour durations.

The operational limits for the AP1000 containment include a technical specification (TS) limit on the temperature of the air inside containment, TS 3.6.5, ''Containment Air Temperature,'' of less than or equal to 120 °F. In addition, there is a limit on the water temperature in the PCS storage tank specified in TS 3.6.6, ''Passive Containment Cooling System—Operating,'' of greater than or equal to −40 °F and less than or equal to 120 °F. If the water temperature is at or below 50 °F, or at or above 100 °F, the surveillance frequency to check the temperature is reduced from 7 days to 24 hours. The operational limits and the site parameters provide reasonable assurance that the AP1000 can be operated without undue risk to the public health and safety. Conservative evaluations of the potential effect of solar radiation on the operation and performance of the AP1000 PCS show that the AP1000 TS provide reasonable assurance that off-normal conditions can be detected and appropriate actions taken to preclude operations outside the current design-base assumptions. Based on the estimated time needed to exceed the current operational temperature limits (10 days of uninterrupted extreme environmental conditions), it is reasonable to conclude that the AP1000 operational limits will not be exceeded even for sites with high solar radiation. In the unlikely event that the shield building might heat up, a containment response analysis showed the pressure increase to be small, 0.75 pounds per square inch (psi), and based on the current margin of 1.2 psi (DCD Table 6.2.1.1–1), the design pressure limit of 73.7 pounds per square inch absolute (psia) would not be exceeded. Therefore, the effect of heat of solar radiation on the performance of the PCS has been resolved.

Comment Summary. The accelerated schedule for the AP1000 led to cutting regulatory corners and was further accelerated by granting the FDA before the FSER was made available to the public.

Response. The NRC disagrees with this comment. In a letter to Mr. W.E. Cummins (Westinghouse), dated July 12, 2002, it is true that the NRC provided an expected schedule for the AP1000 review, which was significantly shorter than previous DCRs. However, the shorter schedule was due to efficiencies that the NRC expected to achieve as a result of the similarities between the previously-approved AP600 design and the AP1000 design. Also, the AP1000 FSER was made available to the public on September 20, 2004, the same day that the FDA was made available to the public.

B. Design Certification Rule

It is the Commission's goal to maintain as much consistency as possible in the rule language for all of the DCRs. Many of the following

comments from NEI appear to be applicable to all of the DCRs but some repeat comments NEI submitted previously during the 2003 proposed rule to amend 10 CFR part 52 (68 FR 40025; July 3, 2003).

Comment Summary. NEI recommends that Section III.B of the Supplementary Information (70 FR 20064) be revised to delete the phrase ''not just incorporate by reference.''

Response. The NRC disagrees with this request. The NRC does agree that the plant-specific DCD should be part of the final safety analysis report (FSAR) for a combined license (COL) application. The NRC believes that the generic DCD should also be part of the FSAR, not just incorporated by reference, in order to facilitate the NRC staff's review of any departures or exemptions. However, any changes made to existing DCRs if part 52 is revised would also be made to the AP1000 DCR.

Comment Summary. NEI recommends clarification of the review status of ''operational requirements'' in Section III.F of the Supplementary Information (70 FR 20067).

Response. The NRC agrees that the special backfit provisions of 10 CFR 52.63 do not apply to operational requirements in the DCD. However, the NRC believes that the discussion in Section III.F of the Supplementary Information section of the proposed rule document accurately states the review status of operational requirements and does not need to be revised.

Comment Summary. NEI recommends modification of the definition of generic TS in section II.B of the AP1000 DCR.

Response. The NRC disagrees with this comment. The NRC stated in the Supplementary Information (70 FR 20063) that the values in brackets are neither part of the AP1000 DCR nor are they binding. The NRC believes that amending the definition of generic TS is not necessary and also wants to maintain consistent rule language for all DCRs.

Comment Summary. NEI recommends replacement of the term ''investment protection'' in section II.E of the AP1000 DCR and elsewhere in the DCD by the term ''non-safety-related severe accident equipment.'' In addition, NEI recommends that the AP1000 DCR and Supplementary Information be revised so that bracketed information in the investment protection short-term availability controls will be treated like bracketed information in generic TS.

Response. The NRC disagrees with NEI's request to change this terminology. Use of the term ''investment protection short-term availability controls'' was requested by the applicant (Westinghouse Electric Company, LLC) and was also used in the AP600 DCR. Furthermore, the origin of investment protection short-term availability controls comes from implementing the regulatory treatment of non-safety systems process, which typically results in requirements to achieve higher reliability for certain active, non-safety systems. These systems are not limited to severe accident design features. Therefore, even if the NRC agreed to a generic change to the term ''investment protection,'' the proposed term ''non-safety-related severe accident equipment'' would not be an acceptable replacement.

The NRC agrees that the bracketed values in the investment protection short-term availability controls have the same status as the bracketed values in the generic TS. As a result, the NRC refers to the availability controls in section III.H of the Supplementary Information in this **Federal Register** notice.

Comment Summary. NEI recommends that the phrase ''or licensees'' be deleted from the rule language in section VIII.C.2 of the AP1000 DCR.

Response. The NRC agrees with this comment and section VIII.C.2 of the AP1000 DCR has been amended as suggested by NEI. The Commission may consider amending the DCRs to adopt the language recommended by NEI if 10 CFR part 52 is revised.

Comment Summary. NEI recommends amending the rule language in section VIII.C.6 of the AP1000 DCR to delete the requirement that changes to the plant-specific TS be treated as license amendments.

Response. The NRC disagrees with this request. The requirement that changes to the plant-specific TS be treated as license amendments is correct. If the Commission decides to clarify this issue for the DCRs in any potential revision to 10 CFR part 52, the NRC will also clarify the AP1000 DCR accordingly as part of that rulemaking.

Comment Summary. NEI recommends amending the rule language in section IX.B.1 of the AP1000 DCR to restore the phrase ''based solely thereon.''

Response. The NRC agrees to amend section IX.B.1 of the AP1000 DCR, in order to make all of the DCRs consistent. However, the NRC notes that inclusion of the phrase ''based solely thereon,'' does not change the meaning of section IX.B.1. The determination of inspection, test, analysis, and acceptance criteria (ITAAC) completion will always be based on information that is material to the acceptance criteria.

Comment Summary. NEI recommends amending the rule language in section X.A.1 of the AP1000 DCR to require the design certification applicant to include all generic changes to the generic TS and other operational requirements in the generic DCD.

Response. The NRC agrees with this comment, section X.A.1 of the AP1000 DCR has been amended as suggested by NEI. The Commission may consider amending the DCRs to adopt the language recommended by NEI if 10 CFR part 52 is revised.

Comment Summary. NEI recommends that sections IV.A.2 and IV.A.3 of the AP1000 DCR be amended to be consistent with respect to inclusion of information in the plant-specific DCD or explain the difference between the terms ''include'' and ''physically include'' in section IV.A (70 FR 20076).

Response. The NRC agrees that use of the terms ''include'' and ''physically include'' in section IV.A of the AP1000 DCR should be clarified. The Commission may consider amending all of the DCRs to clarify this issue if 10 CFR part 52 is revised.

Comment Summary. NEI recommends amending the definition of Tier 2 in section II.E.1 of the AP1000 DCR to exclude the design-specific PRA and the evaluation of SAMDAs.

Response. The NRC agrees with this comment, section II.E.1 of the AP1000 DCR has been amended as suggested by NEI. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. The Commission may consider amending the DCRs to adopt the language recommended by NEI if 10 CFR part 52 is revised.

Comment Summary. NEI recommends amending the rule language in section III.E of the AP1000 DCR to use the terminology for ''site characteristics'' consistently.

Response. The NRC agrees with this comment, section III.E of the AP1000 DCR has been amended to be consistent with the other DCRs in the proposed part 52 rule. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52.

Comment Summary. NEI recommends clarifying the rule language in section IV.A.2 of the AP1000 DCR regarding ''same'' information and ''generic DCD.''

Response. The NRC agrees with this comment, section IV.A.2 of the AP1000 DCR has been amended to be consistent with the other DCRs in the proposed part 52 rule. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52.

Comment Summary. NEI recommends amending section VIII.B.6.a of the AP1000 DCR to be consistent with section VI.B.5 regarding plant-specific departures.

Response. The NRC disagrees with this request. It was determined during the first two DCRs that departures from Tier 2* information would not receive finality or be treated as a resolved issue within the meaning of section VI of the DCR. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. If the Commission decides to adopt NEI's proposed language for the DCRs in any potential revision to 10 CFR part 52, the NRC will also amend the AP1000 DCR accordingly as part of that rulemaking.

Comment Summary. NEI recommends amending section VIII.C.3 of the AP1000 DCR to require the NRC to meet the backfit requirements of 10 CFR 50.109 in addition to the special circumstances in 10 CFR 2.758(b) for plant-specific departures from operational requirements.

Response. The NRC disagrees with this request. In the first two DCRs, the Commission decided on different standards for changes made under section VIII.C of the DCRs (see the discussion at 62 FR 25800; May 12, 1997). The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. If the Commission decides to adopt NEI's proposed language for the DCRs in any potential revision to 10 CFR part 52, the NRC will also amend the AP1000 DCR accordingly as part of that rulemaking.

Comment Summary. NEI recommends amending section VIII.C.4 of the AP1000 DCR to revise the standards for making changes to operational requirements.

Response. The NRC disagrees with this request. In the first two DCRs, the Commission decided on different standards for changes made under section VIII.C of the DCRs (see the discussion at 62 FR 25800; May 12, 1997). In addition, the Commission determined that exemptions from operational requirements would not receive finality or be treated as a resolved issue within the meaning of section VI of the DCR. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. If the Commission decides to adopt NEI's proposed language for the DCRs in any potential revision to 10 CFR part 52, the NRC will also amend the AP1000 DCR accordingly as part of that rulemaking.

Comment Summary. NEI recommends amending section IX.B.1 of the AP1000 DCR to specify the type of action to be performed by the NRC staff regarding ITAAC.

Response. The NRC disagrees with this request. Individual DCRs should not address the scope of the NRC staff's activities with respect to ITAAC verification. This is a generic matter that, if it is to be addressed in a rulemaking, is more appropriate for inclusion in subpart C of part 52 dealing generally with combined licenses.

The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. If the Commission decides to adopt NEI's proposed language for the DCRs in any potential revision to 10 CFR part 52, the NRC will also amend the AP1000 DCR accordingly as part of that rulemaking.

Comment Summary. NEI recommends amending section IX.B.3 of the AP1000 DCR to clarify the rule language.

Response. The NRC disagrees with this editorial request and has decided to maintain the original rule language for this provision. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. If the Commission decides to adopt NEI's proposed language for the DCRs in any potential revision to 10 CFR part 52, the NRC will also amend the AP1000 DCR accordingly as part of that rulemaking.

Comment Summary. NEI recommends amending sections X.B.1 and X.B.3 of the AP1000 DCR to clarify the rule language regarding DCDs.

Response. The NRC agrees with this comment and section X.B of the AP1000 DCR has been amended to clarify the language. The NRC notes that NEI submitted the same comment during the 2003 proposed rule to amend 10 CFR part 52. The Commission may consider amending the existing DCRs in any potential revision to 10 CFR part 52.

III. Section-by-Section Analysis

The following discussion sets forth the purpose and key aspects of each section and paragraph of the final AP1000 DCR. All section and paragraph references are to the provisions in appendix D to 10 CFR part 52. The final DCR for the AP1000 standard plant design is nearly identical to the AP600 DCR, which the NRC previously codified in 10 CFR part 52, appendix C (Design Certification Rule for the AP600 Design, 64 FR 72015, December 23, 1999). Many of the procedural issues and their resolutions for the AP600 DCR, as well as the initial two DCRs for the ABWR and ABB–CE System 80+, (e.g., the two-tier structure, Tier 2*, the scope of issue resolution) were developed after extensive public discussions with stakeholders, including Westinghouse. Also, Westinghouse requested that policy resolutions for the AP600 design review be applied to the AP1000. Accordingly, the NRC has modeled the AP1000 DCR on the existing DCRs, with certain departures where necessary, to account for differences in the AP1000 design documentation, design features, and environmental assessment (including severe accident mitigation design alternatives (SAMDAs).

A. Introduction

The purpose of section I of appendix D to 10 CFR part 52 (this appendix) is to identify the standard plant design that is approved by this DCR, and the applicant for certification of the standard design. Identification of the design certification applicant is necessary to implement this appendix, for two reasons. First, the implementation of 10 CFR 52.63(c) depends on whether an applicant for a COL contracts with the design certification applicant to provide the generic DCD and supporting design information. If the COL applicant does not use the design certification applicant to provide this information, then the COL applicant must meet the requirements in 10 CFR 52.63(c). Also, paragraph X.A.1 of this appendix requires the design certification applicant to maintain the generic DCD throughout the time this appendix may be referenced.

B. Definitions

During development of the first two DCRs, the Commission decided that there would be both generic (master) DCDs maintained by the NRC and the design certification applicant, as well as individual plant-specific DCDs maintained by each applicant and licensee that reference this appendix. This distinction is necessary in order to specify the relevant plant-specific requirements to applicants and licensees referencing the appendix. The master DCDs would include generic changes to the version of the DCD approved in this design certification rulemaking. These changes would occur as the result of generic rulemaking by the Commission, under the change criteria in section VIII of this appendix. The Commission also requires each applicant and licensee referencing this appendix to submit and maintain a plant-specific DCD.

This plant-specific DCD would contain (not just incorporate by reference) the information in the generic DCD. The plant-specific DCD would be

updated as necessary to reflect the generic changes to the DCD that the Commission may adopt through rulemaking, plant-specific departures from the generic DCD that the Commission imposed on the licensee by order, and any plant-specific departures that the licensee chooses to make in accordance with the relevant processes in section VIII of this appendix. Thus, the plant-specific DCD would function like an updated FSAR because it would provide the most complete and accurate information on a plant's licensing basis for that part of the plant within the scope of this appendix. Therefore, this appendix would define both a generic DCD and a plant-specific DCD.

Also, the Commission decided to treat the TS in section 16.1 of the generic DCD as a special category of information and to designate them as generic TS in order to facilitate the special treatment of this information under this appendix. A COL applicant must submit plant-specific TS that consist of the generic TS, which may be modified under paragraph VIII.C of this appendix, and the remaining plant-specific information needed to complete the TS. The FSAR that is required by 10 CFR 52.79(b) will consist of the plant-specific DCD, the site-specific portion of the FSAR, and the plant-specific TS.

The terms Tier 1, Tier 2, Tier 2*, and COL action items (license information) are defined in this appendix because these concepts were not envisioned when 10 CFR part 52 was developed. The design certification applicants and the NRC used these terms in implementing the two-tiered rule structure that was proposed by representatives of the nuclear industry after issuance of 10 CFR part 52. Therefore, appropriate definitions for these additional terms are included in this appendix. The nuclear industry representatives requested a two-tiered structure for the DCRs to achieve issue preclusion for a greater amount of information than was originally planned for the DCRs, while retaining flexibility for design implementation. The Commission approved the use of a two-tiered rule structure in its staff requirements memorandum (SRM), dated February 14, 1991, on SECY–90–377, ''Requirements for Design Certification Under 10 CFR Part 52,'' dated November 8, 1990. This document and others are available in the Regulatory History of Design Certification (see section IV, Availability of Documents, of this Statement of Consideration (SOC)).

The Tier 1 portion of the design-related information contained in the DCD is certified by this appendix and, therefore, is subject to the special backfit provisions in paragraph VIII.A of this appendix. An applicant who references this appendix is required to incorporate by reference and comply with Tier 1, under paragraphs III.B and IV.A.1 of this appendix. This information consists of an introduction to Tier 1, the system based and non-system based design descriptions and corresponding ITAAC, significant interface requirements, and significant site parameters for the design. The design descriptions, interface requirements, and site parameters in Tier 1 were derived from Tier 2, but may be more general than the Tier 2 information. The NRC staff's evaluation of the Tier 1 information is provided in section 14.3 of the FSER. Changes to or departures from the Tier 1 information must comply with section VIII.A of this appendix.

The Tier 1 design descriptions serve as commitments for the lifetime of a facility referencing the design certification. The ITAAC verifies that the as-built facility conforms with the approved design and applicable regulations. Under 10 CFR 52.103(g), the Commission must find that the acceptance criteria in the ITAAC are met before authorizing operation. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not constitute regulatory requirements for licensees or for renewal of the COL. However, subsequent modifications to the facility must comply with the design descriptions in the plant-specific DCD unless changes are made under the change process in section VIII of this appendix. The Tier 1 interface requirements are the most significant of the interface requirements for systems that are wholly or partially outside the scope of the standard design. Tier 1 interface requirements were submitted in response to 10 CFR 52.47(a)(1)(vii) and must be met by the site-specific design features of a facility that references this appendix. An application that references this appendix must demonstrate that the site parameters (both Tier 1 and Tier 2) are met at the proposed site (refer to paragraph III.D of this SOC).

Tier 2 is the portion of the design-related information contained in the DCD that is approved by this appendix but not certified. Tier 2 information is subject to the backfit provisions in paragraph VIII.B of this appendix. Tier 2 includes the information required by 10 CFR 52.47 (with the exception of generic TS, conceptual design information, and the evaluation of SAMDAs) and the supporting information on inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met. As with Tier 1, paragraphs III.B and IV.A.1 of this appendix require an applicant who references this appendix to incorporate Tier 2 by reference and to comply with Tier 2, except for the COL action items, including the investment protection short-term availability controls in section 16.3 of the generic DCD. The definition of Tier 2 makes clear that Tier 2 information has been determined by the Commission, by virtue of its inclusion in this appendix and its designation as Tier 2 information, to be an approved sufficient method for meeting Tier 1 requirements. However, there may be other acceptable ways of complying with Tier 1. The appropriate criteria for departing from Tier 2 information are specified in paragraph VIII.B of this appendix. Departures from Tier 2 do not negate the requirement in paragraph III.B to reference Tier 2.

A definition of ''combined license action items'' (COL information), which is part of the Tier 2 information, has been added to clarify that COL applicants who reference this appendix are required to address COL action items in their license application. However, the COL action items are not the only acceptable set of information. An applicant may depart from or omit COL action items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless they are restated in the FSAR. For additional discussion, see Section D.

The investment protection short-term availability controls, which are set forth in section 16.3 of the generic DCD, were added to the information that is part of Tier 2 to make it clear that the availability controls are not operational requirements for the purposes of paragraph VIII.C of this appendix. Rather, the availability controls are associated with specific design features. The availability controls may be changed if the associated design feature is changed under paragraph VIII.B of this appendix. For additional discussion, see section III.C of this SOC.

Certain Tier 2 information has been designated in the generic DCD with brackets and italicized text as ''Tier 2*'' information and, as discussed in greater detail in the section-by-section explanation for section H, a plant-specific departure from Tier 2* information requires prior NRC approval. However, the Tier 2* designation expires for some of this

information when the facility first achieves full power after the finding required by 10 CFR 52.103(g). The process for changing Tier 2* information and the time at which its status as Tier 2* expires is set forth in paragraph VIII.B.6 of this appendix. Some Tier 2* requirements concerning special pre-operational tests are designated to be performed only for the first plant or first three plants referencing the AP1000 DCR. The Tier 2* designation for these selected tests will expire after the first plant or first three plants complete the specified tests. However, a COL action item requires that subsequent plants also perform the tests or justify that the results of the first-plant-only or first-three-plants-only tests are applicable to the subsequent plant.

In an earlier rulemaking (64 FR 53582; October 4, 1999), the Commission revised 10 CFR 50.59 to incorporate new thresholds for permitting changes to a plant as described in the FSAR without NRC approval. For consistency and clarity, the Commission proposes to use these new thresholds in the proposed AP1000 DCR. Inasmuch as § 50.59 is the primary change mechanism for operating nuclear plants, the Commission believes that future plants referencing the AP1000 DCR should utilize thresholds as close to § 50.59 as is practicable and appropriate. Because of some differences in how the change control requirements are structured in the DCRs, certain definitions contained in § 50.59 are not applicable to 10 CFR part 52 and are not being included in this rule. One definition that the Commission is including is the definition from the new § 50.59 for a ''departure from a method of evaluation,'' (paragraph II.G), which is appropriate to include in this rulemaking so that the eight criteria in paragraph VIII.B.5.b of the final rule will be implemented as intended.

C. Scope and Contents

The purpose of section III of this appendix is to describe and define the scope and contents of this design certification and to set forth how documentation discrepancies or inconsistencies are to be resolved. Paragraph III.A is the required statement of the Office of the **Federal Register** (OFR) for approval of the incorporation by reference of Tier 1, Tier 2, and the generic TS into this appendix. Paragraph III.B requires COL applicants and licensees to comply with the requirements of this appendix. The legal effect of incorporation by reference is that the incorporated material has the same legal status as if it were published in the *Code of Federal Regulations.* This material, like any other properly-issued regulation, has the force and effect of law. Tier 1 and Tier 2 information, as well as the generic TS, have been combined into a single document called the generic DCD, in order to effectively control this information and facilitate its incorporation by reference into the rule. The generic DCD was prepared to meet the requirements of the OFR for incorporation by reference (1 CFR part 51). One of the requirements of the OFR for incorporation by reference is that the design certification applicant must make the generic DCD available upon request after the final rule becomes effective. Therefore, paragraph III.A of this appendix identifies a Westinghouse representative to be contacted in order to obtain a copy of the generic DCD.

Paragraphs III.A and III.B also identify the investment protection short-term availability controls in section 16.3 of the generic DCD as part of the Tier 2 information. During its review of the AP1000 design, the NRC determined that residual uncertainties associated with passive safety system performance increased the importance of non-safety-related active systems in providing defense-in-depth functions that back-up the passive systems. As a result, Westinghouse developed administrative controls to provide a high level of confidence that active systems having a significant safety role are available when challenged. Westinghouse named these additional controls ''investment protection short-term availability controls.'' The Commission included this characterization in section III of this appendix to ensure that these availability controls are binding on applicants and licensees that reference this appendix and will be enforceable by the NRC. The NRC's evaluation of the availability controls is provided in Chapter 22 of the FSER.

The generic DCD (master copy) for this design certification will be electronically accessible in NRC's Agencywide Documents Access and Management System (ADAMS) and at the OFR. Copies of the generic DCD will also be available at the NRC's Public Document Room (PDR). Questions concerning the accuracy of information in an application that references this appendix will be resolved by checking the master copy of the generic DCD in ADAMS. If a generic change (rulemaking) is made to the DCD by the change process provided in section VIII of this appendix, then at the completion of the rulemaking the NRC would request approval of the Director, OFR, for the changed incorporation by reference and change its copies of the generic DCD and notify the OFR and the design certification applicant to change their copies. The Commission is requiring that the design certification applicant maintain an up-to-date copy under paragraph X.A.1 of this appendix because it is likely that most applicants intending to reference the standard design will obtain the generic DCD from the design certification applicant. Plant-specific changes to and departures from the generic DCD will be maintained by the applicant or licensee that references this appendix in a plant-specific DCD under paragraph X.A.2 of this appendix.

In addition to requiring compliance with this appendix, paragraph III.B clarifies that the conceptual design information and Westinghouse's evaluation of SAMDAs are not considered to be part of this appendix. The conceptual design information is for those portions of the plant that are outside the scope of the standard design and are contained in Tier 2 information. As provided by 10 CFR 52.47(a)(1)(ix), these conceptual designs are not part of this appendix and, therefore, are not applicable to an application that references this appendix. Therefore, the applicant is not required to conform with the conceptual design information that was provided by the design certification applicant. The conceptual design information, which consists of site-specific design features, was required to facilitate the design certification review. Conceptual design information is neither Tier 1 nor Tier 2. Section 1.8 of Tier 2 identifies the location of the conceptual design information. Westinghouse's evaluation of various design alternatives to prevent and mitigate severe accidents does not constitute design requirements. The Commission's assessment of this information is discussed in Section VII of this SOC on environmental impacts.

Paragraphs III.C and III.D set forth the way potential conflicts are to be resolved. Paragraph III.C establishes the Tier 1 description in the DCD as controlling in the event of an inconsistency between the Tier 1 and Tier 2 information in the DCD. Paragraph III.D establishes the generic DCD as the controlling document in the event of an inconsistency between the DCD and the FSER for the certified standard design.

Paragraph III.E makes it clear that design activities that are wholly outside the scope of this design certification may be performed using site-specific design parameters, provided the design activities do not affect Tier 1 or Tier 2, or conflict with the interface requirements in the DCD. This provision applies to site-specific portions of the

plant, such as the administration building. Because this statement is not a definition, this provision has been located in Section III of this appendix.

D. Additional Requirements and Restrictions

Section IV of this appendix sets forth additional requirements and restrictions imposed upon an applicant who references this appendix. Paragraph IV.A sets forth the information requirements for these applicants. This paragraph distinguishes between information and/or documents which must actually be included in the application or the DCD, versus those which may be *incorporated by reference* (*i.e.*, referenced in the application as if the information or documents were included in the application). Any incorporation by reference in the application should be clear and should specify the title, date, edition, or version of a document, the page number(s), and table(s) containing the relevant information to be incorporated.

Paragraph IV.A.1 requires an applicant who references this appendix to incorporate by reference this appendix in its application. The legal effect of such an incorporation by reference is that this appendix is legally binding on the applicant or licensee. Paragraph IV.A.2.a requires that a plant-specific DCD be included in the initial application to ensure that the applicant commits to complying with the DCD. This paragraph also requires the plant-specific DCD to use the same format as the generic DCD and reflect the applicant's proposed departures and exemptions from the generic DCD as of the time of submission of the application. The Commission expects that the plant-specific DCD will become the plant's FSAR, by including information, *i.e.*, site-specific information, for the portions of the plant outside the scope of the referenced design, including related ITAAC, and other matters required to be included in an FSAR by 10 CFR 50.34 and 52.79. Integration of the plant-specific DCD and remaining site-specific information into the plant's FSAR, will result in an application that is easier to use and should minimize ''duplicate documentation'' and the attendant possibility for confusion. Paragraph IV.A.2.a also requires that the initial application include the reports on departures and exemptions as of the time of submission of the application.

Paragraph IV.A.2.b requires that an application referencing this appendix include the reports required by paragraph X.B of this appendix for exemptions and departures proposed by the applicant as of the date of submission of its application. Paragraph IV.A.2.c requires submission of plant-specific TS for the plant that consists of the generic TS from section 16.1 of the DCD, with any changes made under paragraph VIII.C of this appendix, and the TS for the site-specific portions of the plant that are either partially or wholly outside the scope of this design certification. The applicant must also provide the plant-specific information designated in the generic TS, such as bracketed values.

Paragraph IV.A.2.d requires the applicant referencing this appendix to provide information demonstrating that the proposed site falls within the site parameters for this appendix and that the plant-specific design complies with the interface requirements, as required by 10 CFR 52.79(b). If the proposed site has a characteristic that exceeds one or more of the site parameters in the DCD, then the proposed site is unacceptable for this design unless the applicant seeks an exemption under section VIII of this appendix and provides adequate justification for locating the certified design on the proposed site. Paragraph IV.A.2.e requires submission of information addressing COL action items, identified in the generic DCD as COL information in the application. The COL information identifies matters that need to be addressed by an applicant who references this appendix, as required by subpart C of 10 CFR part 52. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in its application (FSAR). Paragraph IV.A.2.f requires that the application include the information specified by 10 CFR 52.47(a) that is not within the scope of this rule, such as generic issues that must be addressed, in whole or in part, by an applicant that references this rule. Paragraph IV.A.3 requires the applicant to physically include, not simply reference, the proprietary and safeguards information referenced in the DCD, or its equivalent, to ensure that the applicant has actual notice of these requirements.

Paragraph IV.B reserves to the Commission the right to determine in what manner this DCR may be referenced by an applicant for a construction permit or operating license under 10 CFR part 50. This determination may occur in the context of a subsequent rulemaking modifying 10 CFR part 52 or this design certification rule, or on a case-by-case basis in the context of a specific application for a 10 CFR part 50 construction permit or operating license. This provision is necessary because the previous DCRs were not implemented in the manner that was originally envisioned at the time that 10 CFR part 52 was promulgated. The Commission's concern is with the way ITAAC were developed and the lack of experience with design certifications in license proceedings. Therefore, it is appropriate that the Commission retain some discretion regarding the way this appendix could be referenced in a 10 CFR part 50 licensing proceeding.

E. Applicable Regulations

The purpose of section V of this appendix is to specify the regulations that were applicable and in effect at the time this design certification was approved. These regulations consist of the technically relevant regulations identified in paragraph V.A, except for the regulations in paragraph V.B that are not applicable to this certified design.

Paragraph V.A identifies the regulations in 10 CFR parts 20, 50, 73, and 100 that are applicable to the AP1000 design. After the NRC staff issued its FSER for the AP1000 design (NUREG–1793, September 2004), the Commission amended several existing regulations and adopted new regulations. The Commission reviewed these regulations to determine if they are applicable to this design and, if so, to determine if the design meets these regulations. The Commission finds that none of these new regulations are applicable to the AP1000 design. The Commission's determination of the applicable regulations was made as of the date specified in paragraph V.A of this appendix, which is the date that this appendix was approved by the Commission and signed by the Secretary of the Commission.

In paragraph V.B of this appendix, the Commission identifies the regulations that do not apply to the AP1000 design. The Commission has determined that the AP1000 design should be exempt from portions of 10 CFR 50.34, 50.62, and Appendix A to part 50, as described in the FSER (NUREG–1793) and summarized below:

(1) Paragraph (f)(2)(iv) of 10 CFR 50.34—Plant Safety Parameter Display Console. Under 10 CFR 52.47(a)(ii), an applicant for design certification must demonstrate compliance with any technically relevant Three Mile Island (TMI) requirements in 10 CFR 50.34(f). The requirement in 10 CFR 50.34(f)(2)(iv) states that an application must provide a plant safety parameter display console that will display a minimum set of parameters defining the safety status of the plant, be capable of displaying a full range of important plant parameters and data trends on

demand, and be capable of indicating when process limits are being approached or exceeded. Westinghouse addresses this requirement, in section 18.8.2 of the DCD, with an integrated design rather than a stand-alone, add-on system, as is used at most current operating plants. Specifically, Westinghouse integrated the safety parameter display system (SPDS) requirements into the design requirements for the alarm and display systems. The NRC staff has determined that the function of a separate SPDS may be integrated into the overall control room design. Therefore, the Commission has determined that the special circumstances for allowing an exemption as described in 10 CFR 50.12(a)(2)(ii) exist because the requirement for an SPDS console need not be applied in this particular circumstance to achieve the underlying purpose because Westinghouse has provided an acceptable alternative that accomplishes the intent of the regulation. On this basis, the Commission concludes that an exemption from the requirements of 10 CFR 50.34(f)(2)(iv) is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security.

(2) Paragraph (c)(1) of 10 CFR 50.62—Auxiliary Feedwater System. The AP1000 design relies on the passive residual heat removal system (PRHR) in lieu of an auxiliary or emergency feedwater system as its safety-related method of removing decay heat. Westinghouse requested an exemption from a portion of 10 CFR 50.62(c)(1), which requires auxiliary or emergency feedwater as an alternate system for decay heat removal during an anticipated transient without scram (ATWS) event. The NRC staff concluded that Westinghouse met the intent of the rule by relying on the PRHR system to remove the decay heat and, thereby, met the underlying purpose of the rule. Therefore, the Commission has determined that the special circumstances for allowing an exemption described in 10 CFR 50.12(a)(2)(ii) exist because the requirement for an auxiliary or emergency feedwater system is not necessary to achieve the underlying purpose of 10 CFR 50.62(c)(1). This is because Westinghouse has adopted acceptable alternatives that accomplish the intent of this regulation, and the exemption is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security.

(3) Appendix A to 10 CFR part 50, GDC 17—Second Offsite Power Supply Circuit. Westinghouse requested a partial exemption from the requirement in General Design Criteria (GDC) 17 for a second offsite power supply circuit. The AP1000 plant design supports an exemption to this requirement by providing safety-related ''passive'' systems. These passive safety-related systems only require electric power for valves and the related instrumentation. The onsite Class 1E batteries and associated dc and ac distribution systems can provide the power for these valves and instrumentation. In addition, if no offsite power is available, it is expected that the non-safety-related onsite diesel generators would be available for important plant functions. However, this non-safety-related ac power is not relied on to maintain core cooling or containment integrity. Therefore, the Commission has determined that the special circumstances for allowing an exemption as described in 10 CFR 50.12(a)(2)(ii) exist because the requirement need not be applied in this particular circumstance to achieve the underlying purpose of having two offsite power sources. This is because the AP1000 design includes an acceptable alternative approach to accomplish safety functions that do not rely on power from the offsite system and, therefore, accomplishes the intent of the regulation. On this basis, the Commission concludes that a partial exemption from the requirements of GDC 17 is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security.

F. Issue Resolution

The purpose of section VI of this appendix is to identify the scope of issues that are resolved by the Commission in this rulemaking and; therefore, are ''matters resolved'' within the meaning and intent of 10 CFR 52.63(a)(4). The section is divided into five parts: (A) The Commission's safety findings in adopting this appendix, (B) the scope and nature of issues which are resolved by this rulemaking, (C) issues which are not resolved by this rulemaking, (D) the backfit restrictions applicable to the Commission with respect to this appendix, and (E) the availability of secondary references.

Paragraph VI.A describes the nature of the Commission's findings in general terms and makes the finding required by 10 CFR 52.54 for the Commission's approval of this DCR. Furthermore, paragraph VI.A explicitly states the Commission's determination that this design provides adequate protection of the public health and safety.

Paragraph VI.B sets forth the scope of issues that may not be challenged as a matter of right in subsequent proceedings. The introductory phrase of paragraph VI.B clarifies that issue resolution as described in the remainder of the paragraph extends to the delineated NRC proceedings referencing this appendix. The remainder of paragraph VI.B describes the categories of information for which there is issue resolution. Specifically, paragraph VI.B.1 provides that all nuclear safety issues arising from the Atomic Energy Act of 1954, as amended, that are associated with the information in the NRC staff's FSER (NUREG–1793) and Supplement No. 1, the Tier 1 and Tier 2 information (including the availability controls in Section 16.3 of the generic DCD), and the rulemaking record for this appendix are resolved within the meaning of 10 CFR 52.63(a)(4). These issues include the information referenced in the DCD that are requirements (*i.e.*, ''secondary references''), as well as all issues arising from proprietary and safeguards information which are intended to be requirements.

Paragraph VI.B.2 provides for issue preclusion of proprietary and safeguards information. Paragraphs VI.B.3, VI.B.4, VI.B.5, and VI.B.6 clarify that approved changes to and departures from the DCD which are accomplished in compliance with the relevant procedures and criteria in section VIII of this appendix continue to be matters resolved in connection with this rulemaking. Paragraphs VI.B.4, VI.B.5, and VI.B.6, which characterize the scope of issue resolution in three situations, use the phrase *''but only for that plant.''* Paragraph VI.B.4 describes how issues associated with a design certification rule are resolved when an exemption has been granted for a plant referencing the design certification rule. Paragraph VI.B.5 describes how issues are resolved when a plant referencing the design certification rule obtains a license amendment for a departure from Tier 2 information.

Paragraph VI.B.6 describes how issues are resolved when the applicant or licensee departs from the Tier 2 information on the basis of paragraph VIII.B.5, which will waive the requirement for NRC approval. In all three situations, after a matter (*e.g.*, an exemption in the case of paragraph VI.B.4) is addressed for a specific plant referencing a design certification rule, the adequacy of that matter *for that plant* will not ordinarily be subject to challenge in any subsequent proceeding or action for that plant (*e.g.*, an enforcement action) listed in the

introductory portion of paragraph IV.B. There will not, by contrast, be any issue resolution on that subject matter for any other plant.

Paragraph VI.B.7 provides that, for those plants located on sites whose site parameters do not exceed those assumed in Westinghouse's evaluation of SAMDAs, all issues with respect to SAMDAs arising under the National Environmental Policy Act of 1969, as amended (NEPA), associated with the information in the environmental assessment for this design and the information regarding SAMDAs in Appendix 1B of the generic DCD are also resolved within the meaning and intent of 10 CFR 52.63(a)(4). If an exemption from a site parameter is granted, the exemption applicant has the initial burden of demonstrating that the original SAMDA analysis still applies to the actual site parameters but; if the exemption is approved, requests for litigation at the COL stage must meet the requirements of 10 CFR 2.309 and present sufficient information to create a genuine controversy in order to obtain a hearing on the site parameter exemption.

Paragraph VI.C reserves the right of the Commission to impose operational requirements on applicants that reference this appendix. This provision reflects the fact that operational requirements, including generic TS in section 16.1 of the DCD, were not completely or comprehensively reviewed at the design certification stage. Therefore, the special backfit provisions of 10 CFR 52.63 do not apply to operational requirements. However, all design changes will be controlled by the appropriate provision in section VIII of this appendix. Although the information in the DCD that is related to operational requirements is necessary to support the NRC's safety review of this design, the review of this information was not sufficient to conclude that the operational requirements are fully resolved and ready to be assigned finality under 10 CFR 52.63. As a result, if the NRC wanted to change a temperature limit and that operational change required a consequential change to a design feature, then the temperature limit backfit would be controlled by paragraph VIII.A or VIII.B of this appendix. However, changes to other operational requirements, such as inservice testing and inservice inspection programs, post-fuel load verification activities, and requirements governing shutdown risk that do not require a design change would not be restricted by 10 CFR 52.63 (see paragraph VIII.C of this appendix).

Paragraph VI.C allows the NRC to impose future operational requirements (distinct from design matters) on applicants who reference this design certification. Also, license conditions for portions of the plant within the scope of this design certification, *e.g.*, start-up and power ascension testing, are not restricted by 10 CFR 52.63. The requirement to perform these testing programs is contained in Tier 1 information. However, ITAAC cannot be specified for these subjects because the matters to be addressed in these license conditions cannot be verified prior to fuel load and operation, when the ITAAC are satisfied. Therefore, another regulatory vehicle is necessary to ensure that licensees comply with the matters contained in the license conditions. License conditions for these areas cannot be developed now because this requires the type of detailed design information that will be developed during a combined license review. In the absence of detailed design information to evaluate the need for and develop specific post-fuel load verifications for these matters, the Commission is reserving the right to impose license conditions by rule for post-fuel load verification activities for portions of the plant within the scope of this design certification.

Paragraph VI.D reiterates the restrictions (contained in section VIII of this appendix) placed upon the Commission when ordering generic or plant-specific modifications, changes or additions to structures, systems, or components, design features, design criteria, and ITAAC (paragraph VI.D.3 would address ITAAC) within the scope of the certified design.

Paragraph VI.E provides the procedure for an interested member of the public to obtain access to proprietary or safeguards information for the AP1000 design, in order to request and participate in proceedings identified in paragraph VI.B of this appendix, viz., proceedings involving licenses and applications which reference this appendix. Paragraph VI.E specifies that access must first be sought from the design certification applicant. If Westinghouse refuses to provide the information, the person seeking access shall request access from the Commission or the presiding officer, as applicable. Access to the proprietary or safeguards information may be ordered by the Commission, but must be subject to an appropriate non-disclosure agreement.

G. Duration of This Appendix

The purpose of section VII of this appendix is in part, to specify the period during which this design certification may be referenced by an applicant for a COL, under 10 CFR 52.55. This section also states that the design certification remains valid for an applicant or licensee that references the design certification until the application is withdrawn or the license expires. Therefore, if an application references this design certification during the 15-year period, then the design certification will be effective until the application is withdrawn or the license issued on that application expires. Also, the design certification will be effective for the referencing licensee if the license is renewed. The Commission intends for this appendix to remain valid for the life of the plant that references the design certification to achieve the benefits of standardization and licensing stability. This means that changes to, or plant-specific departures from, information in the plant-specific DCD must be made under the change processes in section VIII of this appendix for the life of the plant.

H. Processes for Changes and Departures

The purpose of section VIII of this appendix is to set forth the processes for generic changes to or plant-specific departures (including exemptions) from the DCD. The Commission adopted this restrictive change process in order to achieve a more stable licensing process for applicants and licensees that reference this DCR. Section VIII is divided into three paragraphs, which correspond to Tier 1, Tier 2, and operational requirements. The language of section VIII of this appendix distinguishes between generic *changes* to the DCD versus plant-specific *departures* from the DCD. Generic *changes* must be accomplished by rulemaking because the intended subject of the change is this DCR itself, as is contemplated by 10 CFR 52.63(a)(1). Consistent with 10 CFR 52.63(a)(2), any generic rulemaking changes are applicable to all plants, absent circumstances which render the change [''modification'' in the language of 10 CFR 52.63(a)(2)] ''technically irrelevant.'' By contrast, plant-specific *departures* could be either a Commission-issued order to one or more applicants or licensees; or an applicant or licensee-initiated departure applicable only to that applicant's or licensee's plant(s), similar to a 10 CFR 50.59 departure or an exemption. Because these plant-specific departures will result in a DCD that is unique for that plant, section X of this appendix requires an applicant or licensee to maintain a plant-specific DCD. For

purposes of brevity, this discussion refers to both generic changes and plant-specific departures as ''change processes.''

Section VIII of this appendix refers to an exemption from one or more requirements of this appendix and the criteria for granting an exemption. The Commission cautions that when the exemption involves an underlying substantive requirement (applicable regulation), then the applicant or licensee requesting the exemption must also show that an exemption from the underlying applicable requirement meets the criteria of 10 CFR 50.12.

Tier 1 information

The change processes for Tier 1 information are covered in paragraph VIII.A. Generic changes to Tier 1 are accomplished by rulemakings that amend the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). This provision provides that the Commission may not modify, change, rescind, or impose new requirements by rulemaking except when necessary either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time of approval of the design certification or to ensure adequate protection of the public health and safety or common defense and security. The rulemakings must provide for notice and opportunity for public comment on the proposed change, as required by 10 CFR 52.63(a)(1). Departures from Tier 1 may occur in two ways: (1) The Commission may *order* a licensee to depart from Tier 1, as provided in paragraph VIII.A.3; or (2) an applicant or licensee may request an *exemption* from Tier 1, as provided in paragraph VIII.A.4. If the Commission seeks to order a licensee to depart from Tier 1, paragraph VIII.A.3 requires that the Commission find both that the departure is necessary for adequate protection or for compliance, and that special circumstances are present. Paragraph VIII.A.4 provides that exemptions from Tier 1 requested by an applicant or licensee are governed by the requirements of 10 CFR 52.63(b)(1) and 52.97(b), which provide an opportunity for a hearing. In addition, the Commission will not grant requests for exemptions that may result in a significant decrease in the level of safety otherwise provided by the design.

Tier 2 information

The change processes for the three different categories of Tier 2 information, namely, Tier 2, Tier 2*, and Tier 2* with a time of expiration, are set forth in paragraph VIII.B. The change process for Tier 2 has the same elements as the Tier 1 change process, but some of the standards for plant-specific orders and exemptions are different. As stated in section III, of this SOC, it is the Commission's intent that this appendix emulates Appendix C to 10 CFR part 52. However, the Commission has revised the 10 CFR 50.59-like change process in paragraph VIII.B.5 of this appendix to be commensurate with the new 10 CFR 50.59 (64 FR 53613, October 4, 1999).

The process for generic Tier 2 changes (including changes to Tier 2* and Tier 2* with a time of expiration) tracks the process for generic Tier 1 changes. As set forth in paragraph VIII.B.1, generic Tier 2 changes are accomplished by rulemaking amending the generic DCD and are governed by the standards in 10 CFR 52.63(a)(1). This provision provides that the Commission may not modify, change, rescind, or impose new requirements by rulemaking except when necessary, either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time of approval of the design certification or to ensure adequate protection of the public health and safety or common defense and security. If a generic change is made to Tier 2* information, then the category and expiration, if necessary, of the new information would also be determined in the rulemaking and the appropriate change process for that new information would apply.

Departures from Tier 2 may occur in five ways: (1) The Commission may order a plant-specific departure, as set forth in paragraph VIII.B.3; (2) an applicant or licensee may request an exemption from a Tier 2 requirement as set forth in paragraph VIII.B.4; (3) a licensee may make a departure without prior NRC approval under paragraph VIII.B.5 [similar to the process in 10 CFR 50.59]; (4) the licensee may request NRC approval for proposed departures which do not meet the requirements in paragraph VIII.B.5 as provided in paragraph VIII.B.5.d; and (5) the licensee may request NRC approval for a departure from Tier 2* information under paragraph VIII.B.6.

Similar to Commission-ordered Tier 1 departures and generic Tier 2 changes, Commission-ordered Tier 2 departures cannot be imposed except when necessary either to bring the certification into compliance with the Commission's regulations applicable and in effect at the time of approval of the design certification or to ensure adequate protection of the public health and safety or common defense and security, as set forth in paragraph VIII.B.3. However, the special circumstances for the Commission-ordered Tier 2 departures do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the plant-specific order, as required by 10 CFR 52.63(a)(3). The Commission determined that it was not necessary to impose an additional limitation similar to that imposed on Tier 1 departures by 10 CFR 52.63(a)(3) and (b)(1). This type of additional limitation for standardization would unnecessarily restrict the flexibility of applicants and licensees with respect to Tier 2 information.

An applicant or licensee may request an exemption from Tier 2 information as set forth in paragraph VIII.B.4. The applicant or licensee must demonstrate that the exemption complies with one of the special circumstances in 10 CFR 50.12(a). In addition, the Commission will not grant requests for exemptions that may result in a significant decrease in the level of safety otherwise provided by the design. However, the special circumstances for the exemption do not have to outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. If the exemption is requested by an applicant for a license, the exemption is subject to litigation in the same manner as other issues in the license hearing, consistent with 10 CFR 52.63(b)(1). If the exemption is requested by a licensee, then the exemption is subject to litigation in the same manner as a license amendment.

Paragraph VIII.B.5 allows an applicant or licensee to depart from Tier 2 information, without prior NRC approval, if the proposed departure does not involve a change to, or departure from, Tier 1 or Tier 2* information, TS, or does not require a license amendment under paragraphs VIII.B.5.b or VIII.B.5.c. The TS referred to in VIII.B.5.a of this paragraph are the TS in section 16.1 of the generic DCD, including bases, for departures made prior to issuance of the COL. After issuance of the COL, the plant-specific TS are controlling under paragraph VIII.B.5. The bases for the plant-specific TS will be controlled by the bases control procedures for the plant-specific TS (analogous to the bases control provision in the Improved Standard Technical Specifications). The requirement for a license amendment in paragraph VIII.B.5.b will be similar to the definition in the new 10 CFR 50.59 and apply to all information in Tier 2 except for the information that resolves the severe accident issues.

The Commission believes that the resolution of severe accident issues should be preserved and maintained in the same fashion as all other safety issues that were resolved during the design certification review (refer to SRM on SECY–90–377). However, because of the increased uncertainty in severe accident issue resolutions, the Commission has adopted separate criteria in paragraph VIII.B.5.c for determining if a departure from information that resolves severe accident issues would require a license amendment. For purposes of applying the special criteria in paragraph VIII.B.5.c, severe accident resolutions are limited to design features where the intended function of the design feature is relied upon to resolve postulated accidents when the reactor core has melted and exited the reactor vessel, and the containment is being challenged. These design features are identified in section 1.9.5 and Appendix 19B of the DCD, with other issues, and are described in other sections of the DCD. Therefore, the location of design information in the DCD is not important to the application of this special procedure for severe accident issues. However, the special procedure in paragraph VIII.B.5.c does not apply to design features that resolve so-called ''beyond design-basis accidents'' or other low-probability events. The important aspect of this special procedure is that it is limited to severe accident design features, as defined above. Some design features may have intended functions to meet ''design basis'' requirements and to resolve ''severe accidents.'' If these design features are reviewed under paragraph VIII.B.5, then the appropriate criteria from either paragraphs VIII.B.5.b or VIII.B.5.c are selected depending upon the function being changed.

An applicant or licensee that plans to depart from Tier 2 information, under paragraph VIII.B.5, is required to prepare an evaluation which provides the bases for the determination that the proposed change does not require a license amendment or involve a change to Tier 1 or Tier 2* information, or a change to the TS, as explained above. In order to achieve the Commission's goals for design certification, the evaluation needs to consider all of the matters that were resolved in the DCD, such as generic issue resolutions that are relevant to the proposed departure. The benefits of the early resolution of safety issues would be lost if departures from the DCD were made that violated these resolutions without appropriate review.

The evaluation of the relevant matters needs to consider the proposed departure over the full range of power operation from startup to shutdown, as it relates to anticipated operational occurrences, transients, design-basis accidents, and severe accidents. The evaluation must also include a review of all relevant secondary references from the DCD because Tier 2 information, which is intended to be treated as a requirement, is contained in the secondary references. The evaluation should consider Tables 14.3–1 through 14.3–8 and 19.59–18 of the generic DCD to ensure that the proposed change does not impact Tier 1 information. These tables contain cross-references from the safety analyses and probabilistic risk assessment in Tier 2 to the important parameters that were included in Tier 1.

A party to an adjudicatory proceeding (e.g., for issuance of a COL) who believes that an applicant or licensee has not complied with paragraph VIII.B.5 when departing from Tier 2 information, is permitted to petition to admit such a contention into the proceeding under paragraph VIII.B.5.f. This provision was included because an incorrect departure from the requirements of this appendix essentially places the departure outside of the scope of the Commission's safety finding in the design certification rulemaking. Therefore, it follows that properly founded contentions alleging such incorrectly implemented departures cannot be considered ''resolved'' by this rulemaking. As set forth in paragraph VIII.B.5.f, the petition must comply with the requirements of 10 CFR 2.309 and show that the departure does not comply with paragraph VIII.B.5. Any other party may file a response to the petition. If on the basis of the petition and any responses, the presiding officer in the proceeding determines that the required showing has been made, the matter shall be certified to the Commission for its final determination. In the absence of a proceeding, petitions alleging nonconformance with paragraph VIII.B.5 requirements applicable to Tier 2 departures will be treated as petitions for enforcement action under 10 CFR 2.206.

Paragraph VIII.B.6 provides a process for departing from Tier 2* information. The creation of and restrictions on changing Tier 2* information resulted from the development of the Tier 1 information for ABWR design certification (Appendix A to part 52) and the ABB–CE System 80+ design certification (Appendix B to part 52). During this development process, these applicants requested that the amount of information in Tier 1 be minimized to provide additional flexibility for an applicant or licensee who references these appendices. Also, many codes, standards, and design processes, which were not specified in Tier 1 that are acceptable for meeting ITAAC, were specified in Tier 2. The result of these actions is that certain significant information only exists in Tier 2 and the Commission does not want this significant information to be changed without prior NRC approval. This Tier 2* information is identified in the generic DCD with italicized text and brackets (See Table 1–1 of AP1000 DCD Introduction).

Although the Tier 2* designation was originally intended to last for the lifetime of the facility, like Tier 1 information, the NRC determined that some of the Tier 2* information could expire when the plant first achieves full (100 percent) power, after the finding required by 10 CFR 52.103(g), while other Tier 2* information must remain in effect throughout the life of the facility. The factors determining whether Tier 2* information could expire after the first full power was achieved were whether the Tier 1 information would govern these areas after first full power and the NRC's determination that prior approval was required before implementation of the change due to the significance of the information. Therefore, certain Tier 2* information listed in paragraph VIII.B.6.c ceases to retain its Tier 2* designation after full-power operation is first achieved following the Commission finding under 10 CFR 52.103(g). Thereafter, that information is deemed to be Tier 2 information that is subject to the departure requirements in paragraph VIII.B.5. By contrast, the Tier 2* information identified in paragraph VIII.B.6.b retains its Tier 2* designation throughout the duration of the license, including any period of license renewal.

Certain preoperational tests in paragraph VIII.B.6.c are designated to be performed only for the first plant or first three plants that reference this appendix. Westinghouse's basis for performing these ''first-plant-only'' and ''first-three-plants-only'' preoperational tests is provided in section 14.2.5 of the DCD. The NRC found Westinghouse's basis for performing these tests and its justification for only performing the tests on the first plant or first three plants acceptable. The NRC's decision was based on the need to verify that plant-specific manufacturing and/or construction variations do not adversely impact the predicted performance of certain passive safety systems, while recognizing that these special tests will result in significant thermal transients being applied to critical plant

components. The NRC believes that the range of manufacturing or construction variations that could adversely affect the relevant passive safety systems would be adequately disclosed after performing the designated tests on the first plant, or the first three plants, as applicable. The COL action item in section 14.4.6 of the DCD states that subsequent plants shall either perform these preoperational tests or justify that the results of the first-plant-only or first-three-plant-only tests are applicable to the subsequent plant. The Tier 2* designation for these tests will expire after the first plant or first three plants complete these tests, as indicated in paragraph VIII.B.6.c.

If Tier 2* information is changed in a generic rulemaking, the designation of the new information (Tier 1, 2*, or 2) would also be determined in the rulemaking and the appropriate process for future changes would apply. If a plant-specific departure is made from Tier 2* information, then the new designation would apply only to that plant. If an applicant who references this design certification makes a departure from Tier 2* information, the new information is subject to litigation in the same manner as other plant-specific issues in the licensing hearing. If a licensee makes a departure from Tier 2* information, it will be treated as a license amendment under 10 CFR 50.90 and the finality will be determined under paragraph VI.B.5 of this appendix. Any requests for departures from Tier 2* information that affects Tier 1 must also comply with the requirements in paragraph VIII.A of this appendix.

Operational Requirements

The change process for TS and other operational requirements in the DCD is set forth in paragraph VIII.C. This change process has elements similar to the Tier 1 and Tier 2 change process in paragraphs VIII.A and VIII.B, but with significantly different change standards. Because of the different finality status for TS and other operational requirements (refer to paragraph III.F of this SOC), the Commission designated a special category of information, consisting of the TS and other operational requirements, with its own change process in proposed paragraph VIII.C. The key to using the change processes proposed in section VIII is to determine if the proposed change or departure requires a change to a design feature described in the generic DCD. If a design change is required, then the appropriate change process in paragraph VIII.A or VIII.B applies. However, if a proposed change to the TS or other operational requirements does not require a change to a design feature in the generic DCD, then paragraph VIII.C applies. The language in paragraph VIII.C also distinguishes between generic (section 16.1 of DCD) and plant-specific TS to account for the different treatment and finality accorded TS before and after a license is issued.

The process in paragraph VIII.C.1 for making generic changes to the generic TS in section 16.1 of the DCD or other operational requirements in the generic DCD is accomplished by rulemaking and governed by the backfit standards in 10 CFR 50.109. The determination of whether the generic TS and other operational requirements were completely reviewed and approved in the design certification rulemaking is based upon the extent to which an NRC safety conclusion in the FSER is being modified or changed. If it cannot be determined that the TS or operational requirement was comprehensively reviewed and finalized in the design certification rulemaking, then there is no backfit restriction under 10 CFR 50.109 because no prior position was taken on this safety matter. Generic changes made under proposed paragraph VIII.C.1 are applicable to all applicants or licensees (refer to paragraph VIII.C.2), unless the change is irrelevant because of a plant-specific departure.

Some generic TS and investment protection short-term availability controls contain values in brackets []. The brackets are placeholders indicating that the NRC's review is not complete, and represent a requirement that the applicant for a combined license referencing the AP1000 DCR must replace the values in brackets with final plant-specific values. The values in brackets are neither part of the design certification rule nor are they binding. Therefore, the replacement of bracketed values with final plant-specific values does not require an exemption from the generic TS or investment protection short-term availability controls.

Plant-specific departures may occur by either a Commission order under paragraph VIII.C.3 or an applicant's exemption request under paragraph VIII.C.4. The basis for determining if the TS or operational requirement was completely reviewed and approved for these processes is the same as for paragraph VIII.C.1 above. If the TS or operational requirement is comprehensively reviewed and finalized in the design certification rulemaking, then the Commission must demonstrate that special circumstances are present before ordering a plant-specific departure. If not, there is no restriction on plant-specific changes to the TS or operational requirements, prior to the issuance of a license, provided a design change is not required. Although the generic TS were reviewed and approved by the NRC staff in support of the design certification review, the Commission intends to consider the lessons learned from subsequent operating experience during its licensing review of the plant-specific TS. The process for petitioning to intervene on a TS or operational requirement contained in paragraph VIII.C.5 is similar to other issues in a licensing hearing, except that the petitioner must also demonstrate why special circumstances are present.

Finally, the generic TS will have no further effect on the plant-specific TS after the issuance of a license that references this appendix. The bases for the generic TS will be controlled by the change process in paragraph VIII.C of this appendix. After a license is issued, the bases will be controlled by the bases change provision set forth in the administrative controls section of the plant-specific TS.

I. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

The purpose of section IX of this appendix is to set forth how the ITAAC in Tier 1 of this design certification rule are to be treated in a license proceeding. Paragraph IX.A restates the responsibilities of an applicant or licensee for performing and successfully completing ITAAC, and notifying the NRC of such completion. Paragraph IX.A.1 clarifies that an applicant may proceed at its own risk with design and procurement activities subject to ITAAC, and that a licensee may proceed at its own risk with design, procurement, construction, and preoperational testing activities subject to an ITAAC, even though the NRC may not have found that any particular ITAAC has been successfully completed. Paragraph IX.A.2 requires the licensee to notify the NRC that the required inspections, tests, and analyses in the ITAAC have been completed and that the acceptance criteria have been met.

Paragraphs IX.B.1 and IX.B.2 reiterate the NRC's responsibilities with respect to ITAAC as set forth in 10 CFR 52.99 and 52.103(g).[1] Finally, paragraph IX.B.3 states that ITAAC do not, by virtue of their inclusion in the DCD, constitute regulatory requirements after the licensee has received authorization to load fuel or has been granted a

[1] For discussion of the verification of ITAAC, see SECY–00—92, ''Combined License Review Process,'' dated April 20, 2000.

renewal of its license. However, subsequent modifications to the terms of the COL must comply with the design descriptions in the DCD unless the applicable requirements in 10 CFR 52.97 and section VIII of this appendix have been met. As discussed in paragraph III.D of this SOC, the Commission will defer a determination of the applicability of ITAAC and its effect in terms of issue resolution in 10 CFR part 50 licensing proceedings until a part 50 applicant decides to reference this appendix.

J. Records and Reporting

The purpose of section X of this appendix is to set forth the requirements that will apply to maintaining records of changes to and departures from the generic DCD, which are to be reflected in the plant-specific DCD. Section X also sets forth the requirements for submitting reports (including updates to the plant-specific DCD) to the NRC. This section of the appendix is similar to the requirements for records and reports in 10 CFR part 50, except for minor differences in information collection and reporting requirements.

Paragraph X.A.1 of this appendix requires that a generic DCD and the proprietary and safeguards information referenced in the generic DCD be maintained by the applicant for this rule. The generic DCD was developed, in part, to meet the requirements for incorporation by reference, including availability requirements. Therefore, the proprietary and safeguards information could not be included in the generic DCD because they are not publicly available. However, the proprietary and safeguards information was reviewed by the NRC and, as stated in paragraph VI.B.2 of this appendix, the Commission considers the information resolved within the meaning of 10 CFR 52.63(a)(4). Because this information is not in the generic DCD, the proprietary and safeguards information, or its equivalent, is required to be provided by an applicant for a license. Therefore, to ensure that this information will be available, a requirement for the design certification applicant to maintain the proprietary and safeguards information was added to proposed paragraph X.A.1 of this appendix. The acceptable version of the proprietary and safeguards information is identified (referenced) in the version of the DCD that is incorporated into this rule. The generic DCD and the acceptable version of the proprietary and safeguards information must be maintained for the period of time that this appendix may be referenced.

Paragraphs X.A.2 and X.A.3 place recordkeeping requirements on the applicant or licensee that references this design certification so that its plant-specific DCD accurately reflects both generic changes to the generic DCD and plant-specific departures made under Section VIII of this appendix. The term ''plant-specific'' was added to paragraph X.A.2 and other sections of this appendix to distinguish between the generic DCD that is incorporated by reference into this appendix, and the plant-specific DCD that the applicant is required to submit under paragraph IV.A of this appendix. The requirement to maintain changes to the generic DCD is explicitly stated to ensure that these changes are not only reflected in the generic DCD, which will be maintained by the applicant for design certification, but also in the plant-specific DCD. Therefore, records of generic changes to the DCD will be required to be maintained by both entities to ensure that both entities have up-to-date DCDs.

Paragraph X.A of this appendix does not place recordkeeping requirements on site-specific information that is outside the scope of this rule. As discussed in paragraph III.D of this SOC, the FSAR required by 10 CFR 52.79 will contain the plant-specific DCD and the site-specific information for a facility that references this rule. The phrase ''site-specific portion of the final safety analysis report'' in paragraph X.B.3.c of this appendix refers to the information that is contained in the FSAR for a facility (required by 10 CFR 52.79) but is not part of the plant-specific DCD (required by paragraph IV.A of this appendix). Therefore, this rule does not require that duplicate documentation be maintained by an applicant or licensee that references this rule, because the plant-specific DCD is part of the FSAR for the facility.

Paragraph X.B.1 requires applicants or licensees that reference this rule to submit reports, which describe departures from the DCD and include a summary of the written evaluations. The requirements for the written evaluations are set forth in paragraph X.A.1. The frequency of the report submittals is set forth in paragraph X.B.3. The requirement for submitting a summary of the evaluations is similar to the requirement in 10 CFR 50.59(d)(2).

Paragraph X.B.2 requires applicants or licensees that reference this rule to submit updates to the DCD, which include both generic changes and plant-specific departures. The frequency for submitting updates is set forth in paragraph X.B.3. The requirements in paragraph X.B.3 for submitting the reports and updates will vary according to certain time periods during a facility's lifetime. If a potential applicant for a combined license who references this rule decides to depart from the generic DCD prior to submission of the application, then paragraph X.B.3.a will require that the updated DCD be submitted as part of the initial application for a license. Under paragraph X.B.3.b, the applicant may submit any subsequent updates to its plant-specific DCD along with its amendments to the application provided that the submittals are made at least once per year. Because amendments to an application are typically made more frequently than once a year, this should not be an excessive burden on the applicant.

Paragraph X.B.3.b also requires that the reports required by paragraph X.B.1 be submitted semi-annually. This increase in reporting frequency during the period of construction and application review is consistent with Commission guidance. Also, more frequent reporting of design changes during the period of detailed design and construction is necessary to closely monitor the status and progress of the facility. In order to make the finding under 10 CFR 52.103(g), the NRC must monitor the design changes made under proposed section VIII of this appendix. Frequent reporting of design changes would be particularly important when the number of design changes could be significant, such as during the procurement of components and equipment, detailed design of the plant before and during construction, and during preoperational testing. After the facility begins operation, the frequency of reporting will revert to the requirement in paragraph X.B.3.c, which is consistent with the requirements for plants licensed under 10 CFR 50.57.

IV. Availability of Documents

The NRC is making the documents identified below available to interested persons through one or more of the following:

Public Document Room (PDR). The NRC's Public Document Room is located at 11555 Rockville Pike, Public File Area O–1 F21, Rockville, Maryland 20852. Copies of publicly available documents related to this rulemaking can be viewed electronically on public computers in the PDR. The PDR reproduction contractor will make copies of documents for a fee.

Rulemaking Web site (Web). The NRC's interactive rulemaking Web site is located at *http://ruleforum.llnl.gov*. Selected documents may be viewed and

downloaded electronically via this Web site.

Public Electronic Reading Room (ADAMS). The NRC's Public Electronic Reading Room (PERR) is located at *http://www.nrc.gov/reading-rm/adams.html.* Through this site, the public can gain access to ADAMS, which provides text and image files of NRC's public documents.

Document	PDR	Web	ADAMS
AP1000 Design Control Document, Revision 15	X	.....	ML053460400
AP1000 Final Environmental Assessment	X	.....	ML053630176
AP1000 Final Safety Evaluation Report [NUREG–1793]	X	.....	ML043570339
NUREG–1793, Supplement 1, AP1000 FSER	X	.....	ML053410203
SECY–05–0227, Final Rule—AP1000 Design Certification	X	X	ML053250288
Regulatory History of Design Certification [2]	X	.....	ML003761550

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Act), Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless using such a standard is inconsistent with applicable law or is otherwise impractical. In this final rule, the NRC is approving the AP1000 standard plant design for use in nuclear power plant licensing under 10 CFR parts 50 or 52. Design certifications are not generic rulemakings establishing a generally applicable standard with which all parts 50 and 52 nuclear power plant licensees must comply. Design certifications are Commission approvals of specific nuclear power plant designs by rulemaking. Furthermore, design certifications are initiated by an applicant for rulemaking, rather than by the NRC. For these reasons, the NRC concludes that the Act does not apply to this final rule.

VI. Finding of No Significant Environmental Impact: Availability

The Commission has determined under NEPA, and the Commission's regulations in 10 CFR part 51, subpart A, that this design certification rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an Environmental Impact Statement (EIS) is not required. The basis for this determination, as documented in the environmental assessment (EA), is that this amendment to 10 CFR part 52 does not authorize the siting, construction, or operation of a facility using the AP1000 design; it only codifies the AP1000 design in a rule. The NRC will evaluate the environmental impacts and issue an EIS as appropriate under NEPA as part of the application(s) for the construction and operation of a facility referencing the AP1000 design certification rule.

In addition, as part of the environmental assessment for the AP1000 design, the NRC reviewed Westinghouse's evaluation of various design alternatives to prevent and mitigate severe accidents in Appendix 1B of the AP1000 DCD Tier 2. Based upon review of Westinghouse's evaluation, the Commission finds that: (1) Westinghouse identified a reasonably complete set of potential design alternatives to prevent and mitigate severe accidents for the AP1000 design; (2) none of the potential design alternatives are justified on the basis of cost-benefit considerations; and (3) it is unlikely that other design changes would be identified and justified in the future on the basis of cost-benefit considerations, because the estimated core damage frequencies for the AP1000 are very low on an absolute scale. These issues are considered resolved for the AP1000 design.

The EA, upon which the Commission's Finding of No Significant Impact is based, and the AP1000 DCD are available for examination and copying at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The NRC sent a copy of the EA and proposed rule to every State Liaison Officer and no comments were received. Single copies of the EA are also available from Lauren M. Quinones-Navarro, Mailstop O–4D9A, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

VII. Paperwork Reduction Act Statement

This final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150–0151.

The burden to the public for these information collections is estimated to average 8 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV*; and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0151), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

VIII. Regulatory Analysis

The NRC has not prepared a regulatory analysis for this final rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications are not generic rulemakings in the sense that design certifications do not establish standards or requirements with which all licensees must comply. Rather, design certifications are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification, rather than the NRC. Preparation of a regulatory analysis in

[2] The regulatory history of the NRC's design certification reviews is a package of 100 documents that is available in NRC's PERR and in the PDR. This history spans a 15-year period during which the NRC simultaneously developed the regulatory standards for reviewing these designs and the form and content of the rules that certified the designs.

this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

IX. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this final rule will not have a significant economic impact upon a substantial number of small entities. The final rule provides for certification of a nuclear power plant design. Neither the design certification applicant, nor prospective nuclear power plant licensees who reference this design certification rule, fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act, or the Small Business Size Standards set out in regulations issued by the Small Business Administration in 13 CFR part 121. Thus, this rule does not fall within the purview of the Regulatory Flexibility Act.

X. Backfit Analysis

The Commission has determined that this final rule does not constitute a backfit as defined in the backfit rule (10 CFR 50.109), because this design certification does not impose new or changed requirements on existing 10 CFR part 50 licensees, nor does it impose new or change requirements on existing DCRs in appendices A–C of part 52. Therefore, a backfit analysis was not prepared for this rule.

XI. Congressional Review Act

In accordance with the Congressional Review Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

List of Subjects in 10 CFR Part 52

Administrative practice and procedure, Antitrust, Backfitting, Combined license, Early site permit, Emergency planning, Fees, Incorporation by reference, Inspection, Limited work authorization, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Reporting and recordkeeping requirements, Standard design, Standard design certification.

■ For the reasons set out in this SOC and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 52.

PART 52—EARLY SITE PERMITS; STANDARD DESIGN CERTIFICATIONS; AND COMBINED LICENSES FOR NUCLEAR POWER PLANTS

■ 1. The authority citation for 10 CFR part 52 continues to read as follows:

Authority: Secs. 103, 104, 161, 182, 183, 186, 189, 68 Stat. 936, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2133, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846); sec. 1704, 112 Stat. 2750 (44 U.S.C. 3504 note).

■ 2. In § 52.8, paragraph (b) is revised to read as follows:

§ 52.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 52.15, 52.17, 52.29, 52.35, 52.45, 52.47, 52.51, 52.57, 52.63, 52.75, 52.77, 52.78, 52.79, 52.89, 52.91, 52.99, and appendices A, B, C, and D to this part.

■ 3. A new Appendix D to 10 CFR part 52 is added to read as follows:

Appendix D to Part 52—Design Certification Rule for the AP1000 Design

I. Introduction

Appendix D constitutes the standard design certification for the AP1000 [3] design, in accordance with 10 CFR part 52, subpart B. The applicant for certification of the AP1000 design is Westinghouse Electric Company LLC.

II. Definitions

A. *Generic design control document* (generic DCD) means the document containing the Tier 1 and Tier 2 information and generic technical specifications that is incorporated by reference into this appendix.

B. *Generic technical specifications* means the information required by 10 CFR 50.36 and 50.36a for the portion of the plant that is within the scope of this appendix.

C. *Plant-specific DCD* means the document maintained by an applicant or licensee who references this appendix consisting of the information in the generic DCD as modified and supplemented by the plant-specific departures and exemptions made under section VIII of this appendix.

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions;

2. Design descriptions;

3. Inspections, tests, analyses, and acceptance criteria (ITAAC);

4. Significant site parameters; and

5. Significant interface requirements.

E. *Tier 2* means the portion of the design-related information contained in the generic DCD that is approved but not certified by this appendix (Tier 2 information). Compliance with Tier 2 is required, but generic changes to and plant-specific departures from Tier 2 are governed by section VIII of this appendix. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in section VIII of this appendix. Regardless of these differences, an applicant or licensee must meet the requirement in paragraph III.B to reference Tier 2 when referencing Tier 1. Tier 2 information includes:

1. Information required by 10 CFR 52.47, with the exception of generic TS, the design-specific PRA, the evaluation of SAMDAs, and conceptual design information;

2. Information required for a final safety analysis report under 10 CFR 50.34;

3. Supporting information on the inspections, tests, and analyses that will be performed to demonstrate that the acceptance criteria in the ITAAC have been met; and

4. COL action items (COL information), which identify certain matters that shall be addressed in the site-specific portion of the FSAR by an applicant who references this appendix. These items constitute information requirements but are not the only acceptable set of information in the FSAR. An applicant may depart from or omit these items, provided that the departure or omission is identified and justified in the FSAR. After issuance of a construction permit or COL, these items are not requirements for the licensee unless such items are restated in the FSAR.

5. The investment protection short-term availability controls in section 16.3 of the DCD.

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in paragraph VIII.B.6 of this appendix. This designation expires for some *Tier 2** information under paragraph VIII.B.6.

G. *Departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses* means:

1. Changing any of the elements of the method described in the plant-specific DCD unless the results of the analysis are conservative or essentially the same; or

2. Changing from a method described in the plant-specific DCD to another method unless that method has been approved by the NRC for the intended application.

H. All other terms in this appendix have the meaning set out in 10 CFR 50.2, 10 CFR 52.3, or section 11 of the Atomic Energy Act of 1954, as amended, as applicable.

[3] AP1000 is a trademark of Westinghouse Electric Company LLC.

III. Scope and Contents

A. Tier 1, Tier 2 (including the investment protection short-term availability controls in Section 16.3), and the generic TS in the AP1000 DCD (Revision 15, dated December 8, 2005) are approved for incorporation by reference by the Director of the Office of the Federal Register on February 27, 2006 under 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the generic DCD may be obtained from Ronald P. Vijuk, Manager, Passive Plant Engineering, Westinghouse Electric Company, P.O. Box 355, Pittsburgh, Pennsylvania 15230–0355. A copy of the generic DCD is also available for examination and copying at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852. Copies are available for examination at the NRC Library, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, telephone (301) 415–5610, e-mail *LIBRARY@NRC.GOV* or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030 or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html*.

B. An applicant or licensee referencing this appendix, in accordance with Section IV of this appendix, shall incorporate by reference and comply with the requirements of this appendix, including Tier 1, Tier 2 (including the investment protection short-term availability controls in section 16.3 of the DCD), and the generic TS except as otherwise provided in this appendix. Conceptual design information in the generic DCD and the evaluation of SAMDAs in appendix 1B of the generic DCD are not part of this appendix.

C. If there is a conflict between Tier 1 and Tier 2 of the DCD, then Tier 1 controls.

D. If there is a conflict between the generic DCD and either the application for design certification of the AP1000 design or NUREG–1793, ''Final Safety Evaluation Report Related to Certification of the AP1000 Standard Design,'' (FSER) and Supplement No. 1, then the generic DCD controls.

E. Design activities for structures, systems, and components that are wholly outside the scope of this appendix may be performed using site characteristics, provided the design activities do not affect the DCD or conflict with the interface requirements.

IV. Additional Requirements and Restrictions

A. An applicant for a license that wishes to reference this appendix shall, in addition to complying with the requirements of 10 CFR 52.77, 52.78, and 52.79, comply with the following requirements:

1. Incorporate by reference, as part of its application, this appendix.

2. Include, as part of its application:

a. A plant-specific DCD containing the same type of information and using the same organization and numbering as the generic DCD for the AP1000 design, as modified and supplemented by the applicant's exemptions and departures;

b. The reports on departures from and updates to the plant-specific DCD required by paragraph X.B of this appendix;

c. Plant-specific TS, consisting of the generic and site-specific TS that are required by 10 CFR 50.36 and 50.36a;

d. Information demonstrating compliance with the site parameters and interface requirements;

e. Information that addresses the COL action items; and

f. Information required by 10 CFR 52.47(a) that is not within the scope of this appendix.

3. Physically include, in the plant-specific DCD, the proprietary and safeguards information referenced in the AP1000 DCD.

B. The Commission reserves the right to determine in what manner this appendix may be referenced by an applicant for a construction permit or operating license under part 50 of this chapter.

V. Applicable Regulations

A. Except as indicated in paragraph B of this section, the regulations that apply to the AP1000 design are in 10 CFR parts 20, 50, 73, and 100, codified as of January 23, 2006, that are applicable and technically relevant, as described in the FSER (NUREG–1793) and Supplement No. 1.

B. The AP1000 design is exempt from portions of the following regulations:

1. Paragraph (f)(2)(iv) of 10 CFR 50.34—Plant Safety Parameter Display Console;

2. Paragraph (c)(1) of 10 CFR 50.62—Auxiliary (or emergency) feedwater system; and

3. Appendix A to 10 CFR part 50, GDC 17—Second offsite power supply circuit.

VI. Issue Resolution

A. The Commission has determined that the structures, systems, components, and design features of the AP1000 design comply with the provisions of the Atomic Energy Act of 1954, as amended, and the applicable regulations identified in section V of this appendix; and therefore, provide adequate protection to the health and safety of the public. A conclusion that a matter is resolved includes the finding that additional or alternative structures, systems, components, design features, design criteria, testing, analyses, acceptance criteria, or justifications are not necessary for the AP1000 design.

B. The Commission considers the following matters resolved within the meaning of 10 CFR 52.63(a)(4) in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under to 10 CFR 52.103, and enforcement proceedings involving plants referencing this appendix:

1. All nuclear safety issues, except for the generic TS and other operational requirements, associated with the information in the FSER and Supplement No. 1, Tier 1, Tier 2 (including referenced information, which the context indicates is intended as requirements, and the investment protection short-term availability controls in section 16.3 of the DCD), and the rulemaking record for certification of the AP1000 design;

2. All nuclear safety and safeguards issues associated with the information in proprietary and safeguards documents, referenced and in context, are intended as requirements in the generic DCD for the AP1000 design;

3. All generic changes to the DCD under and in compliance with the change processes in sections VIII.A.1 and VIII.B.1 of this appendix;

4. All exemptions from the DCD under and in compliance with the change processes in sections VIII.A.4 and VIII.B.4 of this appendix, but only for that plant;

5. All departures from the DCD that are approved by license amendment, but only for that plant;

6. Except as provided in paragraph VIII.B.5.f of this appendix, all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant;

7. All environmental issues concerning SAMDAs associated with the information in the NRC's EA for the AP1000 design and Appendix 1B of the generic DCD, for plants referencing this appendix whose site parameters are within those specified in the SAMDA evaluation.

C. The Commission does not consider operational requirements for an applicant or licensee who references this appendix to be matters resolved within the meaning of 10 CFR 52.63(a)(4). The Commission reserves the right to require operational requirements for an applicant or licensee who references this appendix by rule, regulation, order, or license condition.

D. Except under the change processes in section VIII of this appendix, the Commission may not require an applicant or licensee who references this appendix to:

1. Modify structures, systems, components, or design features as described in the generic DCD;

2. Provide additional or alternative structures, systems, components, or design features not discussed in the generic DCD; or

3. Provide additional or alternative design criteria, testing, analyses, acceptance criteria, or justification for structures, systems, components, or design features discussed in the generic DCD.

E.1. Persons who wish to review proprietary and safeguards information or other secondary references in the AP1000 DCD, in order to request or participate in the hearing required by 10 CFR 52.85 or the hearing provided under 10 CFR 52.103, or to request or participate in any other hearing relating to this appendix in which interested persons have adjudicatory hearing rights, shall first request access to such information from Westinghouse. The request must state with particularity:

a. The nature of the proprietary or other information sought;

b. The reason why the information currently available to the public in the NRC's public document room is insufficient;

c. The relevance of the requested information to the hearing issue(s) which the person proposes to raise; and

d. A showing that the requesting person has the capability to understand and utilize the requested information.

2. If a person claims that the information is necessary to prepare a request for hearing, the request must be filed no later than 15 days after publication in the **Federal Register** of the notice required either by 10 CFR 52.85

or 10 CFR 52.103. If Westinghouse declines to provide the information sought, Westinghouse shall send a written response within ten (10) days of receiving the request to the requesting person setting forth with particularity the reasons for its refusal. The person may then request the Commission (or presiding officer, if a proceeding has been established) to order disclosure. The person shall include copies of the original request (and any subsequent clarifying information provided by the requesting party to the applicant) and the applicant's response. The Commission and presiding officer shall base their decisions solely on the person's original request (including any clarifying information provided by the requesting person to Westinghouse), and Westinghouse's response. The Commission and presiding officer may order Westinghouse to provide access to some or all of the requested information, subject to an appropriate non-disclosure agreement.

VII. Duration of This Appendix

This appendix may be referenced for a period of 15 years from February 27, 2006, except as provided for in 10 CFR 52.55(b) and 52.57(b). This appendix remains valid for an applicant or licensee who references this appendix until the application is withdrawn or the license expires, including any period of extended operation under a renewed license.

VIII. Processes for Changes and Departures

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3 or A.4 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in 10 CFR 52.63(a)(3).

4. Exemptions from Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.97(b). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

B. Tier 2 Information

1. Generic changes to Tier 2 information are governed by the requirements in 10 CFR 52.63(a)(1).

2. Generic changes to Tier 2 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 information by plant-specific order while this appendix is in effect under 10 CFR 52.55 or 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in 10 CFR 50.12(a) are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The Commission will deny a request for an exemption from Tier 2, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5.a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information, Tier 2* information, or the TS, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident issue identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by 10 CFR 50.90.

e. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

f. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under 10 CFR 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of 10 CFR 2.309, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a 10 CFR 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6.a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and 10 CFR 52.63(a)(4).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under 10 CFR 50.90.

(1) Maximum fuel rod average burn-up.

(2) Fuel principal design requirements.

(3) Fuel criteria evaluation process.

(4) Fire areas.

(5) Human factors engineering.

(6) Small-break loss-of-coolant accident (LOCA) analysis methodology.

c. A licensee who references this appendix may not, before the plant first achieves full power following the finding required by 10 CFR 52.103(g), depart from the following Tier 2* matters except under paragraph B.6.b of this section. After the plant first achieves full power, the following Tier 2* matters revert to Tier 2 status and are subject to the departure provisions in paragraph B.5 of this section.

(1) Nuclear Island structural dimensions.

(2) American Society of Mechanical Engineers Boiler & Pressure Vessel Code (ASME Code), Section III, and Code Case-284.

(3) Design Summary of Critical Sections.

(4) American Concrete Institute (ACI) 318, ACI 349, American National Standards Institute/American Institute of Steel Construction (ANSI/AISC)–690, and American Iron and Steel Institute (AISI), ''Specification for the Design of Cold Formed Steel Structural Members, Part 1 and 2,'' 1996 Edition and 2000 Supplement.

(5) Definition of critical locations and thicknesses.

(6) Seismic qualification methods and standards.

(7) Nuclear design of fuel and reactivity control system, except burn-up limit.

(8) Motor-operated and power-operated valves.

(9) Instrumentation and control system design processes, methods, and standards.

(10) Passive residual heat removal (PRHR) natural circulation test (first plant only).

(11) Automatic depressurization system (ADS) and core make-up tank (CMT) verification tests (first three plants only).

(12) Polar crane parked orientation.

(13) Piping design acceptance criteria.

(14) Containment vessel design parameters.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

C. Operational Requirements

1. Generic changes to generic TS and other operational requirements that were completely reviewed and approved in the design certification rulemaking and do not require a change to a design feature in the generic DCD are governed by the requirements in 10 CFR 50.109. Generic changes that require a change to a design feature in the generic DCD are governed by the requirements in paragraphs A or B of this section.

2. Generic changes to generic TS and other operational requirements are applicable to all applicants who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs C.3 or C.4 of this section.

3. The Commission may require plant-specific departures on generic TS and other operational requirements that were completely reviewed and approved, provided a change to a design feature in the generic DCD is not required and special circumstances as defined in 10 CFR 2.335 are present. The Commission may modify or supplement generic TS and other operational requirements that were not completely reviewed and approved or require additional TS and other operational requirements on a plant-specific basis, provided a change to a design feature in the generic DCD is not required.

4. An applicant who references this appendix may request an exemption from the generic TS or other operational requirements. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of 10 CFR 50.12(a). The grant of an exemption must be subject to litigation in the same manner as other issues material to the license hearing.

5. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license, or for operation under 10 CFR 52.103(a), who believes that an operational requirement approved in the DCD or a TS derived from the generic TS must be changed may petition to admit such a contention into the proceeding. The petition must comply with the general requirements of 10 CFR 2.309 and must demonstrate why special circumstances as defined in 10 CFR 2.335 are present, or demonstrate compliance with the Commission's regulations in effect at the time this appendix was approved, as set forth in section V of this appendix. Any other party may file a response to the petition. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. All other issues with respect to the plant-specific TS or other operational requirements are subject to a hearing as part of the license proceeding.

6. After issuance of a license, the generic TS have no further effect on the plant-specific TS. Changes to the plant-specific TS will be treated as license amendments under 10 CFR 50.90.

IX. Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC)

A.1 An applicant or licensee who references this appendix shall perform and demonstrate conformance with the ITAAC before fuel load. With respect to activities subject to an ITAAC, an applicant for a license may proceed at its own risk with design and procurement activities. A licensee may also proceed at its own risk with design, procurement, construction, and preoperational activities, even though the NRC may not have found that any particular ITAAC has been satisfied.

2. The licensee who references this appendix shall notify the NRC that the required inspections, tests, and analyses in the ITAAC have been successfully completed and that the corresponding acceptance criteria have been met.

3. If an activity is subject to an ITAAC and the applicant or licensee who references this appendix has not demonstrated that the ITAAC has been satisfied, the applicant or licensee may either take corrective actions to successfully complete that ITAAC, request an exemption from the ITAAC under section VIII of this appendix and 10 CFR 52.97(b), or petition for rulemaking to amend this appendix by changing the requirements of the ITAAC, under 10 CFR 2.802 and 52.97(b). Such rulemaking changes to the ITAAC must meet the requirements of paragraph VIII.A.1 of this appendix.

B.1 The NRC shall ensure that the required inspections, tests, and analyses in the ITAAC are performed. The NRC shall verify that the inspections, tests, and analyses referenced by the licensee have been successfully completed and, based solely thereon, find that the prescribed acceptance criteria have been met. At appropriate intervals during construction, the NRC shall publish notices of the successful completion of ITAAC in the **Federal Register**.

2. Under 10 CFR 52.99 and 52.103(g), the Commission shall find that the acceptance criteria in the ITAAC for the license are met before fuel load.

3. After the Commission has made the finding required by 10 CFR 52.103(g), the ITAAC do not, by virtue of their inclusion within the DCD, constitute regulatory requirements either for licensees or for renewal of the license; except for specific ITAAC, which are the subject of a section 103(a) hearing, their expiration will occur upon final Commission action in such a proceeding. However, subsequent modifications must comply with the Tier 1 and Tier 2 design descriptions in the plant-specific DCD unless the licensee has complied with the applicable requirements of 10 CFR 52.97 and section VIII of this appendix.

X. Records and Reporting

A. Records

1. The applicant for this appendix shall maintain a copy of the generic DCD that includes all generic changes to Tier 1, Tier 2, and the generic TS and other operational requirements. The applicant shall maintain the proprietary and safeguards information referenced in the generic DCD for the period that this appendix may be referenced, as specified in section VII of this appendix.

2. An applicant or licensee who references this appendix shall maintain the plant-specific DCD to accurately reflect both generic changes to the generic DCD and plant-specific departures made under section VIII of this appendix throughout the period of application and for the term of the license (including any period of renewal).

3. An applicant or licensee who references this appendix shall prepare and maintain written evaluations which provide the bases for the determinations required by section VIII of this appendix. These evaluations must be retained throughout the period of application and for the term of the license (including any period of renewal).

B. Reporting

1. An applicant or licensee who references this appendix shall submit a report to the NRC containing a brief description of any plant-specific departures from the DCD, including a summary of the evaluation of each. This report must be filed in accordance with the filing requirements applicable to reports in 10 CFR 50.4.

2. An applicant or licensee who references this appendix shall submit updates to its DCD, which reflect the generic changes to and plant-specific departures from the generic DCD made under section VIII of this appendix. These updates shall be filed under the filing requirements applicable to final safety analysis report updates in 10 CFR 50.4 and 50.71(e).

3. The reports and updates required by paragraphs X.B.1 and X.B.2 must be submitted as follows:

a. On the date that an application for a license referencing this appendix is

submitted, the application must include the report and any updates to the generic DCD.

b. During the interval from the date of application for a license to the date the Commission makes its findings under 10 CFR 52.103(g), the report must be submitted semi-annually. Updates to the plant-specific DCD must be submitted annually and may be submitted along with amendments to the application.

c. After the Commission has made its finding under 10 CFR 52.103(g), the reports and updates to the plant-specific DCD must be submitted, along with updates to the site-specific portion of the final safety analysis report for the facility, at the intervals required by 10 CFR 50.59(d)(2) and 50.71(e)(4), respectively, or at shorter intervals as specified in the license.

Dated at Rockville, Maryland, this 23rd day of January 2006.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

[FR Doc. 06–788 Filed 1–26–06; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2005–20034; Directorate Identifier 2004–NM–178–AD; Amendment 39–14463; AD 2006–02–11]

RIN 2120–AA64

Airworthiness Directives; McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F, MD–11, and MD–11F Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain McDonnell Douglas transport category airplanes. This AD requires doing repetitive detailed inspections for accumulation of debris (blockage) in the drain holes of the pitot tubes, and cleaning the hole if any evidence of debris is found. This AD results from reports of blocked drain holes of the pitot tubes. We are issuing this AD to prevent blocked drain holes of the pitot tubes, which could result in the accumulation of water in the pitot-static system and consequent failure of that system. Failure of the pitot-static system could result in erroneous airspeed indications in the cockpit and consequent loss of airspeed control.

DATES: This AD becomes effective March 3, 2006.

ADDRESSES: You may examine the AD docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL–401, Washington, DC.

Contact Boeing Commercial Airplanes, Long Beach Division, 3855 Lakewood Boulevard, Long Beach, California 90846, Attention: Data and Service Management, Dept. C1–L5A (D800–0024), for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Brett Portwood, Aerospace Engineer, Systems and Equipment Branch, ANM–130L, FAA, Los Angeles Aircraft Certification Office, 3960 Paramount Boulevard, Lakewood, California 90712–4137; telephone (562) 627–5350; fax (562) 627–5210.

SUPPLEMENTARY INFORMATION:

Examining the Docket

You may examine the airworthiness directive (AD) docket on the Internet at *http://dms.dot.gov* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the street address stated in the **ADDRESSES** section.

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to include an AD that would apply to certain McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F, MD–11, and MD–11F airplanes. That NPRM was published in the **Federal Register** on January 12, 2005 (70 FR 2062). That NPRM proposed to require doing repetitive detailed inspections for accumulation of debris (blockage) of the drain holes of the pitot tubes, and cleaning the hole if any evidence of debris is found.

Comments

We provided the public the opportunity to participate in the development of this AD. We have considered the comments received.

Support for the NPRM

One commenter supports the NPRM.

Requests To Extend Repetitive Interval

Three commenters request that the 650-flight-hour interval for the repetitive detailed inspections in paragraph (f) of the NPRM be increased. One commenter, the airplane manufacturer, states that it originally recommended an interval of 650 flight hours because that was believed to be greater than the A-check interval in use at that time. The commenter points out that an A-check for some operators is now approaching 1,000 flight hours and recommends that interval. The commenter also states that inspection data, which cover as much as ten years, show that there have been no findings of blockage of the holes of the pitot tube drain tube since implementation of repetitive inspections.

A second commenter states that it has performed the proposed repetitive inspections on its fleet every 2,000 flight hours since July 1999. The results of an analysis conducted by the commenter revealed no events of all three pitot tube drains being blocked and only two events where the drain holes on one of the three pitot tubes were blocked. Based on this service history, the commenter does not support a repetitive interval of less than 2,000 flight hours.

A third commenter states that an interval shorter than an A-check would require operators to perform the proposed visual and forced-air inspections during turnaround of the airplane. The commenter's normal turnaround time is 2 hours. The commenter further states that the proposed visual and forced air inspections take at least one hour, and that it takes at least an additional 20 minutes for the pitot probes to cool down. In addition, the commenter states that its airplanes have never had blockage through calcium build-up; however, it has heard from other operators that calcium blockage takes more than a year to build up. Therefore, the commenter concludes that it would be costly to do the proposed inspections during a turnaround and suggests an interval of at least 850 flight hours, preferably 1,000 flight hours.

We agree that the repetitive inspection interval can be extended somewhat. Since issuance of the NPRM, we have analyzed further in-service data from the airplane manufacturer and failure rate data for a blocked pitot tube from DC–10, MD–10, and MD–11 service history, which included 22 reported events.

The airplane manufacturer performed an analysis using four maintenance intervals: 650, 700, 1,000, and 1,500 flight hours. The results of the analysis

predicted the expected number of occurrences of a single blocked pitot tube and the expected number of occurrences of multiple blocked pitot tubes, assuming the blockage occurred as a random event. Based on the results of this analysis, the calculated probability of multiple blocked pitot tubes within the four maintenance intervals was documented. The airplane manufacturer assumed that treating the blockage as a random event would address a slow blockage build-up, such as calcium build-up, but would not adequately address foreign object blockage. Furthermore, it was noted that, if the right environmental conditions are present, such as flying through a bug storm, a large blockage of more than one pitot tube could occur within a maintenance interval established solely based on a slow blockage build-up.

Based on the results of the airplane manufacturer's analysis, we determined that we cannot rely on the random event analysis, alone, to determine a minimum, safe maintenance interval. As a result, we assessed additional safety margins to account for the non-random large blockage events and determined that a maintenance interval of more than 1,000 flight hours would result in an unacceptable risk of additional occurrences of multiple blocked pitot tubes. Therefore, we have made a change to the final rule to increase the repetitive time interval to 1,000 flight hours.

Request To Delete Forced-Air Check

One commenter, the airplane manufacturer, requests that the forced-air check in paragraph (h) of the NPRM be deleted. The commenter states that it is unsure that the forced-air check provides a benefit, and that there is a potential for damaging the air data equipment if the system were to be overpressurized during the test procedure.

We agree. Although the forced-air check is intended to provide additional assurance that any microscopic debris is cleared from the drain holes of the pitot tubes, the airplane manufacturer is aware of in-service reports or incident data indicating that the forced-air check has caused damage to air data equipment on airplanes. Therefore, we have made a change to the final rule to remove the forced-air check.

Request To Revise Reference to Airplane Maintenance Manual (AMM)

One commenter, the airplane manufacturer, requests that the reference to Chapter 34–11–02 of the AMM specified in paragraph (j) of the NPRM (re-designated as paragraph (h) in final rule) be revised to Chapter 34–11. The commenter states that Chapter 34–11–02 is correct for Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, and MD–10–30F airplanes, but Chapter 34–11–01 is correct for Model MD–11 and MD–11F airplanes.

We partially agree. We do not agree to reference Chapter 34–11 because that reference is too general. However, we will revise paragraph (h) of the AD to refer to the correct chapter for the affected airplane models as indicated by the commenter.

Request To Change Reference to Special Compliance Item (SCI)

One commenter requests that Boeing SCI 34–2 be approved as an alternative method of compliance (AMOC) in the NPRM. The commenter believes that the current Boeing MD–11 Time Controlled Task Card, developed per Boeing SCI 34–2, provides an equivalent level of safety and complies with the intent of the NPRM.

We do not agree. We have determined that Boeing SCI 34–2 is not reasonably available to all operators and the public like most Boeing service bulletins referenced in ADs are. Therefore, we have determined that incorporating by reference that service document in this AD would be inappropriate. However, under the provisions of paragraph (i) of this AD, we may consider requests for approval of such an AMOC.

Clarification of AMOC Paragraph

We have revised this action to clarify the appropriate procedure for notifying the principal inspector before using any approved AMOC on any airplane to which the AMOC applies.

Conclusion

We have carefully reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously. We have determined that these changes will neither increase the economic burden on any operator nor increase the scope of the AD.

Costs of Compliance

There are about 314 airplanes of the affected design in the worldwide fleet. This AD will affect about 216 airplanes of U.S. registry. The required inspections will take about 2 work hours per airplane, at an average labor rate of $65 per work hour. Based on these figures, the estimated cost of the AD for U.S. operators is $28,080, or $130 per airplane, per inspection cycle.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in subtitle VII, part A, subpart III, section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866;

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006–02–11 McDonnell Douglas: Amendment 39–14463. Docket No. FAA–2005–20034; Directorate Identifier 2004–NM–178–AD.

Effective Date

(a) This AD becomes effective March 3, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all McDonnell Douglas Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, MD–10–30F, MD–11, and MD–11F airplanes; certificated in any category.

Unsafe Condition

(d) This AD was prompted by reports of blocked drain holes of the pitot tubes. We are issuing this AD to prevent blocked drain holes of the pitot tubes, which could result in the accumulation of water in the pitot-static system and consequent failure of that system. Failure of the pitot-static system could result in erroneous airspeed indications in the cockpit and consequent loss of airspeed control.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Repetitive Inspections

(f) Within 90 days after the effective date of this AD, do a detailed inspection for accumulation of debris (blockage) in the drain holes of the pitot tubes in accordance with paragraph (g) of this AD. Repeat the inspection thereafter at intervals not to exceed 1,000 flight hours.

Note 1: For the purposes of this AD, a detailed inspection is ''an intensive examination of a specific item, installation, or assembly to detect damage, failure, or irregularity. Available lighting is normally supplemented with a direct source of good lighting at an intensity deemed appropriate. Inspection aids such as mirrors magnifying lenses, etc. may be necessary. Surface cleaning and elaborate procedures may be required.''

Visual Check

(g) Do a visual check in accordance with paragraphs (g)(1) through (g)(3) of this AD. The visual check must be done by certificated maintenance personnel.

(1) Make certain that the pitot heat is off and the pitot tubes are not hot.

Note 2: Caution. Exercise care in checking pitot tubes to prevent severe burns to your hands.

(2) Attempt to look through the left and right drain holes of each pitot tube.

(3) Make sure that ambient light (or flashlight) is visible through both drain holes of each pitot tube.

Corrective Action

(h) If any evidence of drain hole blockage is found during any inspection required by paragraph (f) or (g) of this AD, before further flight, clean the hole in accordance with a method approved by the Manager, Los Angeles Aircraft Certification Office (ACO), FAA. Chapter 34–11–02 of the Boeing DC–10 or MD–10 Airplane Maintenance Manual is one approved method for Model DC–10–10, DC–10–10F, DC–10–15, DC–10–30, DC–10–30F (KC–10A and KDC–10), DC–10–40, DC–10–40F, MD–10–10F, and MD–10–30F airplanes; as applicable. Chapter 34–11–01 of the applicable Boeing MD–11 Airplane Maintenance Manual is one approved method for Model MD–11 and MD–11F airplanes.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Los Angeles ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Material Incorporated by Reference

(j) None.

Issued in Renton, Washington, on January 19, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–734 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2006–23703; Directorate Identifier 2005–NM–052–AD; Amendment 39–14465; AD 2006–03–01]

RIN 2120–AA64

Airworthiness Directives; Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Empresa Brasileira de Aeronautica S.A. (EMBRAER) Model ERJ 170 airplanes. This AD requires, when certain SmartProbes are installed, revising the Limitations section of the airplane flight manual to limit the maximum take-off weight of the airplane and increase the reference speed during certain landing conditions. This AD results from reports of variable calibration values of certain sensors of the SmartProbes, which could result in the transmission of erroneous information to the air data system. We are issuing this AD to prevent reduced controllability of the airplane.

DATES: This AD becomes effective February 13, 2006.

We must receive comments on this AD by March 28, 2006.

ADDRESSES: Use one of the following addresses to submit comments on this AD.

- DOT Docket Web site: Go to *http://dms.dot.gov* and follow the instructions for sending your comments electronically.
- Government-wide rulemaking Web site: Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- Mail: Docket Management Facility; U.S. Department of Transportation, 400 Seventh Street SW., Nassif Building, Room PL–401, Washington, DC 20590.
- Fax: (202) 493–2251.
- Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Contact Empresa Brasileira de Aeronautica S.A. (EMBRAER), P.O. Box 343—CEP 12.225, Sao Jose dos Campos—SP, Brazil, for service information identified in this AD.

FOR FURTHER INFORMATION CONTACT: Todd Thompson, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–1175; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

The Departmento de Aviacao Civil (DAC), which is the airworthiness authority for Brazil, notified us that an unsafe condition may exist on all EMBRAER Model ERJ 170 airplanes. Certain Air Data SmartProbes that may be installed on these airplanes have been reported to be contaminated. A

SmartProbe contains four absolute pressure sensors and one differential pressure (dP) sensor. These five sensors provide the basic input used by the SmartProbe to calculate certain pressure-based data used by the airplane. Operators have reported shifts in the calibrated values of these dP sensors. These shifts have been attributed to contamination during the manufacturing process. Contaminated SmartProbes, if not detected and removed, could affect the correct operation of several airplane systems including the flight control system, and result in reduced controllability of the airplane.

The DAC issued corresponding Brazilian airworthiness directive 2005–02–01, dated March 3, 2005, to ensure the continued airworthiness of these airplanes in Brazil.

FAA's Determination and Requirements of This AD

This airplane model is manufactured in Brazil and is type certificated for operation in the United States under the provisions of section 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DAC has kept the FAA informed of the situation described above. We have examined the DAC's findings, evaluated all pertinent information, and determined that we need to issue an AD for products of this type design that are certificated for operation in the United States.

Therefore, we are issuing this AD to prevent reduced controllability of the airplane. This AD requires, if an affected SmartProbe is installed, revising the Limitations section of the airplane flight manual to limit the maximum take-off weight of the airplane and increase the reference speed during certain landing conditions.

Difference Between AD and Brazilian Airworthiness Directive

In addition to the AFM revision, the Brazilian airworthiness directive requires repetitive tests of certain affected SmartProbes. We have decided, however, to immediately adopt this AD to require only the AFM revision. We may later consider further rulemaking to supersede this AD to add a requirement to repetitively test the SmartProbes. We considered the urgency associated with the subject unsafe condition, the relatively low number of affected SmartProbes that currently exist, and logistical concerns associated with performing the tests within a period of time that corresponds to the normal scheduled maintenance for most affected operators. The planned compliance time to initiate the repetitive tests would allow enough time to provide notice and opportunity for prior public comment on the merits of the tests. We therefore consider this AD interim action.

FAA's Determination of the Effective Date

An unsafe condition exists that requires the immediate adoption of this AD; therefore, providing notice and opportunity for public comment before the AD is issued is impracticable, and good cause exists to make this AD effective in less than 30 days.

Comments Invited

This AD is a final rule that involves requirements that affect flight safety and was not preceded by notice and an opportunity for public comment; however, we invite you to submit any relevant written data, views, or arguments regarding this AD. Send your comments to an address listed in the **ADDRESSES** section. Include ''Docket No. FAA–2006–23703; Directorate Identifier 2005–NM–052–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of the AD that might suggest a need to modify it.

We will post all comments we receive, without change, to *http://dms.dot.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD. Using the search function of that Web site, anyone can find and read the comments in any of our dockets, including the name of the individual who sent the comment (or signed the comment on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78), or you may visit *http://dms.dot.gov.*

Examining the Docket

You may examine the AD docket on the Internet at *http://dms.dot.gov,* or in person at the Docket Management Facility office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Management Facility office (telephone (800) 647–5227) is located on the plaza level of the Nassif Building at the DOT street address stated in the **ADDRESSES** section. Comments will be available in the AD docket shortly after the Docket Management System receives them.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared a regulatory evaluation of the estimated costs to comply with this AD and placed it in the AD docket. See the **ADDRESSES** section for a location to examine the regulatory evaluation.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The Federal Aviation Administration (FAA) amends § 39.13 by adding the following new airworthiness directive (AD):

2006–03–01 Empresa Brasileira de Aeronautica S.A. (EMBRAER): Amendment 39–14465. Docket No. FAA–2006–23703; Directorate Identifier 2005–NM–052–AD.

Effective Date

(a) This AD becomes effective February 13, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to all EMBRAER Model ERJ 170–100 LR, –100 STD, –100 SE, and –100 SU airplanes, certificated in any category.

Unsafe Condition

(d) This AD results from reports of variable calibration values of certain sensors of the Air Data SmartProbes, which could result in the transmission of erroneous information to the air data system. This was caused by contamination during the manufacturing process. We are issuing this AD to prevent reduced controllability of the airplane.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Revision of Airplane Flight Manual (AFM)

(f) As of 30 days after the effective date of this AD: During any time period when any SmartProbe part number 2015G2H2H–4, 2015G2H2H–4A, 2015G2H2H–5, or 2015G2H2H–5A is installed, before further flight, revise the Limitations section of the AFM to include the following operational limitations (this may be done by inserting a copy of this AD into the AFM):

''• Reduce the calculated MTOW by 110 kgf whenever it is defined by obstacle clearance on the final segment.

• Increase the reference speed (VREF) by 1 kt when landing with Flap 5.''

Alternative Methods of Compliance (AMOCs)

(g)(1) The Manager, International Branch, ANM–116, Transport Airplane Directorate, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(h) Brazilian airworthiness directive 2005–02–01, dated March 3, 2005, also addresses the subject of this AD.

Issued in Renton, Washington, on January 19, 2006.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–782 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30476; Amdt. No. 3151]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective January 27, 2006. The compliance date for each SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of January 27, 2006.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Ave, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169; or

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) amends Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in the appropriate FAA Form 8260, as modified by the the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), which is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Code of Federal Regulations. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each

separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these chart changes to SIAPs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in TERPS. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation, as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97:

Air Traffic Control, Airports, Incorporation by reference, and Navigation (air).

Issued in Washington, DC, on January 13, 2006.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

■ By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

** * * Effective Upon Publication*

FDC date	State	City	Airport	FDC number	Subject
12/27/05 ...	MA	FITCHBURG	FITCHBURG MUNI	5/2086	NDB RWY 20, AMDT 6
12/27/05 ...	MA	FITCHBURG	FITCHBURG MUNI	5/2087	RNAV (GPS) RWY 14, ORIG
12/27/05 ...	MA	FITCHBURG	FITCHBURG MUNI	5/2088	RNAV (GPS) RWY 20, ORIG
12/27/05 ...	MA	FITCHBURG	FITCHBURG MUNI	5/2089	RNAV (GPS) RWY 32, ORIG
12/27/05 ...	MA	FITCHBURG	FITCHBURG MUNI	5/2090	NDB–A, AMDT 4
12/29/05 ...	GU	AGANA	GUAM INTL	5/2144	VOR–A, ORIG
12/29/05 ...	AK	SHUNGNAK	SHUNGNAK	5/2168	RNAV (GPS) RWY 27, ORIG
12/29/05 ...	AK	SHUNGNAK	SHUNGNAK	5/2169	RNAV (GPS) RWY 9, ORIG–A
12/30/05 ...	NC	CHARLOTTE	CHARLOTTE/DOUGLAS INTL	5/2215	ILS OR LOC RWY 36L, ILS RWY 36L (CAT II, III), AMDT 15
01/04/06 ...	KY	COVINGTON	CINCINNATI/NORTHERN KENTUCKY INTL.	6/0082	RNAV (GPS) RWY 36L, ORIG
01/11/06 ...	MT	BILLINGS	BILLINGS LOGAN INTL	6/0367	VOR/DME RWY 28R, AMDT 13A
01/11/06 ...	MT	BILLINGS	BILLINGS LOGAN INTL	6/0368	ILS RWY 10L, AMDT 24A
1/11/06	MT	BILLINGS	BILLINGS LOGAN INTL	6/0370	ILS RWY 28R, ORIG–A
01/11/06 ...	AK	NENANA	NENANA MUNI	6/0381	RNAV (GPS) RWY 4L, ORIG
01/11/06 ...	IN	INDIANAPOLIS	INDIANAPOLIS INTL	6/0396	ILS RWY 25, AMDT 2A
01/11/06 ...	ND	GARRISON	GARRISON MUNI	6/0399	RNAV (GPS) RWY 13, ORIG
01/11/06 ...	ND	GARRISON	GARRISON MUNI	6/0400	RNAV (GPS) RWY 31, ORIG

FDC date	State	City	Airport	FDC number	Subject
01/11/06 ...	AK	YAKUTAT	YAKUTAT	6/0401	LOC/DME BC RWY 29, AMDT 4

[FR Doc. 06–740 Filed 1–26–06; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09–05–142]

RIN 1625–AA00

Safety Zone; Chicago Sanitary and Ship Canal, Romeoville, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the Chicago Sanitary and Ship Canal on the Illinois Waterway near Romeoville, Illinois. This safety zone is necessary to close the Chicago Sanitary and Ship Canal during safety testing of the permanent electrical dispersal barrier. This safety zone intended to restrict vessels from a portion of the Canal in Romeoville, IL, at various times over a 45 day period.

DATES: This rule is in effect during intermittent periods, as announced via Broadcast Notice to Mariners, from 7 a.m. (local) on January 30, 2006 until 7 a.m. (local) on February 28, 2006. Captain of the Port Lake Michigan or his on scene representative will inform mariners of enforcement periods via Broadcast Notice to Mariners.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket are part of the docket (CGD09–05–142], and are available for inspection or copying at Commanding Officer, U.S. Coast Guard Marine Safety Unit Chicago, 215 W. 83rd Street Suite D, Burr Ridge, IL, 60527, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: MST1 Kenneth Brockhouse, U.S. Coast Guard, Marine Safety Unit Chicago, at (630) 986–2155.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. This safety zone is temporary in nature and limited time existed for an NPRM. The Coast Guard was not made aware that this operation was to take place with sufficient time to allow for publication of an NPRM followed by a final rule. Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be impracticable and immediate action is necessary to ensure the safety of personnel and vessels during the operational period. During the enforcement of this safety zone, comments will be accepted and reviewed and may result in a modification to the rule.

Background and Purpose

A temporary electrical dispersal barrier is in operation at mile marker 296.5 on the Chicago Sanitary Ship Canal to prevent Asian Carp from entering Lake Michigan.

A second permanent electrical dispersal barrier is being constructed and operational and safety testing must be completed prior to placing the permanent barrier in service. Also, additional safety tests need to be conducted for the temporary electrical dispersal barrier. These tests are scheduled to commence in January 2006. As such, the Captain of the Port Lake Michigan has determined that intermittent closures of the Chicago Sanitary and Ship Canal are necessary to ensure the integrity of the operational and safety tests, as well as the safety of the testing crews. Closures will occur between January 30, 2006 and February 28, 2006. Mariners will be notified of enforcement periods by Broadcast Notice to Mariners. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan or his designated on scene representative via VHF–FM radio Channel 16.

Discussion of Rule

Operational and safety tests are required to determine the electrical parameters of the permanent electrical dispersal barrier, and to evaluate the health and safety risks of the electrical fields generated by both barriers in this portion of the Chicago Sanitary and Ship Canal. Restricting vessel movement through this portion of the Canal is necessary to ensure accurate test results, and to protect the equipment and crews conducting the tests.

The safety zone will encompass all waters of the Chicago Sanitary and Ship Canal from the Romeo Road Bridge at Mile Marker 296.1 to the aerial pipeline arch at Mile Marker 296.7. All commercial and recreational vessels will be prohibited from entering the zone during enforcement periods. Enforcement periods will be announced via Broadcast Notice to Mariners. Vessels may contact the Coast Guard via VHF–FM radio Channel 16 to request permission to transit through the safety zone.

Regulatory Evaluation

This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not ''significant'' under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this established rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

This finding is based on the relatively small percentage of vessels that would fall within the applicability of the regulation, the relatively small size of the limited area around the zone, the minimal amount of time that vessels will be restricted when the zone is being enforced. In addition, vessels that will need to enter the zone may request permission on a case-by-case basis from the Captain of the Port or the designated on-scene representative.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not

dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule may affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit through the safety zone in and around the area.

This rule would not have a significant impact on a substantial number of small entities because the restrictions affect only a limited area for a brief amount of time as this safety zone is effective only when operations are underway. Further, transit through the zone may be permitted with proper authorization from the Captain of the Port Lake Michigan or his designated representative. Additionally, the opportunity to engage in recreational activities outside the limits of the safety zone will not be disrupted.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–800–734–3247.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a ''significant energy action'' under that order because it is not a ''significant regulatory action'' under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have made a preliminary determination that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, we believe that this rule should be categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation. This event establishes a safety zone therefore paragraph (34)(g) of the Instruction applies.

A preliminary ''Environmental Analysis Check List'' is available in the docket where indicated under **ADDRESSES**. Comments on this section will be considered before we make the final decision on whether the rule should be categorically excluded from further environmental review.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–142 to read as follows:

§ 165.T09–142 Safety Zone; Chicago Sanitary and Ship Canal, Romeoville, IL.

(a) *Location.* The following is a safety zone: All waters, bank-to-bank, from the Romeo Road Bridge at Mile Marker 296.1 to the aerial pipeline arch at Mile Marker 296.7 on Chicago Sanitary and Ship Canal.

(b) *Effective time and date.* This rule is in effect from 7 a.m. (local) on January 30, 2006 until 7 a.m. (local) on February 28, 2006. Enforcement periods will be announced via Broadcast Notice to Mariners. Captain of the Port Lake Michigan or the on scene representative may terminate this operation at anytime.

(c) *Regulations.* In accordance with § 165.23, entry into this zone is prohibited unless authorized by the Coast Guard Captain of the Port Lake Michigan, or the designated on-scene representative. Section 165.23 also contains other general requirements.

Dated: January 11, 2006.

S.P. LaRochelle,

Captain, U.S. Coast Guard, Captain of the Port, Lake Michigan.

[FR Doc. 06–768 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2005–IN–0007; FRL–8025–6]

Approval and Promulgation of Air Quality Implementation Plans; Indiana; Removal of Direct Final Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Removal of direct final rule.

SUMMARY: Due to the receipt of an adverse comment, the EPA is removing the November 25, 2005 (70 FR 70999), direct final rule approving revisions to Indiana's sulfur dioxide (SO_2) state implementation plan (SIP) for sources located in Dearborn County. These revisions to the SIP include: Revising SO_2 emission limits for existing sources, making minor corrections by removing obsolete rule language, and updating information for sources listed in the rule. In the direct final rule, EPA stated that if adverse comments were submitted by December 27, 2005, the rule would be withdrawn and not take effect. On December 2, 2005, EPA received a comment. EPA believes this comment is adverse and, therefore, EPA is removing the direct final rule. EPA will address the comment in a subsequent final action based upon the proposed action also published on November 25, 2005 (70 FR 71071). EPA will not institute a second comment period on this action.

DATES: This rule is effective on January 27, 2006.

FOR FURTHER INFORMATION CONTACT: Charles Hatten, Environmental Engineer, Criteria Pollutant Section, Air Programs Branch (AR–18J), EPA, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6031, *hatten.charles@epa.gov.*

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Sulfur dioxides.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: January 18, 2006.

Norman Niedergang,

Acting Regional Administrator, Region 5.

■ Part 52, Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart P—Indiana

§ 52.770 [Amended]

■ 2. Section 52.770 is amended by removing paragraph (c)(171).

[FR Doc. 06–757 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NM–4–1–5208a; FRL–8025–5]

Approval and Promulgation of Implementation Plans; New Mexico, Visibility

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the New Mexico State Implementation Plan (SIP). This revision satisfies the New Source Review (NSR) and monitoring plan requirements for visibility, otherwise known as the ''Phase I, Part I Visibility SIP.'' In addition, this revision includes the implementation control strategies, integral vistas protection, and long term strategies, otherwise known as the ''Phase I, Part II Visibility SIP.'' Lastly, EPA is removing the SIP disapprovals associated Phase I, Parts I and II, and the resultant Federal Implementation Plans (FIPs).

DATES: This rule is effective on March 28, 2006 without further notice, unless EPA receives adverse comment by February 27, 2006. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by File ID No. NM–4–1–5208, by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- U.S. EPA Region 6 ''Contact Us'' Web site: *http://epa.gov/region6/r6coment.htm*. Please click on ''6PD'' (Multimedia) and select ''Air'' before submitting comments.
- E-mail: Mr. Thomas Diggs at *diggs.thomas@epa.gov*. Please also cc the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.
- Fax: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), at fax number 214–665–7263.
- Mail: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.
- Hand or Courier Delivery: Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8 a.m. and 4 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Please include the text ''Public comment on File ID No. NM–4–1–5208'' in the subject line of the first page of your comments. EPA's policy is that all comments received will be included in the public file without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information

(CBI) or other information the disclosure of which is restricted by statute. Do not submit information through regulations.gov or e-mail if you believe that it is CBI or otherwise protected from disclosure. Regulations.gov is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public file and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Official File: Copies of the documents relevant to this action are in the official file which is available at the Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733. The file will be made available by appointment for public inspection in the Region 6 FOIA Review Room between the hours of 8:30 am and 4:30 pm weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at 214–665–7253 to make an appointment. If possible, please make the appointment at least two working days in advance of your visit. There will be a 15 cent per page fee for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

Copies of any State submittals and EPA's TSD are also available for public inspection at the State Air Agency listed below during official business hours by appointment:

New Mexico Environment Depart, Air Quality Bureau, 1190 St. Francis Drive, Santa Fe, New Mexico 87502.

FOR FURTHER INFORMATION CONTACT: Joe Kordzi, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7186; fax number 214–665–7263; e-mail address *kordzi.joe@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

Outline

I. What Is the Background for This Action?

Section 169A of the Clean Air Act (CAA), 42 U.S.C. 7491, requires visibility protection for mandatory Class I Federal areas where EPA has determined that visibility is an important value. ''Mandatory Class I Federal areas'' are certain national parks, wilderness areas, and international parks, as described in Section 162(a) of the CAA, 42 U.S.C. 7472(a), and 40 CFR 81.400–81.437. Section 169A specifically requires EPA to promulgate regulations requiring certain states to amend their SIPs to provide for visibility protection.

On December 2, 1980, EPA promulgated the required visibility regulations at 45 FR 80084, codified at 40 CFR 51.300–51.307. These regulations required States to develop a visibility monitoring and NSR program and to submit SIPs to satisfy those provisions by September 2, 1981 (See 45 FR 80091, codified at 40 CFR 51.302(a)(1)). That rulemaking resulted in numerous parties seeking judicial review of the visibility regulations. Please see the Technical Support Document (TSD) for more details concerning the history behind Phase I, Parts I and II.

On February 13, 1986 (51 FR 5504), EPA promulgated Federal Implementation Plans (FIPs) which included a visibility monitoring strategy (40 CFR 52.26) and the appropriate visibility NSR programs (40 CFR 52.21 and 52.28) for the State. This is known as the Phase I, Part I Visibility FIP, and is the subject of the first part of this action.

On November 24, 1987 (52 FR 45132), EPA promulgated FIPs for 29 States, including New Mexico, to incorporate visibility long-term strategies (40 CFR 52.29). EPA also found that Best Available Retrofit Technology (BART) requirements and other control measures were not necessary in 28 of the States because the visibility impairment could not be attributed to specific sources. This is known as the Phase I, Part II Visibility FIP, and is the subject of the second part of this action.

II. What Did the State Submit and How Did We Evaluate It?

A. Phase I, Part I

On August 21, 1986, EPA Region 6 received a Phase I, Part I SIP Revision from the Governor of New Mexico for Visibility Protection and State regulations for monitoring and new source review. Please see the accompanying TSD for more details of EPA's review.

New Mexico has nine mandatory Class I areas: (1) Bandelier Wilderness Area, (2) Bosque del Apache Wilderness Area, (3) Carlsbad Caverns National Park, (4) Gila Wilderness, (5) Pecos Wilderness Area, (6) Salt Creek Wilderness Area, (7) San Pedro Parks Wilderness Area, (8) Wheeler Peak Wilderness Area, and (9) White Mountain Wilderness Area. The SIP commits the State to visibility protection, consistent with the CAA, for the Class I areas within its boundaries. The SIP is to be reviewed by New Mexico every three years and revised as necessary.

Visibility Monitoring Strategy

40 CFR 51.305 requires each State containing a mandatory Class I Federal area to include in the plan a strategy for evaluating reasonably attributable visibility impairment in any mandatory Class I Federal area by visual observation or other appropriate monitoring techniques. The intent of this requirement is to generate data for evaluating visibility impairment trends, determine potential impacts of new sources, assess the effectiveness of the visibility protection program, and identify major contributing sources. This requirement can be adequately addressed by determining the background visibility conditions in and around visibility protection areas, and documenting the extent of any visibility impairment that can be attributed to a source or small group of sources.

Visibility impairment is the human perception of the effects of natural or man-made conditions which reduce visual range or contrast, or coloration change. Thus, a visibility monitoring program should identify these effects as well as differentiate man-made effects from natural conditions. The program could generate various types of data such as reports from human observers, photographs, and/or automated instruments. The minimum data collection technique that 40 CFR 51.305

requires is visual observation. However, other more objective techniques are available.[1]

The monitoring section of the New Mexico Visibility Protection Plan has been updated since the submission of this SIP Revision for Visibility Protection, and consists of three data collection methods:

(1) Monitoring by the Federal Land Manager (FLM),

(2) Discretionary monitoring by sources proposing to locate or modify in an area where emissions may impact Class I areas, and

(3) Implementation of the state monitoring network.

Monitoring by the FLM is done through the Interagency Monitoring of Protected Visual Environments (IMPROVE) program. The IMPROVE program is a cooperative effort led by a steering committee of representatives from federal and regional-State organizations. The IMPROVE monitoring network was established in 1985 to aid in the construction of SIPs for the protection of visibility in Class I areas, as stipulated in the CAA. The following table lists the FLMs, the Class I areas each presides over, and the kinds of visibility monitoring instrumentation used at each Class I area in New Mexico:

FEDERAL LAND MANAGERS, CLASS I AREAS, AND MONITORING EQUIPMENT IN NEW MEXICO

Federal land manager	Class I areas	Visibility monitoring instrument
Forest Service	Gila Wilderness Area	Nephelometer.
	Pecos Wilderness Area	Represented by transmissometer at Bandelier Wilderness Area.
	San Pedro Parks Wilderness Area	Modular aerosol sampler.
	Wheeler Peak Wilderness Area	Modular aerosol sampler.
	White Mountain Wilderness Area	Modular aerosol sampler.
National Park Service	Bandelier Wilderness Area	Transmissometer.
	Carlsbad Caverns National Park	Represented by transmissometer at Guadalupe Mountains National Park.
Fish and Wildlife Service	Bosque del Apache Wilderness Area	Modular aerosol sampler.
	Salt Creek Wilderness Area	Modular aerosol sampler.

In addition to the IMPROVE network, the State may require sources proposing to locate or modify in the locale where emissions may impact Class I areas to model or monitor visibility if, at the discretion of the New Mexico Environment Department, the emissions from the facility are such that the facility is predicted to have significant impact on visibility. The purpose of this modeling or monitoring would be to quantify impacts to visibility from the facility at the Class I area.

Lastly, the State itself operates 32 separate monitoring sites across the state, each monitoring one or more of the criteria pollutants. This monitoring network includes twelve ozone monitors, eight nitrogen dioxide monitors, five sulfur dioxide monitors, three carbon monoxide monitors, fourteen PM 2.5 (particles 2.5 microns or less in diameter) monitors, and fifteen PM 10 (particles 10 microns or less in diameter) monitors. Additional details of the air quality monitoring in New Mexico can be found at *http://www.nmenv.state.nm.us/aqb/reghaz/Regional-Haze_index.html.*

New Source Review

40 CFR 51.307 requires states to review new major stationary sources and major modifications prior to construction to assess potential impacts on visibility in any visibility protection area, regardless of the air quality status of the area in which the source is located. These requirements ensure that (1) The visibility impact review is conducted in a timely and consistent manner, (2) the reviewing authority considers any timely FLM analysis demonstrating that a proposed source would have an adverse impact on visibility, and (3) public availability of the permitting authority's conclusion.

40 CFR 51.307 addresses visibility NSR in two parts. The first part addresses major stationary sources or major modifications that would be constructed in an area that is designated attainment or unclassified under section 107(d)(1)(D) or (E) of the CAA. For major stationary sources reviewed under the Prevention of Significant Deterioration (PSD) requirements of 40 CFR 51.166 for visibility protection, the State must comply with certain FLM notification requirements, and must consider any FLM visibility impairment analyses. In order to address this requirement, New Mexico incorporated into the NSR section of its visibility SIP, regulation 20.2.74 NMAC, ''Permits—Prevention of Significant Deterioration'' (originally submitted as AQCR 707 and since recodified). EPA approved regulation 20.2.74 NMAC on October 15, 1996 (61 FR 53642). The SIP commits to the notification time frame requirements to the FLM. It also commits to provide an explanation of its decision should it disagree with the FLM's assessment on a proposed source's impact on visibility, and to give notice as to where that explanation can be obtained.

The second part to visibility NSR addresses major stationary sources or major modifications that are proposed in an area classified as nonattainment under section 107(d)(1)(A), (B), or (C) of the CAA. Major sources in nonattainment areas that may impact a visibility protection area must provide a visibility impact analysis, and the State must ensure that the sources' emissions are consistent with the goal of making reasonable progress toward national visibility. In order to address this requirement, New Mexico has incorporated into the NSR section of its visibility SIP, regulation 20.2.79 NMAC, ''Permits—Nonattainment Areas'' (originally submitted as AQCR 709 and since recodified). EPA approved regulation 20.2.79 NMAC on February 8, 2002 (67 FR 6147). The State must also follow the same FLM notification and visibility impairment analyses requirements for major stationary sources reviewed under the visibility PSD requirements, above, which it commits to do in its SIP.

In addition, the SIP revision includes regulations 20.2.60 NMAC, ''Open Burning'' (originally submitted as AQCR 301 and since recodified); 20.2.61 NMAC, ''Smoke and Visible Emissions'' (originally submitted as AQCR 401 and since recodified); and 20.2.10 NMAC, ''Wood Waste Burners'' (originally submitted as AQCR 402 and since

[1] ''Visibility Monitoring Guidance Document'', Office of Air Quality Planning and Standards, June 1999 (EPA 454/R–99–003). This is available at: *http://www.epa.gov/ttn/amtic/files/ambient/visible/r-99-003.pdf.*

recodified). These regulations, among other things, control particulate matter emissions and visible emissions, and provide for smoke management. These regulations have all been adopted by the New Mexico Environmental Improvement Board, were filed at the State Records Center, and have become effective. EPA approved regulations 20.2.10 NMAC, 20.2.60 NMAC, and 20.2.61 NMAC on September 26, 1997 (62 FR 50518).

FLM Coordination

Under Section 165(d) of the CAA, and 40 CFR 51.166(p), the FLM is given an affirmative responsibility to protect air quality related values, including visibility, in lands within a Class I area. The visibility regulations under 40 CFR 51.301 allow the FLM the opportunity to identify visibility impairment and to identify elements for inclusion in monitoring strategies.

The State of New Mexico has accorded the FLM opportunities to participate and comment on its visibility SIP and regulations. Comments by the FLM were considered and incorporated where applicable. The State has committed in the SIP to consult continually with the FLM on the review and implementation of the visibility program. Further, the State recognizes the expertise of the FLM in monitoring and new source applicability analyses for visibility and has agreed to notify the FLM of any advance notification or early consultation with a major new or modifying source prior to the submission of the permit application.

B. Phase I, Part II

On October 8, 1992, EPA Region 6 received a Phase I, Part II SIP from the Governor of New Mexico for implementation control strategies, the identification of integral vistas, and long term strategy requirements. Please see the accompanying TSD for more details of EPA's review.

Implementation Control Strategies for Reasonably Attributable Visibility Impairment

Reasonably Attributable Visibility Impairment (RAVI) is visibility impairment that can be traced to one, or a small number of sources. This contrasts with regional haze (the subject of Phase II visibility control), which is widespread, regionally undifferentiated haze due to a multitude of sources. The implementation control strategies for the RAVI portion of 40 CFR 51.302 include requirements addressing plan revision procedures, State and FLM coordination, and general plan requirements for RAVI.

The plan revision procedures requirements are found in § 51.302(a) and include (1) a deadline for submission of the SIP; (2) a requirement to conduct public hearings prior to adoption of any SIP that address RAVI; and (3) written notification of the hearings to the FLMs and other affected States, and opportunity for the public to inspect the FLM comments. Because EPA promulgated a FIP due to New Mexico's failure to submit a Phase I, Part II SIP, the SIP submission deadline requirement of § 51.302(a) is moot. In addition, as described in the TSD, New Mexico has satisfied the remaining plan revision procedural requirements of § 51.302(a), by conducting a public hearing prior to adoption of the SIP and providing for inspection of the FLM comments.

The State and FLM coordination requirements are found in § 51.302(b) and include requirements that the State identify to the FLMs the person to whom comments should be submitted, and provide an opportunity for consultation prior to, and after adoption of the SIP. New Mexico has demonstrated historic and continuing (through the three year reports, discussed below) communication and cooperation with the FLMs. Additional details regarding how New Mexico satisfied these requirements can be found in the TSD.

The general plan requirements for RAVI are found in § 51.302(c). These requirements provide for the adoption of specific measures designed to control sources that contribute to the RAVI. As the FLMs have not identified RAVI at any Class I areas in New Mexico, the long-term strategy does not require ongoing or additional emission reductions from existing sources. Consequently, the requirements of § 51.302(c) are not applicable.

Identification of Integral Vistas

Section 51.304 provided that on or before December 31, 1985, the FLMs had an opportunity to have identified integral vistas in the State. Integral Vistas means a view perceived from within the mandatory Class I Federal area of a specific landmark or panorama located outside the boundary of the mandatory Class I Federal area. The visibility protection afforded by the Phase I, Part II SIP extends to any integral vistas the FLMs identified. Since the FLMs did not identify any integral vistas within the State prior to the December 31, 1985 deadline, § 51.304 does not apply, and the integral vistas protection requirements within 40 CFR 51.302 to 51.307 do not apply.

Long-Term Strategy Requirements for RAVI

The long-term strategy requirements for RAVI of § 51.306 are designed to ensure reasonable progress toward the national visibility goal. The national visibility goal includes the prevention of any future, and the remedying of any existing, manmade impairment of visibility in Class I areas. As discussed in the TSD in more detail, because the FLMs have not identified any RAVI, or integral vistas, the State's permitting programs for implementing the visibility NSR and PSD requirements are deemed sufficient to meet the long-term strategy requirements for preventing future impairment from major stationary sources or major modifications. The State is also required under § 51.306(c) to perform periodic review, and revisions as appropriate, of the long-term strategy at least every three years. The State has in fact been submitting these reviews every three years, with the last being submitted in June of 2003. They have all been deemed satisfactory.

III. What Is Our Final Action?

The EPA is approving a revision to the New Mexico SIP. This SIP revision and accompanying regulations meet all of the requirements for NSR and visibility monitoring requirements under 40 CFR 51.305 and 51.307 (excluding integral vistas), for a Phase I, Part I Visibility Protection Plan. This SIP revision also meets all of the requirements for implementation control strategies under 40 CFR 51.302, integral vistas protection under 40 CFR 51.302 to 51.307, and long-term strategies under 40 CFR 51.306 for a Phase I, Part II Visibility Protection Plan. In addition, EPA is removing the SIP disapprovals associated Phase I, Parts I and II, and the resultant FIPs.

IV. Why Is This a ''Final Action?''

EPA is publishing this rule without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the SIP revision if adverse comments are received. This rule will be effective on March 28, 2006 without further notice unless we receive adverse comment by February 27, 2006. If we receive adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all

public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if we receive adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

V. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4).

This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have federalism implications because it does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the CAA. This rule also is not subject to Executive Order 13045 ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the CAA. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by March 28, 2006. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements.

Dated: January 18, 2006.

Richard E. Greene,

Regional Administrator, Region 6.

■ Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subchapter GG—New Mexico

■ 2. The table in § 52.1620(e) entitled ''EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures in the New Mexico SIP'' is amended by adding one new entry to the end of the table to read as follows:

§ 52.1620 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE NEW MEXICO SIP

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Explanation
* * *	*	*	*	*
New Mexico Visibility Protection Plan for Phase I, Part I of the Federal Visibility Requirements, August 8, 1986.	Statewide	08/21/86	01/27/06 [Insert *FR* page number where document begins].	
New Mexico Visibility Protection Plan for Phase I, Part II of the Federal Visibility Requirements, September 9, 1992.	Statewide	10/08/92	01/27/06 [Insert *FR* page number where document begins].	

§ 52.1636 [Removed and Reserved]

■ 3. Section 52.1636 is removed and reserved.

[FR Doc. 06–760 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 166

[EPA–HQ–OPP–2004–0038; FRL–7749–3]

RIN 2070–AD36

Pesticides; Emergency Exemption Process Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action revises the regulations governing emergency exemptions that allow unregistered uses of pesticides to address emergency pest conditions for a limited time. One change provides applicants for certain repeat exemptions a simple way to re-certify that the emergency conditions that qualified for an exemption in a previous year continue to exist. Another change revises the criteria for determining when a potential emergency condition is expected to cause a significant economic loss and revises the data requirements for documenting the loss. These revisions streamline and improve the application and review process by reducing the burden to both applicants and the Environmental Protection Agency (EPA, or ''the Agency''), allowing for potentially quicker decisions by the Agency, and providing for consistent and equitable determinations of ''significant economic loss'' as the basis for an emergency. This action also includes several minor revisions to the regulations. None of these various improvements compromise protections for human health and the environment.

DATES: This final rule is effective on March 28, 2006.

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2004–0038. All documents in the docket are listed on the www.regulations.gov web site. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*). Follow the on-line instructions. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Monday through Friday, excluding legal holidays. The Docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Joseph Hogue, Field and External Affairs Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9072; fax number: (703) 305–5884; e-mail address: *hogue.joe@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a federal, State, or territorial government agency that petitions EPA for an emergency use authorization under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Potentially affected entities may include, but are not limited to:

- Federal Government (NAICS Code 9241), i.e., Federal Agencies that petition EPA for section 18 use authorization.
- State or Territorial governments (NAICS Code 9241), i.e., States, as defined in FIFRA section 2(aa), that petition EPA for section 18 use authorization.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the summary of the applicability provisions as found in Unit III. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. An electronic version of 40 CFR part 166 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Purpose

The primary purpose of this rulemaking is to simplify the process of applying for emergency exemptions, and allow for potentially quicker responses to emergency pest conditions, without affecting current protections for human health and the environment. This action revises the regulations at 40 CFR part 166, to make a variety of improvements to the pesticide

emergency exemption program and process. The two most significant of the revised requirements are streamlining provisions intended to reduce the burden to both applicants and the Agency and to expedite decisions on some exemption requests. The first of these revisions expressly authorizes applicants for certain repeat exemptions to re-certify that an emergency condition continues in subsequent years, and to incorporate by reference all information submitted in a previous application rather than annually re-submit complete but perhaps redundant applications.

The second change revises the approach to determining when a potential emergency condition is expected to cause a ''significant economic loss'' (SEL). In addition to reducing the application and review burden, the new economic assessment approach will result in consistent and equitable determinations of whether a significant economic loss is expected. These two streamlining approaches have been tested in limited pilot projects since 2003.

In addition, EPA is making a number of revisions to correct or update minor administrative aspects of the emergency exemption regulations. The reason for each of these minor administrative revisions falls into one of the following categories: Conformance with statutory requirements arising from the Food Quality Protection Act of 1996 (FQPA); codification of improved practices that have been voluntary but widely followed by applicants; and correction of typographical or administrative errors. Also, the Agency is adding specific language to the regulations to clarify that treatment of ''invasive species'' is a valid basis for issuing a quarantine exemption.

III. Statutory Authority

EPA regulates the use of pesticides under the authority of two federal statutes: FIFRA and the Federal Food, Drug, and Cosmetic Act (FFDCA).

FIFRA provides the basis for regulation, sale, distribution, and use of pesticides in the United States. FIFRA generally prohibits the sale and distribution of any pesticide product, unless it has been registered by EPA in accordance with section 3. (7 U.S.C. 136a). Section 18 of FIFRA gives the Administrator of EPA broad authority to exempt any federal or State agency from any provision of FIFRA if the Administrator determines that emergency conditions exist that require such an exemption. (7 U.S.C. 136p). Under section 2(aa) of FIFRA, the term ''State'' is defined to include a ''State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and America Samoa.'' (7 U.S.C. 136(aa)).

Section 408 of FFDCA authorizes EPA to set maximum residue levels, or tolerances, for pesticides used in or on foods or animal feed, or to exempt a pesticide from the requirement of a tolerance, if warranted. (21 USC 346a). Section 408(l)(6) provides that where EPA grants an emergency exemption under FIFRA section 18, the Agency must establish a time-limited tolerance or exemption from the requirement of a tolerance for any residues of the pesticide chemical in food or feed.

IV. Background

A. April 2003 Notice Initiating Pilot for Two Primary Revisions now being Codified

EPA published a Notice in the **Federal Register** on April 24, 2003 (68 FR 20145) (FRL–7293–6), announcing the initiation of a limited pilot program to test two potential improvements to the emergency exemption process. The pilot continued through the end of 2005, but has not been extended for 2006 as it is superceded by this final rule. The two potential improvements included in the pilot were: (1) Allowing applicants for certain repeat exemptions to re-certify that the emergency condition still exists in the second and third years, and to incorporate by reference all information submitted in a previous application rather than annually re-submit to EPA complete new applications and, (2) a new approach to documenting an SEL that focuses on the significance of the potential loss relative to yields and/or revenues without the emergency rather than a comparison to historical profit variation. The April 2003 notice also discussed whether exemptions for the purpose of pest resistance management might be allowed. Finally, the notice solicited public comment on all three potential changes and announced EPA's plan to issue a proposed rule addressing them. The two revised practices included in the pilot are also included in this final rule, with modification. Today's final rule expands the application to all pesticides, beyond the restriction to reduced-risk pesticides under the limited terms of the pilot.

Anyone interested in the background leading up to the pilot program, or other related documents, may wish to review the announcement of the pilot, and the related documents. EPA considers the comments on the pilot program to be part of the administrative record for this rulemaking. A public docket was established for that announcement under docket ID number EPA–HQ–OPP–2002–0231. Interested parties should follow instructions under **ADDRESSES** for accessing the docket, but should use docket ID number EPA–HQ–OPP–2002–0231 to access the docket for the April 24, 2003, announcement.

B. September 2004 Proposed Rule

EPA published a proposed rule on September 3, 2004 (69 FR 53866) (FRL–7371–3). The proposed rule included proposals for the two revised practices in the pilot program, but without the limitation to reduced-risk pesticides, as well as a number of minor administrative revisions. Key public comments and Agency responses are briefly summarized in Unit V. of this document and, more completely, in a separate Response to Comments document available in the public docket.

Those interested in seeing the proposed rule, related documents, and public comments submitted may access them in the docket. A public docket was established for this rulemaking under docket ID number EPA–HQ–OPP–2004–0038. Interested parties should follow instructions under **ADDRESSES** for accessing the docket.

C. Summary of Pilot Experience

The pilot was started on April 24, 2003, and will not be extended for the 2006 growing season as it is being superceded by today's final rule. Applicability of the pilot was restricted to ''reduced-risk'' pesticides in order to limit the scope and effectively add an additional margin of safety while the new procedures were tested. Although participation in the pilot was limited, the process worked well for both applicants and EPA.

For the 2003 growing season, 16 exemptions were identified by EPA as eligible for re-certification, of which 7 submitted re-certification applications. In 2004, 12 exemptions were eligible, of which 4 applied by re-certification, while in 2005, 10 exemptions were eligible for re-certification and 6 used the process. EPA made expedited decisions on re-certification requests under the pilot in an average of 9 days in 2003, 14 days in 2004, and 8 days in 2005, counted from receipt of the request until the decision was made. Of the exemptions that were eligible but for which no re-certification was submitted, some were for pesticide uses that had obtained federal registration under FIFRA section 3 since the previous year's exemption, some were not requested at all (indicating that the

emergency ended), and the others were requested using conventional exemption requests.

The revised approach to determining an SEL applied to any new exemption request, as long as the requested chemical was designated as reduced-risk. However, for all 3 years of the pilot, EPA voluntarily conducted economic evaluations of exemption requests using both the current approach of historical 5–year data, as well as the proposed new loss-based (tiered) approach. This experience indicates that the new approach will not cause EPA to find SEL more commonly, nor expand the definition of emergency. A retrospective analysis to develop the loss-based approach, covering 2000 through 2003, showed that approximately the same number of requests would result in an SEL finding using the new, loss-based approach as actually occurred under the existing approach. The new criteria will, in most cases, reduce applicants' data burden and thereby streamline the exemption process.

V. Public Comments, EPA Responses, and Modifications for Final Rule

This unit briefly discusses the major public comments received on the proposed rule, EPA's responses to those comments, and changes made in the final rule as a result. All comments leading to modifications to the proposed revisions for the final rule are included here, as are opposing comments on the same issues, and comments opposed to proposed revisions for which modifications were not made. A more detailed, complete summary of public comments and Agency responses is available in a separate document in the public docket for this rule. That document also addresses comments and responses on the April 2003 document that announced the pilot program.

A total of 28 submissions of public comments on the proposed rule were received. A total of 41 commenters were represented by these comments, as some were submitted jointly by multiple parties. For ease of discussion and a better understanding of the sources of the various comments, commenters are grouped according to the type of organization or interest. The number of comment submissions on the proposed rule, by type of commenter are: Two by education/research groups; 3 by agriculture/food industry groups; 1 by environmental/public interest groups (joint submission by 13 groups); 12 by grower groups; 2 by pesticide industry/registrants; 1 by a private citizen; and, 10 by States (9 State lead pesticide regulatory agencies and 1 by the American Association of Pesticide Control Officials, which represents the States in pesticide regulatory matters).

Generally, all except for the environmental/public interest groups and the private citizen favored both of the two primary proposals, although a few only commented on one of the two, and some suggested modifications. The 13 environmental/public interest groups and the private citizen were opposed to both of the primary revisions, but the environmental/public interest groups also suggested some modifications to the proposals.

All changes made in the final rule relative to the proposed rule are explained in this unit, while a summary of all provisions of the final rule is in Unit VI. EPA decided to make these changes to the proposed revisions after considering public comments on the proposed rule. Each substantive comment is briefly paraphrased, followed by EPA's response to that comment. Where multiple commenters made a substantially similar comment, it is stated once, with an indication of how many made the comment and the types of organizations the commenters represent.

This unit is organized into separate sections for the two main provisions of the final rule, a section on all other aspects of the rule, and a section on miscellaneous comments not covered in the first three sections. Within each section, one or more issues raised by commenters is addressed. For each issue, all applicable comments are presented, followed by EPA's response, including the resulting modification to the proposed revision, if any, and the rationale for making the change or not.

A. Re-certification of Emergency Condition by Applicants

EPA has significantly reorganized § 166.20(b)(5) for improved clarity, but no substantive changes relative to the proposed rule are intended, except as discussed below.

1. *Commenter Issue: Allow re-certification beyond third year*—(a) *Comments requesting modification to proposal*. The proposed rule would have allowed re-certification applications only in the second and third years of an exemption for an applicant, assuming the exemption met the eligibility criteria (e.g., type of emergency condition that could reasonably be expected to continue). Many commenters stated that eligibility to use a streamlined re-certification application for repeat requests should not be limited to the second and third years of an exemption, but rather be longer or indefinite, as there is no compelling reason to limit it to 3 years. These commenters argued that re-certification is specifically and solely for the purpose of determining the existence of an emergency condition, and that EPA could still decline a valid re-certification application based on new risk information, availability of new alternative controls, or insufficient progress toward registration of the requested use.

In addition, full registration of a pesticide product often takes longer than 3 years, particularly for minor uses, even when States move expeditiously to identify the need. The commenters felt that States and affected growers should not be penalized when registration actions take more than 3 years. Commenters who supported allowing re-certification beyond the third year suggested various alternative limitations, including no limit. These general comments were made by 22 commenters (9 grower groups, 7 State lead agencies, 2 education/research groups, 2 agriculture/food industry groups, and 2 pesticide industry/registrants).

(b) *Opposing comments*. Other commenters felt that applicants should not be allowed to re-certify emergency conditions at all. They stated that repeat conditions are routine, and therefore not an emergency, as defined in the regulations. These commenters believe that repeat requests reflect poor management by growers and that repeat exemptions should be more difficult, not easier, to obtain. They contend that EPA already grants too many repeat exemptions and ignores progress-toward-registration requirements. Allowing applicants to re-certify emergency conditions would only make matters worse. These comments were made by 13 environmental/public interest groups in a joint submission, and by one private citizen.

(c) *EPA Response, including decision on re-certification limits*. EPA has carefully considered the comments summarized above concerning whether, and how long, to allow re-certification applications. The Agency is convinced not only that the re-certification process will provide the intended benefits of reduced burden and potentially quicker emergency response without negative consequences, but also that it would afford the same benefits in subsequent years as it would in the second and third years. Therefore, benefits would increase with the greater applicability of this improved process. Any specific limit to the number of years of eligibility for re-certification would be arbitrary. Therefore, in the final rule EPA has chosen to remove the applicability

restriction for re-certification that would have limited it to the second and third years.

However this modification to the proposed 40 CFR 166.20(b)(5) includes the authority for EPA to declare an exemption ineligible for re-certification at any time, on a case-by-case basis. In determining whether to end eligibility for re-certification, the Agency will consider the continued validity of the information, generally from the original application, that documents the projected losses, as well as whether any of the other information needs to be updated. If EPA decides that updating the documentation of an SEL is likely to significantly improve the projected loss estimates, or, if any other information casts doubt on whether the initial conditions still exist, then the Agency may declare the exemption ineligible for re-certification. The applicant for any exemption that is ineligible for re-certification may use a standard, full application format.

In response to comments questioning whether re-certification, or any repeat exemption requests, should be allowed at all, EPA has recognized for many years that an emergency may continue for multiple years when the emergency condition continues relative to the routine situation prior to the first occurrence of the emergency. This most commonly occurs when a pesticide, formerly relied upon by growers, becomes unavailable for use or loses effectiveness and no other effective means of pest control is available. Such a situation would generally continue until an alternative control becomes available, e.g., an effective alternative pesticide becomes registered for the use (often the chemical requested for the exemption), or an effective alternative non-chemical control becomes available.

The ability to indefinitely re-certify emergency conditions is not expected to increase the number of exemption requests submitted or the number of exemptions granted. EPA expects that when an emergency condition continues in a subsequent year, States would submit a repeat application regardless of whether a streamlined or full application were required. This rule reduces the burden in such situations. EPA believes that the reduced burden afforded by this rule would not induce applicants to make a repeat request.

Re-certification that an emergency condition continues to exist, for a previously granted exemption, would be part of a streamlined application for an emergency exemption. If the same emergency condition exists in a subsequent year that existed for the first year of an exemption, then EPA would generally again find that the emergency condition exists, regardless of whether a full application or a re-certification application were submitted. A re-certification application would simply reduce the burden on the applicant and help the Agency make the emergency determination more quickly. However, a determination by EPA that an emergency condition exists is not sufficient basis for an exemption to be approved. A re-certification application is no more likely to be approved than a full application for the same repeat request. Like a full application, a re-certification application would also be reviewed for, and could be denied owing to any of the following: New risk information; availability of new, effective alternative controls; or insufficient progress toward registration of the requested pesticide use.

Some commenters believe EPA grants too many repeat exemptions and that some exemptions are repeated for too many years. EPA would like to limit the number and length of long-running exemptions, and is pursuing new opportunities for minimizing such outcomes. Each year, EPA makes registration decisions on a large number of pesticide uses sought separately by State applicants under the emergency exemption program. For the fiscal years 2001 through 2004, EPA transitioned 313 uses to federal labels that had been requested under the section 18 exemption program, thereby precluding further repeat exemptions for those uses. These products are registered after a comprehensive analysis of the risks posed by these uses.

In addition, the Pesticide Registration Improvement Act (PRIA), enacted in early 2004, established time limits for EPA to make decisions on registration actions under section 3 of FIFRA which should further accelerate the pace of registration decision-making for all actions. Because of the emphasis within PRIA on review schedules, EPA is processing registration decisions more quickly than in the past. Pesticide uses that are requested for repeat exemptions will either gain registration more quickly than in the past, or their registration application could be not granted or denied in the same timeframe. The congressionally mandated review schedules under PRIA all become shorter and more compressed in upcoming years. For instance, the Agency's available review period for a new food use for a conventional pesticide goes from 38 months in FY 2004 to 22 months in FY 2006. Similarly, the review schedule for each type of registration action becomes shorter in later implementation years of the law. Although PRIA shortens the timeframe for registration decisions, the law also provides more resources through registrant fees and does not compromise the rigorous, comprehensive nature of the risk analysis necessary to support each registration decision. In this manner, EPA expects that each registration action will be evaluated within the context of PRIA. Under the previous priority planning scheme, certain actions did not receive priority due to resource and policy considerations. Additionally, EPA is mandated to complete re-registration of older pesticides by the end of 2006. Remaining decisions on eligibility to re-register pesticide products are also expected to affect repeat exemptions, leading to the denial of some and paving the way for the registration of others.

The Interregional Research Project No. 4 (IR-4) program is a highly successful cooperative effort and partnership of the State land grant universities, industry, the U.S. Department of Agriculture (USDA), and EPA, to address the chronic shortage of pest control options for minor crops. In many cases, the crop protection industry lacks economic incentive to pursue registrations on minor crops because of low acreage and limited sales potential. IR-4 generates and supplies research data needed by EPA in order to register compounds for use on minor crops. The IR-4 process continues to improve, and registrations for repeat exemptions are among the highest priorities in the IR-4 queue. In 1999, IR-4 initiated a streamlined project schedule of 30 months for its highest priority clearance projects. Pest management gaps associated with section 18 applications qualify for this highest priority schedule of 30 months. IR-4 is also increasingly performing research on pesticides which are presumed to pose less hazard than traditional synthetic chemicals. Over three quarters of the pesticides IR-4 evaluates and then submits for review to EPA are classified as reduced-risk materials under the Agency's programs for supporting transition to lower toxicity and sustainable means of pest management. Additionally, the review schedule under PRIA also favors and places a bias in support of submissions involving reduced-risk pesticides. For instance, the Agency's review time period under PRIA for a new use of a conventional pesticide in FY 2006 is 22 months whereas the review period for a reduced-risk pesticide in FY 2006 is 20 months. These incentives could help IR-4 and its collaborators realize a large

number of clearances. EPA anticipates that the processes discussed above will further enhance recent successes in registering repeat uses faster, as well as ensure that regulatory evaluations for any pending registration actions associated with a section 18 use will take place efficiently.

EPA has authority under § 166.32 to revoke any exemption during its active use period, if the Agency learns that the emergency no longer exists, the risks are unacceptable, the use is not effective, or users are not complying with the terms and conditions of the exemption. When necessary and appropriate, this provides another means to end long-running exemptions quickly, without waiting for an exemption to expire.

2. *Commenter Issue: Make voluntarily canceled pesticides ineligible for re-certification*—(a) *Comments requesting modification to proposal.* Some commenters felt that voluntarily canceled pesticides should be added to the list of pesticide categories for which, when requested for an exemption, the applicant is not eligible to use a re-certification application. The proposal already lists several categories of pesticides (e.g., new active ingredient, first food use, canceled pesticides) that warrant heightened review and public notice, and are therefore not eligible for re-certification. These commenters contended that EPA should not allow re-certification for voluntarily canceled pesticides. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments.* No other comments were received on the issue of pesticide categories ineligible for re-certification.

(c) *EPA Response, including decision on modification.* The proposed rule listed several categories of pesticides as ineligible for re-certification. Specifically, the existing regulations at 40 CFR 166.24(a) identify a number of situations where, upon receipt of an application for an emergency exemption, the regulatory status of a pesticide product calls for public notice and comment. EPA believes there is a legitimate need for heightened review and awareness of exemption requests with the listed regulatory statuses. Both the notice-and-comment requirements as well as the need for heightened review would preclude the benefit of an expedited review that would otherwise be expected from a re-certification application. The categories proposed as ineligible for re-certification include new pesticide active ingredients, first food uses, canceled or suspended pesticides, and pesticides that have been the subject of a Special Review. Because a pesticide that has been voluntarily canceled by its registrant may be similar to these other categories of pesticides, the Agency agrees with this comment and believes this category of pesticide uses should also be ineligible for re-certification. Therefore, the proposed 40 CFR 166.20(b)(5) is modified accordingly in the final rule. Also, EPA is expanding the provision for 40 CFR 166.24 to add this category of pesticide uses to those for which EPA will issue a Notice of Receipt. Therefore, a Notice of Receipt will be published in connection with the submission of emergency exemption uses that involve pesticide uses which have been voluntarily canceled. Therefore, while applicants may still request exemptions for a voluntarily canceled pesticide, the streamlined re-certification application process will not be allowed for such uses.

3. *Commenter Issue: Add to documentation requirements for repeat exemptions*—(a) *Comments requesting modification to proposal.* Some commenters suggested that repeat applicants should be required to document at least:

(i) What effect the exemption had on the emergency condition during the first year,

(ii) Why the exemption continues to be necessary,

(iii) That there are no feasible non-chemical alternatives, and,

(iv) That the original predictions of economic harm are legitimate. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments.* No other comments were received on the issue of modifying the documentation requirements for repeat exemption requests.

(c) *EPA Response, including decision on modification.* EPA's responses below correspond to the lettered list of the commenters' suggested documentation requirements for repeat requests:

(i) Annually, in a post-exemption report per § 166.32, and with any repeat application per § 166.20(a)(11), applicants will still be required to include a description of the effect the exemption had on the emergency condition.

(ii) A re-certification application must contain a certification that the same emergency condition previously documented continues and is the reason the exemption continues to be necessary.

(iii) EPA believes that the applicant is in a better position than the Agency to identify availability of a non-chemical alternative, i.e., cultural practice, for the specific use in their State. EPA agrees that it would be appropriate to have applicants (which are primarily State agencies) for repeat exemptions document availability and effectiveness of new non-chemical controls identified since the previous year's application, or to certify that none are known. Therefore, in the final rule EPA has added a requirement, at § 166.20(b)(5)(v)(E), that applicants certify that they are not aware of any alternative non-chemical practice that may offer a meaningful level of pest control, or else provide documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible. In situations where such effective and feasible cultural practices are available, EPA would not grant the exemption because there would not be an emergency condition, by definition.

(iv) One way to validate the reasonableness of the estimated losses would be to allow them to happen, i.e., to grow the crop under the emergency condition without use of the requested pesticide. EPA already has the discretion to grant a repeat exemption subject to the condition that some research areas be grown under the emergency condition without use of the requested pesticide, although such validation has generally not been required. Occasionally, confirmatory data, such as comparative product performance studies, are required on repeat requests. The re-certification program would not alter this practice. Furthermore, re-certification requires that other economic factors that result in a projection of an SEL (e.g. cost of alternative, crop prices) have not changed substantially, and that there is no new information about pest damage.

B. Determining and Documenting ''Significant Economic Loss'' (SEL)

1. *Commenter Issue: Lower quantitative thresholds for SEL, add flexibility*—(a) *Comments requesting modification to proposal.* Some commenters said that the thresholds for the three tiers for determining SEL should be lower, as the proposed thresholds require total elimination of net income to qualify. Also, EPA should be allowed flexibility to use judgement to make an SEL finding for situations not meeting any of the thresholds. Commenters argued that total elimination of annual net income is too severe a threshold, and that some lesser loss constitutes a significant economic loss. These commenters feel the three tiers should be screens to identify obvious emergencies, and that flexibility, which does not clearly exist

in the proposed rule, should be added to identify the less obvious emergencies. No commenter suggested an alternative level for any threshold, or a basis on which to develop one. This general comment was made by 17 commenters (9 grower groups, 4 State lead agencies, 2 agriculture/food industry groups, and 2 pesticide industry/registrants).

(b) *Opposing comments.* Other commenters felt that the proposed quantitative thresholds for determining SEL are already too low. They stated that the proposed tiered approach to document an SEL with the selected thresholds would unreasonably expand the definition of emergency and make it easier to find that an emergency exists. These commenters felt that the proposed method allows prohibited pesticide uses for profit. They assert that the proposed new approach together with the quantitative thresholds for the three tiers are unlawful, arbitrary and capricious, and contrary to congressional intent. This comment was made by 13 environmental/public interest groups in a joint submission.

(c) *EPA Response, including decision on modification.* After considering all comments, EPA believes that the proposed thresholds are appropriate and should not be relaxed, but that flexibility should be available to allow EPA to use judgement to make an SEL finding where projected losses are particularly difficult to quantify or other factors warrant an emergency exemption. Some commenters concluded that the proposal provided no flexibility for EPA to use judgement to determine an SEL for situations not meeting any threshold, regardless of how close to a threshold quantitative loss projections may come. To the extent that this comment reflects a concern that EPA would consider only quantitative data in determining whether the loss thresholds are met, EPA notes that it interprets the language of both the proposed and final rule to allow for consideration of estimates based on qualitative information, either alone or in addition to quantitative information, in determining whether losses under the emergency condition would exceed the thresholds for SEL. However, EPA intends to limit the use of qualitative information to document projected losses, relying on such information only in cases where credible quantitative information is not available.

In response to the concern that the quantitative loss thresholds of § 166.3(h)(1) may not apply to all pest activity primarily affecting the current growing season, EPA has expanded § 166.3(h)(2) so that EPA may use its broader criteria wherever they are more appropriate. The proposed rule provided a loss-based approach with quantitative thresholds applicable to pest activity primarily affecting the current growing season under § 166.3(h)(1), and ''for all other pest activity'' included in a provision at § 166.3(h)(2) to determine an SEL for situations where the loss-based approach does not adequately address the expected loss, similar to a provision in the existing regulations. Such losses include those not confined to the current year or those that impact capital assets rather than productive activities. This change to § 166.3(h)(2) will allow the flexibility to apply an appropriate methodology for assessing the consequences of an emergency, and help ensure that any of the widely variable situations potentially causing an SEL can be adequately addressed.

Although no commenter addressed the issue, EPA has corrected the scope of the proposed SEL definition. The SEL criteria under the proposed § 166.3(h)(1) would have applied to ''pest activity that primarily affects the current crop.'' For the final rule ''or other output'' is added after ''current crop,'' so that non-crop productive activities (e.g., dairy production) may also be assessed under the loss-based, tiered approach. For the same reason, EPA has removed the word ''crop'' from §§ 166.3(h)(1)(i) and 166.20(b)(4)(i).

As explained above, some commenters believe that the proposed thresholds for SEL are too high, arguing that these thresholds effectively require total elimination of net income to qualify. Other commenters believe that the proposed thresholds make it easier to find that an emergency exists, allowing unregistered pesticide uses for profit. Actually, the selected thresholds neither raise nor lower the standard for SEL. EPA's retrospective analysis of past exemption requests, discussed in the Economic Analysis available in the public docket for this final rule, shows that the new approach would not make SEL findings any more common and would not otherwise expand the definition of emergency. The analysis indicates that virtually the same number of requests would result in an SEL finding using the new approach as actually occurred under the current approach, although different findings (in both directions) may occur in some individual cases.

Although the new tiered approach for determining SEL maintains the same overall standard to qualify, its fixed, quantitative thresholds intentionally make the standard consistent, in contrast to the current variable standard. However, the fixed SEL standard allows an easy comparison of the quantitative thresholds to farm income statistics. It is true that, according to USDA statistics, the new thresholds for SEL are roughly equivalent to elimination of net farm income from the affected crop, if fixed costs are also considered. Because the new SEL standard is comparable to the average of the current standard, for the first time it is apparent that the current standard is approximately equivalent to elimination of net farm income. However, when the States recommended revising the approach to determining SEL, their stated reason was to establish a fixed standard that is more equitable and easier to document. EPA had extensive interaction with stakeholders during the development of this rule, but received no input saying that the existing standard for SEL was too high.

EPA acknowledges that economic terms such as ''net revenue'' and ''net farm income'' may be confusing and are not always used the same way by all parties. Although the proposed threshold for the third tier for SEL is 50% of ''net revenues,'' as defined in the preamble to the proposed rule, this is not equivalent to ''profits'' because it does not include fixed costs. For the purpose of this rule, EPA defines net revenue as gross revenue less variable operating costs. A calculation of ''profit'' would typically subtract fixed costs from this amount. In this case, ''profit'' is roughly equivalent to the gross pay of a typical salaried employee and is essentially the return to the farmer's labor and managerial skills. This is also referred to as ''net farm income.'' If typical fixed costs were included in the consideration of impacts on income, a loss of 50% of net revenues (Tier 3 threshold) would, according to USDA statistics, result in approximate elimination of net farm income. With this as the context for the SEL thresholds, EPA believes that there is no basis for concern that farmers might unduly profit from emergency exemptions.

Section 18 of FIFRA provides broad discretion for EPA to define and determine, by regulation, when an emergency exists. The Agency believes that the new approach and thresholds are not arbitrary or capricious, as they are essentially refinements to make the standard that has been used for years more uniform and equitable, without raising or lowering it. Furthermore, while this standard may seem severe to some, the standard for SEL was always intended to identify and avert true economic emergencies, and was not intended to maintain farm income at or

near a certain level. EPA believes that there should be a high standard for allowing an exemption from the requirements of registration. Even if EPA were to consider a lower standard, the Agency is not aware of a basis for selecting a lower standard that would not be arbitrary.

C. Other Regulatory Provisions

1. *Commenter Issue: Confirm efficacy and economics of non-chemical alternatives*—(a) *Comments requesting modification to proposal*. Commenters stated that EPA should use section 18 to promote Integrated Pest Management (IPM) by confirming the efficacy and economics of non-chemical alternatives for pesticide uses requested for an emergency exemption. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response, including decision on modification*. The existing § 166.20(a)(4)(ii) already requires applicants to explain why alternative practices would not provide adequate control or would not be economically or environmentally feasible. Some time after this final rule is issued, EPA plans to provide new guidance for applicants to improve the quality and consistency of information submitted on non-chemical alternatives. Although EPA supports and encourages IPM and use of risk-reducing, alternative, non-chemical controls, as evidenced by the Agency's voluntary Pesticide Environmental Stewardship Program, the Agency does not directly regulate cultural practices. For this reason and because applicants are typically State agricultural agencies, EPA believes that the applicant is in a better position than the Agency to identify availability of a non-chemical alternative practice for the specific use in their State, and to assess its effectiveness and feasibility. In this final rule, a new provision has been added at § 166.20(b)(5)(v)(E) to require that applicants using the re-certification process separately certify that they are not aware of any available chemical alternatives or reasonable non-chemical alternative practices, or if they know of any such practice that they include with the application documentation demonstrating that the chemical or practice does not provide adequate control or is not economically or environmentally feasible.

2. *Commenter Issue: Clarify or improve notification/confirmation for crisis exemptions*—(a) *Comments requesting modification to proposal*. Commenters stated that for crisis exemptions, the proposal to have applicants notify EPA and receive verbal confirmation from the Agency of no risk-based objections before using the crisis provisions needs clarification and possible revision. The proposal says that EPA will attempt to provide such confirmation as quickly as possible, and within 36 hours. Commenters stated that they may not be able to reach the appropriate EPA contact on a Friday, a weekend, or a holiday, which could delay confirmation and use of the crisis exemption until 36 hours after the beginning of the next work day. They suggest that EPA make someone available at all times, or, add a provision that notification can be made by voicemail, and a consent by default would be assumed after 36 hours if the applicant has not heard back from EPA by that time. One commenter also suggested that EPA should make exceptions to the 36–hour waiting period for EPA confirmation for some uses, including public health crises, bioterrorism attacks, and non-food uses. This comment was made by two State lead agencies.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response, including decision on modification*. The reason for this revision is to replace the current ambiguous language at 40 CFR 166.43(a), which allows for the possibility of a State or federal agency notifying EPA after beginning use of the crisis provisions. The revision will codify a process that has been widely practiced and accepted by applicants, and that has become more necessary after enactment of FQPA. FQPA expressly required that time-limited tolerances be established for emergency exemption uses that may result in residues in food. EPA maintains that it is in the best interest of all parties (including States, EPA, users of pesticides under section 18, the food processing and marketing industries, etc.) that there is some assurance before the use begins that EPA will be able to establish a ''safe'' tolerance for a pesticide to be used under a crisis exemption. Without that assurance, users run the risk of producing an adulterated crop that results in unsafe pesticide residues and would be illegal to sell. It is also important that EPA be given the opportunity to voice other objections to a use being considered for a crisis exemption. The Agency may be aware of risk issues unknown to the applicant, and has the authority to deny crisis provisions for a particular pesticide use, under § 166.41(a).

EPA is keenly aware of the time-sensitivity of emergency situations for which crisis exemptions are needed. The Agency will continue to make every effort to receive and quickly respond to notifications of intent to declare a crisis. EPA believes that the concerns raised by these commenters can be adequately addressed in the same manner that EPA has managed these issues since enactment of FQPA. It is true that EPA staff are not available at all times, such as at night or during weekends, to receive notification of a State's intent to declare a crisis. However, EPA believes that applicants generally first become aware of the need for a crisis exemption at least a few days before notifying EPA of its intent to issue a crisis exemption. If an applicant notifies the Agency of their intent to declare a crisis as soon as possible, even before they have gathered all of the necessary information, EPA should be able to provide confirmation before use of the pesticide is needed. The Agency believes that the existing confirmation process now being codified has not caused significant delays to use of crisis exemptions in the past. In fact, there have been cases where EPA staff have worked with applicants during weekends in order to provide timely confirmation, and in extraordinary circumstances EPA will continue to do this in the future. A default presumption of no EPA objection to a crisis exemption, in cases when the Agency cannot be immediately reached, would provide neither the necessary assurances for users of the pesticide, nor proper protections for human health and the environment.

EPA is not taking the commenter's suggestion that an exception to the need for EPA confirmation be made in cases of non-food uses, or public health or bioterrorism threats. For non-food uses, EPA can generally provide confirmation more quickly than for food uses, but must still be allowed the opportunity to identify other unacceptable risks. In the case of major public health threats or bioterrorism, a national emergency network and system is in place that will enable applicants to contact EPA at any time, and EPA will quickly respond. Through the National Infrastructure Protection Plan, as part of a network of federal, State, and local governments, agencies can quickly contact EPA whenever a public health threat arises, including terrorism. In such cases, the Agency expects to be able to act very quickly and at any time. For certain listed biological threats, there is an expedited process in place whereby, once notified of the emergency need for an unregistered pesticide or use, EPA would evaluate the applicant's remedial action plan and, after considering the

safety and efficacy of such use, would decide whether to issue a crisis decision.

The Agency has modified the proposed language at § 166.43(a) for the final rule, to remove references to EPA's confirmation and the 36–hour time period, as it is not appropriate in this paragraph for notification by applicants to EPA. EPA will strive to provide the confirmation as quickly as possible and within the customary 36 hours, and will attempt to match the urgency of decision-making with the urgency of the situation. This final rule does not attempt to change the timeframe in which EPA provides confirmation. The Agency's practice will continue that the 36–hour clock does not start until EPA actually receives and acknowledges the notice, and only applies to business days. The lack of a response in 36 hours should not be interpreted as approval of the crisis exemption; this final rule does not include decision by default. The language in the proposed § 166.40(c) is modified for this final rule to allow EPA to withhold confirmation due to any objection, not just risk-based objections.

D. Miscellaneous Comments

Protections for endangered species under the emergency exemption program and pest resistance management issues are discussed in Unit VIII. These are important issues that were discussed in the preamble to the proposed rule, but for which no regulatory revisions were proposed. Some comments received on these issues are addressed in Unit VIII, while other significant miscellaneous comments are included below.

1. *Commenter Issue: The section 18 pilot violates the Administrative Procedure Act*—(a) *Comment summary*. Commenters stated that the section 18 pilot violates the Administrative Procedure Act (APA) as a binding regulation without notice and comment. These commenters went on to say that EPA solicited public comment on the pilot provisions in the **Federal Register** Notice that initiated the pilot, but failed to respond to those comments. This comment was made by 13 environmental/public interest groups in a joint submission.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response*. The comment that the pilot violated the APA is not relevant to the proposed or final rule and to whatever extent it might have been relevant to the pilot program, the issue is moot because EPA has ended the pilot program. EPA disagrees with the comment because the section 18 pilot program was not a binding regulation and did not require notice and comment rulemaking under section 553 of the APA. EPA believes that participants in the section 18 pilot program conformed to the requirements of the Agency's existing regulations pertaining to emergency exemption requests at 40 CFR part 166. The purpose of the pilot was to gain experience and gather information for the rulemaking on improvements to the section 18 process. The pilot was intentionally limited in scope. During the course of the pilot, less than 5% of all applications received were eligible for the pilot and utilized its provisions. No applicant was required to use the pilot. EPA is confident that the pilot's standard for an emergency finding was no higher or lower than the current standard. The risk side of the assessment and decision process was not changed for the pilot. Furthermore, an additional safety margin was essentially added to the pilot by limiting application to ''reduced-risk'' pesticides.

During development of the proposed rule, EPA carefully considered public comments received on the **Federal Register** Notice that initiated the pilot. Those comments and EPA responses are summarized in the separate response-to-comments document that also addressed comments on the proposed rule and is available in the public docket.

2. *Commenter Issue: Documentation for endangered species needs clarification*—(a) *Comment summary*. Commenters stated that documentation requirements for endangered species concerns in emergency exemption requests need clarification and further guidance. They also said that EPA, the U.S. Fish and Wildlife Service and the National Marine Fisheries Service have data on endangered species that States do not have, and these federal agencies should either provide such data, or make it readily available to States. One commenter suggested that when measures are necessary to protect endangered species, EPA should involve the State early (before decision). This comment was made by three State lead agencies and by AAPCO.

(b) *Opposing comments*. No other comments were received on this issue.

(c) *EPA Response*: EPA believes that an important aspect of assuring protections of endangered and threatened species in the implementation of the emergency exemption program is to have available good information on the potential exposure and risk of a requested use to a listed species and its habitat. Some time after promulgation of this final rule, EPA plans to issue improved guidance on what information regarding threatened and endangered species should be included with an application. EPA will continue to involve applicants in the discussion of possible mitigation measures whenever it appears that threatened or endangered species may be at risk.

VI. Final Rule Revisions to Emergency Exemption Process

While Unit V. summarizes changes in the regulatory provisions of the final rule from those in the proposed rule, Unit VI. summarizes how this final rule revises the existing regulations at 40 CFR part 166 that govern the emergency exemption process.

A. Re-certification of Emergency Condition by Applicants

1. *How the re-certification process will work*. This final rule adds a new paragraph (b)(5) to 40 CFR 166.20 that allows applicants for eligible repeat exemptions to submit streamlined ''re-certification'' applications. The re-certification application process applies only to specific exemptions, and is not available to applicants for quarantine exemptions, public health exemptions, or crisis exemptions. In addition, re-certification can only be used if the same exemption was approved for the same applicant the previous year, or use period, and meets other eligibility criteria discussed below. Subject to limitations specified in § 166.20(b)(5) and discussed below, where an emergency condition that originally qualified for an emergency exemption continues in a subsequent year, eligible applicants may re-certify that the same emergency condition continues and rely on the preceding year's submission to document the economic impact of the pest emergency. This re-certification approach allows applicants to incorporate by reference all information submitted in a previous application, instead of submitting a complete new application and supporting documentation. The re-certification of the emergency condition by the applicant combined with other information available to EPA will serve as the basis for EPA's determination as to whether an emergency condition continues to exist.

While a re-certification application may allow for speedier preparation of exemption requests and quicker determinations by EPA that an emergency condition exists, it will not result in automatic granting of an emergency exemption. In addition to an emergency finding, before granting an exemption EPA must also determine that, among other things, there are no

effective registered alternatives to the requested pesticide use, no feasible alternative practices that provide adequate control are available, the requested pesticide use will not cause unreasonable adverse effects on human health or the environment, and there has been sufficient progress towards registration of the requested use. If an effective product has been registered for the requested use since the previous exemption was approved, an emergency condition may no longer exist. If the Agency has received new risk information since approving the previous exemption, then the risk will be re-evaluated. Likewise, if the request includes any change in the conditions of use that may increase exposure, such as application rate, number of applications, type of application, pre-harvest interval, re-entry interval, total number of acres, or change in the geographic area proposed for treatment, then the risk will also be re-evaluated. EPA may determine that sufficient progress towards registration has not been made for a requested pesticide use. The risk evaluation process for repeat requests is not changed by this rule.

Not all repeat exemption requests will be eligible for re-certification. Upon approval of any specific exemption, EPA intends to make an initial assessment regarding potential eligibility for a streamlined re-certification application the following year, in the event that the applicant reapplies the next year. EPA will consider the following in determining potential eligibility to use a streamlined re-certification application:

1. *Whether the emergency situation could reasonably be expected to continue for longer than 1 year.* An emergency situation could reasonably be expected to continue where, for example, a registered product relied upon by growers becomes permanently unavailable, a pest expands its range, or a registered product ceases to be effective against a pest. Situations that would not be expected to continue, and therefore not be eligible for re-certification, would include a temporary supply problem of a registered product, an isolated weather event, or a sporadic pest outbreak.

2. *Whether the pesticide product, owing to its regulatory status, warrants heightened review before any additional use is approved.* EPA will rely primarily on the same criteria used in the existing regulations at 40 CFR 166.24(a), which identifies a number of different situations where, upon receipt of an application for an emergency exemption, the regulatory status of a pesticide product calls for public notice and comment. The first five categories listed below are from the existing 40 CFR 166.24(a), while the sixth is a similar category, added for the final rule, as discussed in Unit V.A.2. An applicant will be ineligible to use a re-certification application when the following categories of pesticides are requested for an exemption:

(a) A new chemical;

(b) The first food use of an active ingredient;

(c) Any use of a pesticide if the pesticide has been subject to a suspension notice under section 6(c) of the Act;

(d) A pesticide which:

(i) Was the subject of a notice under section 6(b) of the Act and was subsequently canceled, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was the subject of the notice under section 6(b);

(e) A pesticide which:

(i) Contains an active ingredient which is or has been the subject of a Special Review, and

(ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which is or has been the subject of the Special Review;

(f) A pesticide which:

(i) Contains an active ingredient which was contained in a pesticide product that was voluntarily canceled by its registrant, and

(ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled by its registrant.

Furthermore, EPA may declare that an exemption that was previously eligible for re-certification is no longer eligible. In determining whether to end eligibility for re-certification, the Agency will consider the continued validity of the information, generally from the original application, that documents the projected losses, as well as whether any of the other information needs to be updated. If EPA decides that updating the documentation of an SEL is likely to significantly improve the projected loss estimates, or, if any other information casts doubt on whether the initial conditions still exist, then the Agency may declare the exemption ineligible for re-certification. The applicant for any exemption that is ineligible for re-certification may use a standard application.

In instances where EPA determines that an exemption is potentially eligible for re-certification, EPA will advise the successful applicant that, should it reapply the following year, they appear eligible to use a re-certification application. EPA anticipates that this advice will be included in the notice of approval of the current year's application. However, if an exemption is not classified as a candidate for re-certification in the approval notice, and an applicant believes that subsequent information would make it eligible, the applicant may contact the Agency to request an eligibility determination. In some instances, EPA may determine that an emergency condition exists, and that the exemption appears eligible for a re-certification application the following year, yet conclude that additional information should be gathered in order to support approval in future years. In such instances, EPA may indicate in the approval notice that the exemption appears eligible for re-certification provided the applicant submits the specified information. Finally, EPA reserves the authority to declare an emergency exemption ineligible for re-certification where, in the Agency's sole discretion, it determines that a complete application is necessary.

An acceptable re-certification application must include not only the applicant's re-certification that the emergency condition continues, but also its certification to several other specific facts, or be accompanied by additional information. An eligible re-certification applicant will be exempted from the information requirements of § 166.20(a)(1) through (a)(10), and of the existing § 166.20(b), where the applicant certifies that:

(i) The emergency condition described in the preceding year's application continues to exist;

(ii) Except as expressly identified, all information submitted in the preceding year's application is still accurate;

(iii) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;

(iv) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied;

(v) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or, if any, has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.

Applicants meeting the requirements of § 166.20(b)(5), as discussed above, would not need to submit new, updated documentation that the emergency condition continues or the data elements otherwise required under 40 CFR 166.20, except that the interim

report specified in § 166.20(a)(11) would still be required where a re-certification is filed before the final report on the previous exemption is available.

2. *Rationale for new re-certification process.* Allowing applicants for eligible exemption requests to recertify the existence of an ongoing emergency condition and to incorporate by reference all information submitted in a previous application is expected to reduce the burden to both applicants and EPA as well as allow for potentially quicker decisions. When an applicant certifies the continuation of the emergency condition and incorporates previously submitted materials by reference, a complete new application sufficient to characterize the situation in accordance with 40 CFR 166.20 will not be required. This will save applicants time and effort in gathering data and preparing their submissions. The Agency will save time and resources by not having to annually repeat each administrative step of its review of the documents supporting the exemption requests. If no pesticides that could avert the emergency have been newly registered, no new non-chemical controls have been developed, and nothing has changed to affect the assessment of risk, then re-certification of an emergency will lead to significantly shorter Agency review.

For repeat exemption requests where the emergency situation has not changed, EPA's experience with full, annual applications indicates that projected yield and revenue losses are generally comparable to those found the first year and a significant economic loss is again found. This is reasonable since applicable losses are those resulting from the emergency situation relative to the situation prior to the first occurrence of the emergency. Therefore, with the applicant's certification that the emergency condition continues and that all information in the earlier application is still accurate, reliance on the previously submitted data and other supporting information should be adequate to support an emergency finding. Re-certification only alters the process for an emergency finding, whereas determinations of acceptable risk, availability of alternative controls, and progress toward registration are not changed by this final rule. With a re-certification application, the applicant and Agency must still address these other areas necessary to approve or deny the request, just as with a full application. Furthermore, the final rule provides that EPA may declare an exemption ineligible for re-certification at any time, should the Agency decide that a full application is more appropriate. For the reasons discussed above, EPA believes that the re-certification process will provide the benefits of reduced burden and quicker emergency response, without compromising either the quality of decisions or protections for human health and the environment.

B. Determining and Documenting ''Significant Economic Loss''

1. *How determination of significant economic loss (SEL) will work.* This rule re-defines ''significant economic loss'' at 40 CFR 166.3(h). Under the new definition, the method for determining the amount of the projected loss due to the emergency condition will not change, although the calculation will be done in steps (tiers) and sometimes the later steps will be unnecessary. However, the new definition of SEL changes how EPA will determine whether the loss is considered ''significant.'' The revised approach provides standard criteria for determining the significance of the projected loss, rather than comparing losses to past variations in revenue or profit. The goal of the criteria is to compare losses to farm or firm income in the absence of the emergency in a manner that can be easily and consistently measured. Successive screening levels (tiers) have been chosen that permit situations that clearly qualify to be resolved quickly, with a minimum of data. Each tier has a quantitative loss threshold that generally applies to all eligible emergency exemption applications. If the pest situation does not appear likely to result in a significant economic loss based on the first tier analysis, it might qualify based on further analysis in succeeding tiers. Each additional tier requires more data and involves more analysis on how the emergency affects revenues.

Tier 1: Yield Loss - Tier 1 is based on quantity loss, i.e., crop yield or other output loss. If the projected yield loss due to the emergency condition is sufficiently large, EPA would conclude that a significant economic loss will occur, due to the magnitude of the expected revenue loss. The yield loss threshold in Tier 1 is 20% for all situations. This threshold is set at a sufficiently high level such that a loss that exceeded the threshold would also meet the thresholds in Tiers 2 and 3, if the additional economic data were submitted and analyzed. Therefore, for such large yield losses it is not necessary to separately estimate economic loss, which would require detailed economic data.

Tier 2: Economic Loss as a Percentage of Gross Revenues - A quantity or yield loss that does not satisfy the threshold in Tier 1 may nonetheless cause a significant economic loss because such loss alone may not reflect all economic losses. Quality losses may result in reductions in prices received and/or there may be changes in production costs, such as pest control costs and harvesting costs. For situations with yield or output losses that do not meet the significant economic loss criterion for Tier 1, EPA would evaluate estimates of economic loss as a percent of gross revenue in Tier 2, to determine if the loss meets that threshold for a significant economic loss. The economic loss threshold in Tier 2 is 20% of gross revenue for all situations. Again, this threshold in Tier 2 is set with the intention that losses exceeding the threshold would also meet the threshold in Tier 3, if the additional Tier 3 analysis were performed.

Tier 3: Economic Loss as a Percentage of Net Revenues - If neither quantity nor economic losses are above the thresholds in Tiers 1 and 2, EPA will compare impacts to net revenues. Net revenues are defined for the purposes of this rule as gross revenues minus operating costs. The loss threshold in Tier 3 is 50% of net revenues for all situations. Emergency conditions that fall short of the thresholds in Tiers 1 and 2 may qualify as a significant economic loss in Tier 3, particularly for enterprises with high costs of production relative to gross revenue.

Applicants should first determine whether their projected loss meets the Tier 1 yield loss threshold of 40 CFR 166.3(h)(1)(i), analytically the least burdensome criterion. The associated data requirements appear in § 166.20(b)(4)(i). If the projected loss does not meet this threshold, applicants should determine whether their projected loss meets the Tier 2 gross revenue threshold of § 166.3(h)(1)(ii), providing additional data as noted in § 166 20(b)(4)(ii). Failing to meet that threshold, applicants should submit the data to perform the analysis necessary for the Tier 3 net revenue threshold of § 166.3(h)(1)(iii) as given in § 166.20(b)(4)(iii). The three tiers established in § 166.3(h)(1)(i), (ii), and (iii) are designed such that when an emergency condition qualifies for significant economic loss under a lower tier, data for higher tiers are not required, and the burden and cost of preparing the emergency exemption application are reduced. Each successive tier builds upon the previous one. That is, the information required for estimating a lower tier is also

necessary in estimating each higher tier. This allows an applicant to collect data, and build a case for significant economic loss, as needed and determined by the conditions, without requiring additional data. Applicants will continue to submit data to demonstrate the emergency nature of the pest outbreak including the basis for expected losses in quantity, and sometimes quality and/or additional production costs. However, applicants no longer need to submit historical economic data demonstrating variations in revenues, although historical data may be appropriate to define the baseline, routine, or ''without emergency'' scenario. The new guidance document that EPA is issuing in conjunction with this final rule includes a description of information that EPA expects applicants to submit in order to demonstrate an SEL.

This loss-based approach is designed to capture the economic impact of pest activity as it affects the current production season, which will be sufficient for most emergency exemption applications. Although § 166.3(h)(1) applies the loss-based approach to pest activity primarily affecting the current growing season, EPA has reserved the authority to use a case-by-case approach in the new § 166.3(h)(2). Where EPA determines that the loss-based approach of § 166.3(h)(1) would not adequately describe the expected loss, for example long-term losses in orchard crops, the Agency would continue to make its significant economic loss determinations based on other criteria (i.e., a substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity) where the applicant demonstrates significant losses that would not be recognized under § 166.3(h)(1).

2. *Rationale for revised SEL approach.* The revised methodology for determining an SEL is intended to streamline the data and analytical requirements for emergency exemption requests, and allow for potentially quicker decisions by EPA. In addition, the methodology is designed to reflect more accurately the significance of an anticipated economic loss. Specifically, this approach makes a more direct comparison between the losses anticipated owing to the emergency situation and the yield and/or revenues without the pest emergency, rather than a comparison to the historical range of profit variability. Year-to-year profit variability often reflects market forces entirely unrelated to pest pressure. Although EPA has attempted to make allowances for crops' differing profit variability when determining the economic significance of losses under the current approach, EPA believes that the loss-based approach better and more directly permits EPA to evaluate the significance of economic losses.

An analysis of past emergency exemption requests suggests that this revised approach will not cause a significant change in the overall likelihood of an SEL finding, although findings may differ in individual cases. The results of this analysis are discussed in the Economic Analysis of the final rule, available in the public docket. The analysis shows that in many cases an SEL can be adequately demonstrated with less data and without loss of reliability or flexibility through the revised methodology. The new approach is expected to lead to savings to both applicants and EPA from reduced data and analytical burdens. Under the new procedure, applicants may elect to submit the minimum amount of data necessary to demonstrate a significant economic loss in one of three increasingly refined tiers. If the first tier is sufficient, the burden is reduced most significantly, as it identifies the most obvious emergencies with less data. The loss-based approach requires less data from applicants in cases that qualify under Tier 1, where the same conclusion of a significant economic loss would be made with the additional data and analysis under the higher tiers. Even in the highest tier, the burden may be reduced relative to the current approach as the analysis focuses on the current year rather than historical data. Like re-certification of emergencies, this approach is expected to save applicants time and resources in gathering data and preparing submissions. The Agency's burden should be reduced due to the simplified approach and clear, consistent thresholds.

Because the loss-based approach in today's final rule shifts the focus from annual price variability to actual pest-related losses, it is expected to lead to more consistent and transparent findings of the significance of economic losses. Under the current approach, producers of crops that have very wide fluctuations in net revenues, even if due to price variability, may experience a large economic loss due to non-routine pest-related conditions, without a significant economic loss finding by EPA under strict adherence to the current approach. Other crops and cases may have very little variation in historical net revenues, which could lead to a small economic loss being found significant under the current approach. Again, the new, loss-based approach is designed so that it would not cause a significant change in the overall likelihood of a significant economic loss finding, but it may change the findings in individual cases so that determinations of significance are more accurate, appropriate, and equitable.

C. Specifying Invasive Species as Targets under Quarantine Exemptions

Existing regulations describe four types of emergency exemptions, one of which is a quarantine exemption. The purpose of a quarantine exemption is stated in 40 CFR 166.2(b) as follows:

> (b) *Quarantine exemption.* A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

Quarantine exemptions are not necessarily for the purpose of, or approved on the basis of, averting a significant economic loss, although they may ultimately help prevent large economic losses. In addition to being for the control of pests that are not widely prevalent or distributed in the U.S., quarantine exemptions are intended to control recently-introduced, non-native species. In recent years such species have come to be commonly known as ''invasive species.'' Because of the potentially widespread and devastating impacts of invasive species to ecosystems, the environment, and the economy, the challenge of preventing their introduction, and when necessary controlling them, has garnered increasing attention in recent years. Although invasive species implicitly fall within the scope of quarantine exemptions, the now widely-recognized term does not appear in the existing regulations, probably because it was not widely used at the time 40 CFR part 166 was promulgated. This final rule adds the term ''invasive species'' to § 166.2(b) and to § 166.3(d)(3)(i), to clarify that the intent of making quarantine exemptions available includes the control of invasive species. The rule also adds, at § 166.3(k), a definition of ''invasive species'' that is derived from that used in Executive Order 13112 (64 FR 6183, February 3, 1999).

D. Updating Administrative and Communication Processes

A number of minor revisions to 40 CFR part 166 are made with this final rule to correct errors or update administrative aspects of the emergency exemption regulations, particularly in light of the fact that the Food Quality

Protection Act (FQPA), which amended FIFRA and the FFDCA, was enacted since the regulations under part 166 were last revised. Each of these revisions is made for one of the following reasons: (1) To correct typographical or administrative errors or inaccuracies, (2) to bring the regulations into agreement with current requirements put in place by the FQPA, or (3) to reflect improvements to the process that have been identified since 40 CFR part 166 was last revised, and that have been voluntarily practiced by applicants. Each of these revisions are non-substantive or reflect minor changes to the regulatory requirements, but all correct, improve, or update the regulations. The corrections of typographical or administrative errors or inaccuracies are self-explanatory. The revisions for the other reasons are discussed below.

Under FFDCA section 408(l)(6), as amended by FQPA, EPA is required to establish time-limited tolerances, or exemptions from the requirement of a tolerance, for pesticide residues in food or feed resulting from uses under emergency exemptions. The existing regulations predate FQPA and therefore do not reflect this requirement. Four revisions are made to bring 40 CFR part 166 into agreement with current practices as required by the FFDCA. Inasmuch as FFDCA section 408(l)(6) applies to all food-use emergency exemptions, regardless of whether its requirements are reflected in 40 CFR part 166, these changes to 40 CFR part 166 do not substantively change the applicable law. For ease of discussion, below, ''tolerance'' is used to refer to a tolerance or exemption from the requirement of a tolerance.

First, this rule amends § 166.3(e) to revise the definition of ''first food use.'' The existing definition includes an explanation that no permanent tolerance or food additive regulation has been established for such a use. The word ''permanent'' is removed in the revised definition so that any tolerance would be included, and the reference to ''food additive regulation'' is removed because, owing to the FQPA amendments, EPA no longer issues food additive regulations.

Second, under § 166.25--Agency Review, the regulations state that the review enables EPA to make a determination with respect to several items, including the level of residues in or on all food resulting from the proposed use. The final rule revises § 166.25(a)(2) to add the establishment of a time-limited tolerance for such residues, where necessary.

The third revision made necessary by FQPA is to add, under § 166.40, an additional limitation to the authority of a State or federal agency to issue a crisis exemption, namely, that they may issue a crisis exemption for a food use only where a tolerance or exemption is already in effect, or where EPA has provided verbal confirmation that a time-limited tolerance for the proposed use can be established in a timely manner. It is in the best interests of applicants and potential users of the pesticide under the crisis exemption that there is some assurance that an exemption can be established in a timely manner before use of the pesticide begins. This revision at § 166.40(c) also stipulates that all crisis exemptions be conditioned upon EPA confirming that it has no other objection to the use of the pesticide under the crisis provisions.

The fourth change is to remove from § 166.30(b) and § 166.47 the now-superfluous requirement that EPA directly notify the U.S. Food and Drug Administration (FDA), USDA, and State health officials. The original purpose of this requirement was to notify these agencies of levels of pesticides that may occur in food and feed items as a result of an emergency exemption use. Prior to FQPA, EPA did not routinely establish tolerances for food use pesticides applied under an emergency exemption program. This notification provision served to advise other agencies of the exemption and to support field enforcement activities. Now, however, with the FQPA requirement that time-limited tolerances be established in accordance with FFDCA section 408(l)(6), such levels are published in the **Federal Register**, along with detailed background regarding safety of these tolerances, as well as incorporated into 40 CFR part 180. Therefore, EPA considers providing separate notification to the other regulatory organizations (FDA, USDA, and State health officials) on an individual basis redundant to the **Federal Register** notice and incorporation of the regulatory decision in the appropriate section of 40 CFR part 180.

Several revisions are made in this final rule to codify minor improvements to the process that have been identified since the existing regulations became effective. Applicants have been generally following these practices, in most cases for several years, and EPA believes that the public will generally agree that these are improvements to the regulatory requirements. First, under § 166.20, ''Application for a specific, quarantine, or public health exemption,'' paragraph (a)(2)(i)(A) is revised so that an application must include a copy of the EPA-approved label for each specific pesticide product requested, instead of the existing requirement to include the registration number and name of the product. This will facilitate the review of applications.

Next, under § 166.20(a)(3), the final rule adds a new item, and revises several of the others, to specify that the conditions of use requested in an application must include the maximum number of applications, the period of time for which the use is proposed, and the earliest possible harvest dates of the treated crop. Such information is clearly necessary for both risk assessment and tolerance setting, and in those rare occasions in the past where it was not apparent from the application, EPA had to contact the applicant to obtain the information. Expressly requiring this information in § 166.20(a)(3) will expedite review of applications and allow tolerances to be established in an orderly fashion.

Additionally, this rule revises § 166.20(a)(9) to specify that in addition to the registrant or manufacturer being notified of the application submission, the application must also include a statement of support from the registrant or manufacturer, and the expectation that supplies of the requested material will be adequate to meet the needs under the proposed emergency use.

The existing regulations establish a measure of whether adequate progress toward the registration of a repeat requested use is being made. Existing regulations suggest that the lack of a request for registration within 3 years of an emergency exemption first being requested for the use suggests that adequate progress is not being made. This final rule revises § 166.24(a)(6)(i) and § 166.25(b)(2)(ii) to relax this presumption for repeat emergency exemption applications for uses being supported by IR-4. The IR-4 program is a cooperative effort of the state land grant universities, USDA and EPA, to address the chronic shortage of pest control options for minor crops. In many cases, the crop protection industry lacks economic incentive to pursue registrations on minor crops because of low acreage. IR-4 generates and supplies research data needed by EPA in order to register compounds for use on minor crops. Owing to the limited pest control options available for minor use crops, the significance of the need evidenced by IR-4 action, and the limits on IR-4 resources, a somewhat slower rate of progress towards registration is reasonable for emergency exemptions for uses being supported by the IR-4 program. Accordingly, this rule

revises § 166.24(a)(7)(i) and § 166.25(b)(2)(ii) so that the presumption against adequate progress toward registration of repeat emergency exemptions for uses being supported by the IR-4 program would begin after 5 years, 2 years more than allowed for uses supported by other, typically commercial, parties. For uses supported by parties other than IR-4, the 3-year presumption in the existing regulations remains in effect.

This rule revises § 166.30(a)(1) to reflect that EPA will not process incomplete applications, and that action on such submissions will be halted until required additional information is submitted.

The rule clarifies § 166.32(b) to ensure that applicants submit interim use reports for exemptions when requesting a repeated emergency exemption prior to the due date of the final report.

This rule also clarifies the authority of an applicant to issue a crisis exemption by specifying in § 166.40(a) that crisis exemptions are to be used only for unpredictable emergency conditions. This change is strictly for purposes of clarification, as the term ''unpredictable'' already appears in the introductory language of § 166.40, and does not represent any intention by EPA to change the criteria for crisis exemptions. This rule also adds a paragraph (c) under § 166.40, so that the state's authority to exercise the crisis exemption is stayed pending verbal confirmation by EPA that a tolerance can be established in a timely manner and that the Agency has no other objections.

This final rule also revises § 166.43(a)(1) to improve the notification process for crisis exemptions, reflect the standard practice of the state agencies, and provide for advance notice so that EPA may make a determination of whether a tolerance may be supported in accordance with FFDCA section 408 requirements. Section 166.43(a)(1) is revised to require advance notification for crisis exemptions by applicants. This replaces the currently ambiguous requirement that notification must be made at least 36 hours in advance, or no later than 24 hours after the decision of a state to avail itself of a crisis exemption. Notification after the crisis has been declared does not allow EPA to evaluate whether a crisis use can be supported with a section 408 safety finding, or whether other potential risks are unacceptable, before use of the pesticide begins. In any case, EPA will continue to provide the necessary verbal confirmations as quickly as possible, thereby often allowing use of the crisis exemption in less than 36 hours. This final rule does not attempt to change the customary 36–hour timeframe for Agency response to notification. The Agency recognizes that speed is important for all crisis exemptions, and that certain situations may be particularly urgent, including, but not necessarily limited to, national security threats and some requests under USDA's Animal and Plant Health Inspection Service quarantine program. EPA believes that these requests can be reviewed in a timely manner through the appropriate use of OPP resources.

To clarify necessary information for a crisis exemption, this rule revises § 166.43(b)(1) and (b)(4), to specify submission of the registered label(s) for the pesticide product(s) proposed for crisis use, as well as proposed use directions specific to the crisis use, and the timeframe for the anticipated use, including end date.

To bring the reporting requirements for crisis exemption requests into agreement with those for specific, quarantine, and public health exemption requests, this rule revises § 166.49(a)(1) through (a)(4) and deletes § 166.49(a)(5), to clarify information requirements, such as applicant, product used, site treated, and contact information.

VII. Implementation of Final Rule

This final rule becomes effective March 28, 2006. Applicants submitting exemption requests that are received by the Agency after publication of the final rule, but before the effective date, will have the option of using the revised approaches for re-certification or documenting an SEL, or using the outgoing application method and approach. Applications received by EPA after the effective date will be processed under the approach described in today's final rule. However, applicants for exemptions eligible to use a streamlined re-certification request may still submit a full application, even after the effective date. EPA recognizes that persons who have previously obtained emergency exemptions have not yet been advised whether those emergency exemptions are eligible for the re-certification program. The Agency will use submissions received in fiscal year 2005 as the baseline year for evaluating whether emergency exemptions are eligible for the new re-certification program. As soon as possible, and before the effective date of this final rule, EPA intends to share with applicants and post on its web page a list of candidate exemptions that appear to Agency reviewers to be eligible for the re-certification program. Applicants that believe an exemption is eligible for re-certification may submit a re-certification application prior to EPA's release of the eligibility list. However, upon receipt, the Agency must agree that it was eligible for re-certification in order to process the request in that fashion.

Applications that have already been received by EPA as of today's publication date, January 27, 2006, will be processed and reviewed in the context of the existing framework and authorities, unless the applicant submits a replacement request under the provisions of the final rule. The section 18 pilot program is terminated as a result of the promulgation of this final rule.

Mindful that this national program has many stakeholders, EPA plans to provide training on how this final rule affects the application, review, and approval process for emergency exemptions. EPA intends to hold public meetings and develop information materials to help applicants comply with this final rule and help others understand its new provisions. A guidance document concerning the re-certification process and the new, loss-based approach for determining and documenting an SEL is being issued in conjunction with this final rule. EPA plans to issue new guidance on other aspects of the final rule, or revised guidance on other areas, in the future as it is needed and available.

VIII. Related Issues and Emergency Exemption Program Context

A. Pest Resistance Management

The April 24, 2003 **Federal Register** Notice, that initiated the pilot to test the re-certification and revised SEL processes, indicated that EPA was considering addressing pest resistance management (RM) in this rulemaking. However, after carefully considering public comments on that Notice and re-considering the possibility of emergency exemptions for the purpose of resistance management, EPA decided not to include such a change in the proposed rule. Additional comments on this issue were received in response to the proposed rule and considered by the Agency. EPA believes that section 18 is an inappropriate avenue for addressing the worthy goal of managing pest resistance, for several reasons.

Some who commented on the proposed rule also stated that exemptions for the purpose of RM should be allowed. Some commenters said that although the recently enacted Pesticide Registration Improvement Act (PRIA) may help bring more RM tools to

market sooner, it will not be sufficient to address the lack of RM tools, particularly for minor crops. While these commenters recognize the need to prevent abuse of RM exemptions, and the difficulty in developing clear criteria for approval of an exemption for RM, they believe that there is ample middle ground between liberally allowing RM exemptions and allowing no such exemptions. This general comment was made by 19 commenters (nine grower groups, four State lead agencies, two education/research groups, two agriculture/food industry groups, and two pesticide industry/ registrants).

Virtually all commenters that addressed RM agree with EPA that any potentially successful approach for RM exemptions would be proactive, allowing exemptions before resistance has occurred for a particular use in the field. Most also agree that predicting and documenting a case of resistance would be highly variable and complex. The Agency believes that the burden to applicants of preparing a request for an RM exemption that included such documentation would be substantially higher than the burden of preparing other requests. EPA believes such costly and complex burden is contrary to the purpose of this rulemaking. Likewise, the burden to EPA of reviewing and deciding on such a request would be high, diverting resources from other priorities. EPA feels that such a burden is not the best use of Agency resources, and that other means of dealing with RM would be both more efficient and more appropriate. Furthermore, a need for an RM tool to address a future problem arguably does not fit within a conventional interpretation of ''emergency.''

EPA understands the importance of pest resistance management and continues to explore how to best use its regulatory and non-regulatory authorities to support and facilitate effective RM. The Agency believes that RM capabilities will be improved through a multi-faceted approach involving incorporating RM considerations into pesticide labeling (i.e., Pesticide Registration Notice 2001–5), registering more pesticides for minor crops, resistance management education programs, crop management and stewardship programs, further crop grouping for tolerance setting, and outreach efforts with stakeholders. Under PRIA, EPA is making more timely decisions and accelerating the registration of many products expected to be useful for RM. EPA's process for classifying a pesticide product as ''reduced-risk'' considers RM as an important factor. New products that would address significant RM needs would reach the market sooner, thereby providing a strong incentive to registrants to incorporate RM in their registration submissions. Also, the IR-4 process has continued to improve in recent years, identifying priority pesticide needs for minor crops and facilitating quicker registrations, including many useful RM tools.

B. Endangered Species Considerations

The existing emergency exemption regulations include information requirements for applicants and review requirements for EPA concerning threatened and endangered species. In the proposed rule, EPA did not propose to revise these requirements. However, a discussion of plans for improving the process for ensuring that pesticides used under emergency exemptions do not affect threatened and endangered species was included in the preamble. One comment submission on the proposed rule claimed that EPA's section 18 activities routinely violate the Endangered Species Act (ESA). These commenters said that the streamlining proposals would make matters worse. The commenters said that EPA does not list a single example of consultation with the U.S. Fish and Wildlife Service (FWS) or the National Marine Fisheries Service (NMFS) in the course of a section 18 review. They also cite a recent letter from FWS to EPA Region 2 stating that the section 18 process insufficiently addresses EPA's consultation obligations under ESA. This comment was made by 13 environmental/public interest groups in a joint submission, and no other comments were received on this issue.

EPA disagrees that this final rule in any way lessens protections for threatened and endangered species. As noted, the regulatory provisions regarding submission and consideration of information relating to listed species have not been altered by the rule nor have EPA's obligations under the ESA been altered. EPA also disagrees that its plans for improving its processes will make matters worse. Indeed, EPA plans, as discussed in the proposal, explain that the Agency and FWS and NMFS (the Services) have developed mechanisms to provide increased and more expeditious scrutiny to these issues than the Agency has in the past.

The Services, in collaboration with EPA and USDA, have developed a counterpart regulation (50 CFR part 402), that would make the process of consultation about EPA actions involving pesticides - including any necessary consultations for emergency exemptions under section 18 - more efficient, effective, and timely, thereby strengthening the protections for endangered and threatened species. As part of the work supporting the counterpart rule, the Services and EPA reviewed the Agency's approach to the assessment of potential risks to listed species resulting from pesticide use. The Services agreed that EPA's approach to ecological risk assessment ''will produce effects determinations that reliably assess the effects of pesticides on listed species and critical habitat pursuant to section 7 of the ESA and implementing regulations.'' (69 FR at 47735).

EPA looks closely at potential ecological risks of pesticide use in connection with decisions on requests for emergency exemptions. As a result of the Services' acceptance of the Agency's ecological risk assessment process, the Agency intends to provide new guidance and to work closely with applicants for emergency exemptions, to improve the information submitted concerning threatened and endangered species and possible effects on them of the requested use. EPA anticipates that these measures will fall within existing requirements but should increase the availability of essential information needed to make a timely and substantive determination of the potential impact to endangered and threatened species. As EPA develops this new guidance, EPA will look for opportunities to enhance consideration of these impacts in its emergency exemption decision process, including any need to consult with FWS and NMFS.

C. Improving Transparency in Decisions

One of the ongoing challenges for EPA in relation to the emergency exemption program is to ensure that State agencies and interested stakeholders have useful, accurate, and timely information on the status of applications they are interested in as well as other key information that could help clarify pesticide use directions and facilitate observance of necessary safety restrictions that have been placed on the exempted use pattern. Along these lines, EPA is striving to upgrade the quality of the information available to States, pesticides users, extension agents and other key stakeholders under the section 18 program and also to enhance the transparency of this program in general. One activity that the Agency has developed in this area is a searchable section 18 data system that is supported on the Office of Pesticide Programs' web page. This data system, located at *http://cfpub1.epa.gov/oppref/section18/search.cfm* permits basic queries of

submissions and overall status information for emergency exemption applications. EPA also publishes information notices in the **Federal Register** in accordance with 40 CFR 166.30. These are retrospective summaries of the section 18 activity sorted and presented on the basis of the requesting agency.

EPA is also exploring other means of providing useful status and regulatory information for emergency exemptions that involve pest management concerns of national significance. For instance, in connection with the response to the newly identified select agent that causes the plant disease soybean rust, EPA has developed a special web page (*http://www.epa.gov/oppfod01/cb/csb_page/updates/soybean_rust.htm*) that provides the public with a comprehensive listing of all of the products that have claims for control of the soybean rust pathogen. Soybean rust is a serious disease of soybean crops and has been identified as a select agent under the Agricultural Bioterrorism Control Act. Due to the national scope of the soybean industry, there has been significant interest on the part of the public in learning which pesticides have regulatory clearances for this pest. Finally, EPA is exploring another initiative for sharing information on the section 18 program more extensively. Specifically, EPA is investigating ways to post more comprehensively its decision documents under this program. Section 18 decision letters are public documents which the Agency transmits to the requesting state agency. However, certain stakeholders have requested copies of these materials directly. To this end, EPA has plans for posting its decision documents under section 18 on the Agency's web page.

IX. FIFRA Review Requirements

In accordance with FIFRA section 25(a), this final rule was submitted to the FIFRA Science Advisory Panel (SAP), the Secretary of Agriculture (USDA), and appropriate congressional committees. The SAP has waived its review of this final rule, and no comments were received from any of the congressional committees or USDA.

X. Statutory and Executive Order Reviews

A. Executive Order 12866

Under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), the Office of Management and Budget (OMB) has determined that this final rule is not a ''significant regulatory action'' under section 3(f) of the Executive Order.

In addition, EPA has prepared an economic analysis, entitled *Economic Analysis of the Pesticides Emergency Exemption Process Revisions*, of the potential regulatory impacts of this final action on those affected. A copy of this Economic Analysis is available in the public docket for this action and is briefly summarized here.

This action is not expected to cause any significant adverse economic impacts. There are no direct impacts on local governments or small entities, because this action directly affects only Federal and State agencies that petition EPA for section 18 use authorization, neither of which qualify as a small entity under the Regulatory Flexibility Act (RFA). The only substantive impacts expected are burden reductions to applicants for emergency exemptions, and to EPA in the review process, as well as quicker responses to emergency conditions. As detailed in the Economic Analysis prepared for this final rule, based on predicted future applications affected by the regulatory revisions, EPA estimates the annual combined savings for applicants and EPA of around $1.5 million; nearly $1.2 million from re-certification, and over $0.3 million from changing to the loss-based method of determining SEL.

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden that would require additional approval by OMB under the Paperwork Reduction Act (PRA), 44 USC 3501 *et seq*. This rule is expected to reduce the existing burden that is approved under OMB Control No. 2070–0032 (EPA ICR No. 596), which covers the information collection activities contained in the existing regulations at 40 CFR part 166, and under the pilot program announced April 23, 2003 (68 FR 20145).

The annual respondent burden for the collection of information currently approved by OMB is estimated to average 99 hours per application. A copy of the OMB approved Information Collection Request (ICR) has been placed in the public docket for this rulemaking, and the Agency's estimated burden reduction is presented in the Economic Analysis that has been prepared for this rule.

Under the PRA, ''burden'' means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An agency may not conduct or sponsor, and a person is not required to respond to an information collection request unless it displays a currently valid OMB control number. The OMB control number assigned to this final rule (No. 2070–0032) will be listed in 40 CFR part 9.

C. Regulatory Flexibility Act

Pursuant to section 605(b) of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, the Agency hereby certifies that this rulemaking will not have a significant adverse economic impact on a substantial number of small entities. This action will only directly impact State and Federal agencies, neither of which qualify as a small entity under the RFA. This final rule does not have any direct adverse impacts on small businesses, small non-profit organizations, or small local governments. Section 18 only applies to Federal and State governments.

D. Unfunded Mandates Reform Act

Under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4), EPA has determined that this action does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any 1 year. This final rule only applies to Federal and State government agencies, the only entities that can petition the EPA under FIFRA section 18. As such, this action will not impact local or tribal governments or the private sector, and will not significantly or uniquely affect small governments. In addition, as described in Unit X.A., this final rule is expected to result in an overall reduction of existing costs for applicants and EPA of around $1.5 million. Accordingly, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132

Pursuant to Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), EPA has determined that this final rule does not have ''federalism implications,'' because it

will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in the Order. As indicated above, this final rule is expected to reduce burden on Federal and State government agencies that petition EPA under FIFRA section 18, and on EPA in processing the applications. Thus, Executive Order 13132 does not apply to this final rule. In the spirit of the Order, and consistent with EPA policy to promote communications between the Agency and State governments, EPA specifically solicited comment from State officials on the proposed rule.

F. Executive Order 13175

As required by Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000), EPA has determined that this final rule does not have tribal implications because it will not have any effect on tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in the Order. As indicated above, this rule only applies to State and Federal government agencies. FIFRA section 18 does not apply to tribal governments. Thus, Executive Order 13175 does not apply to this final rule.

G. Executive Order 13211

This final rule is not subject to Executive Order 13211, *Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) because it is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit X.A.), nor is it likely to have any significant adverse effect on the supply, distribution, or use of energy.

H. Executive Order 13045

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997) does not apply to this final rule because this action is not designated as an ''economically significant'' regulatory action as defined by Executive Order 12866 (see Unit X.A.), nor does it establish an environmental standard, or otherwise have a disproportionate effect on children.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures) that are developed or adopted by voluntary consensus standards bodies. This final rule does not impose any technical standards that would require EPA to consider any voluntary consensus standards.

J. Executive Order 12898

This final rule does not have an adverse impact on the environmental and health conditions in low-income and minority communities. Therefore, under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), the Agency has not considered environmental justice-related issues.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq*., generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report that includes a copy of the rule to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 166

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2006.

Stephen L. Johnson,

Administrator.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 166—[AMENDED]

■ 1. The authority citation for part 166 continues to read as follows:

Authority: 7 U.S.C. 136–136y.

■ 2. Section 166.2 is amended by revising paragraph (b) to read as follows:

§ 166.2 Types of exemptions.

* * * * *

(b) *Quarantine exemption.* A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species, or is otherwise new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.

* * * * *

■ 3. Section 166.3 is amended by revising paragraphs (a), (d)(3)(i), (e), (h), and adding paragraphs (k) and (l) to read as follows:

§ 166.3 Definitions.

* * * * *

(a) The term *the Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq*.

* * * * *

(d) * * *

(3) * * *

(i) Involves the introduction or dissemination of an invasive species or a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or

* * * * *

(e) The term *first food use* refers to the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no tolerance or exemption from the requirement of a tolerance for residues of the pesticide on any food has been established for the pesticide under section 408(b)(2) and (c)(2) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

(h) The term *significant economic loss* means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:

(1) For pest activity that primarily affects the current crop or other output, one or more of the following:

(i) Yield loss greater than or equal to 20%;

(ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues;

(iii) Economic loss, including revenue losses and cost increases, greater than or equal to 50% of net revenues;

(2) For any pest activity where EPA determines that the criteria in paragraph

(h)(1) would not adequately describe the expected loss, substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.

* * * * *

(k) The term *invasive species* means, with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health.

(l) The term *IR-4 program* means the Interregional Research Project No. 4, a cooperative effort of the state land grant universities, the U.S. Department of Agriculture and EPA, to address the chronic shortage of pest control options for minor crops, which are generally of too small an acreage to provide economic incentive for registration by the crop protection industry.

■ 4. Section 166.20 is amended by revising paragraphs (a)(2)(i)(A), (a)(3), (a)(9), (b)(4), and adding paragraph (b)(5) to read as follows:

§ 166.20 Application for a specific, quarantine, or public health exemption.

(a) * * *

(2) * * *

(i) * * *

(A) A copy of the label(s) if a specific product(s) is/are requested; or the formulation(s) requested if a specific product is not requested; and

* * * * *

(3) *Description of the proposed use.* The application shall identify all of the following:

(i) Sites to be treated, including their locations within the State;

(ii) The method of application;

(iii) The rate of application in terms of active ingredient and product;

(iv) The maximum number of applications;

(v) The total acreage or other appropriate unit proposed to be treated;

(vi) The total amount of pesticide proposed to be used in terms of both active ingredient and product;

(vii) All applicable restrictions and requirements concerning the proposed use which may not appear on labeling;

(viii) The duration of the proposed use; and

(ix) Earliest possible harvest dates.

* * * * *

(9) *Acknowledgment by registrant.* The application shall contain a statement by the registrants of all pesticide products proposed for use acknowledging that a request has been made to the Agency for use of the pesticide under this section. This acknowledgment shall include a statement of support for the requested use, including the expected availability of adequate quantities of the requested product under the use scenario proposed by the applicant(s); and the status of the registration in regard to the requested use including appropriate petition numbers, or of the registrant's intentions regarding the registration of the use.

* * * * *

(b) * * *

(4) A discussion of the anticipated significant economic loss, together with data and other information supporting the discussion, that addresses one or more of the following, as appropriate:

(i) Yield or utilized yield reasonably anticipated in the absence of the emergency and expected losses in quantity due to the emergency;

(ii) The information in paragraph (b)(4)(i) of this section plus prices reasonably anticipated in the absence of the emergency and changes in prices and/or production costs due to the emergency;

(iii) The information in paragraph (b)(4)(ii) of this section plus operating costs reasonably anticipated in the absence of the emergency;

(iv) Any other information explaining the economic consequences of the emergency.

(5) *Re-certification of an emergency condition.* Applicants for specific exemptions may submit re-certification applications relying on previously submitted information to satisfy the information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, where all of the following conditions are met:

(i) An exemption was granted for the same pesticide at the same site to the same applicant the previous year;

(ii) The emergency condition could reasonably be expected to continue for longer than 1 year;

(iii) EPA has not declared the use ineligible for re-certification;

(iv) The use is not subject to public notice pursuant to § 166.24(a)(1) through (a)(6);

(v) The applicant certifies that all of the following are true:

(A) The emergency condition described in the preceding year's application continues to exist;

(B) Except as expressly identified, all information submitted in the preceding year's application is still accurate;

(C) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;

(D) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied;

(E) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.

* * * * *

■ 5. Section 166.24 is amended by revising the introductory text of paragraph (a), redesignating paragraphs (a)(6) and (a)(7) as paragraphs (a)(7) and (a)(8) respectively, adding a new paragraph (a)(6), and revising newly redesignated paragraph (a)(7)(i) to read as follows:

§ 166.24 Public notice of receipt of application and opportunity for public comment.

(a) *Publication requirement.* The Administrator shall issue a notice of receipt in the **Federal Register** for a specific, quarantine, or public health exemption and request public comment when any one of the following criteria is met:

* * * * *

(6) The application proposes use of a pesticide which:

(i) Was voluntarily canceled under section 6(f) of the Act, and

(ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled under section 6(f);

(7) * * *

(i) An emergency exemption has been requested or approved for that use in any 3 previous years, or any 5 previous years if the use is supported by the IR-4 program, and

* * * * *

■ 6. Section 166.25 is amended by revising paragraphs (a)(2), (a)(4), and (b)(2)(ii) to read as follows:

§ 166.25 Agency review.

(a) * * *

(2) The Agency's ability and intention to establish a time-limited tolerance(s) or exemption(s) from the requirement of a tolerance for any pesticide residues resulting from the authorized use, identifying the level of permissible residues in or on food or feed resulting from the proposed use;

* * * * *

(4) The potential risks to human health, endangered or threatened species, beneficial organisms, and the environment from the proposed use.

(b) * * *

(2) * * *

(ii) The progress which has been made toward registration of the proposed use, if a repeated specific or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

■ 7. Section 166.30 is amended by revising paragraph (a)(1), removing paragraph (b), and redesignating paragraph (c) as paragraph (b).

§ 166.30 Notice of Agency decision.

(a) * * *

(1) *Incomplete applications.* The Agency may discontinue the processing of any application that does not address all of the requirements of § 166.20 until such time the additional information is submitted by the applicant.

* * * * *

■ 8. Section 166.32 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.

* * * * *

(b) *Interim and final reports.* A final report summarizing the results of pesticide use under any specific, quarantine, or public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. For quarantine exemptions granted for longer than 1 year, interim reports must be submitted annually. When an application for renewal of the exemption is submitted before the expiration of the exemption or before submission of the final report, an interim report must be submitted with the application. The information in interim and final reports shall include all of the following:

* * * * *

■ 9. Section 166.40 is amended by revising paragraph (a), removing the period at the end of paragraph (b) and adding a semi-colon and the word ''and'' at the end of paragraph (b), and adding paragraph (c) to read as follows:

§ 166.40 Authorization.

* * * * *

(a) An unpredictable emergency condition exists;

* * * * *

(c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the requirement of a tolerance can be established in a timely manner, responsive to the projected timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency has no other objection.

■ 10. Section 166.43 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 166.43 Notice to EPA and registrants or basic manufacturers.

(a) * * *

(1) The State or Federal Agency issuing the crisis exemption must notify the Administrator in advance of utilization of the crisis provisions.

* * * * *

(b) *Contents of notice.* Information required to be provided in notices shall include all of the following:

(1) The name of the product and active ingredient authorized for use, along with the common name and CAS number if available, including a copy of the EPA registered label and use directions appropriate to the authorized use;

(2) The site on which the pesticide is to be used or is being used;

(3) The use pattern;

(4) The date on which the pesticide use is to begin and the date when the use will end;

(5) An estimate of the level of residues of the pesticide expected to result from use under the crisis exemption;

(6) Earliest anticipated harvest date of the treated commodity;

(7) Description of the emergency situation; and

(8) Any other pertinent information available at the time.

§ 166.47 [Removed]

■ 11. Section 166.47 is removed.

■ 12. Section 166.49 is amended by revising paragraph (a) to read as follows:

§ 166.49 Public notice of crisis exemptions.

(a) *Periodic notices.* At least quarterly, the Administrator shall issue a notice in the **Federal Register** announcing issuance of crisis exemptions. The notice shall contain all of the following:

(1) The name of the applicant;

(2) The pesticide authorized for use;

(3) The crop or site to be treated; and

(4) The name, address, and telephone number of a person in the Agency who can provide further information.

* * * * *

[FR Doc. 06–743 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0515; FRL–7757–2]

Sorbitol Octanoate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical sorbitol octanoate on all food commodities when applied/used in accordance with label directions. AVA Chemical Ventures, L. L. C. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sorbitol octanoate.

DATES: This regulation is effective January 27, 2006. Objections and requests for hearings must be received on or before March 28, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0515. All documents in the docket are listed on the www.regulations.gov website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the online instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of September 29, 2004 (69 FR 58166) (FRL–7679–1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2E6389) by AVA Chemical Ventures, L. L. C., 80 Rochester Avenue, Suite 214, Portsmouth, NH, 03801. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of sorbitol octanoate. This notice included a summary of the petition prepared by the petitioner AVA Chemical Ventures, L. L. C. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Sorbitol octanoate is a fatty acid ester made from sorbitol and caprylic acid. Caprylic acid, also known as octanoic acid, is a common fatty acid in plants that is derived from edible oils or fats. It also is produced in small quantities in the human body and is marketed as a human dietary supplement (Ref. 1). Sorbitol, a food grade sweetener with about half the sweetness of sucrose, is a hexahydric alcohol and occurs naturally in fruits such as apples, plums, pears, cherries, dates, peaches, and apricots (Ref. 2). Both sorbitol and octanoic acid are on the Agency's List 4 Inerts of Minimal Concern. Sorbitol is cleared for food use in unlimited quantities as an antidusting agent (40 CFR 180.910). While sorbitol octanoate is the subject of this final rule, the raw materials from which it is made are common in crops eaten regularly by humans and animals.

Furthermore, sorbitol octanoate is chemically and toxicologically similar to certain groups of compounds, namely certain sorbitan esters and certain sucrose octanoate esters that have been FDA-approved since 1983 when used as direct additives in food, as emulsifiers in certain processed foods, and as post-harvest protective coatings for certain fruits (21 CFR 172.836, 172.838, 172.840, 172.842 and 172.859). In 1995, FDA expanded the range of foods in which sucrose octanoate esters (SOEs) are permitted (August 29, 1995, 60 FR 44756). Sorbitol octanoate and SOEs both are fatty acid esters, and both are made by reacting sugars with octanoic acid (i.e., both are non-ionic surfactants manufactured by esterifying C_8 fatty acid with a sugar: sorbitol in the case of sorbitol octanoate and sucrose in the case of SOEs). Sorbitol octanoate and SOEs have similar solubility in water, similar degrees of stability, and require a similar concentration to achieve droplet spread. FDA-approved sorbitan esters are different from sorbitol octanoate only in that sorbitol has one more water molecule than sorbitan. Therefore, the toxicological data associated with SOEs and sorbitan esters can be used to support an exemption from the requirement of a tolerance for sorbitol octanoate.

The applicant collected and summarized the toxicological data associated with the cited FDA food-use approvals for SOEs which included sorbitan esters (as they are chemically similar), and submitted this information in support of an earlier tolerance exemption request (64 FR 49010, September 9, 1999) for SOEs (Ref. 3). In turn, the Agency reviewed and accepted both the summaries and the underlying data in granting the tolerance exemption for SOEs (67 FR 60146, September 25, 2002). Because of the substantial similarity between the two active

ingredients (i.e., sorbitol octanoate and SOEs), the Agency allowed the applicant to ''bridge'' to that previously-submitted data/information to support the tolerance exemption requested for sorbitol octanoate.

Toxicity information/data submitted in support of this tolerance exemption are referenced below. Toxicity data requirements that relate to or aggregate with human dietary risk were addressed by requests for data waivers, which were based on publically available information/data that were previously submitted by the applicant, and reviewed and accepted by the Agency, in support of the tolerance exemption that the Agency granted for the chemically-similar SOEs (Refs. 3, 4, and 6). In addition, the Agency found relevant data from additional public sources, including EPA's National Toxicology Program, which contributed to the Agency's review (Ref. 1). All of this information/data, which, in combination, was equivalent to what would normally be provided by guideline studies, and therefore would likely have been adequate to meet each toxicology requirement had they been submitted as such pursuant to 40 CFR 152.90(b)(4), was deemed adequate to support the waiver requests. Sorbitan esters and sucrose fatty acid esters, which are used as food emulsifiers and as post-harvest fruit protectants, have been found to be of no particular toxic concern in studies used to support their safety to the FDA. Sorbitol octanoate is different from the FDA-approved sorbitan esters in that octanoate is the sole fatty acid component and sorbitan anhydrides are derived from sorbitol by removal of one molecule of water. Therefore, results from studies on sorbitan esters can be used to support lack of toxicity concern with sorbitol octanoate. Sorbitol octanoate also rapidly hydrolyzes to sorbitol and octanoic acid, both of which are common human dietary components of no toxicological concern. Both sorbitol and octanoic acid are included in EPA's List 4 inert ingredients, and thus are of minimal concern. Sucrose octanoate has previously been registered by EPA (EPA Reg. No. 70950–2). The rationales for waiver requests for all required mammalian toxicological studies are acceptable. More detailed analyses of these data and information can be found in specific Agency reviews of the studies and technical literature (Refs. 1, 6, 7, 8 and 9).

1. *Acute oral toxicity waiver (OPPTS 870.1100) MRID 444158–03, and amendment number 1.* Acute oral and dietary toxicity data, previously evaluated in three publications by the Food and Agriculture Organization (FAO) of the United Nations World Health Organization (WHO), were submitted in support of this data waiver request (Refs. 3 and 4). The data contained in these reports demonstrated that sorbitan esters and sucrose octanoate esters had extremely low oral toxicity (in laboratory studies), even at concentrations substantially higher than are found in human food.

In studies with rats and humans, it was demonstrated that sorbitan esters and sucrose octanoate esters were rapidly hydrolyzed and absorbed by the body. Sorbitol octanoate is different from the sorbitan esters approved by FDA for direct addition to food for human consumption in the degree to which water is removed during the manufacturing process and the specific fatty acid that is used to make the esters. Sorbitan is a generic name for anhydrides (cyclic ether tetrahydric alcohols) derived from sorbitol by removal of one molecule of water. Octanoic acid is used to make sorbitol octanoate, but the sorbitan esters are made with mixtures of several longer-chain fatty acids. Sorbitan monopalmitate in the diet of rats; sorbitan monostearate in the diet of rats; sorbitan tristearate administered to rats by gavage; and sorbitan monopalmitate, sorbitan monostearate, and sorbitan tristearate in rats (maximum oral dose) caused no toxic symptoms/mortality. The acute oral LD_{50}s for monoleate and sorbitan monolaurate in rats were 39.8 and 37.5 grams/kilogram (g/kg), respectively. An estimate of acceptable daily intake in man of 0-25 milligrams/kilogram (mg/kg) was set by the Expert Committee on Food Additives. Sorbitol octanoate hydrolyzed rapidly to sorbitol and octanoic acid. The LD_{50}s for sorbitol in mice/rats dosed intravenously or orally ranged from 7,100 to 25,700 mg/kg, respectively. The oral LD_{50}s for octanoic acid were 1,283 mg/kg (one study, male rats) and 10,080 mg/kg (another study, male and female rats), amounts far greater than humans would encounter via the oral exposure route from pesticidal use of sorbitol octanoate. Sorbitol (21 CFR 184.1835) and ocatanoic acid (21 CFR 184.1025) are classified as GRAS by the FDA and are in EPA's List 4 - Inerts of Minimal Concern. Because sorbitol octanoate is chemically similar to SOEs, for which an exemption from tolerance already is established, and octanoic acid is a sorbitol octanoate constituent/degradate of no toxicological concern, the information/data described above support waiver from the data requirements for acute oral toxicity studies (classification: acceptable; Toxicity Category IV for the manufacturing-use product and end-use product).

2. *Acute dermal toxicity waiver (OPPTS 870.1200) MRID 444158–03 and amendment number 1.* A data waiver was granted for this guideline study based on the strength of the supporting information/data submitted by the registrant in connection with the tolerance exemption granted for SOEs, which as noted above are chemically and toxicologically similar to sorbitol octanoate. Also, dermal toxicity data on the sorbitan esters is relevant to sorbitol octanoate. The only difference between the sorbitan esters used in cosmetics and sorbitol octanoate is in the degree to which water is removed during the manufacturing process. Sorbitan fatty acid esters were generally minimal to mild skin irritants in animals and humans. In addition, publically available sources list the rabbit dermal LD_{50} for octanoic acid (a sorbitol octanoate constituent/degradate of no toxicological concern) as > 5,000 mg/kg (Ref. 1), an amount far greater than humans would encounter via the dermal exposure route from pesticidal use of sorbitol octanoate and which places it in the Toxicity Category of no concern (IV) (classification: acceptable; Toxicity Category IV for the manufacturing-use product and end-use product).

3. *Acute inhalation toxicity waiver (OPPTS 870.1300) MRID 444158–03 and Amendment number 1.* A data waiver was granted for this guideline study based on the strength of the supporting information/data submitted by the registrant in connection with the tolerance exemption granted for SOEs, which as noted above are chemically and toxicologically similar to sorbitol octanoate (Refs. 1,3,4 and 6). No adverse effects have been reported by researchers working with sorbitol octanoate, and the compound is not volatile. The sorbitol octanoate constituents sorbitol and octanoic acid are classified as Generally Recognized as Safe (GRAS) by the FDA and are among EPA's List 4 Inerts of Minimal Concern. The chemically-similar sorbitan fatty acid esters are waxy solids or viscous liquids which cannot be inhaled (classification: acceptable; Toxicity Category IV for the manufacturing-use product and end-use product).

4. *Hypersensitivity study waiver (OPPTS 870.2600) MRID 455973–01.* No hypersensitivity incidents have been reported for laboratory workers regularly exposed to sorbitol octanoate for up to 7 years. Neither have there been reports of hypersensitivity from

those working with the chemically-similar sucrose octanoate. A waiver for conduct of a dermal sensitization study for sorbitol octanoate thus can be supported. In addition, the registrant is obliged under the Federal Insecticide,Fungicide, and Rodenticide Act (FIFRA) section 6(a)(2) to notify the Agency in the event of such incidents (classification: acceptable).

5. *Genotoxicity and mutagenicity waiver (OPPTS 870.5300, 870.5195) MRID 444158–03 and amendment number 1.* No guideline studies were submitted, but it was determined that none are required because acceptable information/data were submitted from the open technical literature to scientifically justify a waiver of the data requirements for genotoxicity and mutagenicity. This information/data demonstrate that SOEs and sorbitol octanoate (because of their chemical and toxicological similarities) are not genotoxic and/or mutagenic, nor is the active ingredient structurally and/or chemically similar to known mutagens or known classes of mutagens (Refs. 3, 4 and 6). In addition, a study reported by EPA's National Toxicology Program shows octanoic acid, a sorbitol octanoate constituent/degradate of no toxicological concern, to be negative for genotoxicity/mutagenicity (Ref. 1) (classification: acceptable).

6. *Other data requirements waived.* Immune response and all remaining Tier I biochemical toxicology data requirements that relate to or aggregate with human dietary risk were waived (see OPPTS 880.3800 through 870.4200, MRID 444158–03 and amendment number 1) due to the low toxicity of the chemically similar SOEs, as reported in the open technical literature (Refs. 3, 4, 5, 6 and 7). In addition, octanoic acid, a sorbitol octanoate constituent/degradate of no toxicological concern, is considered a nonteratogenic compound even at the very high dose rate of 18.75 millimoles/kg (Ref. 1).

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* An Acceptable Daily Intake (ADI) of SOEs for humans was estimated by FAO/WHO to be up to 16 mg/kg body weight/day, which is equivalent to 1.28 kg of SOEs per day for a 176 lb person (Refs. 3, 4, and 6). There are no reasonably foreseeable circumstances in which the residue levels of SOEs or the chemically- and toxicologically-similar compound sorbitol octanoate would ever approach this amount. Sorbitol octanoate hydrolyzes into its constituents (sorbitol and octanoic acid) shortly after application and then biodegrades. In studies with rats and humans, it was demonstrated that SOEs were rapidly hydrolyzed and absorbed by the body (Ref. 6). Because sorbitol octanoate is made from sorbitol (present in certain fruits) and caprylic acid (derived from edible oils and fats), there is a great likelihood of exposure in the normal human diet to both SOEs (derived from sugar and edible tallow or edible vegetable oils) and sorbitol octanoate, and their components for most, if not all, individuals, including infants and children. Sorbitol and octanoic acid are common components of the human diet. Thus, sorbitol octanoate may be considered a normal part of the human diet. To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to either SOEs (which for years have been FDA-approved food emulsifiers) or the chemically-similar sorbitol octanoate. Even if there is a significant increase in dietary exposure to sorbitol octanoate due to its use as a pesticide, the acute toxicity information from the National Toxicology Program and the information submitted by the registrant demonstrating extremely low mammalian toxicity (Toxicity Category IV) for SOEs (which, again, are chemically similar to sorbitol octanoate) indicate that any possible risk associated with acute exposures by the oral, dermal and inhalation routes to sorbitol octanoate would be low to non-existent. Further, any increased exposure due to the proposed products would be negligible because the active ingredient sorbitol octanoate will rapidly hydrolyze into its constituent components (sorbitol and octanoic acid), which subsequently will be rapidly metabolized by soil bacteria, thus limiting the general public's contact with treated plants or food products.

2. *Drinking water exposure.* No drinking water exposure is expected. Sorbitol octanoate is not applied directly to water, does not persist in the environment and biodegrades following application/use. Even if sorbitol octanoate residues were to enter drinking water, we do not expect any significant risk since sorbitol octanoate will rapidly hydroloyze into its consituent components (sorbitol and octanoic acid), which then would biodegrade prior to consumption by microorganisms before the general public would contact drinking water containing residues of sorbitol octanoate.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to sorbitol octanoate residues for the general population, including infants and children, is unlikely because the uses are limited to applications to horticultural and agricultural crops. The sorbitol octanoate constituents sorbitol and octanoic acid are normal parts of the human diet. Sorbitol octanoate toxicity from a dietary exposure standpoint has been determined to be extremely low. Therefore, while there exists a great likelihood of prior exposure for most, if not all, individuals to both sorbitol octanoate and SOEs, any increased non-occupational exposure due to the proposed products would be negligible because the active ingredient sorbitol octanoate will rapidly hydrolyze into its constituent components (sorbitol and octanoic acid) which will be rapidly metabolized by soil bacteria, thus limiting the general public's contact with treated plants or food products via the dermal or inhalation routes.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' These considerations include the possible cumulative effects of such residues on infants and children.

Except through ocular exposure, which is only expected in the occupational setting and can be prevented by the use of protective eyewear, neither sorbitol octanoate nor SOEs are toxic, and it is not anticipated that there would be cumulative effects from common mechanisms of toxicity. EPA does not have, at this time, available data to suggest whether sorbitol octanoate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity

finding as to sorbitol octanoate and any other substances and sorbitol octanoate does not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that sorbitol octanoate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S Population, Infants and Children

1. *U.S. population.* The Agency has determined that there is a reasonable certainty that no harm will result from aggregate exposure to residues of sorbitol octanoate to the U.S. population. This includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. The Agency arrived at this conclusion based on the extremely low levels of mammalian dietary toxicity associated with SOEs and, by extension, sorbitol octanoate due to the fact it is nearly identical chemically. Accordingly, it is unlikely that any toxic effects will result from exposure to sorbitol octanoate via the oral, dermal or inhalation pathways when the registered sorbitol octanoate products are used according to proposed label directions (Ref. 6). Based upon the data submitted in connection with SOEs and, by extension, the chemically-similar compound sorbitol octanoate, the amount of sorbitol octanoate applied to food crops is many orders of magnitude lower than the concentrations of sorbitol octanoate needed to cause toxicological effects. Because the worst case scenario exposure is far below the level of any dietary toxicity known for SOEs or sorbitol octanoate, or their components and degradates, EPA has determined that residues will not pose a dietary risk under reasonably foreseeable circumstances and that granting a tolerance exemption is appropriate.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure for infants and children in the case of threshold effects unless the Agency determines, based on reliable data, that a different margin is safe. Margins of exposure are referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness in the data base. Based on all the reliable available information the Agency reviewed on SOEs and, by extension, sorbitol octanoate due to the fact that it is nearly identical chemically, the Agency concludes that sorbitol octanoate is practically non-toxic to mammals from a dietary standpoint, including infants and children. Thus, there are no threshold effects of concern and an additional margin of safety is not necessary to protect infants and children.

VII. Other Considerations

A. Endocrine Disruptors

EPA is required under the FFDCA as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, sorbitol octanoate may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on available data, no endocrine system-related effects have been identified with consumption of sorbitol octanoate. To date, there is no evidence to suggest that sorbitol octanoate affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including low toxicity and low exposure from the pesticidal use of sorbitol octanoate. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for sorbitol octanoate.

C. Codex Maximum Residue Level

There are no CODEX maximum residue levels for sorbitol octanoate.

VIII. Conclusions

Based on the toxicology information/data submitted and other information available to the Agency, there is a reasonable certainty that no harm will result from aggregate exposure to residues of sorbitol octanoate to the U.S. population, including infants and children, under reasonably foreseeable circumstances, when the biochemical pesticide is used in accordance with product label directions and good agricultural practices. This includes all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information. The Agency has arrived at this conclusion based on the information/data submitted (and publically available) demonstrating negligible toxicity of the chemically-similar SOEs and sorbitan esters, and of sorbitol octanoate's constituents (sorbitol and octanoic acid). As a result, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA section 408(c) for residues of sorbitol octanoate in or on all food commodities.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period

for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP-2005–0515 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 28, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0515, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. References

1. USEPA. Brief summary of toxicity information to support registration/ tolerance exemptions for sucrose octanoate. R. S. Jones to D. Greenway; August 8, 2002.

2. Lawson, M.E. 1997. Kirk-Othmer's Encyl Chem Tech. 4th Ed. J.I. Kroschwitz (ed). John Wiley & Sons, NY.

3. Barrington, T., and C. L. Hartman. Sucrose fatty acid esters- Safety data in support of petition proposing a temporary (sic) exemption from the requirement of a tolerance for use in all food commodities (MRID 444158–03); October 2, 1997.

4. Barrington, T. and W. L. Biehn. Sucrose fatty acid esters-safety data in support of petition proposing an exemption from the requirement of a tolerance for use in all food commodities, Amendment number 1 to MRID 444158–03; July 13, 1998.

5. Barrington, A. Waiver request; July 12, 2002.

6. USEPA. Science review in support of registration of sucrose octanoate esters. R.S. Jones to D. Greenway; February 14, 2000.

7. USEPA. Sucrose octanoate esters; A request for concurrence on a decision to waive the requirement for 90–day feeding study (870.3100) and Developmental Toxicity (Teratogenicity (870.3700) studies, based on the Registrant's correspondence of July 12, 2002. D. Greenway to R. S. Jones; August 7, 2002.

8. USEPA. Secondary Review of Data/ information submitted to support Registration of Sorbitol Octanoate R.D. Sjoblad to D. Greenway; December 29, 2004

9. USEPA. Endangered Species Risk Assessment for Sorbitol Octanoate. R. S. Jones to D. Greenway; September 13, 2005.

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a

substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled*Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801*et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2006.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1262 is added to subpart D to read as follows:

§ 180.1262 Sorbitol octanoate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sorbitol octanoate in or on all food commodities when used in accordance with label directions.

[FR Doc. 06–756 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1167–F]

RIN 0938–AN02

Medicare Program; Payment for Respiratory Assist Devices With Bi-Level Capability and a Backup Rate

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule clarifies that respiratory assist devices with bi-level capability and a backup rate must be paid as capped rental items of durable medical equipment (DME) under the Medicare program and not paid as items requiring frequent and substantial servicing (FSS), as defined in section 1834(a)(3) of the Social Security Act. Before 1999, respiratory assist devices with bi-level capability (with or without a backup rate feature) were referred to as ''intermittent assist devices with continuous positive airway pressure devices'' under the Medicare program and in the Healthcare Common Procedure Coding System (HCPCS). This final rule responds to public comments received on a proposed rule published in the **Federal Register** on August 22, 2003, and finalizes the policy in that proposed rule. The rule will ensure that respiratory assist devices are consistently and properly paid under Medicare as capped rental items.

DATES: The provisions of this final rule are effective on April 1, 2006.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786–4499.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative Authority for Payment for Durable Medical Equipment (DME)

Section 1834(a) of the Social Security Act (the Act) sets forth the payment methodology and requirements for payment for the purchase or rental of new and used durable medical equipment (DME) for Medicare beneficiaries under Medicare Part B (Supplementary Medical Insurance). In accordance with section 1834(a) of the Act, payment for DME is made on a fee schedule basis. Each item of DME that is paid under Medicare Part B is classified into one of the following payment categories:

- Inexpensive or other routinely purchased DME.
- Items requiring frequent and substantial servicing (FSS).
- Customized items.
- Oxygen and oxygen equipment.
- Other covered items (other than DME).
- Other items of DME (capped rental (CR) items).

Each category has its own unique payment rules. With the exception of customized items, for each item of DME that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS), a fee schedule amount is calculated. The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item.

Section 1834(a) of the Act provides that Medicare payment for DME is equal

to 80 percent of the lesser of the actual charge for the item or the fee schedule amount for the item. In general, the fee schedule amounts for DME are calculated on a statewide basis using average Medicare payments made in each State from 1986 and 1987 under the former reasonable charge payment methodology. The fee schedule amounts are generally adjusted annually by the change in the Consumer Price Index for All Urban Consumers (CPI–U) for the 12-month period ending June 30 of the preceding year. The fee schedule amounts are limited by a ceiling (upper limit) and floor (lower limit) equal to 100 percent and 85 percent, respectively, of the median of the statewide fee schedule amounts.

Implementing regulations for these statutory provisions are located in 42 CFR part 414, subpart D.

B. Issuance of Proposed Rulemaking

On August 22, 2003, we published in the **Federal Register** (68 FR 50735) a proposed rule to clarify that one of the items of DME, a respiratory assist device with bi-level capability and a backup rate, must be paid as a CR category item under the Medicare program and not paid as an item that requires FSS. As explained below, we issued this proposal to correct coding and payment errors that have been made by some Medicare contractors that misinterpreted our statutorily prescribed policy and allowed respiratory assist devices to be paid under the category for items requiring FSS. In the August 22, 2003 proposed rule, we proposed to include respiratory assist devices billed using HCPCS codes K0533 and K0534 in the DME fee schedule payment category for other items of DME, or capped rental items, as defined in section 1834(a)(7) of the Act. We proposed that rental claims received on or after the effective date of the final regulation would be considered claims for the initial month of rental for capped rental payment purposes.

A summary of the public comments we received on the proposed rule and our responses to those comments appear under section III of this preamble.

II. Payment for Ventilators as DME Under Medicare

A. Payment Methodology

Under section 1834(a) of the Act, payment may be made under Medicare Part B for various types of ventilators as items of DME. Section 1834(a)(3) of the Act, as amended, provides for payment for covered items of DME requiring frequent and substantial servicing such as intermittent positive pressure breathing (IPPB) machines and ventilators, excluding ventilators that are either continuous positive airway pressure (CPAP) devices or intermittent assist devices with CPAP devices (now referred to as respiratory assist devices), to avoid risk to the patient's health. Payment for an item in the FSS category is made on a monthly rental basis, and rental payments continue as long as the item remains medically necessary for the beneficiary. Section 414.222 of our regulations implements the payment provisions for the types of items of DME that are paid under the FSS category. Ventilators that are excluded from the FSS payment category are paid in accordance with section 1834(a)(7) of the Act under the CR category on a rental basis. Section 414.229 of the regulations implements the payment provisions relating to items of DME that are paid under the CR category. Payment for an item in the CR category is made on a monthly rental basis. During the 10th rental month, the supplier is required to offer the beneficiary the option to take over ownership of the item. If the beneficiary chooses this option, Medicare rental payments end after the 13th month of use and the title for the equipment transfers from the supplier to the beneficiary. After the title for the equipment has transferred to the beneficiary, Medicare will make payments for any necessary maintenance and servicing of the patient-owned equipment. If the beneficiary chooses to continue renting the equipment, Medicare rental payments end after the 15th month of use, the supplier continues to own the equipment, and the supplier must continue to supply the item to the beneficiary until the medical necessity ends or Medicare coverage ceases. Beginning 6 months after the 15th month of use, the supplier may bill and receive a semiannual maintenance and servicing payment in an amount not to exceed 10 percent of the purchase price for the equipment as determined in accordance with the statute and § 414.229(c). These maintenance and servicing payments are made regardless of whether maintenance and servicing were actually performed on the equipment during the 6-month period. Total Medicare payments made through the 13th and 15th months of rental equal 105 and 120 percent, respectively, of the statutory purchase price of the equipment.

Suppliers of DME must meet the standards specified in regulations at § 424.57. These standards specify that the supplier ''must maintain and replace at no charge or repair directly, or through a service contract with another company, Medicare-covered items it has rented to beneficiaries.'' This requirement applies to items in both the FSS and CR payment categories. Therefore, for rental items in either category, the supplier is responsible for ensuring that the equipment is in good working order. In the case of an item for which the beneficiary has selected the purchase option, the patient arranges for the servicing and repair of the patient-owned equipment. Medicare payments are made as needed for maintenance and servicing of patient-owned equipment in the CR category.

B. Legislative Change Relating to Types of Ventilators Payable Under the FSS Category

Section 13543 of the Omnibus Budget Reconciliation Act of 1993 (OBRA of 1993) (Pub. L. 103–66) amended section 1834(a)(3)(A) of the Act by establishing two exceptions to the previously existing statutory authority that all ventilators were classified as items requiring FSS for Medicare DME payment purposes. One category of ventilators that are excluded from the FSS payment category is ''intermittent assist devices with continuous positive airway pressure devices,'' now referred to under the Medicare program as respiratory assist devices. The legislative history of the House Report accompanying H.R. 3545 (H.R. Conf. Rep. 103–213, 1993 U.S.C.C.A.N. 1088 at 703 (1987)) states that the FSS ''category is intended to include items which require frequent servicing in order to avoid imminent danger to a beneficiary's health.'' As a result of this legislative amendment, ventilators that are excluded from the Medicare DME FSS payment category fall into the DME payment category of CR items.

C. HCPCS Coding for Intermittent Assist Devices

Effective January 1, 1992, code E0452 with the description of ''intermittent assist device with continuous positive airway pressure device (CPAP)'' was added to the HCPCS. This code was added to describe respiratory assist devices with bi-level air pressure capability, with or without a backup rate, and with the ability to switch to CPAP mode. Bi-level pressure capability means that the device can deliver a lower level of pressure when the patient exhales than when the patient inhales, as opposed to CPAP, which is the continuous delivery of a single level of positive air pressure. A backup rate feature enables the device to automatically switch between the two

levels of pressure at predetermined intervals. The original manufacturer of bi-level respiratory assist devices submitted documentation to us as part of our HCPCS coding recommendation. The manufacturer stated the following in the documentation:

• The word ''intermittent'' refers to devices that are designed to be used by the patient for only part of the day, usually during the hours of sleep.

• The bi-level equipment requires very little maintenance and servicing.

• Other than monthly replacement of the air inlet filter on the front of the system, there is no routine maintenance required.

The manufacturer recommended that a performance verification be performed after each year of operation to ensure that the device is functioning properly.

The nomenclature for code E0452, intermittent assist device with continuous positive airway pressure (CPAP) device, was established to describe positive airway pressure devices with bi-level capability, with or without a backup rate feature. The term ''respiratory assist device'' is used today to refer to this exact same group of items. As indicated earlier, in accordance with OBRA of 1993, intermittent assist devices or respiratory assist devices are excluded from the FSS payment category for DME and are classified under the CR payment category under Medicare.

Effective January 1, 1992, code E0453 with the description of ''therapeutic ventilator; suitable for use 12 hours or less per day'' was added to the HCPCS. This code was added to describe ventilators that are used on a part-time basis by patients who are dependent on stationary ventilators (HCPCS code E0450) for more than 12 hours a day. The premise behind the therapeutic ventilator (code E0453) is similar to portable oxygen equipment. The stationary ventilator (code E0450), like stationary oxygen equipment, would be the primary equipment used by the patient. The portable therapeutic ventilator, like portable oxygen equipment, would be used part of the day by the patient to move about in order to exercise muscles, prevent decubitus ulcers, and achieve other therapeutic goals. Therapeutic ventilators were properly classified in the FSS payment category because they were not one of the types of ventilators (CPAPs or intermittent assist devices) excluded from this category by OBRA of 1993.

D. Billing for Intermittent Assist Devices With a Backup Rate

Beginning as early as May 25, 1992, some Medicare carriers issued erroneous guidance to suppliers that intermittent assist devices with a backup rate should be billed to Medicare using HCPCS code E0453 for therapeutic ventilators (in the FSS payment category) instead of HCPCS code E0452, the code category established for intermittent assist devices (in the CR payment category). We are not certain to what extent carriers and suppliers were using code E0453 as opposed to code E0452 to bill for intermittent assist devices with a backup rate. However, this practice continued to some extent through 1993 and 1994, the years in which the OBRA of 1993 change in payment categories for intermittent assist devices was, respectively, enacted and implemented. Responsibility for processing DME claims was transferred during this time from 34 local carriers to 4 regional carriers known as Durable Medical Equipment Regional Carriers (DMERCs). The DMERCs also issued erroneous guidance to suppliers that intermittent assist devices with a backup rate should be billed using code E0453 instead of code E0452.

The classification of intermittent assist devices or respiratory assist devices with a backup rate under the FSS payment category versus the CR payment category results in a substantial increase in Medicare payments. Total Medicare payments for one device furnished to one patient under the FSS payment category would be as much as $38,530 after 5 years as opposed to $12,201 if the device were classified under the CR payment category.[1] This difference in costs highlights the fact that the correct classification of these devices for Medicare payment purposes is a significant issue in terms of safeguarding the Medicare Trust Fund.

In 1998, for the first time, the DMERCs conducted an in-depth review of the use of intermittent assist devices and issued proposed medical review policies that included a recommendation to revise the nomenclature for the HCPCS codes for these devices. The term ''respiratory assist device, bi-level pressure capability'' was proposed to replace the HCPCS wording of ''intermittent assist device with continuous positive airway pressure (CPAP),'' and separate HCPCS codes were proposed to differentiate between devices with a backup rate and devices without a backup rate.

E. Public Meeting on Payment for Respiratory Assist Devices

During the course of reviewing the DMERC medical review policies on intermittent assist devices (now referred to as respiratory assist devices), we became aware that the carriers and DMERCs had been allowing HCPCS code E0453 to be used primarily for the billing of respiratory assist devices with a back-up rate. As a result, we intended to take action to clarify that these respiratory assist devices belonged in the CR payment category. Because of concerns raised by the industry on the appropriate coding and payment classification for these devices, we announced in the **Federal Register** on June 4, 1999 (64 FR 30042) the convening of a public meeting on June 25, 1999, to obtain input from the supplier community regarding the appropriate DME payment category for respiratory assist devices with a backup rate. We made presentations at the June 25, 1999 public meeting. Representatives of the Food and Drug Administration (FDA) and the National Institutes of Health, respiratory assist device manufacturers, suppliers, clinicians, beneficiaries, and others also made presentations at the meeting.

Testimony was given at the public meeting to support the claim that there is a need for FSS of respiratory assist devices with bi-level capability and a backup rate. Speakers described the need to have a respiratory therapist visit the beneficiary to make sure that the device is being used appropriately by the beneficiary and that the beneficiary is complying with the treatment regimen. The testimony pointed out that after the respiratory therapist performs an assessment of the beneficiary and has consulted with the beneficiary's physician, it may be determined that the pressure setting on the equipment needs to be adjusted. However, no information was presented at the public meeting that would indicate that the equipment itself requires FSS, as required by section 1834(a)(3)(A) of the Act.

The DMERC medical review policies on respiratory assist devices were implemented on October 1, 1999. The following HCPCS codes were added as part of these new policies:

• K0532 Respiratory Assist Device, Bi-Level Pressure Capability, Without Back-Up Rate Feature, Used With Noninvasive Interface, E.G., Nasal Or Facial Mask (Intermittent Assist Device

[1] The CR payment includes 15 monthly rental payments plus 7 payments for maintenance and servicing that can be billed every 6 months beginning 6 months after the 15th rental payment has been made.

With Continuous Positive Airway Pressure Device)

- K0533 Respiratory Assist Device, Bi-Level Pressure Capability, With Back-Up Rate Feature, Used With Noninvasive Interface, E.G., Nasal Or Facial Mask (Intermittent Assist Device With Continuous Positive Airway Pressure Device)
- K0534 Respiratory Assist Device, Bi-Level Pressure Capability, With Back-Up Rate Feature, Used With Invasive Interface, E.G., Tracheostomy Tube (Intermittent Assist Device With Continuous Positive Airway Pressure Device)

These codes were added to better describe those respiratory assist devices, or intermittent assist devices, that had been coded under codes E0452 and E0453 of the HCPCS since 1992. Code K0532 describes those intermittent assist devices that did not have a backup rate and were previously coded under code E0452 (the CR payment category). Codes K0533 and K0534 describe those intermittent assist devices that did have a backup rate, but had been coded under code E0453 (the FSS payment category). It was also decided that no code was needed for therapeutic ventilators, the devices originally intended to fall under code E0453. Although the DMERC medical review policies were implemented on October 1, 1999, we delayed our decision regarding the appropriate DME payment category for devices with the backup rate (codes K0533 and K0534) to allow more time for consideration of comments made at the June 25, 1999 public meeting. Since that time, code numbers K0532, K0533, and K0534 have been replaced in the HCPCS by code numbers E0470, E0471, and E0472, respectively.

After reviewing all of the information presented at the June 25, 1999 public meeting, we concluded that respiratory assist devices with bi-level pressure capability and a backup rate do not require FSS payment. We also concluded that these devices are a type of intermittent assist device with CPAP and, therefore, are excluded from the FSS payment category by section 1834(a)(3)(A) of the Act. We concluded that all payments made for these devices in the past under the FSS payment category were erroneous.

As a result of these conclusions (and in conjunction with the findings of the 1999 OIG report discussed in section II.F of this preamble), we issued the August 22, 2003 proposed rule. As noted above, the only regular servicing necessary for these devices is changing the filter once a year; thus, we believe that it is not necessary for a respiratory therapist to perform the maintenance and servicing of respiratory assist devices. If DME suppliers perform maintenance and servicing of equipment, Medicare pays for this service, regardless of whether the item is in the FSS or the CR category. At the time that we issued the proposed rule, we were confident that this change in payment category would not result in a decrease in the current level of service being provided to Medicare beneficiaries. After consideration of all comments, we have maintained the proposed provisions in this final rule.

F. Office of Inspector General (OIG) Report on Respiratory Assist Devices

As we explained in the August 2003 proposed rule, in 1999, the OIG began an inspection to determine if respiratory assist devices with a backup rate receive frequent and substantial servicing. To assess whether devices received frequent and substantial servicing, the OIG reviewed a stratified random sample of Medicare claims and associated supplier records. The OIG also conducted surveys of beneficiaries, suppliers, manufacturers, and accreditation agencies. In June 2001, the OIG issued its report on respiratory assist devices with a backup rate (OEI–07–99–00440) and recommended that these devices be moved from the FSS payment category to the CR payment category. The OIG made its recommendation based on information gathered from the surveys it conducted. The OIG included the following findings in its report:

- Supplier services consist primarily of routine maintenance and patient monitoring.
- For most beneficiaries, actual supplier visits do not meet the suppliers' own protocols or recommendations for frequency of visits that are developed in the absence of official guidelines regarding the number of visits that are necessary for the device.
- Contrary to supplier protocols, the number of beneficiaries receiving visits declines over time.
- Covering the respiratory assist device with backup rate in the capped rental category would have saved Medicare $11.5 million annually.

Therefore, the OIG, after conducting a detailed inspection, determined that respiratory assist devices with a backup rate do not receive FSS.

III. Public Comments Received on the Proposed Rule and Departmental Responses

We received 15 timely pieces of correspondence containing multiple comments on the August 22, 2003 proposed rule. A summary of these public comments and the Department's responses to those comments follow:

Comment: All of the commenters opposed the proposed change in the Medicare payment category for respiratory assist devices with backup rate capability (HCPCS code K0533 or E0471) from the FSS category to the CR category. Some commenters viewed the proposed change as a reduction in payment rather than a correction of a coding error and requested withdrawal of the proposal because the rationale was unsupportable. The commenters stated that the alleged payment error originally occurred when, they believe, CMS incorrectly relabeled what the industry now refers to as bi-level ventilators or noninvasive positive pressure ventilators (NPPVs) as respiratory assist devices. The commenters indicated that the term ''respiratory assist device'' is ambiguous and its use is inconsistent with current practice, with medical literature, and with the FDA classification of these devices. The commenters pointed out that the FDA classifies NPPVs as ventilators and, as such, their purpose and function require monitoring and servicing to avoid risk to the patient's health, and, thus, classification under the Medicare FSS payment category. The commenters added that Medicare payment policy is the only area where these ventilators are referred to as ''respiratory assist devices.''

Response: Respiratory assist devices with bi-level capability and a backup rate, or NPPVs as they are referred to by suppliers and manufacturers of these devices, are a type of intermittent assist device with CPAP and, therefore, are excluded from the FSS payment category by law. CPAP devices and intermittent assist devices with CPAP are indeed referred to as ventilators in the statute, but are nonetheless excluded from the FSS category under section 1834(a)(3) of the Act. This statutory provision does not allow us to exempt certain types of intermittent assist devices (that is, those with backup rate features). The terms ''intermittent assist device'' and ''respiratory assist device'' describe the same general category of bi-level positive airway pressure device technology that was brought onto the market under the trade name of BiPAP® and that still exists today. While some bi-level devices include a backup rate feature and some do not, the term ''intermittent assist devices'' was developed for HCPCS code E0452 to describe all bi-level devices, and this is the statutory language that was used to exclude

certain ventilators from the FSS payment category. Therefore, the law requires this change.

We note that FDA classification of devices for the purpose of clearing products for market distribution does not determine Medicare coverage and payment rules or our policy development. Likewise, our definitions and classification of devices under the Medicare program have no direct effect on FDA classification of drugs and devices. The process of clearing devices for marketing and determining coverage and payment of devices under Medicare are two different programs with different parameters.

Comment: A number of commenters stated that CMS does not have the legal authority under the plain meaning of the language in the statute to change the payment category for NPPVs or respiratory assist devices with bi-level capability and backup rate. In addition, they believed CMS is taking too narrow a view of the term ''servicing'' in the language of the 1993 statutory amendments to the Act and the legislative history. The commenters stated that the House Report language clarifies that ''frequent and substantial servicing'' refers more broadly to the servicing, monitoring, and adjustments needed to make certain that these ventilators are both functioning properly and being used properly by the patient, not just to the equipment itself. Further, one commenter indicated that the House Report further states that these items are typically quite expensive and often subject to relatively rapid technological changes. Therefore, the commenters pointed out, NPPV ventilators fit the statutory definition for the FSS payment category.

Response: As indicated above, respiratory assist devices with bi-level capability and a backup rate, or NPPVs as they are referred to by suppliers and manufacturers of these devices, are a type of intermittent assist device with CPAP and, therefore, are excluded from the FSS payment category by section 1834(a)(3) of the Act. This statutory provision does not allow us to exempt certain types of intermittent assist devices (that is, those with backup rate features). Therefore, we do not have the discretion to place these items in the FSS category. Even assuming arguendo that the items did require frequent and substantial servicing, which we believe they do not, based on information we have received, including the OIG report on this subject, the law excludes them from this category of items.

Comment: A number of commenters suggested that if CMS wanted to take corrective action against suppliers who are noncompliant with established protocols pertaining to the FSS category, the better approach would be to sanction those providers for inappropriate or fraudulent billing practices, not to reduce payments for the devices. Another commenter who agreed with the OIG report believed that CMS must protect beneficiaries and take action when suppliers of DME fail to properly set up, adjust incrementally, and provide careful followup on the use of the equipment. The commenter believed that corrective action would be proper, but disagreed with the lowering of the payment for the services needed.

Response: Section 1834(a)(20) of the Act, as added by section 302(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), requires us to establish quality standards for suppliers of DME, including respiratory assist devices, to be applied by recognized independent accreditation organizations. We expect to implement this statutory provision in the near future, at which point suppliers of respiratory assist devices will not be allowed to bill Medicare for furnishing these devices if they do not meet the established quality standards. In addition, we will continue to implement and refine our procedures for identifying and sanctioning fraudulent and abusive suppliers under Medicare.

With regard to the lowering of overall Medicare payments for the device that would result from implementation of this rule, it is not the intent of this rule to lower payments in order to take corrective action against suppliers who fail to provide necessary services. This rule would place respiratory assist devices with bi-level capability and a backup rate feature in the CR category in order to comply with section 1834(a)(3) of the Act.

Comment: Several commenters believed that the OIG study investigating the impact of the proposed policy was flawed in design, interpretation of results and conclusions, and they challenged the four major findings cited in the proposed rule (see also section II.D of this final rule). The commenters believed that there were (1) Inconsistent interpretation of the statute and intent of the Congress; (2) disregard for FDA's regulatory classification of NPPVs as ventilators; (3) conclusions regarding the nature and frequency of services to patients using NPPVs that are inconsistent with the underlying data (data that they believed were incorrect and misleading); and (4) recommendations that were in conflict with published medical views of NPPVs that pose health risks and prevent access to devices by beneficiaries.

Response: The overriding issue addressed by the proposed rule and this final rule is the fact that the statute excludes intermittent assist devices or respiratory assist devices from the FSS category. Although the OIG report indicates that suppliers of respiratory assist devices are not performing frequent and substantial servicing of the devices, the report itself cannot affect the legal mandate to exclude these items from the FSS payment category.

Comment: A number of commenters recommended that CMS establish a standard for payment of respiratory care services for patients who require the use of NPPV, as well as guidelines specific to ventilator treatment of patients with amyotrophic lateral sclerosis (ALS). The commenters believed that switching NPPV to the category of capped rental items without simultaneously covering the cost of respiratory care services that the comments state that ventilator dependent patients need would eliminate followup care by clinical personnel for these patients and would endanger the lives of many patients who suffer from respiratory insufficiency due to such diseases as ALS and post-polio syndrome.

Response: As mentioned in an earlier response, section 1834(a)(20) of the Act, as added by section 302(a) of Public Law 108–173, requires us to establish quality standards for suppliers of DME, including respiratory assist devices, to be applied by recognized independent accreditation organizations. We expect to implement this provision in the near future.

With regard to the services of a respiratory therapist and other clinical services related to the care of a patient using a respiratory assist device, these services do not fall within the scope of the DME benefit. The overall clinical care of a beneficiary who receives DME is the responsibility of the beneficiary's treating physician. Therefore, payment under the DME benefit does not include payment for the clinical services of a respiratory therapist or other clinicians that relate to the care of the patient. Further clarification of this issue will be provided through the DME supplier quality standards.

Comment: A number of commenters believed that the proposed change (1) would have a significant adverse impact on beneficiaries' access to ventilator therapy (for people with neuromuscular diseases such as ALS, post-polio syndrome, and multiple sclerosis); (2) would jeopardize the health and safety of disabled beneficiaries with neuromuscular diseases; and (3) would

create additional costs to the Medicare program through an increase in the number of hospitalizations and urgent care visits. Some of the commenters believed that these issues were not adequately addressed in the proposed rule, despite their presentation at the 1999 public meeting.

Commenters acknowledged that there is no provision in the Medicare statute that authorizes coverage and payment for services of a health care professional who provides ''hands-on'' care for a home ventilator patient. However, the commenters pointed out that, in the real world, a professional who is attempting to provide FSS to the equipment invariably also interacts with and may provide care to the patient, a service that would be eliminated if the category payment change is made. One commenter indicated that loss of payment resulting from the change in payment category means loss of service to needy individuals.

Response: The proposed rule and this final rule pertain only to respiratory assist devices, not to ventilator therapy. They do not affect coverage of ventilators, which continue to be covered under the DME benefit. We disagree that the proposed rule and this final rule will significantly affect beneficiary access to respiratory assist devices. The law requires that intermittent assist devices or respiratory assist devices be excluded from the DME FSS payment category under Medicare. We believe the payments for these respiratory assist devices as capped rental items will cover the costs of medically necessary equipment and services.

Comment: One commenter pointed out that a DME company has no obligation to provide any services for a beneficiary who selects the purchase option and that this creates a hazard to some beneficiaries. The commenter added that it will not be cost-effective to provide necessary services to beneficiaries with severe respiratory problems if the device is moved to the CR payment category.

Response: We do not believe that the provisions of the proposed rule and this final rule will create a hazard for beneficiaries. Medicare will make rental payments for respiratory assist devices as DME under the provisions of the statute and will make payments for any necessary maintenance and servicing of patient-owned equipment if the beneficiary selects the purchase option during the 10th rental month of the 15-month rental. In addition, as we have indicated earlier, we are in the process of developing rules that will establish quality standards for suppliers of DME, including respiratory assist devices, to be applied by recognized independent accreditation organizations. These standards will implement provisions of section 1834(a)(20) of the Act as added by section 302(a) of Pub. L. 108–173.

Comment: A number of commenters believed that the proposed rule would have a disproportionate adverse economic effect on small businesses, given the estimated significant reductions in payments that would occur if the proposed rule were finalized, that is, a 78-percent reduction in payments over a 5-year period. The commenters pointed out the limited number of suppliers of NPPV ventilators nationally and that, of the top 30 suppliers cited by CMS in the proposed rule, 83 percent are probably small businesses. The commenters agreed with CMS' assessment in the proposed rule that the top 30 suppliers account for 50 percent of the use of code K0533 and that 5 of these suppliers account for 40 percent of expenditures for the code. One commenter indicated that as a result of the revised DMERC policy, many companies have already stopped offering respiratory assist services. This commenter believed that most companies would not offer to provide NPPV at all under the proposed change in the payment category.

Response: We agree that some small suppliers may be adversely affected by this rule. However, given that the current monthly fee schedule ceiling for this device is $642.17 and is very generous compared to the monthly fee schedule ceiling of $256.60 for the device without the back-up rate feature, we do not believe that many of the current suppliers of respiratory assist devices will be significantly affected. In addition, we do not anticipate problems with beneficiary access to respiratory assist devices as a result of this rule given this generous payment schedule. We refer readers to a further discussion of the impact of this final rule on small suppliers in section VI of this final rule.

Comment: One commenter believed that the rapid rise in Medicare expenditures for use of ventilators was due to the fact that the benefits of NPPV were relatively unknown until 1995, not to the misuse of the device and coding. The commenter indicated that CMS also failed to consider the cost savings from decreased hospitalizations among the groups of patients receiving NPPVs.

Response: The reasons for the growth in expenditures for respiratory assist devices are not relevant to this final rule. The law requires that these devices be excluded from the DME FSS payment category under Medicare.

Comment: One commenter believed that CMS failed to meet the statutory requirement to analyze options for regulatory relief under the Regulatory Flexibility Act when over half of the small businesses would be seriously impacted by the proposed rule (16 of 25). The commenter wanted to know where and how it could seek relief. This commenter also disagreed with CMS' determination that the costs and benefits of the proposed rule would be economically insignificant, that is, less than $100 million.

Response: The statute specifically excludes intermittent assist devices (now referred to as respiratory assist devices) from the DME FSS payment category under Medicare. The only relief from this statutory exclusion would be a legislative change. As we discuss in detail under section VI of this preamble, we estimate that this final rule will result in total expenditures of less than the $100 million threshold per year defined in the Executive Order as economically significant.

IV. Provisions of the Final Rule

After consideration of the public comments received, we are adopting as final the proposed clarification of the payment category policy for respiratory assist devices under Medicare Part B. In this final rule, we are specifying that respiratory assist devices with bi-level capability and a backup rate must be paid as capped rental items under the Medicare program and not paid as items requiring frequent and substantial servicing. In cases where beneficiaries are currently receiving these items, the capped rental period will begin for claims with dates of service on or after April 1, 2006.

V. Collection of Information Requirements

This final rule does not impose information collection and recordkeeping requirements. Consequently, it does not need to be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

A. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Based on the OIG study (OEI–07–99–00440), moving these devices to the CR payment category will result in annual savings of approximately 27 percent. Based on 2004 expenditures of approximately $70 million for this device, below are the estimated 5-year savings for this regulation.

Fiscal year	Savings * (million)
2006	$0
2007	20
2008	20
2009	20
2010	20

* Rounded to the nearer $10 million.

Since we estimate that this final rule will result in reductions in total expenditures of less than $100 million per year, this final rule is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866.

B. Regulatory Flexibility Analysis

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities either because of their nonprofit status or because they have revenues of $6 million to $29 million or less in any 1 year. For purposes of the RFA, approximately 98 percent of suppliers of DME and prosthetic devices are considered small businesses according to the Small Business Administration's (SBA) size standards. Individuals and States are not included in the definition of a small entity. We estimate that 106,000 entities bill Medicare for DME, prosthetics, orthotics, surgical dressings, and other equipment and supplies each year. We believe the impact on the DME industry and small businesses in general will be minimal because most companies supply more than this one type of equipment. We estimate that total Medicare expenditures for DME are approximately $7 billion per year.

As indicated above, we estimate that the overall impact on Medicare revenue associated with moving respiratory assist devices with a backup rate to the CR payment category will be payment reductions that range from approximately $15 million in FY 2005 to $45 million in FY 2009. Therefore, the overall impact on the total industry annual receipts will be small, that is, less than a 1-percent reduction in Medicare revenue. However, while the overall impact is small, some suppliers will be seriously affected as a result of the mix of DME that they furnish to Medicare beneficiaries. Namely, suppliers who specialize in furnishing respiratory assist devices will be seriously affected by this final rule. We have reviewed data from the statistical analysis conducted by DMERCs for the top 30 suppliers of respiratory assist devices with backup rate that were furnished during the period of October through December 2003 and billed using HCPCS code K0533. These suppliers accounted for over 66 percent of the total allowed charges in that quarter for code K0533. For these suppliers, the percentage of total DME allowed charges that were made up by allowed charges for code K0533 was 22.5 percent on average. The top 3 DME suppliers of code K0533 accounted for over 50 percent of the total allowed charges for code K0533 and are not small suppliers based on Medicare allowed charges attributed to these suppliers. For these 3 suppliers, the percentage of total DME allowed charges that were made up by allowed charges for code K0533 ranged from 1.4 percent to 2.9 percent. All but one of the other 30 suppliers would be considered small suppliers based on Medicare allowed charge data alone (we are not certain what revenue sources these entities may have other than Medicare). The percentage of total DME allowed charges that were made up by allowed charges for code K0533 was over 50 percent for only 6 of the top 30 suppliers, and the total allowed charges for code K0533 that were associated with these 6 suppliers accounted for only 4.4 percent of total allowed charges for code K0533 during that quarter. Based on these data, we conclude that most small suppliers of respiratory assist devices with backup rate will not be significantly affected by this final rule.

C. Impact on Rural Areas

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing a rural impact analysis because we have determined that this final rule will not have a significant economic impact on the operation of a substantial number of small rural hospitals.

D. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal government, in the aggregate, or by the private sector of $110 million. This final rule will not have an effect on the governments mentioned, and private sector costs will be less than the $110 million threshold.

E. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have determined that this rule does not significantly affect State or local governments.

F. Executive Order 12866

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

■ For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR part 414 as follows:

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr (b)(1)).

■ 2. In § 414.222 paragraph (a)(1) is revised to read as follows:

§ 414.222 Items requiring frequent and substantial servicing.

(a) *Definition.* * * *

(1) Ventilators (except those that are either continuous airway pressure devices or respiratory assist devices with bi-level pressure capability with or without a backup rate, previously referred to as ''intermittent assist devices with continuous airway pressure devices'').

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 7, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Dated: August 10, 2005.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register January 24, 2006.

[FR Doc. 06–798 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–21; MB Docket No. 05–16; RM–11143, RM–11295]

Radio Broadcasting Services; La Grange, Shallotte, Swansboro, Topsail Beach, and Wrightsville Beach, NC

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In response to a *Notice of Proposed Rule Making,* 70 FR 7220 (February 11, 2005), this *Report and Order* upgrades Channel 279C3, Station WBNU(FM), Shallotte, North Carolina, to Channel 279C2, reallots Channel 279C2 to Wrightsville Beach, North Carolina, and modifies the license of Station WBNU(FM) accordingly. The coordinates for Channel 279C2 at Wrightsville Beach are 33–59–56 NL and 77–54–35 WL, with a site restriction of 25.4 kilometers (15.8 miles) southwest of Wrightsville Beach. The *Report and Order* also upgrades Channel 229A, Station WBNE(FM, Wrightsville Beach, to Channel 229C3, reallots Channel 229C3 to Topsail Beach and modifies the license of Station WBNE(FM) accordingly. The coordinates for Channel 229C3 at Topsail Beach are 34–25–37 NL and 77–38–33 WL, with a site restriction of 7.0 kilometers (4.3 miles) north of Topsail Beach. In addition, the *Report and Order* downgrades Channel 280C3, Station WWTB(FM), Topsail Beach, North Carolina, to Channel 281A, reallots Channel 281A to Swansboro, North Carolina, and modifies the license of Station WWTB(FM) accordingly. The coordinates for Channel 281A at Swansboro are 34–42–41 NL and 77–16–07 WL, with a site restriction of 13.9 kilometers (8.7 miles) west of Swansboro. Lastly, the Report and Order upgrades Channel 284C3, Station WZUP(FM), La Grange, North Carolina, to Channel 284C2. The coordinates for Channel 284C2 at LaGrange are 35–07–39 NL and 77–42–59 WL, with a site restriction of 20.9 kilometers (13.0 miles) south of La Grange.

DATES: Effective February 21, 2006.

FOR FURTHER INFORMATION CONTACT: R. Barthen Gorman, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 05–16, adopted January 4, 2006, and released January 6, 2006. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The document may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC 20554, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.* The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

Part 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for Part 73 reads as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under North Carolina, is amended by removing Channel 284C3 and adding Channel 284C2 at La Grange; by removing Channel 279C3 at Shallotte, by adding Swansboro, Channel 281A, by removing Channel 280C3 and adding Channel 229C3 at Topsail Beach and by removing Channel 229A and by adding Channel 279C2 at Wrightsville Beach.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 06–800 Filed 1–26–06; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–13; MB Docket No. 03–147, RM–10722; MB Docket No. 03–148, RM–10724; MB Docket No. 03–177, RM–10749; MB Docket No. 03–178; RM–10750; and MB Docket No. 03–180, RM 10753]

Radio Broadcasting Services; Anacoco, LA; Barstow, CA; Erie, PA, Greenfield, CA; and Newcastle, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Audio Division, at the request of Linda A. Davidson, allots Channel 267A at Barstow, California, as the community's third local FM transmission service. *See* 68 FR 42664, July 18, 2003. Channel 267A can be allotted to Barstow in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 267A at Barstow are 34–53–55 North Latitude and 117–01–19 West Longitude. Because Barstow is located within 320 kilometers (199 miles) of the U.S.-Mexican border, Mexican concurrence has been requested. However, concurrence of the Mexican government has not yet been received. If a construction permit for Channel 267A at Barstow is granted prior to the Commission's receipt of formal concurrence in the allotment by the Mexican Government, the construction permit will include the following condition: ''Use of this allotment is subject to suspension, modification, or termination without right to hearing, if found by the Commission to be necessary in order to conform to the 1992 USA-Mexico FM Broadcast Agreement or if specifically objected to

by Mexico's Secretaria de Communicaciones Y Transportes.'' *See* Supplementary Information, infra.

DATES: Effective February 21, 2006. The window period for filing applications for these channels will not be opened at this time. Instead, the issue of opening filing windows for these allotments for auction will be addressed by the Commission in a subsequent order.

FOR FURTHER INFORMATION CONTACT: Sharon P. McDonald, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket Nos. 03–147, 03–148, 03–177, 03–178, and 03–180, adopted January 4, 2006, and released January 6, 2006. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Information Center, Portals II, 445 12th Street, SW., Room CY–A257, Washington, DC 20554. The complete text of this decision also may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554, (800) 378–3160, or via the company's Web site, *http://www.bcpiweb.com.* The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* U.S.C. 801(a)(1)(A).

The Audio Division, at the request of Charles Crawford, allots Channel 263A at Newcastle, Texas, as the community first local aural transmission service. *See* 68 FR 42664, July 18, 2003. Channel 263A can be allotted to Newcastle in compliance with the Commission's minimum distance separation requirements with a site restriction of 3.6 kilometers (2.2 miles) northeast to avoid a short-spacing to the licensed site of Station KHYS(FM), Channel 264C1 at Abilene, Texas.

The Audio Division, at the request of Charles Crawford allots Channel 276C3 at Anacoco, Louisiana, as the community's first local aural transmission service. *See* 68 FR 47284, August 8, 2003. Channel 276C3 can be allotted to Anacoco in compliance with the Commission's minimum distance separation requirements with a site restriction of 13 kilometers (8.1 miles) northwest to avoid a short-spacing to the licensed site of Station KAJN–FM, Channel 275C, Crowley, Louisiana.

The Audio Division, at the request of Dana J. Puopolo allots Channel 240A at Erie, Pennsylvania, as the community's fifth local FM transmission service. *See* 68 FR 47284, August 8, 2003. Channel 240A can be allotted to Erie in compliance with the Commission's minimum distance separation requirements with a site restriction of 8.8 kilometers (5.5 miles) northeast to avoid a short-spacing to the licensed site of Station WAKZ(FM), Channel 240A, Sharpsville, Pennsylvania. Canadian concurrence as a specially-negotiated, short-spaced allotment has been received because Erie is located within 320 kilometers (200 miles) of the U.S.-Canadian border, and the allotment is short-spaced to Station CFPL–FM, Channel 240C1, London, Ontario.

The Audio Division, at the request of Daniel R. Freely, allots Channel 254A at Greenfield, California, as the community's third local FM transmission service. *See* 68 FR 47284, August 8, 2003. Channel 254A can be allotted to Greenfield in compliance with the Commission's minimum distance separation requirements at city reference coordinates. The coordinates for Channel 254A at Greenfield are 36–19–23 North Latitude and 121–14–41 West Longitude.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of title 47 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under California, is amended by adding Channel 267A at Barstow; by removing Channel 300B, and adding Channel 254A and Channel 300B1 at Greenfield.

■ 3. Section 73.202(b), the Table of FM Allotments under Louisiana, is amended by adding Anacoco, Channel 276C3.

■ 4. Section 73.202(b), the Table of FM Allotments under Pennsylvania, is amended by adding Channel 240A at Erie.

■ 5. Section 73.202(b), the Table of FM Allotments under Texas, is amended by adding Newcastle, Channel 263A.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 06–794 Filed 1–26–06; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–18; MB Docket No. 03–257; RM–10814]

Radio Broadcasting Services; Hartford and South Haven, MI

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document grants a petition filed by WSJM, Inc., licensee of Station WZBL(FM), Channel 279A, Hartford, Michigan and Station WCSY–FM, Channel 252A, South Haven, Michigan, requesting the reallotment of pre-1989 grandfathered Station WCSY–FM, Channel 252A from South Haven to Hartford, Michigan, relocation of transmitter site and modification of the Station WCSY–FM license accordingly. *See* 69 FR 612, published January 6, 2004. To accommodate the Station WCSY–FM reallotment, this document reallots Station WZBL(FM), Channel 279A from Hartford to South Haven, Michigan and modifies the Station WZBL(FM) license accordingly. Channel 252A can be reallotted to Hartford, Michigan in conformity with the Commission's rules, provided there is a site restriction of 12.5 kilometers (7.8 miles) northwest of Hartford at coordinates 42–14–49 NL and 86–20–06 WL. Channel 279A can be reallotted to South Haven, Michigan using the Station WZBL(FM) authorized site, 42–18–02 NL and 86–15–03 WL. The transmitter site is located 11.2 kilometers (6.9 miles) south of South Haven, Michigan.

DATES: Effective February 21, 2006.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MB Docket No. 03–257, adopted January 4, 2006, and released January 6, 2006. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *http://*

www.BCPIWEB.com. The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under Michigan, is amended by removing Channel 279A and adding Channel 252A at Hartford and by removing Channel 252A and adding Channel 279A at South Haven.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 06–793 Filed 1–26–06; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–9; MB Docket No. 05–98, RM–11187, RM–11252, RM–11253]

Radio Broadcasting Services; Custer, SD, Edgemont, SD, Ellsworth AFB, SD, Gillette, WY, Lusk, WY, Moorcroft, WY, Murdo, SD, Pine Haven, WY, Rock River, WY, Upton, WY, Wall, SD, and Wheatland, WY

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This document grants a petition filed by Mitchell Beranek by allotting Channel 247A at Wheatland, Wyoming, as its fourth FM commercial broadcast service, which requires a site restriction of 2.3 kilometers (1.4 miles) north at reference coordinates 42–04–28 NL and 104–56–51 WL. *See* 70 FR 7219, published February 11, 2005. This document also grants a counterproposal filed jointly by Keyhole Broadcasting, LLC, licensee of Station KXXL(FM), Gillette, Wyoming and Mount Rushmore Broadcasting, Inc., licensee of Station KAWK(FM), Custer, South Dakota by allotting Channel 289C1 at Edgemont, South Dakota, as its first local service; substituting Channel 283C1 for vacant Channel 290C1 and Channel 228A for vacant Channel 283A at Upton, Wyoming; substituting Channel 291A for Channel 228A at Moorcroft, Wyoming and modifying the New Station authorization accordingly; substituting Channel 260C2 for Channel 280C2 at Gillette, Wyoming and modifying the FM Station KXXL license accordingly; substituting Channel 256A for vacant Channel 260A at Pine Haven, Wyoming; substituting Channel 299C for vacant Channel 288C at Wall, South Dakota and substituting Channel 298A for vacant Channel 289A at Wheatland, Wyoming. *See* **SUPPLEMENTARY INFORMATION**.

DATES: Effective February 21, 2006.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Rolanda F. Smith, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Report and Order,* MB Docket No. 05–98, adopted January 4, 2006, and released January 6, 2006. The full text of this Commission decision is available for inspection and copying during normal business hours in the Commission's Reference Center 445 Twelfth Street, SW., Washington, DC 20554. The complete text of this decision may also be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20054, telephone 1–800–378–3160 or *http://www.BCPIWEB.com.* The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Additionally, to accommodate the Edgemont allotment, this document substitutes Channel 285C for Channel 286C1 at Custer, South Dakota, reallots Channel 285C from Custer to Ellsworth AFB, South Dakota, as its first local service and modifies the Station KAWK(FM) license accordingly. To facilitate this reallotment, this document substitutes Channel 283A for Channel 285A at Murdo, South Dakota; and modifies the New Station authorization to reflect this change since the Class C0 upgrade application is still pending.

Channel 289C1 can be allotted to Edgemont in compliance with the Commission's rules provided there is a site restriction of 33.3 kilometers (20.7 miles) northwest of Edgemont at coordinates 43–32–32 NL and 104–04–12 WL. Moreover, Channel 283C1 and Channel 228A can both be allotted to Upton in compliance with the Commission's rules provided there is a site restriction of 8.5 kilometers (5.3 miles) northwest of Upton at coordinates 44–08–58 NL and 104–42–28 WL. Channel 291A can be allotted to Moorcroft at the New Station current authorized site in compliance with the Commission's rules at coordinates 44–16–15 NL and 104–56–00 WL, which requires a site restriction of 1.6 kilometers (1.0 miles) northeast of Moorcroft. Channel 260C2 can be allotted to Gillette at the current licensed site of FM Station KXXL in compliance with the Commission's rules at coordinates 44–13–50 NL and 105–27–45 WL, which requires a site restriction of 7.4 kilometers (4.6 miles) southeast of Gillette. Channel 256A can be allotted to Pine Haven in compliance with the Commission's rules at city reference coordinates 44–21–28 NL and 104–48–36 WL. Channel 299C can be allotted to Wall in compliance with the Commission's rules provided there is a site restriction of 1.9 kilometers (1.2 miles) east of Wall at coordinates 43–59–47 NL and 102–13–07 WL. Channel 298A can be allotted to Wheatland in compliance with the Commission's rules at city reference coordinates 42–03–16 NL and 104–57–08 WL. Additionally, Channel 285C can be allotted to Ellsworth AFB at the current licensed site of Station KAWK(FM) in compliance with the Commission's rules at coordinates 43–44–41 NL and 103–28–52 WL, which requires a site restriction of 55 kilometers (34.2 miles) southwest of Ellsworth AFB. Lastly, Channel 283A can be allotted to Murdo at the New Station current authorized site in compliance with the Commission's rules at coordinates 43–53–24 NL and 100–43–06 WL, which requires a site restriction of 0.5 kilometers (0.3 miles) west of Murdo.

This document also dismisses the counterproposal filed by Kona Coast Radio, LLC, permitee of Station KVAN(FM), Rock River, Wyoming. The counterproposal requested the substitution of Channel 242C1 for Channel 240A at Rock River, Wyoming and modification of the Station KVAN(FM) license accordingly; substitution of Channel 247A for vacant Channel 298A at Wheatland; and substitution of Channel 299C for vacant Channel 242C at Lusk, Wyoming.

List of Subjects in 47 CFR Part 73

Radio, Radio broadcasting.

■ Part 73 of the Code of Federal Regulations is amended as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.202 [Amended]

■ 2. Section 73.202(b), the Table of FM Allotments under South Dakota, is amended by removing Custer, Channel 286C2; adding Edgemont, Channel 289C1; adding Ellsworth AFB, Channel 285C; removing Channel 285A and adding Channel 283A at Murdo; and removing Channel 288C and adding Channel 299C at Wall.

■ 3. Section 73.202(b), the Table of FM Allotments under Wyoming, is amended by removing Channel 282A and adding Channel 260C2 at Gillette; removing Channel 228A and adding Channel 291A at Moorcroft; removing Channel 260A and adding Channel 256A at Pine Haven; removing Channel 283A and Channel 290C1 and adding Channel 228A and Channel 283C1 at Upton; and removing Channel 289A and adding Channel 247A and Channel 298A at Wheatland.

Federal Communications Commission.

John A. Karousos,

Assistant Chief, Audio Division, Media Bureau.

[FR Doc. 06–792 Filed 1–26–06; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 041126332–5039–02; I.D. 011806K]

Fisheries of the Exclusive Economic Zone Off Alaska; Atka Mackerel in the Bering Sea and Aleutian Islands Management Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closures and openings.

SUMMARY: NMFS is prohibiting directed fishing for Atka mackerel with gears other than jig gear in the Eastern Aleutian District and the Bering Sea subarea of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the A Season allowance of the 2006 total allowable catch (TAC) of Atka mackerel in these areas. NMFS is also announcing the opening and closing dates of the first and second directed fisheries within the harvest limit area (HLA) in Statistical Areas 542 and 543. These actions are necessary to prevent exceeding the HLA limits established for the Central (area 542) and Western (area 543) Aleutian Districts pursuant to the 2006 Atka mackerel TAC.

DATES: The effective dates are provided in Table 1 under the **SUPPLEMENTARY INFORMATION** section of this temporary action.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2006 TAC of Atka mackerel specified for other gear in the Eastern Aleutian District and the Bering Sea subarea was established as 3,434 metric tons (mt) by the 2005 and 2006 final harvest specifications for groundfish in the BSAI (70 FR 8979, February 24, 2005). See § 679.20(a)(8)(ii) and (c)(3)(iii).

In accordance with § 679.20(d)(1)(i) and (d)(1)(ii)(B), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that 350 mt of the 2006 Atka mackerel TAC for other gear in the Eastern Aleutian District and the Bering Sea subarea will be necessary as incidental catch to support other anticipated groundfish fisheries. Therefore, the Regional Administrator is establishing a directed fishing allowance of 3,084 mt. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Atka mackerel by vessels using other gear in the Eastern Aleutian District and the Bering Sea subarea.

In accordance with § 679.20(a)(8)(iii)(C), the Regional Administrator is opening the first directed fisheries for Atka mackerel within the HLA in areas 542 and 543, 48 hours after the closure of the Eastern Aleutian District and the Bering Sea subarea Atka mackerel directed fishery. The Regional Administrator has established the opening date for the second HLA directed fisheries as 48 hours after the last closure of the first HLA fisheries in either area 542 or 543. Consequently, NMFS is opening and closing directed fishing for Atka mackerel in the HLA of areas 542 and 543 in accordance with the periods listed under Table 1 of this notice.

TABLE 1. EFFECTIVE DATES AND TIMES

Action	Area	Effective Dates*	
		From	To
Closing Atka Mackerel with gears other than jig gear	Eastern Aleutian District and the Bering Sea subarea	1200 hrs, January 20, 2006	2400 hrs, December 31, 2006
Opening the first directed fishery in the HLA	542	1200 hrs, January 22, 2006	1200 hrs, February 5, 2006
	543	1200 hrs, January 22, 2006	1200 hrs, February 5, 2006

TABLE 1. EFFECTIVE DATES AND TIMES—Continued

Action	Area	Effective Dates*	
		From	To
Opening the second directed fishery in the HLA	542	1200 hrs, February 7, 2006	1200 hrs, February 21, 2006
	543	1200 hrs, February 3, 2006	1200 hrs, February 21, 2006

*Alaska local time

In accordance with § 679.20(a)(8)(iii), vessels using trawl gear for directed fishing for Atka mackerel have previously registered with NMFS to fish in the HLA fisheries in areas 542 and/or 543. NMFS has randomly assigned each vessel to the directed fishery or fisheries for which they have registered. NMFS has notified each vessel owner as to which fishery each vessel has been assigned by NMFS. (71 FR 3247, January 20, 2006).

In accordance with § 679.20(a)(8)(ii)(C)(*1*), the HLA limits of the A season allowance of the 2006 TACs in areas 542 and 543 are 9,851 mt and 5,550 mt, respectively. Based on those limits and the proportion of the number of vessels in each fishery compared to the total number of vessels participating in the HLA directed fishery for area 542 or 543, the harvest limit for each HLA directed fishery in areas 542 and 543 are as follows: for the first directed fishery in area 542, 4,926 mt; for the first directed fishery in area 543, 2,775 mt; for the second directed fishery in area 542, 4,925 mt; and for the second directed fishery in area 543, 2,775 mt. In accordance with § 679.20(a)(8)(iii)(E), the Regional Administrator has established the closure dates of the Atka mackerel directed fisheries in the HLA for areas 542 and 543 based on the amount of the harvest limit and the estimated fishing capacity of the vessels assigned to the respective fisheries. Consequently, NMFS is prohibiting directed fishing for Atka mackerel in the HLA of areas 542 and 543 in accordance with the dates and times listed in Table 1 of this notice.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) and 50 CFR 679.20(b)(3)(iii)(A) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of the Atka mackerel fishery in the Eastern Aleutian District and the Bering Sea subarea and the opening and closing of the fisheries for the HLA limits established for area 542 and area 543 pursuant to the 2006 Atka mackerel TAC. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 12, 2006. The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: January 23, 2006.

Alan D. Risenhoover,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 06–801 Filed 1–24–06; 1:26 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 71, No. 18
Friday, January 27, 2006

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

Organization and Operations of Federal Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice of proposed rulemaking (NPR).

SUMMARY: NCUA is issuing proposed amendments to its rules regarding service to underserved areas. These amendments are being proposed because of NCUA's experience addressing field of membership issues and the uncertainty resulting from recent litigation challenging existing chartering policy. This proposed rule will ensure continued reliable and efficient service to federal credit union members located in underserved areas.

DATES: Comments must be received on or before March 28, 2006.

ADDRESSES: You may submit comments by any of the following methods (Please send comments by one method only):

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- NCUA Web site: *http://www.ncua.gov/news/proposed_regs/proposed_regs.html.* Follow the instructions for submitting comments.
- E-mail: Address to *regcomments@ncua.gov.* Include ''[Your name] Comments on Proposed Rule Part 701.1'' in the e-mail subject line.
- Fax: (703) 518–6319. Use the subject line described above for e-mail.
- Mail: Address to Mary Rupp, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- Hand Delivery/Courier: Same as mail address.

FOR FURTHER INFORMATION CONTACT: Michael J. McKenna, Deputy General Counsel, John K. Ianno, Senior Trial Attorney, or Regina Metz, Staff Attorney, Office of General Counsel, 1775 Duke Street, Alexandria, Virginia 22314 or telephone (703) 518–6540.

SUPPLEMENTARY INFORMATION

A. Background

NCUA's chartering and field of membership policy is set out in NCUA's Chartering and Field of Membership Manual (Chartering Manual), Interpretive Ruling and Policy Statement 03–1. 68 FR 18333, Apr. 15, 2003. The policy is incorporated by reference in NCUA's regulations at 12 CFR 701.1.

In establishing a federal credit union system Congress recognized that a primary purpose was to make credit more available to persons of modest means. This goal has been a long-standing priority of the NCUA Board. From 1994 through 1998, NCUA rules permitted federal credit unions, regardless of charter type, to include low-income communities and associations in their field of membership.

In 1998 Congress passed the Credit Union Membership Access Act (CUMAA) in order to codify the authority of NCUA to charter multiple common-bond credit unions. Pub. L. 105–219, 112 Stat. 914 (1998). As part of that legislation, Congress expressly recognized that multiple common-bond credit unions would be authorized to serve persons or organizations within an area that was underserved. CUMAA also provided a definition of an ''underserved area.'' In response, NCUA changed its field of membership regulations to utilize the term ''underserved area'' and its definition, instead of the previous authority for all charter types to serve low-income communities and associations. Since then, service to underserved areas, as defined in Chapter 3 of the Chartering Manual, has remained a priority of the NCUA Board.

Recently certain Utah banks and the American Bankers Association (collectively the Bankers) have filed suit challenging NCUA's policy related to adding underserved areas. The Bankers' complaint recognizes that CUMAA expressly authorizes the chartering of multiple common-bond credit unions but argues that the legislation permits only that type of charter to serve underserved areas.

One of CUMAA's primary purposes was to codify in statute the legality of multiple common-bond credit unions. NCUA believes that the statutory language also reflects Congress' intent to make clear that this new charter type was authorized to add underserved areas, not as the Bankers argue, to prohibit the other two federal charter types from doing so. This conclusion is supported by the legislative history and the fact that at the time Congress enacted CUMAA it was aware of NCUA's long-standing policy allowing all federal charters to serve communities and groups in need of additional financial services.

NCUA is mindful of the ongoing litigation and recognizes that the statutory language is susceptible to different interpretations. We believe that these issues create a degree of uncertainty about the continued authority of non-multiple common-bond credit unions to serve underserved areas. We are concerned about the financial effect of continuing to approve new requests to serve underserved areas by non-multiple common-bond credit unions that then invest resources in serving these areas. We also believe that it is unfair to provide persons of limited means with needed financial services where the possibility exists that they could suddenly be deprived of those services.

Faced with this uncertainty, on December 29, 2005, the NCUA Board issued a moratorium suspending that portion of its chartering policy allowing non-multiple-common-bond credit unions to add new underserved areas. That moratorium will remain in place until further notice.

Since establishing a moratorium the NCUA has conducted a comprehensive review of its underserved area policy. As a result of this review, the NCUA Board believes it prudent to propose two amendments to its field of membership policy. Both changes will apply only prospectively.

The first change will limit the addition of new underserved areas to only multiple common-bond credit unions.

The second change is to the definition and location of the service facility when adding underserved areas. The Board believes that a physical presence in the underserved areas is likely to assure better service to members in these locations. The definition of a service facility and where it may be located has

been modified. This will assure a physical presence in the area and further encourage a very active role by the credit union in the underserved area. There has been no change to the requirement that the service facility be established within two years.

B. Request for Comments

The NCUA Board welcomes all comments on its existing policy regarding service to underserved areas. In addition we are particularly interested in comments related to the following areas:

(1) NCUA's authority to permit expansions into underserved areas for all three federal charter types;

(2) The impact of limiting expansions into underserved areas to only multiple common-bond credit unions;

(3) Whether, if only multiple common-bond credit unions are permitted to add underserved areas, they should be permitted to retain these areas in the event they change charter type;

(4) The type and extent of existing investment by non-multiple common-bond credit unions in underserved areas including for example; capital investment, loans, share deposits, and other programs targeting low income people; and

(5) The impact to members of underserved areas, and non-multiple common-bond credit unions, of restrictions on the addition of new members in underserved areas they are currently serving.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a regulation may have on a substantial number of small credit unions (primarily those under $10 million in assets). The proposed amendments will not have a significant economic impact on a substantial number of small credit unions and therefore, a regulatory flexibility analysis is not required.

Paperwork Reduction Act

The Office of Management and Budget control numbers assigned to Section 701.1 are 3133–0133 and 3133–0116. NCUA has determined that the proposed amendments will not increase paperwork requirements and a paperwork reduction analysis is not required.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. In adherence to fundamental federalism principles, NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order. The proposed rule would not have substantial direct effects on the states, on the connection between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. NCUA has determined that this proposed rule does not constitute a policy that has federalism implications for purposes of the executive order.

The Treasury and General Government Appropriations Act, 1999—Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule would not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act of 1999, Pub. L. 105–277, 112 Stat. 2681 (1998).

List of Subjects in 12 CFR Part 701

Credit, Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on January 19, 2006.

Mary Rupp,

Secretary of the Board.

For the reasons stated in the preamble, the National Credit Union Administration proposes to amend 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, 1789. Section 701.6 is also authorized by 15 U.S.C. 3717. Section 701.31 is also authorized by 15 U.S.C. 1601, *et seq.*, 42 U.S.C. 1981 and 3601–3610. Section 701.35 is also authorized by 12 U.S.C. 4311–4312.

2. Section 701.1 is revised to read as follows:

§ 701.1 Federal credit union chartering, field of membership modifications, and conversions.

National Credit Union Administration policies concerning chartering, field of membership modifications, and conversions are set forth in Interpretive Ruling and Policy Statement 03–1, Chartering and Field of Membership Manual, as amended by IRPS 06–1, Copies may be obtained by contacting NCUA at the address found in § 792.2(g)(1) of this chapter.

(Approved by the Office of Management and Budget under control number 3133–0015 and 3133–0116.)

Note: The text of the IRPS 03–1, as amended by the IRPS 06–1, does not appear in the Code of Federal Regulations.

3. IRPS 03–1, Chapter 3, Section III.A is revised to read as follows:

A multiple common-bond federal credit union may include in its field of membership, without regard to location, communities satisfying the definition of underserved areas in the Federal Credit Union Act. Adding an underserved area will not change the charter type of the multiple common-bond federal credit union. More than one multiple common-bond federal credit union can serve the same underserved area. The Federal Credit Union Act defines an underserved area as a local community, neighborhood, or rural district that is an ''investment area'' as defined in Section 103(16) of the Community Development Banking and Financial Institutions Act of 1994.

For an underserved area, the well-defined local community, neighborhood, or rural district requirement is met if:

- The area to be served is in a recognized single political jurisdiction, i.e., a city, county, or their political equivalent, or any contiguous portion thereof;
- The area to be served is in multiple contiguous political jurisdictions, i.e., a city, county, or their political equivalent, or any contiguous portion thereof and if the population of the requested well-defined area does not exceed 500,000; or
- The area to be served is a Metropolitan Statistical Area (MSA) or its equivalent, or a portion thereof, where the population of the MSA or its equivalent does not exceed 1,000,000.

If the area to be served does not meet the MSA or multiple political jurisdiction requirements outlined above, the application must include documentation to support that it is a well-defined local community, neighborhood, or rural district.

For an underserved area, an investment area includes any of the following (as reported in the most recently completed decennial census or equivalent government data):

- An area that wholly consists of or is wholly located within an Empowerment Zone or Enterprise Community designated under section 1391 of the Internal Revenue Code (26 U.S.C. 1391);

- An area where the percentage of the population living in poverty is at least 20 percent;
- An area in a Metropolitan Area where the median family income is at or below 80 percent of the Metropolitan Area median family income or the national Metropolitan Area median family income, whichever is greater;
- An area outside of a Metropolitan Area, where the median family income is at or below 80 percent of the statewide non-Metropolitan Area median family income or the national non-Metropolitan Area median family income, whichever is greater;
- An area where the unemployment rate is at least 1.5 times the national average;
- An area meeting the criteria for economic distress that may be established by the Community Development Financial Institutions Fund (CDFI) of the United States Department of the Treasury.

In addition, the local community, neighborhood, or rural district must be underserved, based on data considered by the NCUA Board and the Federal banking agencies.

Once an underserved area has been added to a federal credit union's field of membership, the credit union must establish and maintain an office or service facility in the community within two years. A service facility is defined as a place where shares are accepted for members' accounts, loan applications are accepted and loans are disbursed. This definition includes a credit union owned branch, a shared branch, a mobile branch, or an office operated on a regularly scheduled weekly basis. This definition does not include an ATM or the credit union's Internet Web site.

The federal credit union adding the underserved community must document that the community meets the definition for serving underserved areas in the Federal Credit Union Act. The charter type of a multiple common-bond federal credit union adding such a community will not change. Therefore, the multiple common-bond federal credit union will not be able to receive the benefits afforded to low-income designated credit unions, such as expanded use of nonmember deposits and access to the Community Development Revolving Loan Program for Credit Unions.

A federal credit union that desires to include an underserved community in its field of membership must first develop a business plan specifying how it will serve the community. The business plan, at a minimum, must identify the credit and depository needs of the community and detail how the credit union plans to serve those needs. The credit union will be expected to regularly review the business plan to determine if the community is being adequately served. The regional director may require periodic service status reports from a credit union about the underserved area to ensure that the needs of the community are being met as well as requiring such reports before NCUA allows a multiple common-bond federal credit union to add an additional underserved area.

[FR Doc. E6–908 Filed 1–26–06; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 292

[Docket No. RM06–10–000]

New PURPA Section 210(m) Regulations Applicable to Small Power Production and Cogeneration Facilities

Issued January 19, 2006.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Energy Regulatory Commission (Commission) is proposing to amend its regulations governing small power production and cogeneration in response to section 1253 of the Energy Policy Act of 2005 (EPAct 2005), which added section 210(m) to the Public Utility Regulatory Policies Act of 1978 (PURPA). The Commission seeks public comment on the amended regulations proposed herein.

DATES: Comments are due February 27, 2006. Reply Comments are due March 28, 2006.

ADDRESSES: Comments may be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. Commenters unable to file comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street, NE., Washington, DC 20426. Refer to the Comment Procedures section of the preamble for additional information on how to file comments.

FOR FURTHER INFORMATION CONTACT:

Deborah Wyrick (Technical Information), Office of Energy Markets and Reliability, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–6113.

Marka Shaw (Technical Information), Office of Energy Markets and Reliability, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8641.

Samuel Higginbottom (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8561.

Giuseppe Fina (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, (202) 502–8696.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Joseph T. Kelliher, Chairman; Nora Mead Brownell, and Suedeen G. Kelly.

I. Introduction

1. On August 8, 2005, the Energy Policy Act of 2005 (EPAct 2005) [1] was signed into law. Section 1253(a) of EPAct 2005 adds a new section 210(m) to the Public Utility Regulatory Policies Act of 1978 (PURPA) [2] which provides for termination of an electric utility's obligation to purchase energy and capacity from qualifying cogeneration facilities and qualifying small power production facilities (QFs), if the Federal Energy Regulatory Commission (Commission) finds that certain conditions are met. Section 210(m) [3]: (1) Provides a procedure for an electric utility to file an application for relief from the mandatory purchase obligation on a service territory-wide basis; (2) provides a procedure for any affected entity or person to apply to the Commission for an order reinstating the electric utility's obligation to purchase energy; (3) provides for termination of an electric utility's obligation to sell to QFs energy and capacity if the Commission finds that certain conditions are met; (4) protects existing rights and remedies under any contract or obligation in effect or pending approval involving the purchase of energy or capacity or sale of energy or capacity to a QF; and (5) allows the Commission to issue and enforce

[1] Public Law 109–58, § 1253, 119 Stat. 594 (2005).

[2] 16 U.S.C. 824a–3 (2000).

[3] We note that the Commission has issued a notice of proposed rulemaking regarding added section 210(n) in Docket No. RM05–36–000. That section makes clear that no new qualifying cogeneration facility can enter into a contract with an electric utility unless the cogeneration facility satisfies criteria for new qualifying cogeneration facilities that will be established by the Commission. *Revised Regulations Governing Small Power Production and Cogeneration Facilities*, Notice of Proposed Rulemaking, 70 FR 60,456 (Oct. 18, 2005), FERC Stats. & Regs. ¶ 32,590 (2005).

regulations to ensure that an electric utility recovers all prudently incurred costs associated with the purchase of energy from a QF.

2. The Commission proposes to amend its regulations, specifically 18 CFR 292.303, to implement the requirements in section 210(m).[4] The Commission seeks public comment on the regulations proposed herein.

II. Background

3. When Congress enacted section 210 of PURPA, it required the Commission to prescribe rules as the Commission determined necessary to encourage cogeneration and small power production, including rules requiring electric utilities to offer to purchase electric power from and sell electric power to QFs. Additionally, section 210 of PURPA authorized the Commission to exempt QFs from certain federal and state laws and regulations.

4. Under section 201 of PURPA, cogeneration facilities and small power production facilities which meet certain standards and which are not owned by persons primarily engaged in the generation or sale of electric power [5] can become QFs, and thus become eligible for the rates and exemptions pursuant to section 210 of PURPA and found in our regulations.[6]

5. A cogeneration facility is defined in the Federal Power Act (FPA) [7] as a facility which produces electric energy and steam or forms of useful energy (such as heat) which are used for industrial, commercial, heating, or cooling purposes.[8] Thus, cogeneration facilities simultaneously produce two forms of useful energy, namely electric power and heat. Cogeneration facilities can use significantly less fuel to produce electricity and steam (or other forms of energy) than would be needed to produce the two separately.

6. Small power production facilities as defined in the FPA use biomass, waste, or renewable resources, including wind, solar energy and water, to produce electric power and have a power production capacity which, together with any other facilities located at the same site, are not greater than 80 megawatts.[9] Reliance on these sources of energy can reduce the need to consume fossil fuels to generate electric power.

7. Prior to the enactment of PURPA, a cogenerator or small power producer seeking to establish interconnected operation with a utility faced three major obstacles. First, utilities were not generally willing to purchase this electric output or were not willing to pay an appropriate rate for that output. Second, utilities generally charged discriminatorily high rates for back-up service to cogenerators and small power producers. Third, a cogenerator or small power producer which provided electricity to a utility's grid ran the risk of being considered a public utility and thus being subjected to extensive state and federal regulation.

8. Section 210 of PURPA was designed to remove these obstacles. Each electric utility is required under section 210 to offer to purchase available electric energy from cogeneration and small power production facilities which obtain qualifying status. The rates for such purchases from QFs must be just and reasonable to the ratepayers of the utility, in the public interest, and must not discriminate against cogenerators or small power producers. Rates also must not exceed the incremental cost to the electric utility of alternative electric energy (also known as the electric utility's ''avoided costs''). Section 210 also requires electric utilities to provide electric service to QFs at rates which are just and reasonable, in the public interest, and which do not discriminate against cogenerators and small power producers.

9. Since Congress enacted PURPA, electric utilities have complained that their obligation to purchase from and sell to QFs, as implemented by the Commission in 18 CFR 292.303(a)–(b), was not economically beneficial and that they were purchasing energy they did not need and selling energy they did not want to sell. In 1995, the Commission clarified that in determining the avoided cost rate, the electric utility must take into account all alternative sources including third-party suppliers and does not have to buy power it does not need.[10] In the past decade, with the development of exempt wholesale generators (EWGs) introduced by the Energy Policy Act of 1992,[11] and increasing competition in wholesale electric markets as well as some retail electric markets, Congress has debated whether to repeal PURPA altogether, or to revise it. The result is new section 210(m), which is the subject of this rulemaking, and new section 210(n), which is being addressed in Docket No. RM05–36–000. New section 210(m) requires the Commission to lift the mandatory purchase obligation if it finds, in effect, that there is a sufficiently competitive market for the QF to sell its power. While the provision permits electric utilities to file applications for relief from the mandatory purchase obligation, and requires the Commission to act on such applications within 90 days, the Commission has determined that it can more appropriately address this issue through rulemaking.

III. Proposed Revisions to Regulations

A. Obligation To Purchase

10. Section 292.303(a) of the Commission's regulations, 18 CFR 292.303(a), states that:

Obligation to purchase from qualifying facilities. Each electric utility shall purchase, in accordance with § 292.304, any energy and capacity which is made available from a qualifying facility:

(1) Directly to the electric utility; or

(2) Indirectly to the electric utility in accordance with paragraph (d) of this section.

11. The new PURPA section 210(m)(1) amends the obligation to purchase and states that:

* * * no electric utility shall be required to enter into a new contract or obligation to purchase electric energy from a qualifying cogeneration facility or a qualifying small power production facility under this section if the Commission finds that the qualifying cogeneration facility or qualifying small power production facility has nondiscriminatory access to—

(A)(i) Independently administered, auction-based day ahead and real time wholesale markets for the sale of electric energy; and (ii) wholesale markets for long-term sales of capacity and electric energy; or

(B)(i) Transmission and interconnection services that are provided by a Commission-approved regional transmission entity and administered pursuant to an open access transmission tariff that affords nondiscriminatory treatment to all customers; and (ii) competitive wholesale markets that provide a meaningful

[4] We will generally refer to EPAct 2005's added section 210(m) of PURPA as ''amended section 210.'' All other references to PURPA section 210 are as it currently exists.

[5] The ownership requirement was codified in sections 3(17)(A) and 3(18)(A) of the FPA. Section 1253(b) of EPAct 2005 removed the ownership requirement from sections 3(17)(A) and 3(18)(A) of the FPA, and the Commission has proposed to remove the ownership requirement from its regulations in Docket No. RM05–36–000. *Revised Regulations Governing Small Power Production and Cogeneration Facilities*, Notice of Proposed Rulemaking, 70 FR 60456 (Oct.18, 2005), FERC Stats. & Regs. ¶ 32,590 (2005).

[6] 18 CFR Part 292 (2005).

[7] 16 U.S.C. 824 *et seq.* (2000).

[8] 16 U.S.C. 796(18) (2000).

[9] 16 U.S.C. 796(17)(A)(i)–(ii) (2000).

[10] *Southern California Edison Company and San Diego Gas & Electric Company,* 70 FERC ¶ 61,215 at 61,677–78, *reconsideration denied*, 71 FERC ¶ 61,269 at 62,078 (1995) (finding that the determination of avoided cost must take into account ''all sources'').

[11] Energy Policy Act of 1992, Public Law No. 102–486, 106 Stat. 2776, (1993) (EPAct 1992). EPAct 1992 added a new section 32 to the Public Utility Holding Company Act of 1935 (PUHCA) to permit a category of sellers called EWGs to be exempt from PUHCA.

opportunity to sell capacity, including long-term and short-term sales, and electric energy, including long-term, short-term and real-time sales, to buyers other than the utility to which the qualifying facility is interconnected. In determining whether a meaningful opportunity to sell exists, the Commission shall consider, among other factors, evidence of transactions within the relevant market; or

(C) Wholesale markets for the sale of capacity and electric energy that are, at a minimum, of comparable competitive quality as markets described in subparagraphs (A) and (B).

Section 210(m)(1) thus relieves an electric utility of its obligation to enter into a new contract or obligation to purchase QF power upon a Commission finding that certain market conditions exist.

12. As discussed below, the Commission will: (1) Discuss its interpretation of the criteria for electric utility relief from the purchase obligation; (2) make a preliminary finding that QFs interconnected with utilities that are members of Midwest Independent Transmission System Operator, Inc. (Midwest ISO), PJM Interconnection, L.L.C. (PJM), ISO New England, Inc. (ISO–NE), and New York Independent System Operator (NYISO) have nondiscriminatory access to those markets and that those markets satisfy the section 210(m)(1)(A) criteria for removing the obligation of those electric utilities to enter into new contracts or obligations with QFs; and (3) provide guidance on the definition of ''nondiscriminatory access,'' and ''new contract or obligation.''

1. Meaning of Section 210(m)(1)

13. Section 210(m)(1) states that no utility shall be obligated to enter into a new contract or obligation if the Commission finds that QFs have nondiscriminatory access to one of the three market circumstances described in section 210(m)(1)(A), (B), and (C). In effect, Congress has required the Commission to remove the mandatory purchase obligation if it finds that there is access to a sufficiently competitive market for QFs to sell their power. Based on this statutory language, in this section, we discuss our interpretation of what type of markets are required by section 210(m)(1) of PURPA to relieve a utility of the mandatory purchase obligation.

14. Subparagraph (A) waives the purchase obligation if QFs have nondiscriminatory access to (i) independently administered, auction-based day-ahead and real-time wholesale markets for the sale of electric energy; and (ii) wholesale markets for long-term sales of capacity and electric energy. We conclude that the most reasonable interpretation of subsection (A) is that it was crafted to apply in regions in which Independent System Operators (ISO) and Regional Transmission Organizations (RTO) administer day-ahead and real-time markets, and bilateral long-term contracts for the sale of capacity and electric energy are available to participants/QFs in these markets.

15. We note that the second prong of subparagraph (A) does not require auction-based long-term capacity or energy markets and such an interpretation would not be consistent with the statutory text. First, subparagraph (A)(ii) does not use the terms ''organized,'' ''independently administered,'' or ''competitive'' when describing the long term markets. As evidenced by subparagraph (B)(ii), discussed below, Congress could have imposed such requirements for the long-term wholesale markets, but did not. Therefore, we conclude that no such requirement was intended for the long-term markets of section 210(m)(1)(A)(ii). Second, unlike subparagraph (B)(ii), subparagraph (A)(ii) does not require the Commission to consider ''evidence of transactions within the relevant market'' when determining whether QFs have meaningful opportunities to sell into wholesale markets outside the host utility. This suggests that Congress presumed there was a meaningful opportunity to sell for QFs that have ''nondiscriminatory access to'' ISO and RTO regions with day-ahead and real-time markets.

16. A reasonable interpretation of subparagraph (B) is that it is intended to apply in non-auction-based markets because it waives the mandatory purchase requirement so long as there is (i) a Commission-approved regional transmission entity providing nondiscriminatory transmission and interconnection services; and (ii) ''competitive wholesale markets'' for short- and long-term energy and capacity sales and real-time energy sales. To meet subparagraph (B)(i), QFs must have nondiscriminatory access to transmission and interconnection service that is nondiscriminatory, which we interpret to mean access pursuant to a Commission-approved open access transmission tariff (OATT) and interconnection rules and provided by an entity that is regional in scope. Amended section 210 does not contain any express definition, and, therefore, the Commission has discretion in this context to deem an entity to be ''regional'' based on factors such as sufficient regional scope or configuration or the multiple discrete transmission systems it controls.

17. As to the second prong, subparagraph (B)(ii) requires that QFs have access to ''*competitive* wholesale markets that provide a *meaningful opportunity*'' to sell capacity and energy on both a short- and long-term basis and energy on a real-time basis (emphasis added). ''Meaningful opportunity'' is to be determined by the Commission after considering, among other factors, ''evidence of transactions within the relevant market.'' Taken together, the terms ''competitive,'' ''meaningful opportunity'' and ''evidence of transactions'' suggest that Congress intended that waiver occur in a non-auction-based market only if it could be established that QFs had opportunities to sell their output into competitive wholesale markets.

18. Subparagraph (C) removes the purchase obligation in wholesale markets for the sale of capacity and electric energy that are, ''at a minimum,'' of comparable competitive quality as markets described in subparagraphs (A) and (B). Although this provision is not clear on its face, its reference to subparagraphs (A) and (B) requires the Commission to be mindful, in interpreting the provision, of the two types of requirements that are embodied in those sections, *i.e.,* (1) nondiscriminatory access to transmission and interconnection services, and (2) competitive short-term and long-term markets. These provisions appear to require a case-by-case approach, but we seek comments on whether the Commission can make generic findings on these provisions.

19. The Commission's existing OATT, adopted in Order No. 888,[12] and interconnection rules, adopted in Order Nos. 2003 [13] and 2006,[14] are designed to

[12] Promoting Wholesale Competition Through Open Access Non-discriminatory Transmission Services by Public Utilities and Recovery of Stranded Costs by Public Utilities and Transmitting Utilities, Order No. 888, FERC Stats. & Regs. Regulations Preambles January 1991-June 1996 ¶ 31,036 (1996), Order No. 888–A, FERC Stats. & Regs., Regulations Preambles July 1996–December 2000 ¶ 31,048 (1997), *order on reh'g,* Order No. 888–B, 81 FERC ¶ 61,248 (1997), *order on reh'g,* Order No. 888–C, 82 FERC ¶ 61,046 (1998), *aff'd in relevant part sub nom. Transmission Access Policy Study Group* v. *FERC,* 225 F.3d 667 (D.C. Cir. 2000), *aff'd sub nom. New York* v. *FERC,* 535 U.S. 1 (2002).

[13] Standardization of Generator Interconnection Agreements and Procedures, Order No. 2003, 68 FR 49,845 (Aug. 19, 2003), FERC Stats. & Regs. ¶ 31,146 (2003), *order on reh'g,* Order No. 2003–A, 69 FR 15,932 (Mar. 26, 2004), FERC Stats. & Regs. ¶ 31,160 (2004), *order on reh'g,* Order No. 2003–B, 70 FR 265 (Jan. 4, 2005), FERC Stats. & Regs. ¶ 31,171 (2004), *order on reh'g,* Order No. 2003–C, 70 FR 37,661 (June 30, 2005), FERC Stats. & Regs. ¶ 31,190 (2005).

[14] Standardization of Small Generator Interconnection Agreements and Procedures, Order

eliminate undue discrimination in the provision of transmission and interconnection services. Although the Commission recently issued a Notice Of Inquiry regarding changes to the OATT, the OATT has been considered sufficient to provide non-discriminatory access to transmission until such time as modified. Accordingly, we conclude that QFs have non-discriminatory access to transmission and interconnection if they have access to utilities providing service under an Order No. 888 OATT (or to utilities providing service under a Commission-accepted reciprocity tariff) and interconnection services pursuant to the Commission's interconnection rules. However, we seek comment on whether there are any circumstances in which an OATT should be considered insufficient for purposes of section 210(m). We also seek comment on whether a Commission-accepted reciprocity tariff filed by a nonjurisdictional electric utility has the same effect as an OATT for purposes of meeting section 210(m)(1)(C). We also seek comment on whether nonjurisdictional utilities provide nondiscriminatory interconnection services for purposes of section 210(m)(1)(C) of PURPA.

20. We also recognize that small QFs may be in a unique situation with respect to nondiscriminatory access because they interconnect with the host utility at a distribution level. For instance, Granite State has recently filed a petition in Docket No. EL06–26–000 asking the Commission to initiate a rulemaking implementing section 210(m) of PURPA and as part of that rulemaking, issue rules retaining the mandatory purchase obligation for small QFs (those with a nameplate capacity of 5 MW or less) and creating a rebuttable presumption in favor of retaining the mandatory purchase obligation for small power production facilities with a capacity over 5 MW and up to 20 MW. Granite State suggests that small hydro QFs do not have nondiscriminatory access to RTO/ISO markets. Therefore, we seek comment on whether the purchase obligation should be retained for small renewable projects and, if so, how to define ''small,'' *e.g.*, 5 MWs or below, 20 MWs or below as proposed by Granite State. In addition, we seek comment on whether there may be other categories of QFs that lack nondiscriminatory access to RTO/ISO short-term or long-term wholesale markets for which we should retain the obligation to purchase.

21. With respect to whether the second prong of section 210(m)(B)(ii) is met in non-ISO/non-RTO markets, *i.e.,* whether QFs in non-ISO/non-RTO markets have access to wholesale markets for long-term sales of capacity and electric energy, would that prong be satisfied if there is a demonstration that an organized power procurement process exists in which QFs can participate (albeit not an auction-based process)? We seek comments on ways the prong may be satisfied.

2. Implementation of Section 210(m)(1)

(a) Subparagraph A

22. As we discussed above, the Commission interprets section 210(m)(1)(A) to apply in regions in which ISOs and RTOs administer day-ahead and real-time markets, and bilateral long-term contracts for the sale of capacity and electric energy are available to participants/QFs in these markets. The Commission proposes to find that the Midwest ISO, PJM, ISO–NE, and NYISO satisfy the requirements of section 210(m)(1)(A).[15] These entities are Commission approved ISO or RTOs that provide non-discriminatory open access transmission services and independently administer auction-based wholesale markets for day-ahead and real-time energy sales. Additionally, with respect to (A)(ii), the existence of bilateral long-term contracts for long-term sales of capacity and energy is an indication of a market. It is reasonable to conclude that the second prong of subparagraph (A) is met because bilateral long-term contracts are available to participants in the footprints of the Midwest ISO, PJM, ISO–NE, and NYISO. Therefore, we propose to find that electric utilities that are members of the Midwest ISO, PJM, ISO–NE, and NYISO would meet the requirements for relief from the mandatory purchase obligation. We describe these markets in more detail below.

(1) Midwest ISO

23. On December 20, 2001, the Commission found that the Midwest ISO satisfied the requirements, including independence from market participants, of Order No. 2000, and thus granted the Midwest ISO RTO status.[16] Thus, we believe that the Midwest ISO ''independently administers'' auction-based real-time markets. With respect to subparagraph (1)(A)(i), the Commission approved the Midwest ISO's proposed Transmission and Energy Markets Tariff (TEMT), which allowed the Midwest ISO to initiate Day 2 operations in its 15-state region.[17] The Midwest ISO's Day 2 operations include, among other things, day-ahead and real-time energy markets and a Financial Transmission Rights (FTR) market for transmission capacity. The Midwest ISO began Day 2 operations on April 1, 2005. Since market participants have access to the Midwest ISO's day-ahead and real-time energy markets to sell their electric energy, a QF that has ''non-discriminatory access'' would have the same opportunity. Also, bilateral contracts exist in the Midwest ISO for the long-term sales of capacity and energy. Accordingly, we would expect that such long-term sales would be available to all participants in the Midwest ISO's footprint. Based on the foregoing, we propose to find that the Midwest ISO meets the conditions of subparagraph (A).

(2) PJM

24. PJM received Commission approval as an independent regional transmission organization on July 12, 2001.[18] Since independence from market participants is one of four characteristics that PJM had shown for Commission approval to operate as an RTO, PJM satisfies the ''independently administered'' condition. Second, since 1997, PJM has operated auction-based, day-ahead and real-time wholesale energy markets pursuant to its OATT and Operating Agreement.[19] Because PJM's market participants have access to auction-based day ahead and real time wholesale energy markets, a QF would have the same opportunity as other generators to sell energy in that market. Also, there are bilateral contracts in PJM for the long-term sales of capacity and

No. 2006, 70 FR 34,100 (Jun. 13, 2005), FERC Stats. & Regs. ¶ 31,180 at 31,406–31,551 (2005), *order on reh'g,* Order No. 2006–A, 70 FR 71,760 (Nov. 30, 2005), FERC Stats. & Regs. ¶ 31,196 (2005).

[15] While Southwest Power Pool, Inc. (SPP) and the California Independent System Operator Corporation (Cal ISO), respectively are a Commission-approved RTO and ISO, they do not satisfy the requirements of section 210(m)(1)(A) because neither has day-ahead markets. However, any utility within SPP and Cal ISO may file an application with the Commission to seek relief from the mandatory purchase obligation under sections 210(m)(1)(B) or (C), on a case-by-case basis.

[16] *See Midwest Independent Transmission System Operator, Inc.,* 97 FERC ¶ 61,326 (2001) *order on reh'g,* 103 FERC ¶ 61,169 (2003).

[17] *See Midwest Independent Transmission System Operator, Inc.,* 108 FERC ¶ 61,163 (Midwest ISO, FERC Electric Tariff, Third Revised Volume No. 1, Module C), *order on reh'g,* 109 FERC ¶ 61,157 (2004), *order on reh'g,* 111 FERC ¶ 61,043 (2005).

[18] *PJM Interconnection, L.L.C.,* 96 FERC ¶ 61,061 (2001). On December 20, 2002, in *PJM Interconnection, L.L.C.,* 101 FERC ¶ 61,345 (2002), PJM was granted full, rather than provisional, RTO status. Independence was one of the matters considered in the 2002 Order.

[19] PJM Interconnection, L.L.C., FERC Electric Tariff, Sixth Revised Volume No. 1.

energy. Accordingly, we would expect that such long-term sales would be available to all participants in PJM's footprint. Therefore, we propose to find that PJM meets the conditions of subparagraph (A).

(3) ISO–NE

25. ISO–NE received Commission approval as an independent regional transmission operator on March 24, 2004, by having satisfied the Commission's criterion of independence from market participants.[20] Due to ISO–NE's status as an RTO, we believe that the ISO–NE satisfies the ''independently administered'' condition of subparagraph (A)(i). With respect to the second condition of subparagraph (A)(i), ISO–NE, pursuant to Market Rule 1 of its OATT, commenced operation of its auction-based energy markets on March 1, 2003. Since ISO–NE's market participants have access to auction-based day ahead and real time wholesale energy markets, a QF would have the same opportunity. Also, there are bilateral contracts in ISO–NE for the long-term sales of capacity and energy. Accordingly, we would expect that such long-term sales would be available to all participants in ISO–NE's footprint. Therefore we propose to find that ISO–NE meets the conditions of subparagraph (A).

(4) NYISO

26. The NYISO received Commission authorization to operate as an independent transmission operator on June 30, 1998 after showing that it is independent of market participants.[21] On November 18, 1999, the NYISO commenced operation of its auction-based energy markets. Under the ISO Market Administration and Control Area Services Tariff, NYISO's market participants have access to auction-based day ahead and real time wholesale energy markets,[22] and a QF would have the same opportunity as other generators within NYISO to sell energy into NYISO's auction-based day ahead and real time wholesale energy markets. Also, there are bilateral contracts in NYISO for the long-term sales of capacity and energy. Accordingly, we would expect that such long-term sales would be available to all participants in NYISO's footprint. Therefore we propose to find that NYISO meets the conditions of subparagraph (A).

(5) Conclusion

27. The Commission thus proposes to find in this rulemaking proceeding that QFs interconnected with electric utilities that are members of Midwest ISO, PJM, ISO–NE, and NYISO have nondiscriminatory access to those markets and those markets meet the section 210(m)(1)(A) criteria for removing the obligation of those electric utilities to enter into new contracts or obligations with the QFs. We seek comments, including specific evidence, which either support or refute this preliminary finding Finally, as noted previously, we seek comment on whether the obligation to purchase should be retained in these markets for ''small'' QFs.

28. Under our proposed regulations, to claim relief from the purchase obligation, electric utilities that are members of Midwest ISO, PJM, ISO–NE, and NYISO will need to make compliance filings pursuant to section 210(m)(3). This compliance filing is discussed in more detail in our discussion of section 210(m)(3).

(b) Subparagraphs B and C

29. The Commission proposes to determine on a case-by-case basis [23] whether a utility has met the requirements of sections 210(m)(1)(B) and 210(m)(1)(C) for relief from its purchase obligation. An electric utility filing an application claiming to meet the requirements of section 210(m)(1)(B) or section 210(m)(1)(C) of PURPA must demonstrate the ''factual basis upon which relief is requested.'' Applicants should provide, among other evidence, actual sales data for (1) long-term and short-term capacity and (2) long-term, short-term, and real-time electric energy as well as evidence that the utility operates in a competitive wholesale market. Accordingly, to be relieved of their mandatory purchase obligations, electric utilities that are not members of Midwest ISO, PJM, ISO–NE, and NYISO would be required to file such applications with the Commission pursuant to section 210(m)(3) of PURPA.

30. We propose that other markets, *i.e.*, both non-auction-based markets and non-RTO markets, as well as new auction-based markets, and utility-specific markets would be addressed on a case-by-case basis, pursuant to section 210(m)(3) discussed below. In addition, subsequent changes to market conditions in all markets would be handled on a case-by-case basis, pursuant to section 210(m)(4) discussed below.

3. Other Issues

31. Section 210(m)(1) states that no electric utility shall be obligated to purchase from a QF if the Commission finds that the QF has *nondiscriminatory access* to the market conditions identified in each subparagraph. We propose that there be a rebuttable presumption that a utility provides *nondiscriminatory access* if it has an open access transmission tariff in compliance with our *pro forma* OATT (or a Commission-approved reciprocity tariff).[24] We also propose that QFs or any other affected party should be allowed to rebut that presumption, for example, by providing specific and credible evidence that the QF does not have non-discriminatory access to wholesale markets. However, the presumption cannot be rebutted by an argument that the utility has not properly implemented or administered its OATT. Improper implementation of an OATT is more properly the subject of a complaint and the Commission will take appropriate steps in response to a complaint to ensure that the OATT is properly implemented.

32. Section 210(m)(1) also states that no electric utility ''shall be required to enter into a new contract or obligation'' to purchase electric energy from a QF if the Commission makes the required finding. The Commission proposes to find that when a contract terminates by its own accord, an electric utility is not compelled to enter into a new, successor contract with the QF if the Commission has found that the QF has nondiscriminatory access to markets that satisfy the criteria of section 210(m)(1). Some have alleged that the grant of QF status means that electric utilities have an ''obligation'' to purchase from that QF in perpetuity. We disagree. That a facility has QF status does not mean that an electric utility has an ''obligation'' to purchase from the QF in perpetuity, or, conversely, that the QF has the right to demand that the utility purchase at avoided-cost rates in perpetuity. The Commission proposes to find that if a contract is entered into after August 8, 2005, the date of enactment, but before the

[20] *ISO New England, Inc.,* 106 FERC 61,280 (2004).

[21] *Central Hudson Gas & Electric Co.,* 83 FERC ¶ 61,352 (1998), *order on reh'g,* 87 FERC ¶ 61,135 (1999).

[22] New York Independent System Operator, Inc., FERC Electric Tariff Original Volume No. 2.

[23] We will allow joint applications to be filed by a number of utilities in a region if the applications for relief from the purchase obligation present common issues of law and fact. We would expect common issues of law and fact to exist where one or more utilities operate within the same market.

[24] In Docket No. RM05–25–000, the Commission is currently reviewing the adequacy and sufficiency of the pro forma OATT to ensure that it prevents undue discrimination in the provision of transmission service.

Commission has determined that an electric utility is entitled to relief from the obligation to purchase from a QF, the contract already entered into will be treated as though it was in effect on August 8, 2005 for purposes of section 210(m)(1).

B. Purchase and Sale Obligations for New Cogeneration Facilities

33. Section 210(m)(2)(A) of PURPA reads:

REVISED PURCHASE AND SALE OBLIGATIONS FOR NEW FACILITIES—(A) After the date of enactment of this subsection, no electric utility shall be required pursuant to this section to enter into a new contract or obligation to purchase from or sell electric energy to a facility that is not an existing qualifying cogeneration facility unless the facility meets the criteria for qualifying cogeneration facilities established by the Commission pursuant to the rulemaking required by subsection (n).

34. This provision reinforces the requirement that new qualifying cogeneration facilities must satisfy the section 210(n) criteria for new qualifying cogeneration facilities, which the Commission is implementing in pending Docket No. RM05–36–000. The Commission proposes to make this clarification in section 292.309(d) of its regulations.

35. Section 210(m)(2)(B) defines the term ''existing qualifying cogeneration facility'' to mean a facility that: (i) Was a qualifying cogeneration facility on the date of enactment of subsection (m), or (ii) had filed with the Commission a notice of self-certification, self-recertification or an application for Commission certification under 18 CFR 292.207 prior to the date on which the Commission issues the final rule required by subsection 210(n). The Commission proposes to adopt this definition in new section 292.309(b)(1) of its regulations.

C. Application for Relief

36. Section 210(m)(3) of PURPA states:

COMMISSION REVIEW—Any electric utility may file an application with the Commission for relief from the mandatory purchase obligation pursuant to this subsection on a service territory-wide basis. Such application shall set forth the factual basis upon which relief is requested and describe why the conditions set forth in subparagraphs (A), (B) or (C) of paragraph (1) of this subsection have been met. After notice, including sufficient notice to potentially affected qualifying cogeneration facilities and qualifying small power production facilities, and an opportunity for comment, the Commission shall make a final determination within 90 days of such application regarding whether the conditions set forth in subparagraphs (A), (B) or (C) of paragraph (1) have been met.

37. The Commission proposes to include in new section 292.310 the language of section 210(m)(3) of PURPA. Since the enactment of EPAct 2005, two applications for relief from the mandatory purchase obligation have been filed with the Commission.[25] In *Alliant*, the Commission explained that, in order to meet the express statutory requirement of ''notice,'' including ''sufficient notice to potentially affected qualifying cogeneration facilities and qualifying small power production facilities,'' contained in section 210(m)(3) of PURPA, it would require that an applicant identify all potentially affected QFs in any application for relief filed pursuant to section 210(m)(3).[26] The Commission then described which facilities constitute ''all potentially affected QFs.'' [27]

38. Consistent with *Alliant* and *Montana-Dakota*, before the Commission will consider an application filed pursuant to section 210(m)(3) of PURPA, an applicant must first identify in the application all potentially affected QFs (with their names and current addresses)—including: (1) Those QFs that have existing power purchase contracts with the applicant; (2) other QFs that sell their output to the applicant or that have pending requests for the applicant to purchase their output; (3) any developer of generating facilities with whom the applicant has agreed to enter into power purchase contracts or is discussing power purchase contacts; (4) the developers of facilities that have pending state avoided cost proceedings; and (5) any other QFs that the applicant reasonably believes to be affected by its petition. This will ensure that the statutory obligation is met to provide notice and an opportunity to comment to all potentially affected QFs. The Commission proposes to incorporate this interpretation of ''sufficient notice'' and ''all potentially affected QFs'' in new section 292.310(b) and (c).

39. We point out that under section 210(m)(3) the Commission must make a *finding* regarding an application for relief of the purchase obligation and that the finding must be made within 90 days of the date of such application. The Commission, accordingly, will expect an application for relief to be fully supported by documentation upon which the required finding can be made, *i.e.*, a case in chief. For those not in one of the Commission-certified markets, such documentation should include, but is not limited to: (1) Prepared testimony; (2) affidavits; (3) exhibits; and (4) any other evidence. Given the statutory 90-day time limit for finding, we stress that the burden will be on the applicant to provide a fully-supported application in the first instance.

40. With regard to applications filed by electric utilities that are members of Midwest ISO, PJM, NYISO, or ISO–NE, an electric utility need only submit a compliance filing showing that: (1) It is a member of one of these RTOs/ISOs; (2) the Commission has made a final finding that the RTO/ISO that it is a member of provides QFs with nondiscriminatory access;[28] (3) a list of all potentially affected QFs; and (4) the QFs have the right to request service under an OATT or OATTs (or reciprocity tariffs) on file. Once a final rule issues and the Commission has acted on rehearing of the final rule, the Commission will not reevaluate its decision on specific markets made in the instant proceeding, absent changed circumstances. The Commission seeks comments on whether there are any QFs within the service territories of members of the Midwest ISO, PJM, ISO–NE, and NYISO that, although they have access to an OATT or OATTs (or reciprocal tariffs), nonetheless do not have nondiscriminatory access to those markets.

41. We anticipate that the compliance filings of the electric utilities that are members of the Midwest ISO, PJM, NYISO, or ISO–NE and seeking relief from the purchase obligation will be essentially ministerial; we do not expect the findings made in this rulemaking to be re-litigated in the compliance filing proceeding. In this regard, we conclude that the existence of a filed OATT (or reciprocity tariff) will be construed to provide nondiscriminatory access. If a QF believes that the administration or implementation of the OATT denies it access to markets, it is not an issue for the compliance filing proceeding; instead the QF may file a complaint challenging the implementation or administration of an OATT.

[25] *See Alliant Energy Corporate Services, Inc.*, 113 FERC ¶ 61,024 (2005) (*Alliant*); *Montana-Dakota Utilities Co.*, 113 FERC ¶ 61,045 (2005) (*Montana-Dakota*). In both instances, the Commission dismissed petitions for declaratory orders pursuant to section 210(m)(3) of PURPA requesting relief from the mandatory purchase obligation on the grounds of insufficient notice.

[26] *Alliant*, 113 FERC ¶ 61,024 at P 18.

[27] *Id.* at P 19–20.

[28] The final rule in this proceeding must have become effective before an electric utility may rely upon it. As a result, any electric utilities that file early and seek to rely on the preliminary findings with respect to Midwest ISO, PJM, NYISO or ISO–NE in this NOPR will not be permitted to do so.

D. Reinstatement of Obligation To Purchase

42. Section 210(m)(4) provides:

REINSTATEMENT OF OBLIGATION TO PURCHASE. At any time after the Commission makes a finding under paragraph (3) relieving an electric utility of its obligation to purchase electric energy, a qualifying cogeneration facility, a qualifying small power production facility, a State agency, or any other affected person may apply to the Commission for an order reinstating the electric utility's obligation to purchase electric energy under this section. Such application shall set forth the factual basis upon which the application is based and describe why the conditions set forth in subparagraphs (A), (B) or (C) of paragraph (1) of this subsection are no longer met. After notice, including sufficient notice to potentially affected utilities, and opportunity for comment, the Commission shall issue an order within 90 days of such application reinstating the electric utility's obligation to purchase electric energy under this section if the Commission finds that the conditions set forth in subparagraphs (A), (B) or (C) of paragraph (1) which relieved the obligation to purchase, are no longer met.

43. The Commission views this section as an opportunity for a QF, a state agency, or any affected person to seek to reinstate the purchase obligation should there be a material change in the circumstances under which the Commission granted relief. We note that the applicant bears the burden to ''set forth the factual basis'' upon which the application is based. The requirement for a ''factual basis'' indicates that allegations of a change in the conditions upon which relief was granted must be supported with evidence. The Commission proposes to consider these applications on a case-by-case basis.

44. Consistent with our interpretation of ''notice'' under section 210(m)(3), the Commission will require an applicant to identify all potentially affected utilities in the application so that the Commission will be able to meet its statutory requirement to provide sufficient notice and an opportunity for comment.

E. Obligation To Sell

45. Section 292.303(b) of the Commission's regulations, 18 CFR 292.303(b), states that: ''Each electric utility shall sell to any qualifying facility, in accordance with § 292.305, any energy and capacity requested by the qualifying facility.'' Under new section 210(m)(5), this mandatory obligation to sell can be terminated if the Commission finds that: ''Competing retail electric suppliers are willing and able to sell and deliver electric energy to the qualifying cogeneration facility or qualifying small power production facility; and the electric utility is not required by State law to sell electric energy in its service territory.''

46. The Commission proposes to incorporate the language of section 210(m)(5) of PURPA in new section 292.312 of the Commission's regulations. The Commission proposes to interpret the phrase ''new contract or obligation'' contained in section 210(m)(3) consistently with its interpretation of the same words contained in section 210(m)(1) of PURPA.[29]

47. The Commission is also proposing to include a provision, section 292.313, allowing a QF, State agency, or any other affected person to apply to the Commission for an order reinstating the electric utility's obligation to sell electric energy if the factual predicate for the determination that the obligation to purchase should be terminated no longer exists.

F. Section 210(m)(6)

48. Section 210(m)(6) of PURPA requires that:

Nothing in this subsection affects the rights or remedies of any party under any contract or obligation, in effect *or* pending approval before the appropriate State regulatory authority or non-regulated electric utility on the date of enactment of this subsection, to purchase electric energy or capacity from or to sell electric energy or capacity to a qualifying cogeneration facility or qualifying small power production facility under this Act (including the right to recover costs of purchasing electric energy or capacity).

49. We propose to implement section 210(m)(6) of PURPA by adopting the language of the statute in section 292.314. In addition, the Commission will clarify that the stage of the construction of a facility has no bearing on whether the protections of section 210(m)(6) are triggered. The Commission interprets section 210(m)(6) to protect the rights and remedies under a contract or obligation in effect *or* pending approval before the state regulatory authority, regardless of the construction stage of the facility that may be the subject of the contract or obligation. We solicit comments on whether further or different language and/or clarifications other than those proposed here should be incorporated into our regulations.

G. Section 210(m)(7)

50. Section 210(m)(7) of PURPA requires that:

(A) The Commission shall issue and enforce such regulations as are necessary to ensure that an electric utility that purchases electric energy or capacity from a qualifying cogeneration facility or qualifying small power production facility in accordance with any legally enforceable obligation entered into or imposed under this section recovers all prudently incurred costs associated with the purchase. (B) A regulation under subparagraph (A) shall be enforceable in accordance with the provisions of law applicable to enforcement of regulations under the Federal Power Act (16 U.S.C. 791a *et seq.*).

51. The Commission does not believe that regulations are necessary at this time; this is a matter that the Commission can address on a case-by-case basis. However, the Commission will consider a regulation under this section in the future if a need becomes apparent.

52. We solicit comments on whether there is a need for the Commission to consider a regulation, and if so what that regulation should state, to ensure that an electric utility that purchases electric energy or capacity from a cogeneration QF or qualifying small power production facility in accordance with any legally enforceable obligation entered into or imposed under section 210(m)(7) recovers all prudently incurred costs associated with the purchase.

IV. Information Collection Statement

53. The Commission is submitting the following collection of information contained in this proposed rulemaking to the Office of Management and Budget (OMB) for review under section 3507(d) of the Paperwork Reduction Act of 1995.[30] The Commission identifies the information provided for under part 292 as FERC–556. These collections of information are specifically mandated by statute.

54. The Commission solicits comments on the Commission's need for this information, whether the information will have practical utility, the accuracy of the provided burden estimates, ways to enhance the quality and clarity of the information that the Commission will collect, and any suggested methods for minimizing the respondent's burden, including the use of information techniques. The burden estimates for complying with this proposed rule are as follows:

[29] *See* P 29 *supra.*

[30] 44 U.S.C. 3507(d) (2000).

Data collection FERC–556	Number of respondents	Number of responses	Hour per response	Total annual hours
§ 292.310	230	1	2	460
§ 292.312	230	1	2	460
§ 292.413	630	1	3	1,890
Totals	860	1		2,810

Total Annual Hours for the Collection: (reporting + recordkeeping if appropriate)

Information Collection Costs: Because of the regional differences and the various staffing levels that will be involved in preparing the documentation (legal, technical and support) the Commission is using an hourly rate of $150 to estimate the costs for filing and other administrative processes (reviewing instructions, searching data sources, completing and transmitting the collection of information). The estimated cost is anticipated to be $421,500.

Title: FERC–556 Small Power Production and Cogeneration Facilities.

Action: Proposed Data Collections.

OMB Control Nos.: 1902–0075.

Upon approval of a collection of information, OMB will assign an OMB control number and an expiration date. Respondents subject to the filing requirements of this rule will not be penalized for failing to respond to these collections of information unless the collections of information display a valid OMB control number or the Commission has provided justification as to why the control number should not be displayed.

Respondents: Businesses or other for profit, state, local or tribal government.

Necessity of the Information: The Commission proposes amending its regulations to implement section 210(m) of PURPA which was enacted in section 1253 of the EPAct 2005; specifically, its regulations governing purchases of electric energy from and sales of electric energy to qualifying small power production and cogeneration facilities

These requirements conform to the Commission's plan for efficient information collection, communication, and management within the energy industry. The Commission has assured itself, by means of internal review, that there is specific, objective support for the burden estimates associated with the information requirements.

Interested persons may obtain information on the reporting requirements by contacting the following: Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426 [Attention: Michael Miller, Office of the Executive Director, Phone: (202) 502–8415, fax: (202) 273–0873, e-mail: *michael.miller@ferc.gov*].

55. For submitting comments concerning the collection(s) of information and the associated burden estimate(s), please send your comments to the contact listed above and to the Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, [Attention: Desk Officer for the Federal Energy Regulatory Commission, phone: (202) 395–4650, fax: (202) 395–7285, e-mail: *oira_submission@omb.eop.gov.*

V. Environmental Analysis

56. The Commission is required to prepare an Environmental Assessment or an Environmental Impact Statement for any action that may have a significant adverse effect on the human environment. The Commission has categorically excluded certain actions from this requirement as not having a significant effect on the human environment. As explained above, this proposed rule is clarifying in nature. It interprets several amendments made to PURPA by EPAct 2005, and clarifies the applicability of these amendments to electric utilities and QFs; it does not substantially change the effect of the legislation. Accordingly, no environmental consideration is necessary.

VI. Regulatory Flexibility Act Analysis

57. The Regulatory Flexibility Act of 1980 (RFA) [31] generally requires a description and analysis of rules that will have significant economic impact on a substantial number of small entities and where notice and comment rulemaking is required. Certain rules are exempt from notice and comment from the RFA requirements; exempt rules include interpretative rules, general statements of policy, or rules of agency organization procedure or practice.[32] Interpretative rules ''generally interpret the intent expressed by Congress, where an agency does not insert its own judgments or interpretations in implementing a rule and simply regurgitates statutory language.'' [33] The rule we are proposing in this docket is an interpretative rule. Accordingly, no regulatory flexibility analysis is required.

VII. Comment Procedures

58. The Commission invites interested persons to submit comments on the matters and issues proposed in this notice to be adopted, including any related matters or alternative proposals that commenters may wish to discuss. Comments are due February 27, 2006. Reply comments are due March 28, 2006. Comments and reply comments must refer to Docket No. RM06–10–000, and must include the commenters' names, the organizations they represent, if applicable, and their address in their comments. Comments and reply comments may be filed either in electronic or paper format.

59. Comments and reply comments may be filed electronically via the eFiling link on the Commission's Web site at *http://www.ferc.gov*. The Commission accepts most standard word processing formats and commenters may attach additional files with supporting information in certain other file formats. Commenters filing electronically do not need to make paper filings. Commenters that are not able to file comments and reply comments electronically must send an original and 14 copies of their comments to: Federal Energy Regulatory Commission, Office of the Secretary, 888 First Street, NE., Washington, DC 20426.

60. All comments and reply comments will be placed in the Commission's public files and may be viewed, printed, or downloaded remotely as described in the Document Availability section below. Commenters on this proposal are not required to serve copies of their comments and reply comments on other commenters.

VIII. Document Availability

61. In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all

[31] 5 U.S.C. 601–12.

[32] 5 U.S.C. 553(b)(A).

[33] ''How to Comply with the Regulatory Flexibility Act: A Guide for Government Agencies'', Small Business Administration, Office of Advocacy, P.5, May 2003.

interested persons an opportunity to view and/or print the contents of this document via the Internet through the Commission's Home Page (*http://www.ferc.gov*) and in the Commission's Public Reference Room during normal business hours (8:30 a.m. to 5 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

62. From the Commission's Home Page on the Internet, this information is available in the Commission's document management system, eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

63. User assistance is available for eLibrary and the Commission's Web site during normal business hours. For assistance, please contact FERC Online Support at 1–866–208–3676 (toll free) or (202) 502–8222 (e-mail at *FERCOnlineSupport@FERC.gov*), or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659 (e-mail at *public.referenceroom@ferc.gov*).

List of Subjects in 18 CFR Part 292

Electricity, Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

By direction of the Commission.

Magalie R. Salas,

Secretary.

In consideration of the foregoing, the Commission proposes to amend part 292, Chapter I, Title 18, *Code of Federal Regulations*, as follows:

PART 292—REGULATIONS UNDER SECTIONS 201 AND 210 OF THE PUBLIC UTILITY REGULATORY POLICIES ACT OF 1978 WITH REGARD TO SMALL POWER PRODUCTION AND COGENERATION

1. The authority citation for part 292 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

2. Section 292.303 is amended by revising paragraphs (a) and (b) to read as follows:

§ 292.303 Electric utility obligations under this subpart.

(a) *Obligation to purchase from qualifying facilities.* Each electric utility shall purchase, in accordance with § 292.304, unless exempted by § 292.309, any energy and capacity which is generated from a qualifying facility

(1) Directly to the electric utility; or

(2) Indirectly to the electric utility in accordance with paragraph (d) of this section.

(b) *Obligation to sell to qualifying facilities.* Each electric utility shall sell to any qualifying facility, in accordance with § 292.305, unless exempted by § 292.312 of this chapter, energy and capacity requested by the qualifying facility.

* * * * *

3. Sections 292.309 through 292.314 are added to read as follows:

§ 292.309 Termination of obligation to purchase from qualifying facilities.

(a) An electric utility shall no longer be required to enter into a new contract or obligation to purchase electric energy from a qualifying cogeneration facility or a qualifying small power production facility if the Commission finds that the qualifying cogeneration facility or qualifying small power production facility has nondiscriminatory access to:

(1)(i) Independently administered, auction-based day ahead and real time wholesale markets for the sale of electric energy; and

(ii) Wholesale markets for long-term sales of capacity and electric energy; or

(2)(i) Transmission and interconnection services that are provided by a Commission-approved regional transmission entity and administered pursuant to an open access transmission tariff that affords nondiscriminatory treatment to all customers; and

(ii) Competitive wholesale markets that provide a meaningful opportunity to sell capacity, including long-term and short-term sales, and electric energy, including long-term, short-term and real-time sales, to buyers other than the utility to which the qualifying facility is interconnected; in determining whether a meaningful opportunity to sell exists within the meaning of § 292.309(a)(2)(ii), the Commission shall consider, among other factors, evidence of transactions within the relevant market; or

(3) Wholesale markets for the sale of capacity and electric energy that are, at a minimum, of comparable competitive quality as markets described in paragraphs (a)(1) and (a)(2) of this section.

(b) *Definitions.* (1) For purposes of this section, an ''existing qualifying cogeneration facility'' is a facility that:

(i) Was a qualifying cogeneration facility before or on August 8, 2005; or

(ii) Had filed with the Commission a notice of self-certification, self-recertification or an application for Commission certification under § 292.207 prior to [the date the Commission issues a final rule].

(2) For the purposes of this section, a ''new qualifying cogeneration facility'' is a facility that satisfies the criteria for qualifying cogeneration facilities under § 292.205.

(3) For the purposes of this section, a renewal of a contract that expires by its own terms is a ''new contract or obligation.''

(c) For the purposes of this section, there is a rebuttable presumption that there is ''non-discriminatory access'' to wholesale markets when a qualifying facility is provided transmission services pursuant to a Commission-approved open access transmission tariff or reciprocity tariff, and interconnection services pursuant to Commission-approved interconnection rules.

(d) No electric utility shall be required to enter into a new contract or obligation to purchase from or sell electric energy to a facility that is not an existing qualifying cogeneration facility unless the facility meets the criteria for new qualifying cogeneration facilities established by the Commission in § 292.205.

§ 292.310 Procedures for utilities requesting termination of obligation to purchase from qualifying facilities.

(a) Any electric utility may file an application with the Commission for relief from the mandatory purchase obligation in § 292.303(a) pursuant to this section on a service territory-wide basis. Such application shall set forth the factual basis upon which relief is requested and describe why the conditions set forth in § 292.309(a)(1), (2) or (3) have been met. After notice, including sufficient notice to potentially affected qualifying cogeneration facilities and qualifying small power production facilities, and an opportunity for comment, the Commission shall make a final determination within 90 days of such application regarding whether the conditions set forth in § 292.309(a)(1), (2) or (3) have been met; provided, however, that if the Commission has made a determination pursuant to notice and comment rulemaking or order that a particular market meets the criteria for relief in § 292.309(a)(1), (2) or (3), an applicant may make a ministerial application under this section and the application will be treated as a compliance filing.

(b) Sufficient notice shall mean that an electric utility must identify with names and addresses all potentially affected qualifying facilities in an

application filed pursuant to paragraph (a) of this section.

(c) All potentially affected qualifying facilities shall include:

(1) Those qualifying facilities that have existing power purchase contracts with the applicant;

(2) Other qualifying facilities that sell their output to the applicant or that have pending self-certification or Commission certification with the Commission for qualifying facility status whereby the applicant will be the purchaser of the qualifying facility's output;

(3) Any developer of generating facilities with whom the applicant has agreed to enter into power purchase contracts or are in discussion with regard to power purchase contacts;

(4) The developers of facilities that have pending state avoided cost proceedings; and

(5) Any other qualifying facilities that the applicant reasonably believes to be affected by its application filed pursuant to paragraph (a) of this section.

§ 292.311 Reinstatement of obligation to purchase.

At any time after the Commission makes a finding under § 292.310 relieving an electric utility of its obligation to purchase electric energy, a qualifying cogeneration facility, a qualifying small power production facility, a State agency, or any other affected person may apply to the Commission for an order reinstating the electric utility's obligation to purchase electric energy under this section, if there has been a change in the conditions upon which the Commission based its finding. Such application shall set forth the factual basis upon which the application is based and describe why the conditions set forth in § 292.309 (a)(1), (2) or (3) are no longer met. After notice, including sufficient notice to potentially affected utilities, and opportunity for comment, the Commission shall issue an order within 90 days of such application reinstating the electric utility's obligation to purchase electric energy under this section if the Commission finds that the conditions set forth in § 292.309 (a)(1), (2), or (3) which relieved the obligation to purchase, are no longer met.

§ 292.312 Procedures for utilities requesting termination of obligation to sell to qualifying facilities.

(a) An electric utility shall not be required to enter into a new contract or obligation to sell electric energy to a qualifying small power production facility, an existing qualifying cogeneration qualifying facility, or a new qualifying cogeneration facility if the Commission has found that:

(1) Competing retail electric suppliers are willing and able to sell and deliver electric energy to the qualifying cogeneration facility or qualifying small power production facility; and

(2) The electric utility is not required by State law to sell electric energy in its service territory.

(b) Any electric utility may file an application with this Commission for relief from the mandatory obligation to sell under this paragraph on a service territory-wide basis or a single qualifying facility basis. Such application shall set forth the factual basis upon which relief is requested and describe why the conditions set forth in paragraphs (a)(1) and (a)(2) of this section have been met. After notice, including sufficient notice to potentially affected qualifying facilities, and an opportunity for comment, the Commission shall make a final determination within 90 days of such application regarding whether the conditions set forth in paragraphs (a)(1) and (a)(2) of this section have been met.

§ 292.313 Reinstatement of obligation to sell.

At any time after the Commission makes a finding under § 292.312 relieving an electric utility of its obligation to sell electric energy, a qualifying cogeneration facility, a qualifying small power production facility, a State agency, or any other affected person may apply to the Commission for an order reinstating the electric utility's obligation to sell electric energy under this section, if there has been a change in the conditions upon which the Commission based its finding. Such application shall set forth the factual basis upon which the application is based and describe why the conditions set forth in § 292.312 (a)(1) and (a)(2) are no longer met. After notice, including sufficient notice to potentially affected utilities, and opportunity for comment, the Commission shall issue an order within 90 days of such application reinstating the electric utility's obligation to sell electric energy under this section if the Commission finds that the conditions set forth in § 292.312 (a)(1) and (a)(2) are no longer met.

§ 292.314 Existing rights and remedies.

Nothing in this §§ 292.303 through 292.314 affects the rights or remedies of any party under any contract or obligation, in effect or pending approval before the appropriate State regulatory authority or non-regulated electric utility on or before August 8, 2005, to purchase electric energy or capacity from or to sell electric energy or capacity to a qualifying cogeneration facility or qualifying small power production facility (including the right to recover costs of purchasing electric energy or capacity).

[FR Doc. E6–940 Filed 1–26–06; 8:45 am]

BILLING CODE 6717–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Information Security Oversight Office

32 CFR Part 2004

RIN 3095–AB34

Information Security Oversight Office; National Industrial Security Program Directive No. 1

AGENCY: Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA).

ACTION: Implementing directive; proposed rule.

SUMMARY: The Information Security Oversight Office (ISOO), National Archives and Records Administration (NARA), is publishing this Directive as a proposed rule and pursuant to section 102(b)(1) of Executive Order 12829, as amended, relating to the National Industrial Security Program. This order establishes a National Industrial Security Program (NISP) to safeguard Federal Government classified information that is released to contractors, licensees, and grantees of the United States Government. Redundant, overlapping, or unnecessary requirements impede those interests. Therefore, the NISP serves as the single, integrated, cohesive industrial security program to protect classified information and to preserve our Nation's economic and technological interests. This Directive sets forth guidance to agencies to set uniform standards throughout the NISP that promote these objectives.

DATES: Comments must be received on or before March 13, 2006.

ADDRESSES: You may submit comments, identified by ''RIN 3095–AB34,'' by any of the following methods:

Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

E-mail: *comments@nara.gov*. Include ''RIN 3095–AB34'' in the subject line of the message.

Fax: (301) 837–0319.

Mail: Regulation Comments Desk (NPOL), Room 4100, National Archives

and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

Hand Delivery/Courier: Regulation Comments Desk (NPOL), Room 4100, National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: J. William Leonard, Director, ISOO, at 202–219–5250.

SUPPLEMENTARY INFORMATION: This proposed rule is being issued pursuant to the provisions of section 102(b)(1) of Executive Order 12829, January 6, 2003 (58 FR 3479), as amended by Executive Order 12885, December 14, 1993, (58 FR 65863). The purpose of this Directive is to assist in implementing the Order; users of the Directive shall refer concurrently to that Order for guidance. As of November 17, 1995, ISOO became a part of NARA. The drafting, coordination, and issuance of this Directive fulfills one of the responsibilities of the implementation delegated to the ISOO Director. ISOO maintains oversight over Executive Order 12958, as amended, and policy oversight over Executive Order 12829, as amended. Nothing in this directive shall be construed to supersede the authority of the Secretary of Energy or the Nuclear Regulatory Commission under the Atomic Energy Act of 1954, as amended (42 U.S.C. 2011 *et seq.*), or the authority of the Director of Central Intelligence under the National Security Act of 1947, as amended, or Executive Order No. 12333 of December 8, 1981, or the authority of the Director of National Intelligence under the Intelligence Reform and Terrorism Prevention Act of 2004. Requirements of the latter Act will necessitate additional future changes to Executive Order 12829 and this implementing Directive. The interpretive guidance contained in this proposed rule will assist agencies in implementing Executive Order 12829, as amended.

The proposed rule is [not] a significant regulatory action for the purposes of Executive Order 12866. The proposed rule is [not] a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. As required by the Regulatory Flexibility Act, we certify that this proposed rule will [not] have a significant impact on a substantial number of small entities because it applies only to Federal agencies.

List of Subjects in 32 CFR Part 2004

Classified information.

1. For the reasons set forth in the preamble, NARA proposes to amend Title 32 of the Code of Federal Regulations to add part 2004 as follows:

PART 2004—NATIONAL INDUSTRIAL SECURITY PROGRAM DIRECTIVE NO. 1

Subpart A—Implementation and Oversight

Subpart B—Operations

Authority: Section 102(b)(1) of Executive Order 12829, January 6, 2003, 58 FR 3479, as amended by Executive Order 12885, December 14, 1993, 58 FR 65863.

Subpart A—Implementation and Oversight

§ 2004.10 Responsibilities of the Director, Information Security Oversight Office (ISOO) [102(b)].[1]

The Director ISOO shall:

(a) Implement EO 12829, as amended.

(b) Ensure that the NISP is operated as a single, integrated program across the Executive Branch of the Federal Government; i.e., that the Executive Branch departments and agencies adhere to NISP principles.

(c) Ensure that each contractor's implementation of the NISP is overseen by a single Cognizant Security Authority (CSA), based on a preponderance of classified contracts per agreement by the CSAs.

(d) Ensure that all Executive Branch departments and agencies that contract for classified work have included the Security Requirements clause, 52.204–2, from the Federal Acquisition Regulation (FAR), or an equivalent clause, in such contract.

(e) Ensure that those Executive Branch departments and agencies for which the Department of Defense (DoD) serves as the CSA have entered into agreements with the DoD that establish the terms of the Secretary's responsibilities on behalf of those agency heads.

[1] Bracketed references pertain to related sections of Executive Order 12829, as amended by E.O. 12885.

§ 2004.11 Agency implementing regulations, internal rules, or guidelines [102(b)(3)].

(a) *Reviews and Updates.* All implementing regulations, internal rules, or guidelines that pertain to the NISP shall be reviewed and updated by the originating agency, as circumstances require. If a change in national policy necessitates a change in agency implementing regulations, internal rules, or guidelines that pertain to the NISP, the agency shall promptly issue revisions.

(b) *Reviews by ISOO.* The Director, ISOO, shall review agency implementing regulations, internal rules, or guidelines, as necessary, to ensure consistency with NISP policies and procedures. Such reviews should normally occur during routine oversight visits, when there is indication of a problem that comes to the attention of the Director, ISOO, or after a change in national policy that impacts such regulations, rules, or guidelines. The Director, ISOO, shall provide findings from such reviews to the responsible department or agency.

§ 2004.12 Reviews by ISOO [102(b)(4)].

The Director, ISOO, shall fulfill his monitoring role based, in part, on information received from NISP Policy Advisory Committee (NISPPAC) members, from on-site reviews that ISOO conducts under the authority of EO 12829, as amended, and from complaints and suggestions from persons within or outside the Government. Findings shall be reported to the responsible department or agency.

Subpart B—Operations

§ 2004.20 National Industrial Security Program Operating Manual (NISPOM) [201(a)].

(a) The NISPOM applies to release of classified information during all phases of the contracting process.

(b) As a general rule, procedures for safeguarding classified information by contractors and recommendations for changes shall be addressed through the NISPOM coordination process that shall be facilitated by the Executive Agent. The Executive Agent shall address NISPOM issues that surface from industry, Executive Branch departments and agencies, or the NISPPAC. When consensus cannot be achieved through the NISPOM coordination process, the issue shall be raised to the NSC for resolution.

§ 2004.21 Protection of classified information [201(e)].

Procedures for the safeguarding of classified information by contractors are

promulgated in the NISPOM. DoD, as the Executive Agent, shall use standards applicable to agencies as the basis for the requirements, restrictions, and safeguards contained in the NISPOM; however, the NISPOM requirements may be designed to accommodate as necessary the unique circumstances of industry. Any issue pertaining to deviation of industry requirements in the NISPOM from the standards applicable to agencies shall be addressed through the NISPOM coordination process.

§ 2004.22 Operational responsibilities [202(a)].

(a) *Designation of Cognizant Security Authority (CSA).* The CSA for a contractor shall be determined by the preponderance of classified contract activity per agreement by the CSAs. The responsible CSA shall conduct oversight inspections of contractor security programs and provide other support services to contractors as necessary to ensure compliance with the NISPOM and that contractors are protecting classified information as required. DoD, as Executive Agent, shall serve as the CSA for all Executive Branch departments and agencies that are not a designated CSA. As such, DoD shall:

(1) Provide training to industry to ensure that industry understands the responsibilities associated with protecting classified information.

(2) Validate the need for contractor access to classified information, shall establish a system to request personnel security investigations for contractor personnel, and shall ensure adequate funding for investigations of those contractors under Department of Defense cognizance.

(3) Maintain a system of eligibility and access determinations of contractor personnel.

(b) *General Responsibilities.* Executive Branch departments and agencies that issue contracts requiring industry to have access to classified information and are not a designated CSA shall:

(1) Include the Security Requirements clause, 52.204–2, from the FAR in such contracts;

(2) Incorporate a Contract Security Classification Specification (DD 254) into the contracts in accordance with the FAR subpart 4.4;

(3) Sign agreements with the Department of Defense as the Executive Agent for industrial security services; and

(4) Ensure applicable department and agency personnel having NISP implementation responsibilities are provided appropriate education and training.

§ 2004.23 Cost reports [203 (d)].

(a) The Executive Branch departments and agencies shall provide information each year to the Director, ISOO, on the costs within the agency associated with implementation of the NISP for the previous year.

(b) The DoD as the Executive Agent shall develop a cost methodology in coordination with industry to collect the costs incurred by contractors of all Executive Branch departments and agencies to implement the NISP, and shall report those costs to the Director, ISOO, on an annual basis.

§ 2004.24 Definitions.

For the purposes of this part the following definitions apply:

(a) *Cognizant Security Agencies (CSAs)* means the Executive Branch departments and agencies authorized in EO 12829, as amended, to establish industrial security programs: the Department of Defense, designated as the Executive Agent; the Department of Energy; the Nuclear Regulatory Commission; and the Central Intelligence Agency.

(b) *Contractor* means any industrial, education, commercial, or other entity, to include licensees or grantees that has been granted access to classified information. Contractor does not include individuals engaged under personal services contracts.

Dated: December 5, 2005.

J. William Leonard,

Director, Information Security Oversight Office.

Approved: January 14, 2006.

Allen Weinstein,

Archivist of the United States.

[FR Doc. E6–815 Filed 1–26–06; 8:45 am]

BILLING CODE 7515–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NM–4–1–5208b; FRL–8025–4]

Approval and Promulgation of Implementation Plans; New Mexico, Visibility

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve a revision to the New Mexico State Implementation Plan (SIP). This revision satisfies the New Source Review (NSR) and monitoring plan requirements for visibility, otherwise known as the ''Phase I, Part I Visibility SIP.;'' In addition, this revision includes the implementation control strategies, integral vistas protection, and long term strategies, otherwise known as the ''Phase I, Part II Visibility SIP.'' Lastly, EPA is proposing to remove the SIP disapprovals associated with Phase I, Parts I and II, and the resultant Federal Implementation Plans (FIPs).

DATES: Written comments must be received on or before February 27, 2006.

ADDRESSES: Comments may be mailed to Mr. Thomas Diggs, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Joe Kordzi, Air Planning Section (6PD–L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202–2733, telephone (214) 665–7186; fax number 214–665–7263; e-mail address *kordzi.joe@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the ''Rules and Regulations'' section of this **Federal Register**.

Dated: January 18, 2006.

Richard E. Greene,

Regional Administrator, Region 6.

[FR Doc. 06–759 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Parts 70 and 71

RIN 0920–AA03

Control of Communicable Diseases

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Proposed rule; extension of public comment period.

SUMMARY: On November 30, 2005, at 70 FR 71892, CDC published a proposed rule, ''Control of Communicable Diseases,'' to revise existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. and from one state or possession into another. CDC provided a 60 day public comment period. Written comments were to be received on or before January 30, 2006. We have received requests asking for an extension of the comment period. In consideration of these requests, CDC is extending the comment period by 30 days to March 1, 2006.

DATES: Written comments must be received on or before March 1, 2006. Written comments on the proposed information collection requirements must also be submitted on or before March 1, 2006. Please refer to **SUPPLEMENTARY INFORMATION** for additional information.

ADDRESSES: You may submit written comments to the following address: Centers for Disease Control and Prevention, Division of Global Migration and Quarantine, ATTN: Q Rule Comments, 1600 Clifton Road, NE, (E03), Atlanta, GA 30333. Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road, NE, Atlanta, GA 30333. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Global Migration and Quarantine to schedule your visit. Comments also may be viewed at *www.cdc.gov/ncidod/dq.* You may submit written comments electronically via the Internet at *http://www.regulations.gov* or via e-mail to *qrulepubliccomments@cdc.gov.* To download an electronic version of the rule, you may access *http://www.regulations.gov.*

Mail written comments on the proposed information collection requirements to the following address: Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for CDC.

FOR FURTHER INFORMATION CONTACT: Jennifer Brooks, Centers for Disease Control and Prevention, Division of Global Migration and Quarantine,1600 Clifton Road, NE, (E03), Atlanta, GA 30333; telephone (404) 498–2395.

SUPPLEMENTARY INFORMATION: On November 30, 2005, at 70 FR 71892, CDC published a proposed rule, ''Control of Communicable Diseases,'' revising existing regulations related to preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the U.S. and from one state or possession into another. CDC provided a 60 day public comment period. Written comments were to be received on or before January 30, 2006. CDC has received requests asking for an extension of the public comment period beyond the 60 days originally provided. These requests have been made by industry trade organizations that represent businesses that will be affected by the proposed rule. In consideration of these concerns, CDC is extending the comment period by 30 days (until March 1, 2006) in order to give all interested persons the opportunity to comment fully.

CDC's general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change, including any personal identifiers or contact information.

How Can I Get Copies of the NPRM and Other Related Information?

CDC has posted the NPRM and related materials to their Web site. These can be found at *www.cdc.gov/ncidod/dq.*

Dated: January 23, 2006.

Michael O. Leavitt,

Secretary.

[FR Doc. E6–1048 Filed 1–26–06; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 171, 172, 173, 175 and 176

[Docket No. PHMSA–2005–23141 (HM–215F)]

RIN 2137–AD98

Hazardous Materials: Revision and Reformatting of Requirements for the Authorization To Use International Transport Standards and Regulations

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: In this notice of proposed rulemaking, the Pipeline and Hazardous Materials Safety Administration proposes to amend the Hazardous Materials Regulations by revising and consolidating the requirements applicable to the use of the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air, the International Maritime Dangerous Goods Code, the Canadian Transport of Dangerous Goods Regulations, and the International Atomic Energy Agency Safety Standards Series: Regulations for the Safe Transport of Radioactive Material. The revisions and reformatting provide a user-friendly format to promote understanding of the conditions and limitations on the use of international standards and regulations, thereby ensuring that an acceptable level of safety is maintained while facilitating the transportation of hazardous materials.

DATES: Comments must be received by March 28, 2006. To the extent possible, we will consider late filed comments as we develop the final rule.

ADDRESSES: You may submit comments by any of the following methods:

- *Web site: http://dms/dot/gov.* Follow the instructions for submitting comments on the DOT electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Docket Management System; U.S. Department of Transportation, 400 Seventh Street, SW, Nassif Building, Room PL–401, Washington, DC 20590–0001
- *Hand Delivery:* To the Docket Management System; Room PL–401 on the Plaza Level of the Nassif Building, 400 Seventh Street, SW., Washington, DC between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number PHMSA–05–23141 (HM–215F) or the Regulatory Identification Number (RIN) for this notice at the beginning of your comment. Note that all comments received will be posted without change to *http://dms.dot.gov* including any personal information provided. Please see the Privacy Act section of this document.

Docket: You may view the public docket through the Internet at http://dms.dot.gov or in person at the Docket Management System office at the above address.

FOR FURTHER INFORMATION CONTACT: Duane Pfund, International Standards, telephone (202) 366–0656, or Joan McIntyre, Office of Hazardous Materials Standards, telephone (202) 366–8553, Pipeline and Hazardous Materials Safety Administration.

SUPPLEMENTARY INFORMATION:

I. Background

To facilitate the safe and efficient transportation of hazardous materials in international commerce, the Hazardous Materials Regulations (HMR; 49 CFR Parts 171–180), with certain limitations, permit both domestic and international shipments of hazardous materials to be offered for transportation and transported under provisions of the International Civil Aviation Organization's Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), the International Maritime Dangerous Goods Code (IMDG Code), the Canadian Transportation of Dangerous Goods Regulations (TDG Regulations), and the International Atomic Energy Agency Safety Standards Series: Regulations for the Safe Transportation of Radioactive Material (IAEA Regulations), as appropriate.

Uniformity of national and international hazardous materials transportation regulations is critical to enhance safety and facilitate trade. Consistency between U.S. and international regulations helps to assure the safety of international hazardous materials transportation through better understanding of the regulations, an increased level of industry compliance, the smooth flow of hazardous materials from their points of origin to their points of destination, and consistent emergency response in the event of a hazardous materials incident. For example, many shippers find that consistency in requirements aids their understanding of what is required, thereby permitting them to more easily comply with the regulations when shipping hazardous materials in international commerce.

In this notice of proposed rulemaking (NPRM), the Pipeline and Hazardous Materials Safety Administration (PHMSA) proposes to amend the HMR by revising, consolidating, and clarifying the provisions that authorize the use of the ICAO Technical Instructions, the IMDG Code, the TDG Regulations, and the IAEA Regulations, as currently contained in §§ 171.11, 171.12 and 171.12a. Currently these sections permit both domestic and international shipments of hazardous materials to be offered for transportation and transported under the provisions of the applicable transport standards and regulations, subject to certain conditions and limitations:

- Section 171.11 authorizes the offering, acceptance, and transportation of hazardous materials by aircraft and motor vehicle in accordance with the ICAO Technical Instructions.
- Section 171.12 authorizes the offering, acceptance, and transportation of hazardous materials by vessel, motor vehicle, or rail in accordance with the IMDG Code, provided all or part of the transportation is by vessel.
- Section 171.12a authorizes the offering, acceptance, and transportation of hazardous materials by motor vehicle or rail in accordance with the TDG Regulations, for: (1) Shipments that originate in Canada and either terminate in the United States or transit the United States to a Canadian or foreign destination, or (2) the return to Canada of empty bulk packages containing residues of hazardous materials that were initially imported into the United States.
- Section 171.12(d) authorizes the offering, acceptance, and transportation of radioactive materials in accordance with the IAEA Regulations for shipments imported into or exported from the United States or transiting the United States during transportation between places outside the United States.

In addition, § 171.12a requires shipments of hazardous materials being transported by highway or rail between the United States and Mexico to be shipped in accordance with the HMR while being transported within the United States. Even though the Mexican standards, Normas Officiales Mexicanos (NOMs) and the Regulations for Land Transportation of Hazardous Materials and Waste, are to a considerable degree consistent with the HMR, differences do exist and shippers must exercise caution to ensure that shipments are in full compliance with the applicable regulations of each country. For additional information and guidance for preparing shipments of hazardous materials between the United States and Mexico, you may access *http://hazmat.dot.gov/nomslst.htm*.

The Federal hazardous materials transportation law (Federal hazmat law; 49 U.S.C. 5101 *et seq.*) requires PHMSA to align the HMR with international transport standards and requirements to the extent practicable (see § 5120). Harmonization improves safety and compliance, and facilitates the transportation of hazardous materials in international commerce. The Federal hazmat law permits PHMSA to deviate from international transport standards and requirements when such action is in the public interest. Therefore, we continue to align the HMR with international transport standards and regulations through various rulemakings. We also periodically review and revise the provisions for the authorization to use the international transport standards and regulations in order to maintain a safety level equal to that of the HMR, thereby assuring the protection of people, property, and the environment.

II. Consolidation of the Conditions and Limitations for Use of the ICAO Technical Instructions, IMDG Code, and TDG Regulations

The HMR, ICAO Technical Instructions, IMDG Code, and TDG Regulations are based on the UN Recommendations on the Transport of Dangerous Goods (UN Recommendations), which are model regulations issued by the UN Committee of Experts on the Transport of Dangerous Goods and the Globally Harmonized System of Classification and Labeling of Chemicals (UN COE). The authorizations to use the ICAO Technical Instructions, IMDG Code and TDG Regulations in §§ 171.11, 171.12 and 171.12a, respectively, contain many of the same conditions and limitations for use. Therefore, we are propose consolidating into one section those conditions and limitations applicable to all of the authorized international transport standards and regulations. Following that section, we propose separate sections containing the additional provisions specific to each authorized standard. These newly numbered sections are contained in a separate subpart.

The proposed reorganization of part 171, subpart A includes provisions concerning the applicability of the HMR and general requirements for transportation, and provisions for the Paperwork Reduction Act, reference material, definitions and abbreviations,

rules of construction, and units of measure. Proposed subpart B includes provisions for incident reporting, approvals and authorizations issued by the Bureau of Explosives, submission of reports, and investigations and special studies. Proposed subpart C includes the provisions authorizing the use of international standards and regulations for transportation in the United States.

In new subpart C, we propose to consolidate into one section the conditions and limitations that apply to the use of the ICAO Technical Instructions, IMDG Code, the TDG Regulations, and the IAEA regulations. We are proposing to add separate sections specific to the use of the ICAO Technical Instructions, IMDG Code, TDG Regulations, IAEA Regulations, and for shipments to or from Mexico. These separate sections contain additional conditions and limitations for the particular international transport standard or regulation being used. The proposed, reformatted international sections are located in §§ 171.22 through 171.28 in the new subpart C.

We propose to minimize references to other parts of the HMR by incorporating the complete text for certain requirements in place of the reference. Consolidating and reformatting the conditions and limitations into a more user-friendly format provides HMR users with a clearer understanding of the conditions and limitations for the use of authorized international standards, particularly for persons transporting hazardous materials by multiple modes of transportation.

III. Review of Proposed Changes

In this NPRM we are also proposing several revisions to the current conditions and limitations for use of international standards and regulations, including: (1) The removal of certain unnecessary requirements; (2) clarification of labeling requirements for limited quantities of Division 6.1 materials in Packing Groups II and III; (3) revision of shipping paper requirements to require an indication of the international standard being used; (4) clarification of requirements for the use of International Maritime Organization (IMO) Type 5 tanks; and (5) authorization for the use of the TDG Regulations for return shipments from the United States to Canada. These revisions are explained in more detail below.

We are also proposing to incorporate by reference the most recent edition of the TDG regulations—Amendment 5, which was published on September 21, 2005. We invite commenters to address Amendment 5 for incorporation by reference into the HMR.

A. Removal of Unnecessary HMR Requirements

We propose to remove the following conditions and limitations from the HMR because they have been incorporated into the most recent editions of the ICAO Technical Instructions, the IMDG Code, and the TDG regulations:

1. The current HMR restriction in §§ 171.11((d)(12), 171.12(b)(14), and 171.12a(b)(14) precluding ammonium nitrate fertilizer or ammonium nitrate mixed fertilizer from being a Class 1 (explosive).

2. The current limitation on the use of abbreviations in §§ 171.11, 171.12 and 171.12a.

3. The current prohibition in § 171.12a(b)(6) from displaying a product identification number (PIN) preceding a UN number because it is no longer authorized in the TDG Regulations.

4. The requirement in § 171.12a(b)(5)(vi) that shipping papers for shipments of anhydrous ammonia contain an indication that the markings, labels and placards have been applied in conformance with the TDG Regulations. Because of our proposal, discussed below, to require an indication on shipping papers of the regulation utilized for the shipment, this is no longer necessary.

B. Division 6.1 PG II and III Limited Quantity Labeling Requirements

We are proposing to indicate that Division 6.1 materials transported as limited quantities are not excepted from labeling when shipped to, from, or within the United States under the ICAO Technical Instructions, IMDG Code, or TDG Regulations.

C. Entering an Indication of the Transport Standard or Regulation Used on Shipping Papers

In proposed new paragraphs (g)(4) in § 171.22 and (p) in § 172.203, we propose to require shipping papers to include an indication of the international transport standard or regulation (ICAO, IMDG, TDG or IAEA) under which the hazardous materials are being transported. Identifying the particular transport standard or regulation that is being used will expedite shipments by providing on-the-spot information to inspectors, carrier personnel and freight forwarders. Moreover, under the provisions in the ICAO Technical Instructions, IMDG Code, TDG Regulations or IAEA Regulations as authorized, the material preparation or transport requirements may vary in some respect from the detailed requirements of the HMR. Requiring an indication on the shipping paper that the shipment was prepared or is being transported under the provisions of an authorized transport standard or regulation provides the shipper a practical and easily recognizable means to communicate this fact to all interested parties in the transportation chain.

In addition, we are proposing to require the shipper to provide a ''shipper's certification'' as required by § 172.204 of the HMR for all shipments into the United States. The TDG Regulations do not require such a certification. The certification is necessary for determining who has responsibility for compliance with the requirements of the HMR.

D. Use of IMO Type 5 Tanks

In this NPRM, we are proposing in § 171.24 to clarify the conditions under which IMO Type 5 tanks are authorized. An IMO Type 5 tank is only authorized when specifically identified in the applicable packaging section of the HMR. If an IMO Type 5 tank is not specifically listed as an authorized packaging, the portable tank must meet DOT 51 or UN portable tank requirements.

E. Bulk Shipments to Canada

In § 171.12a, the use of the TDG Regulations includes the return to Canada of empty bulk packages containing only a residue of the hazardous materials initially imported into the United States. We are proposing in new § 171.26 to expand this authorization to permit the use of bulk packagings authorized in the TDG regulations to transport hazardous materials while returning to Canada from the United States.

PHMSA and Transport Canada compared the cargo tank, rail tank car and portable tank requirements in the HMR and the TDG Regulations. The Canadian cargo tank motor vehicle and portable tank requirements are incorporated in the Canadian Standards Board (CSA) B620, B621 and B622 (2003 editions) standards and the rail tank car requirements are in the Canadian General Standards Board (CGSB) standard, CGSB–43.147 for the ''Construction, Modification, Qualification, Maintenance and selection and Use of Rail Tank Cars,'' March 2002. These standards provide a level of safety that is equivalent to that established in the HMR for cargo tank trucks, portable tanks, and rail tank cars.

Our proposed expansion of authorization for use of the TDG Regulations in the United States provides additional flexibility and is consistent with the reciprocity afforded to DOT specification bulk packagings in the TDG Regulations. As part of this proposed revision, we are amending the HMR to clarify the parts of the HMR applicable to Canadian specification bulk packagings (*e.g.*, material authorizations in the § 172.101 Hazardous Materials Table (HMT) Special Provision B Codes, material specific requirements in part 173, operational requirements in parts 174 and 177 for rail and motor vehicle transportation, and periodic testing and inspection requirements in part 180).

We are also requesting comments concerning whether we should expand reciprocity and allow the unrestricted use in the United States of cargo tanks, rail tank cars, and portable tanks built to Canadian specifications as Canada permits unrestricted use of similar packagings built to U.S. specifications. Comments should address whether there are safety or operational considerations we should examine before expanding reciprocal treatment beyond the amendments we propose in this NPRM.

We are proposing to remove the statement currently in § 171.12a(a) concerning TDG reciprocal provisions for U.S. shipments. The statement is not regulatory in nature and, thus, is not appropriate for inclusion in the HMR. We also propose to remove the information currently contained in § 171.12a(b) that tells the reader how to obtain copies of the Canadian TDG Regulations; this is covered in the Reference Material provisions of § 171.7.

F. Combustible Liquids

When packaged in non-bulk packagings, a material with a flashpoint of 38 °C (100 °F) or more but less than 60.5 °C (141 °F) may be classed as a combustible liquid under the HMR. Such materials are not subject to the provisions of the HMR when transported by highway or rail. However, these same materials are regulated as flammable liquids when transported by vessel in accordance with the IMDG Code or by air under the ICAO Technical Instructions. We are proposing to include a statement indicating that a material reclassified as a combustible liquid under the HMR may require classification as a flammable liquid when offered for transportation or transported internationally.

A material with a flashpoint greater than 60.5 °C (141 °F) is not regulated as a hazardous material under the ICAO Technical Instructions or the IMDG Code; however, a material with a flashpoint between 60.5 °C (141 °F) and 93 °C (200 °F) is regulated as a combustible liquid under the HMR. When transported in bulk packages, a combustible liquid must be placarded with a COMBUSTIBLE placard (see § 172.544). The COMBUSTIBLE placard is not recognized overseas; thus, shipments prepared to comply with the HMR may be frustrated internationally by inspectors and enforcement personnel who are not familiar with the U.S. requirements. To avoid such frustration, shippers and carriers may remove the COMBUSTIBLE placard prior to placing the shipment on board a vessel for overseas shipment. However, these efforts are complicated by the requirement for the COMBUSTIBLE placard to remain on bulk packages while in the United States. Shipments originating overseas and bound for the United States encounter a similar problem when the shipment arrives in the United States, and the COMBUSTIBLE placard must be affixed prior to the shipment's movement. Therefore, in this NPRM, we are proposing an exception from placarding for bulk shipments of combustible liquids in port areas.

IV. Rulemaking Analyses and Notices

A. Statutory/Legal Authority for This Rulemaking

Under § 5120(b) of Federal hazmat law, the Secretary of Transportation must ensure that, to the extent practicable, regulations governing the transportation of hazardous materials in commerce are consistent with standards adopted by international authorities. We are proposing revisions to the requirements authorizing the use of international standards and regulations in the United States. The continually increasing amount of hazardous materials transported in international commerce warrants harmonization of domestic and international requirements to the greatest extent possible. Harmonization serves to facilitate international transportation; at the same time, harmonization ensures the safety of people, property, and the environment by reducing the potential for confusion and misunderstanding that could result if shippers and transporters were required to comply with two or more conflicting sets of regulatory requirements.

B. Executive Order 12866 and DOT Regulatory Policies and Procedures

This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and was not reviewed by the Office of Management and Budget. This proposed rule is a non-significant rule under the Regulatory Policies and Procedures of the Department of Transportation [44 FR 11034].

This proposed rule reorganizes and clarifies the conditions and limitations on the use of international standards and regulations for transporting hazardous materials in the United States. The proposed rule also removes unnecessary and outdated requirements and includes provisions to increase shipper flexibility for the transport of hazardous materials to Canada. The proposed rule includes a new requirement for shipping papers to include an indication of the international standard or regulation being used; the impact of this new requirement is expected to be minimal.

C. Executive Order 13132

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). Any rule resulting from this rulemaking will preempt State, local and Indian tribe requirements but will not have substantial direct effects on the States, the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal hazmat law contains an express preemption provision (49 U.S.C. 5125(b)) that preempts State, local, and Indian tribe requirements on certain covered subjects. Covered subjects are:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous materials; or

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified

for use in transporting hazardous material.

This proposed rule addresses covered subject items (1), (2), (3), and (5) above and would preempt State, local, and Indian tribe requirements not meeting the ''substantively the same'' standard. Federal hazmat law provides at section 5125(b)(2) that, if DOT issues a regulation concerning any of the covered subjects, DOT must determine and publish in the **Federal Register** the effective date of Federal preemption. The effective date may not be earlier than the 90th day following the date of issuance of a final rule and not later than two years after the date of issuance. The proposed effective date of Federal preemption for this rule is (90 days after publication of a final rule).

D. Executive Order 13175

This proposed rule was analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because this proposed rule does not have tribal implications, does not impose substantial direct compliance costs, and is required by statute, the funding and consultation requirements of Executive Order 13175 do not apply.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines the rule is not expected to have a significant impact on a substantial number of small entities. While the requirements in this NPRM apply to a substantial number of small entities, there will not be a significant economic impact on those small entities.

Identification of potentially affected small entities. Businesses likely to be affected by the rule are persons who offer for transportation or transport hazardous materials in commerce, including hazardous materials manufacturers and distributors; transportation companies, including air, highway, rail, and vessel carriers; hazardous waste generators; and container and packaging manufacturers.

Unless alternative definitions have been established by the agency in consultation with the Small Business Administration (SBA), the definition of ''small business'' has the same meaning as under the Small Business Act. Since no such special definition has been established, we employ the thresholds published by SBA for establishments that will be subject to the proposed amendments if adopted. Based on data for 1997 compiled by the U.S. Census Bureau, upwards of 95 percent of persons that would be affected by this rule are small businesses.

Reporting and recordkeeping requirements. This proposed rule includes no new requirements for reporting or recordkeeping.

Related Federal rules and regulations. There are no related Federal rules or regulations governing the transportation of hazardous materials in domestic or international commerce.

Alternate proposals for small businesses. The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where it is possible to do so and still meet the objectives of applicable regulatory statutes. In the case of hazardous materials transportation, it is not possible to establish exceptions or differing standards and still accomplish our safety objectives.

Conclusion. While the proposed rule would apply to a substantial number of small entities, there will not be a significant impact on those entities. This proposed rule reorganizes and clarifies the conditions and limitations on the use of international standards and regulations for transporting hazardous materials in the United States. The proposed rule also removes unnecessary and outdated requirements and includes provisions to increase shipper flexibility for the transport of hazardous materials to Canada. The proposed rule adds a requirement for shipping papers to include an identification of the international standard or regulation being used; the impact of this new requirement is expected to be minimal.

This proposed rule has been developed in accordance with Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts of draft rules on small entities are properly considered.

F. Paperwork Reduction Act

This NPRM may result in a minimal increase in information collection and recordkeeping burden under OMB Control Number 2137–0034, due to changes to the HMR requiring shipping papers to include an indication of the international transport standard or regulation (ICAO, IMDG, TDG or IAEA) under which the hazardous materials are being transported. PHMSA currently has an approved information collection under OMB Control Number 2137–0034, ''Hazardous Materials Shipping Papers & Emergency Response Information'' with 6,500,000 burden hours and expires on May 31, 2008.

Section 1320.8(d), Title 5, Code of Federal Regulations requires PHMSA to provide interested members of the public and affected agencies an opportunity to comment on information collection and recordkeeping requests. This notice identifies a new information collection request that PHMSA will submit to OMB for approval based on the requirements in this proposed rule.

Requests for a copy of this information collection should be directed to Deborah Boothe or T. Glenn Foster, Office of Hazardous Materials Standards (PHH–11), Pipeline and Hazardous Materials Safety Administration, Room 8430, 400 Seventh Street, SW., Washington, DC 20590–0001, Telephone (202) 366–8553.

Written comments should be addressed to the Dockets Unit as identified in the **ADDRESSES** section of this rulemaking. We must receive comments regarding information collection burdens prior to the close of the comment period identified in the **DATES** section of this rulemaking. Under the Paperwork Reduction Act of 1995, no person is required to respond to an information collection unless it displays a valid OMB control number.

G. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

H. Unfunded Mandates Reform Act

This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $120.7 million or more to either State, local or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the rule.

I. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA) requires Federal agencies to consider the consequences of major Federal actions and prepare a detailed statement on actions significantly affecting the quality of the human environment.

We regulate hazardous materials transported by aircraft, vessel, rail, and highway. The potential for

environmental damage or contamination exists when packages of hazardous materials are involved in accidents or en route incidents resulting from cargo shifts, valve failures, package failures, or loading, unloading, or handling problems. The ecosystems that could be affected by a release include air, water, soil, and ecological resources (for example, wildlife habitats). The adverse environmental impacts associated with releases of most hazardous materials are short-term impacts that can be greatly reduced or eliminated through prompt clean up of the accident scene. Most hazardous materials are not transported in quantities sufficient to cause significant, long-term environmental damage if they are released.

The hazardous material regulatory system is a risk management system that is prevention oriented and focused on identifying a hazard and reducing the probability and quantity of a hazardous material release. Hazardous materials are categorized by hazard analysis and experience into hazard classes and packing groups. The regulations require each shipper to classify a material in accordance with these hazard classes and packing groups; the process of classifying a hazardous material is itself a form of hazard analysis. Further, the regulations require the shipper to communicate the material's hazards through use of the hazard class, packing group, and proper shipping name on the shipping paper and the use of labels on packages and placards on transport vehicles. Thus the shipping paper, labels, and placards communicate the most significant findings of the shipper's hazard analysis. A hazardous material is assigned to one of three packing groups based upon its degree of hazard, from a high hazard, Packing Group I to a low hazard, Packing Group III material. The quality, damage resistance, and performance standards of the packaging in each packing group are appropriate for the hazards of the material transported.

The proposals in this NPRM will improve the effectiveness of the HMR by clarifying the conditions under which international transport standards and regulations may be used for shipments transported in the United States. When used as authorized in this NPRM, the international standards and regulations provide an equivalent level of safety and environmental protection as the HMR. Thus, there are no significant environmental impacts associated with this proposed rule.

J. Privacy Act

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the document (or signing the document, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), which may also be found at *http://dms.dot.gov*.

List of Subjects

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 172

Education, Hazardous materials transportation, Hazardous waste, Labeling, Markings, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 175

Air carriers, Hazardous materials transportation, Incorporation by reference, Radioactive materials, Reporting and recordkeeping requirements.

49 CFR Part 176

Hazardous materials transportation, Maritime carriers, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, we propose to amend 49 CFR Chapter I as follows:

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

1. The authority citation for part 171 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.45 and 1.53; Pub. L. 101–410 section 4 (28 U.S.C. 2461 Note); Pub. L. 104–134 section 31001.

2. In part 171, §§ 171.1 through 171.14 are designated as subpart A and a new subpart A heading is added immediately before § 171.1 to read as follows:

Subpart A—Applicability and General Requirements

* * * * *

§ 171.7 [Revised]

3. In § 171.7, in paragraph (a)(3), in the Table of Material Incorporated by Reference, the following changes are made:

a. The entry ''Canadian General Standards Board'' is added in alphabetical order.

b. The entry ''Canadian Standards Association'' is added in alphabetical order.

c. Under the entry ''International Atomic Energy Agency (IAEA),'' in the entry ''IAEA, Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS–R–1 (ST–1, Revised)'', in the second column, remove ''171.12'' and add ''171.22, 171.27'' in its place.

d. Under the entry ''International Civil Aviation Organization (ICAO)'', in the entry ''Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions), 2005–2006 Edition'', in the second column, remove ''171.11'' and add ''171.22, 171.23, 171.24'' in its place.

e. Under the entry ''International Maritime Organization (IMO)'', in the entry ''International Maritime Dangerous Goods (IMDG) Code, 2004 Edition, Incorporating Amendment 32–04 (English Edition), Volumes 1 and 2'', in the second column, remove ''171.12'' and add ''171.22, 171.23, 171.25'' in its place.

f. Under the entry ''Transport Canada'', revise the entire entry for ''Transportation of Dangerous Goods (TDG) Regulations, August 2001 including Clear Language Amendments SOR/2001–286, Amendment 1 (SOR/2001–306) August 8, 2002; Amendment 2 (SOR/2003–273) July 24, 2003; and Amendment 3 (SOR/2003–400) December 3, 2003''.

The amendments read as follows:

§ 171.7 Reference material.

(a) * * *

(3) *Table of material incorporated by reference.* * * *

Source and name of material	49 CFR reference
* * * * * * *	
Canadian General Standards Board, Place du Portage III, 6B1 11 Laurier Street, Gatineau, Quebec, Canada K1A 1G6	
National Standard of Canada (CAN/CGSB 43.147–2005) Construction, Modification, Qualification, Maintenance, and Selection and Use of Means of Containment for the Handling, Offering for Transport, or Transportation of Dangerous Goods by Rail.	171.26
Canadian Standards Association, 5060 Spectrum Way, Mississauga, Ontario, Canada L4W 5N6	
CSA Standard B620–2003, Highway Tanks and Portable Tanks for the Transportation of Dangerous Goods, July 2003.	171.26
* * * * * * *	
Transport Canada * * *	
Transportation of Dangerous Goods (TDG) Regulations, August 2001 including Clear Language Amendments SOR/2001–286, Amendment 1 (SOR/2002–306) August 8, 2002; Amendment 2 (SOR/2003–273) July 24, 2003; Amendment 3 (SOR/2003–400) December 3, 2003; and Amendment 5 (SOR/2005–279) September 21, 2005.	171.22; 171.23; 171.26; 172.401; 172.502; 172.519; 172.602; 173.301.
* * * * * * *	

§§ 171.11; 171.12; and 171.12a [Removed and Reserved]

4. Remove and reserve §§ 171.11; 171.12; and 171.12a.

5. In part 171, §§ 171.15 through 171.21 are designated as subpart B and a new subpart B heading is added immediately before § 171.15 to read as follows:

Subpart B—Incident Reporting, Notification, BOE Approvals and Authorization

* * * * *

6. In Part 171, new Subpart C is added to read as follows:

Subpart C—Authorization and Requirements for the Use of International Transport Standards and Regulations

Sec.

§ 171.22 Authorization and conditions for use of international standards and regulations.

(a) *Authorized international standards and regulations.* This subpart authorizes, with certain conditions and limitations, the offering for transportation and the transportation in commerce of hazardous materials to, from, or within the United States in accordance with the International Civil Aviation Organization's Technical Instructions for the Transport of Dangerous Goods by Air (ICAO Technical Instructions), the International Maritime Dangerous Goods Code (IMDG Code), the Canadian Transportation of Dangerous Goods Regulations (TDG Regulations), and the International Atomic Energy Agency Regulations for the Safe Transport of Radioactive Material (IAEA Regulations) (IBR, see § 171.7 of this subchapter).

(b) *Compliance.* No person may offer for transportation or transport a hazardous material in commerce in the United States in accordance with the ICAO Technical Instructions, the IMDG Code, Canada's TDG Regulations, or the IAEA Regulations unless the hazardous materials is offered for transportation and transported in accordance with this subpart.

(c) *Limitations on the use of international standards and regulations.* A person may offer for transportation or transport a hazardous material in accordance with the international standards and regulations authorized in paragraph (a) of this section provided:

(1) The hazardous material is subject to the requirements of the applicable international standard or regulation and is offered for transportation or transported in conformance with the applicable standard or regulation; and

(2) The shipment conforms to all applicable requirements of this subpart.

(d) *Materials excepted from regulation under international standards and regulations.* A material designated as a hazardous material under this subchapter, but excepted from or not subject to the international transport standards and regulations authorized in paragraph (a) of this section (*e.g.*, paragraph 1.16 of the TDG Regulations excepts from regulation quantities of hazardous materials less than or equal to 500 kg gross transported by rail) must be transported in accordance with all applicable requirements of this subchapter.

(e) *Materials not regulated under this subchapter.* Materials not designated as hazardous materials under this subchapter but regulated by an international transport standard or regulation authorized in paragraph (a) of this section may be offered for transportation and transported in the United States in full compliance (*i.e.*, packaged, marked, labeled, classed, described, stowed, segregated, secured, etc.) with the applicable international transport standard or regulation.

(f) *Forbidden materials.* No person may offer for transportation or transport a hazardous material that is a forbidden material or package as designated in:

(1) Section 173.21 of this subchapter;

(2) Column (3) of the § 172.101 Table of this subchapter;

(3) Column (9A) of the § 172.101 Table of this subchapter when offered for transportation or transported on passenger aircraft or railcar; or

(4) Column (9B) of the § 172.101 Table of this subchapter when offered for transportation or transported by cargo aircraft.

(g) *Complete information and certification.* (1) Except for shipments into the United States from Canada conforming to § 171.26, each person importing a hazardous material into the United States must provide the forwarding agent at the place of entry into the United States with timely and complete written information as to the requirements of this subchapter applicable to the particular shipment.

(2) The shipper, directly or through the forwarding agent at the place of entry, must provide the initial U.S. carrier with the shipper's certification required by § 172.204 of this subchapter. A carrier may not accept a hazardous material for transportation unless provided a shipper's certification.

(3) All shipping paper information and package markings required in accordance with this subchapter must be in English. The use of shipping papers and a package marked with both English and a language other than English, in order to dually comply with this subchapter and the regulations of a foreign entity, is permitted under this subchapter.

(4) A shipping paper must include the letters ''ICAO'' for a hazardous material offered for transportation in accordance with the ICAO Technical Instructions; ''IMDG'' for a hazardous material offered for transportation in accordance with the IMDG Code; ''TDG'' for a hazardous material offered for transportation in accordance with Canada's TDG Regulations; or ''IAEA'', for a hazardous material offered for transportation in accordance with the IAEA Regulations.

(5) Each person who provides or receives a shipping paper must retain a copy of the shipping paper or an electronic image thereof that is accessible at or through its principal place of business in accordance with § 172.201(e) of this part.

(h) *Additional requirements for the use of international standards and regulations.* All shipments offered for transportation or transported in the United States in accordance with this subpart must conform to the following requirements of this subchapter, as applicable:

(1) The emergency response information requirements in subpart G of part 172 of this subchapter;

(2) The training requirements in subpart H of part 172 of this subchapter, including function-specific training in the use of the international transport standards and regulations authorized in paragraph (a) of this section, as applicable;

(3) The security requirements in subpart I of part 172 of this subchapter;

(4) The incident reporting requirements in §§ 171.15 and 171.16 of this part for incidents occurring within the jurisdiction of the United States including on board vessels in the navigable waters of the United States and aboard aircraft of United States registry anywhere in air commerce;

(5) For export shipments, the general packaging requirements in §§ 173.24 and 173.24a of this subchapter;

(6) The requirements for the reuse, reconditioning, and remanufacture of packagings in § 173.28 of this subchapter; and

(7) The registration requirements in subpart G of part 107 of this chapter.

§ 171.23 Requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Canada's TDG Regulations, or the IAEA Regulations.

All shipments offered for transportation or transported in the United States under the ICAO Technical Instructions, IMDG Code, Canada's TDG Regulations, or the IAEA Regulations must conform to the requirements of this section, as applicable.

(a) *Conditions and requirements for cylinders.* Except as provided in this subchapter, a filled non-DOT specification cylinder, other than a DOT exemption cylinder or a cylinder used as a fire extinguisher in conformance with § 173.309 of this subchapter, may not be offered for transportation or transported to, from, or within the United States. A cylinder manufactured to other than a DOT specification and certified as being in conformance with the transportation standards of another country may be authorized for transportation within a single port, upon written request to, and approval by, the Associate Administrator provided the following requirements are met:

(1) The cylinder must be transported in a closed freight container;

(2) The cylinder is certified by the importer to provide a level of safety at least equivalent to that required by the requirements in this subchapter for a comparable DOT specification cylinder; and

(3) The cylinder is not refilled for export unless in compliance with filling of non-DOT specification cylinder requirements of this subpart for export by any mode of transportation.

(b) *Conditions and requirements specific to certain materials.* (1) *Aerosols.* Except for a limited quantity of a compressed gas in a container of not more than 4 fluid ounces capacity meeting the requirements in § 173.306(a)(1) of this subchapter, the use of the proper shipping name ''Aerosol,'' UN1950, may be used only for a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a nonpoisonous (other than Division 6.1, Packing Group III material) liquid, paste, or powder and fitted with a self-closing release device (see § 171.8). In addition, an aerosol must be in a metal packaging when the packaging exceeds 7.22 cubic inches.

(2) *Air bag inflator, air bag module and seat-belt pretensioner.* For each approved air bag inflator, air bag module and seat-belt pretensioner, the shipping paper description must conform to the requirements in § 173.166(c) of this subchapter:

(i) The EX number or product code must be included in association with the basic shipping description. When a product code is used, it must be traceable to the specific EX number assigned to the inflator, module or seat-belt pretensioner by the Associate Administrator. The EX number or product code is not required to be marked on the outside package.

(ii) The proper shipping name ''Articles, pyrotechnic *for technical purposes*, UN0431'' must be used for all air bag inflators, air bag modules, and seat-belt pretensioners meeting the criteria for a Division 1.4G material.

(3) *Chemical oxygen generators.* Chemical oxygen generators must be approved, classed, described, packaged, and transported in accordance with the requirements of this subchapter.

(4) *Class 1 (explosive) materials.* Prior to being transported, Class 1 (explosive) materials must be approved by the Associate Administrator in accordance with § 173.56 of this subchapter. Each package containing a Class 1 (explosive) material must conform to the marking requirements in § 172.320 of this subchapter.

(5) *Combustible liquids.* A Class 3 material with a flashpoint of at least 38 °C (100 °F) but less than 60.5 °C (141 °F) that is authorized to be reclassified as a combustible liquid in accordance with § 173.150(f) of this subchapter should be packaged, described, marked, labeled and certified as a flammable liquid when offered for transportation or transported in accordance with the ICAO Technical Instructions, IMDG Code, or Canada's TDG Regulations.

(6) *Hazardous substances.* Except for Class 7 (radioactive) materials, a material meeting the definition of a hazardous substance as defined in § 171.8, must conform to the shipping paper requirements in § 172.203(c) of this subchapter and the marking requirements in § 172.324 of this subchapter:

(i) The proper shipping name must identify the hazardous substance by name, or the name of the substance must be entered in parentheses in association with the basic description and marked on the package in association with the proper shipping name. If the hazardous substance meets the definition for a hazardous waste, the

waste code (for example, D001), may be used to identify the hazardous substance;

(ii) The shipping paper and the package markings must identify at least two hazardous substances with the lowest reportable quantities (RQs) when the material contains two or more hazardous substances; and

(iii) The letters ''RQ'' must be entered on the shipping paper either before or after the basic description, and marked on the package in association with the proper shipping name for each hazardous substance listed.

(7) *Hazardous wastes.* A material meeting the definition of a hazardous waste (see § 171.8) must conform to the following:

(i) The shipping paper and the package markings must include the word ''Waste'' immediately preceding the proper shipping name;

(ii) The shipping paper must be retained by the shipper and by each carrier for three years after the material is accepted by the initial carrier (see § 172.205(e)(5)); and

(iii) A hazardous waste manifest must be completed in accordance with § 172.205 of this subchapter.

(8) *Marine pollutants.* Except for marine pollutants (see § 171.8) transported in accordance with the IMDG Code, marine pollutants transported in bulk packages must meet the shipping paper requirements in § 172.203(l) of this subchapter and the package marking requirements in § 172.322 of this subchapter.

(9) *Organic peroxides.* Organic peroxides not identified by technical name in the Organic Peroxide Table in § 173.225(b) of this subchapter must be approved by the Associate Administrator in accordance with § 173.128(d) of this subchapter.

(10) *Poisonous materials, Division 6.1.* (i) For liquid or solid poisonous materials meeting the definition of Division 6.1, Packing Group I or II, the word ''Poison'' or ''Toxic'' must be included on the shipping paper in association with the basic description when the shipping name or hazard class does not describe the material as a poison or toxic material.

(ii) Division 6.1 hazardous materials transported as limited quantities are not excepted from labeling (see § 173.153(b)).

(11) *Poisonous by inhalation materials.* A material poisonous by inhalation (see § 171.8) must conform to the following requirements:

(i) The words ''Poison-Inhalation Hazard'' or ''Toxic-Inhalation Hazard'' and the words ''Zone A,'' ''Zone B,'' ''Zone C,'' or ''Zone D'' for gases, or ''Zone A'' or ''Zone B'' for liquids, as appropriate, must be entered on the shipping paper immediately following the basic shipping description. The word ''Poison'' or ''Toxic'' or the phrase ''Poison-Inhalation Hazard'' or ''Toxic-Inhalation Hazard'' need not be repeated if it otherwise appears in the shipping description;

(ii) The material must be packaged in accordance with the requirements of this subchapter;

(iii) The package must be marked in accordance with § 172.313 of this subchapter; and

(iv) The package must be labeled or placarded with POISON INHALATION HAZARD or POISON GAS, as appropriate, in accordance with Subparts E and F of Part 172 of this subchapter.

(A) For a package transported in accordance with the IMDG Code in a closed transport vehicle or freight container, a label or placard conforming to the IMDG Code specifications for a ''Class 2.3'' or ''Class 6.1'' label or placard may be substituted for the POISON GAS or POISON INHALATION HAZARD label or placard, as appropriate. The transport vehicle or freight container must be marked with the identification numbers for the hazardous material, regardless of the total quantity contained in the transport vehicle or freight container, in the manner specified in § 172.313(c) of this subchapter and placarded as required by subpart F of part 172 of this subchapter.

(B) For a package transported in accordance with Canada's TDG Regulations in a closed transport vehicle or freight container, a label or placard conforming to the TDG Regulations specifications for a ''Class 2.3'' or ''Class 6.1'' label or placard may be substituted for the POISON GAS or POISON INHALATION HAZARD label or placard, as appropriate. The transport vehicle or freight container must be marked with the identification numbers for the hazardous material, regardless of the total quantity contained in the transport vehicle or freight container, in the manner specified in § 172.313(c) of this subchapter and placarded as required by subpart F of part 172 of this subchapter. While in transportation in the United States, the transport vehicle or freight container may also be placarded in accordance with the appropriate TDG Regulations in addition to being placarded with the POISON GAS or POISON INHALATION HAZARD placards.

(12) *Class 7 (radioactive) materials.* (i) Highway route controlled quantities (see § 173.403 of this subchapter) must be shipped in accordance with §§ 172.203(d)(4) and (d)(10); 172.507, and 173.22(c) of this subchapter;

(ii) For fissile materials and Type B, Type B(U), and Type B(M) packagings, the competent authority certification and any necessary revalidation must be obtained from the appropriate competent authorities as specified in §§ 173.471, 173.472, and 173.473 of this subchapter, and all requirements of the certificates and revalidations must be met;

(iii) Type A package contents are limited in accordance with § 173.431 of this subchapter;

(iv) The country of origin for the shipment must have adopted the edition of TS–R–1 of the IAEA Regulations referenced in § 171.7;

(v) The shipment must conform to the requirements of § 173.448, when applicable;

(vi) The definition for ''radioactive material'' in § 173.403 of this subchapter must be applied to radioactive materials transported under the provisions of this subpart;

(vii) Except for limited quantities, the shipment must conform to the requirements of § 172.204(c)(4) of this subchapter; and

(viii) Excepted packages of radioactive material, instruments or articles, or articles containing natural uranium or thorium must conform to the requirements of §§ 173.421, 173.424, or 173.426 of this subchapter, as appropriate.

(13) *Self-reactive materials.* Self-reactive materials not identified by technical name in the Self-reactive Materials Table in § 173.224(b) of this subchapter must be approved by the Associate Administrator in accordance with § 173.124(a)(2)(iii) of this subchapter.

§ 171.24 Additional requirements for the use of the ICAO Technical Instructions.

(a) A hazardous material may be offered for transportation or transported within the United States by aircraft, and by motor vehicle or rail either before or after being transported by aircraft in accordance with the ICAO Technical Instructions (IBR; see § 171.7), as authorized in paragraph (a) of § 171.22, provided the requirements in § 171.22, as applicable, and this section are met.

(b) Any person who offers for transportation or transports a hazardous material in accordance with the ICAO Technical Instructions must conform to the following additional conditions and requirements:

(1) All applicable requirements in parts 171 and 175 of this subchapter (also see 14 CFR 121.135, 121.401,

121.433a, 135.323, 135.327 and 135.333);

(2) The quantity limits prescribed in the ICAO Technical Instructions for transportation by passenger-carrying or cargo aircraft, as applicable;

(3) The conditions or requirements of a United States variation, when specified in the ICAO Technical Instructions.

(c) Highway transportation. For transportation by highway prior to or after transportation by aircraft, a shipment must conform to the applicable requirements of part 177 of this subchapter, and the motor vehicle must be placarded in accordance with subpart F of part 172.

(d) Conditions and requirements specific to certain materials. Hazardous materials offered for transportation or transported in accordance with the ICAO Technical Instructions must conform to the following specific conditions and requirements, as applicable:

(1) Batteries. (i) Nonspillable wet electric storage batteries. Nonspillable wet electric storage batteries are not subject to the requirements of this subchapter provided:

(A) The battery meets the conditions specified in Special Provision 67 of the ICAO Technical Instructions;

(B) The battery, its outer packaging, and any overpack are plainly and durably marked ''NONSPILLABLE'' or ''NONSPILLABLE BATTERY''; and

(C) The batteries or battery assemblies are offered for transportation or transported in a manner that prevents short circuiting or forced discharge, including, but not limited to, protection of exposed terminals.

(ii) Primary lithium batteries and cells. Primary lithium batteries and cells may not be transported aboard passenger carrying aircraft. Equipment containing or packed with primary lithium batteries or cells may not be transported aboard passenger-carrying aircraft except as provided in § 172.102, Special Provision A101 or A103, of this subchapter. Except for primary lithium batteries and cells contained in or packed with equipment, packagings containing primary lithium batteries and cells meeting the exceptions in § 173.185(b) and (c) of this subchapter must be marked ''PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT'' and may be transported aboard cargo-only aircraft.

(iii) Prototype lithium batteries and cells. Prototype lithium batteries and cells are forbidden for transport aboard passenger aircraft and must be approved by the Associate Administrator prior to transportation aboard cargo aircraft, in accordance with the requirements of Special Provision A55 in § 172.102 of this subchapter.

(2) Oxygen cylinders. A cylinder containing *''Oxygen, compressed''* may not be transported aboard a passenger-carrying aircraft, or in an inaccessible cargo location aboard a cargo-only aircraft, unless it is packaged as required by parts 173 and 178 of this subchapter and is placed in an overpack or outer packaging that satisfies the requirements of Special Provision A52 in § 172.102.

§ 171.25 Additional requirements for the use of the IMDG Code.

(a) A hazardous material may be offered for transportation or transported to, from, or within the United States by vessel, and by motor carrier and rail in accordance with the IMDG Code (IBR; see § 171.7 of this subchapter), as authorized in § 171.22, provided all or part of the transportation is by vessel and the requirements in § 171.22, as applicable, and this section are met.

(b) Any person who offers for transportation or transports a hazardous material in accordance with the IMDG Code must conform to the following additional conditions and requirements:

(1) Unless otherwise excepted, a shipment must conform to the requirements in part 176 of this subchapter. For transportation by rail or highway prior to or subsequent to transportation by vessel, a shipment must conform to the applicable requirements of parts 174 and 177 respectively, of this subchapter, and the motor vehicle or rail car must be placarded in accordance with subpart F of part 172 of this subpart. When a hazardous material regulated by this subchapter for transportation by highway is transported by motor vehicle on a public highway under the provisions of this subpart, the segregation requirements of part 7, Chapter 2 of the IMDG Code are authorized.

(2) The stowage and segregation requirements in part 7 of the IMDG Code may be substituted for the stowage and segregation requirements in part 176 of this subchapter.

(c) Conditions and requirements for bulk packagings. Except for IBCs and UN portable tanks used for the transportation of liquids or solids, the bulk packaging requirements of this subchapter must be met. Additionally, the following requirements apply:

(1) UN portable tanks must conform to the requirements in Special Provisions TP37, TP38, TP44 and TP45 when applicable, and any applicable bulk special provisions assigned to the hazardous material in the Hazardous Materials Table in § 172.101 of this subchapter;

(2) IMO Type 5 portable tanks must conform to DOT Specification 51 or UN portable tank requirements, unless specifically authorized in this subchapter or approved by the Associate Administrator;

(3) Except as specified in this subpart, for a material poisonous (toxic) by inhalation, the T Codes specified in Column 13 of the Dangerous Goods List in the IMDG Code may be applied to the transportation of those materials in IM, IMO and DOT Specification 51 portable tanks, when these portable tanks are authorized in accordance with the requirements of this subchapter; and

(4) No person may offer an IM or UN portable tank containing liquid hazardous materials of Class 3, PG I or II, or PG III with a flash point less than 100 § F (38 § C); Division 5.1, PG I or II; or Division 6.1, PG I or II, for unloading while it remains on a transport vehicle with the motive power unit attached, unless it conforms to the requirements in § 177.834(o) of this subchapter.

(d) Use of IMDG Code in port areas. (1) Except for Division 1.1, 1.2, and Class 7 materials, a hazardous material being imported into or exported from the United States or passing through the United States in the course of being shipped between locations outside the United States may be offered and accepted for transportation and transported by motor vehicle within a single port area, including contiguous harbors, when packaged, marked, classed, labeled, stowed and segregated in accordance with the IMDG Code, offered and accepted in accordance with the requirements of subparts C and F of part 172 of this subchapter pertaining to shipping papers and placarding, and otherwise conforms to the applicable requirements of part 176 of this subchapter. When offered for transportation or transported in international transportation (see § 171.8 of this subchapter) a combustible liquid (see § 173.120(b)(1) of this subchapter) is excepted from placarding when transported in a single port area, placed on board a vessel for export, or on board a vessel as an import shipment.

(2) The requirement in § 172.201(d) of this subchapter for an emergency telephone number does not apply to shipments made in accordance with the IMDG Code if the hazardous material is not off-loaded from the vessel, or is off-loaded between ocean vessels at a U.S. port facility without being transported by public highway.

§ 171.26 Additional requirements for the use of Canada's TDG Regulations.

(a) A hazardous material shipment originating in Canada and either terminating in the United States or transiting the United States to Canada or a foreign destination may be offered for transportation or transported by motor carrier and rail in accordance with Canada's TDG Regulations (IBR; see § 171.7 of this subchapter) as authorized in § 171.22, provided the requirements in § 171.22, as applicable, and this section are met. Except as otherwise provided in this subpart, the requirements in parts 172, 173, and 178 of this subchapter do not apply for a material transported in accordance with the TDG if all other requirements of this subpart and the TDG Regulations are met.

(b) *Packaging requirements.* (1) *General.* When the provisions of this subchapter require a DOT specification or UN standard packaging to be used for transporting a hazardous material, a packaging authorized by the TDG Regulations may be used, subject to the limitations of this subpart, and only if it is equivalent to the corresponding DOT specification, UN packaging (see § 173.24(d)(2) of this subchapter) authorized by this subchapter.

(2) *Bulk packagings.* A bulk packaging equivalent to a corresponding DOT specification and conforming to and authorized by the TDG Regulations may be used provided:

(i) An equivalent type of packaging is authorized for the hazardous material according to the § 172.101 table of this subchapter;

(ii) The bulk packaging conforms to the requirements of the applicable part 173 bulk packaging section specified in the § 172.101 table for the material to be transported;

(iii) The bulk packaging conforms to the requirements of all assigned bulk packaging, IBC, and portable tank special provisions (B codes, IB and IP codes, and T and TP codes) in § 172.102 of this subchapter; and

(iv) The bulk packaging conforms to all applicable requirements of §§ 173.31, 173.32, 173.33 and 173.35 of this subchapter, and parts 177 and 180 of this subchapter. The periodic retests and inspections required by §§ 173.31, 173.32 and 173.33 of this subchapter may be performed in accordance with Part 180 of this subchapter or in accordance with the requirements of the TDG Regulations provided that the intervals prescribed in part 180 of this subchapter are met.

(3) *Shipments to Canada.* A cargo tank motor vehicle, rail tank car, or portable tank authorized under the TDG Regulations may be used to transport a hazardous material from the United States to Canada provided the portable tank, cargo tank motor vehicle, or rail tank car conforms to the applicable requirements of this paragraph (b). Highway tanks and portable tanks must conform to the requirements of Canadian Standards Association standard B620–2003 (IBR: see § 171.7 of this subchapter). Rail tank cars must conform to the requirements of Canadian General Standards Board standard 43.146–2005 (IBR; see § 171.7 of this subchapter).

(4) *Cylinders.* A Canadian Transport Commission (CTC) or Transport Canada (TC) specification cylinder manufactured, originally marked, and approved in accordance with the TDG regulations, and in full conformance with the TDG Regulations is authorized for transportation to, from or within the United States provided:

(i) The CTC or TC specification cylinder corresponds with a DOT specification cylinder and the markings are the same as those specified in this subchapter, except that the original markings were ''CTC'' or ''TC'';

(ii) The CTC or TC cylinder has been requalified under a program authorized by the TDG regulations or requalified in accordance with the requirements in § 180.205 of this subchapter within the prescribed requalification period specified for the corresponding DOT specification;

(iii) When the regulations authorize a cylinder for a specific hazardous material with a specification marking prefix of ''DOT,'' a cylinder marked ''CTC'' or ''TC'' otherwise bearing the same markings required of the specified ''DOT'' cylinder may be used; and

(iv) Transportation of the cylinder and the material it contains is in all other respects in conformance with the requirements of this subchapter (for example, valve protection, filling requirements, operational requirements, etc.).

(c) *Class 1 (explosive) materials.* When transporting Class 1 (explosive) material, rail and motor carriers must comply with 49 CFR 1572.9 and 1572.11 to the extent the requirements apply.

§ 171.27 Additional requirements for the use of the IAEA Regulations.

A Class 7 (radioactive) material being imported into or exported from the United States or passing through the United States in the course of being shipped between places outside the United States may be offered for transportation or transported in accordance with the IAEA Regulations as authorized in paragraph (a) of § 171.22, provided the requirements in § 171.22, as applicable, are met.

§ 171.28 Shipments to or from Mexico.

(a) Except as provided in paragraph (b) of this section, hazardous material shipments transported to or from Mexico must conform to all applicable requirements of this subchapter when being transported within the United States.

(b) The requirements of this subchapter apply to a hazardous material meeting that definition of a material poisonous by inhalation (see § 171.8 of this subchapter), except a label or placard conforming to the UN Recommendations (IBR: see § 171.7 of this subchapter) specifications for a Class 2.3 or Class 6.1 label or placard may be substituted for the POISON INHALATION HAZARD or POISON GAS label or placard, as required by § 172.400(a) and 172.504(e) of this subchapter on a package transported in a closed transport vehicle or freight container. The transport vehicle or freight container must be marked with the identification number for the hazardous material regardless of the total quantity contained in the transport vehicle or freight container. The transport vehicle or freight container must be marked in the manner specified in § 172.313(c) of this subchapter, and placarded as required by subpart F of this subchapter.

PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, AND TRAINING REQUIREMENTS

7. The authority citation for part 172 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128; 44701; 49 CFR, 1.53.

8. In § 172.203, add paragraph (p) to read as follows:

§ 172.203 Additional description requirements.

* * * * *

(p) *Use of international standards and regulations.* A shipping paper must include, following the basic description, the acronym ''ICAO'' for a hazardous material offered for transportation in accordance with the ICAO Technical Instructions (IBR, see § 171.7 of this subchapter); ''IMDG'' for a hazardous material offered for transportation in accordance with the IMDG Code (IBR; see § 171.7of this subchapter); ''TDG'' for a hazardous material offered for transportation in accordance with Canada's TDG Regulations (IBR, see

§ 171.7 of this subchapter), or ''IAEA'', for a hazardous material offered for transportation in accordance with the IAEA Regulations (IBR; see § 171.7 of this subchapter). If a hazardous material is accompanied by hazard communications for more than one of the standards listed above then all applicable acronyms must be listed following the basic description of the hazardous material on the shipping paper.

9. In § 172.400a, paragraph (d) is revised to read as follows:

§ 172.400a Exceptions from labeling.

* * * * *

(d) A package containing a material poisonous by inhalation (see § 171.8 of this subchapter) in a closed transport vehicle or freight container may be excepted from the POISON INHALATION HAZARD or POISON GAS label or placard, under the conditions set forth in § 171.23(b)(11) of this subchapter.

10. In § 172.519, paragraph (f) is revised to read as follows:

§ 172.519 General specifications for placards.

* * * * *

(f) *Exceptions.* When hazardous materials are offered for transportation or transported under the provisions of subpart C of part 171 of this subchapter, a placard conforming to the specifications in the ICAO Technical Instructions, the IMDG Code, or Canada's TDG Regulations may be used in place of a corresponding placard conforming to the requirements of this subpart. However, a bulk packaging, transport vehicle, or freight container containing a material poisonous by inhalation (see § 171.8 of this subchapter) must be placarded in accordance with this subpart (see § 171.23(b)(11) of this subchapter).

* * * * *

11. In § 172.704, paragraph (a)(2)(ii) is revised to read as follows:

§ 172.704 Training requirements.

(a) * * *

(2) * * *

(ii) In addition to any relevant function-specific training requirements in this subchapter, training relating to the requirements of the ICAO Technical Instructions, IMDG Code, TDG Regulations and IAEA Regulations (IBR, see § 171.7 of this subchapter) must be provided to the extent such training addresses functions performed as authorized in subpart C of part 171 of this subchapter.

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

12. The authority citation for part 173 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.45, 1.53.

§ 173.21 [Amended]

13. In § 173.21, in paragraph (k), in the first sentence, the phrase ''including § 171.11 and'' is revised and the phrase ''including subpart C of part 171 and'' is inserted in its place.

14. In § 173.24, paragraphs (c)(2) and (i) are revised to read as follows:

§ 173.24 General requirements for packagings and packages.

* * * * *

(c) * * *

(2) The packaging is permitted under, and conforms to, provisions contained in subpart C of part 171 of this subchapter and §§ 173.3, 173.4, 173.5, 173.5a, 173.6, 173.7, 173.8, 173.27, or § 176.11 of this subchapter.

* * * * *

(i) *Air transportation.* Except as provided in subpart C of part 171 of this subchapter, packages offered or intended for transportation by aircraft must conform to the general requirements for transportation by aircraft in § 173.27.

15. In § 173.27, paragraph (f) introductory text is revised to read as follows:

§ 173.27 General requirements for transportation by aircraft.

* * * * *

(f) *Combination packagings.* Unless otherwise specified in this part, or in subpart C of part 171 of this subchapter, when combination packagings are offered for transportation aboard aircraft, inner packagings must conform to the quantity limitations set forth in Table 1 of this paragraph for transport aboard passenger-carrying aircraft and Table 2 of this paragraph for transport aboard cargo aircraft only, as follows:

* * * * *

16. In § 173.56, paragraph (g) is revised to read as follows:

§ 173.56 New explosives—definition and procedures for classification and approval.

* * * * *

(g) An explosive may be transported under subpart C of part 171 or § 176.11 of this subchapter without the approval of the Associate Administrator as required by paragraph (b) of this section if the Associate Administrator has acknowledged in writing the acceptability of an approval issued by the competent authority of a foreign government pursuant to the provisions of the UN Recommendations, the ICAO Technical Instructions, the IMDG Code (IBR; see § 171.7 of this subchapter), or other national or international regulations based on the UN Recommendations. In such a case, a copy of the foreign competent authority approval, and a copy of the written acknowledgement of its acceptance must accompany each shipment of that explosive.

* * * * *

PART 175—CARRIAGE BY AIRCRAFT

17. The authority citation for part 175 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.53.

18. In § 175.30, in paragraph (a)(2), the first sentence is revised to read as follows:

§ 175.30 Accepting and inspecting shipments.

(a) * * *

(2) Described and certified on a shipping paper prepared in duplicate in accordance with part 172 of this subchapter or as authorized by subpart C of part 171 of this subchapter. * * *

* * * * *

19. In § 175.33, paragraph (a)(1)(ii) is revised to read as follows:

§ 175.33 Notification of pilot-in-command.

(a) * * *

(1) * * *

(ii) The ICAO Technical Instructions (IBR, see § 171.7 of this subchapter), any additional information required to be shown on shipping papers by subpart C of part 171 of this subchapter must also be shown in the notification.

* * * * *

PART 176—CARRIAGE BY VESSEL

20. The authority citation for part 176 is revised to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.53.

21. In § 176.11:

A. Amend paragraph (a) introductory text by revising the first sentence.

B. Revise paragraph (b).

§ 176.11 Exceptions

(a) A hazardous material may be offered and accepted for transport by vessel when in conformance with the IMDG Code (IBR, see § 171.7 of this subchapter), subject to the conditions and limitations set forth in subpart C of part 171 of this subchapter. * * *

* * * * *

(b) Canadian shipments and packages may be transported by vessel if they are

transported in accordance with this subchapter. (See subpart C of part 171 of this subchapter.)

* * * * *

§ 176.24 [Amended]

22. In § 176.24, in paragraph (a), the phrase ''authorized by § 171.12 of this subchapter'' is removed and the phrase ''authorized by subpart C of part 171 of this subchapter'' is inserted in its place.

23. In § 176.27, in paragraph (b), the last sentence is revised to read as follows:

§ 176.27 Certificate.

* * * * *

(b) * * * See subpart C of part 171 of this subchapter.

* * * * *

Issued in Washington, DC, on January 10, 2006, under authority delegated in 49 CFR part 106.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety.

[FR Doc. 06–516 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–60–P

Notices

Federal Register
Vol. 71, No. 18
Friday, January 27, 2006

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

January 24, 2006.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: 7 CFR Part 1724, Electric Engineering Architectural Services and Design Policies.

OMB Control Number: 0572–0118.

Summary of Collection: The Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.*, authorization to Rural Utilities Service (RUS) make loans in several States and Territories of the United States for rural electrification and the furnishing and improving of electric energy to persons in rural areas. Title 7 CFR 1724 requires each borrower to select a qualified architect to perform certain architectural services and to use the designated form that provides for these services. The agency has developed standardized contractual forms used by borrowers to contract for services.

Need and Use of the Information: The information collected from the forms is on and as needed basis or when the individual borrower undertakes certain projects. The standardization of the forms by RUS has resulted in substantial savings to borrowers by reducing preparation of the documentation and the costly review by the government.

Description of Respondents: Business or other for-profit; Not-for-profit institutions.

Number of Respondents: 81.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 161.

Rural Utilities Service

Title: Advance of Loan Funds and Budgetary Control and Related Burdens.

OMB Control Number: 0572–0015.

Summary of Collection: The Rural Utilities Service (RUS) is authorized by the Rural Electrification Act (RE Act) of 1936, as amended, ''to make loans in several States and territories of the United States for rural electrification and for the purpose of furnishing and improving electric and telephone service in rural areas and to assist electric borrowers to implement demand side management, energy conservation programs, and on-grid and off-grid renewable energy systems.'' Borrowers will provide the agency with information that supports the use of the funds as well as identify the type of projects for which they will use the funds.

Need and Use of the Information: RUS electric borrowers will submit RUS form 595 and 219. Form 595, Financial Requirement & Expenditure Statement, to request an advance of loan funds remaining for an existing approved loan and to report on the expenditure of previously advanced loan funds. Form 219, Inventory of Work Orders, serves as a connecting line and provides an audit trail that verifies the evidence supporting the propriety of expenditures for construction of retirement projects that supports the advance of funds. The information collected will ensure that loans funds are expended and advanced for RUS approved budget process and amounts. Failure to collect proper information could result in improper determinations of eligibility or improper use of funds.

Description of Respondents: Not-for-profit institutions; Business or other for-profit.

Number of Respondents: 700.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 14,820.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. E6–1034 Filed 1–26–06; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Affirmation of Total Amounts of the Fiscal Year 2006 Tariff-Rate Quotas for Raw Cane Sugar and Certain Imported Sugars, Syrups, and Molasses (Refined Sugar)

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice of affirmation.

SUMMARY: This notice affirms determinations announced by the Secretary of Agriculture on August 12, August 19, September 9, and December 2, 2005, that an aggregate quantity of 1,751,329 metric tons raw value of sugar may be entered under the tariff-rate quota (TRQ) provisions of Additional U.S. Note 5(a) of the Harmonized Tariff Schedule of the United States (HTS) during fiscal year (FY) 2006. The following TRQ quantities were

established for entry: 1,498,212 metric tons raw value of raw sugar under subheading 1701.11.10 of the HTS, and 253,117 metric tons raw value of certain sugars, syrups, and molasses under subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 of the HTS.

DATES: *Effective Dates:*

Raw cane sugar TRQ—October 1, 2005.
Refined sugar TRQ—September 8, 2005.

FOR FURTHER INFORMATION CONTACT: Robert Curtis, Director, Import Policies and Programs Division, Foreign Agricultural Service, AgStop 1021, South Building, U.S. Department of Agriculture, Washington, DC 20250–1021 or telephone (202) 720–2916, fax to (202) 720–0876, or e-mail *Robert.Curtis@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: Paragraph (a)(i) of Additional U.S. Note 5 to chapter 17 of the HTS provides as follows: ''The aggregate quantity of raw cane sugar entered, or withdrawn from warehouse for consumption, under subheading 1701.11.10, during any fiscal year, shall not exceed in the aggregate an amount (expressed in terms of raw value), not less than 1,117,195 metric tons, as shall be established by the Secretary of Agriculture, ('* * * the Secretary'), and the aggregate quantity of sugars, syrups and molasses entered, or withdrawn from warehouse for consumption, under subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10 and 2106.90.44, during any fiscal year, shall not exceed in the aggregate an amount (expressed in terms of raw value), not less than 22,000 metric tons, as shall be established by the Secretary. With either the aggregate quantity for raw cane sugar or the aggregate quantity for sugars, syrups and molasses other than raw cane sugar, the Secretary may reserve a quota quantity for the importation of specialty sugars as defined by the United States Trade Representative.'' Paragraph (a)(iv) provides as follows: ''Sugar entering the United States during a quota period established under this note may be charged to the previous or subsequent quota period with the written approval of the Secretary.''

The provisions of paragraphs (a)(i) and (a)(iv) of Additional U.S. Note 5 to chapter 17 of the HTS authorize the Secretary to establish the fiscal year TRQ amounts (expressed in terms of raw value) of raw cane sugar and certain other sugars, syrups, and molasses that may be entered under the subheadings of the HTS subject to the lower tier of duties and to charge to those amounts sugar that is entered prior to the beginning of the fiscal year. Allocations of the TRQ amounts among supplying countries and areas will be made by the United States Trade Representative.

Notice: In accordance with paragraph (a)(i) of Additional U.S. Note 5 to chapter 17 of the HTS, the Secretary of Agriculture announced on August 12, August 19, and December 2, 2005, that an aggregate quantity of up to 1,498,212 metric tons, raw value, of raw cane sugar described in subheading 1701.11.10 of the HTS may be entered or withdrawn from warehouse for consumption during the period from October 1, 2005, through September 30, 2006. This amount includes the minimum amount authorized by the HTS (1,117,195 metric tons, raw value) and an additional amount of 387,017 metric tons, raw value, which represents the amount of the domestic cane sugar allotment that the Commodity Credit Corporation (CCC) estimates will not be filled in FY 2006. CCC is reassigning this deficit quantity to imports, pursuant to section 359e(b)(1)(D) of the Agricultural Adjustment Act of 1938, as amended (7 U.S.C. 1359ee(b)(1)(D)).

The TRQ is allocated among supplying countries and areas by the United States Trade Representative. Because of changes occurring over time in the domestic marketing of cane sugar, certain shipping pattern restrictions used in previous years are no longer being imposed.

On August 12, September 9, and December 2, 2005, an aggregate quantity of up to 253,117 metric tons, raw value, was announced, for certain refined sugars, syrups, and molasses described in subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 of the HTS to be entered or withdrawn from warehouse for consumption during the fiscal year 2006 quota period, ending September 30, 2006. Out of this quantity of 253,117 metric tons, 28,656 metric tons was reserved for the importation of specialty sugars.

To allow for the orderly marketing of non-specialty, refined sugars, 117,039 metric tons were allowed to be entered beginning September 8, 2005. This amount was allocated among supplying countries and areas by the United States Trade Representative. In addition, four global-origin tranches of 34,019 metric tons were established opening December 9, 2005, December 29, 2005, January 10, 2006, and January 24, 2006. Beginning with the December 9, 2005 tranche, sugar entering under the global refined TRQ was allowed in containers of 120 metric tons or less.

To allow for the orderly marketing of 28,656 metric tons of specialty sugar, 1,656 metric tons were allowed to enter under a first tranche opening October 26, 2005, followed by three tranches of 9,000 metric tons opening November 9, 2005, March 15, 2006, and June 7, 2006. All specialty sugars were allowed to enter under the first tranche. The second, third and fourth tranches are reserved for organic sugar and other specialty sugars not currently commercially produced in the United States of reasonably available from domestic sources.

Signed at Washington, DC the 18th day of January, 2006.

A. Ellen Terpstra,

Administrator Foreign Agricultural Service.

[FR Doc. E6–1029 Filed 1–26–06; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Foreign Agricultural Service

Affirmation of the Total Amount of the Fiscal Year 2006 Tariff-Rate Quota for Sugar and Certain Imported Sugars, Syrups, and Molasses (Refined Sugar) Imported From Mexico

AGENCY: Foreign Agricultural Service, USDA.

ACTION: Notice of Affirmation.

SUMMARY: This notice establishes the aggregate quantity of 250,383 metric tons, raw value, of sugar that may enter the United States Customs Territory from Mexico during fiscal year (FY) 2006 under the market access provisions of Chapter 7, Annex 703.2 of the North American Free Trade Agreement (NAFTA) under subheadings 1701.11.10, 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10, and 2106.90.44 of the Harmonized Tariff Schedule of the United States (HTS).

DATES: *Effective Date:* October 1, 2005.

FOR FURTHER INFORMATION CONTACT: Robert Curtis, Director, Import Policies and Programs Division, Foreign Agricultural Service, AgStop 1021, South Building, U.S. Department of Agriculture, Washington, DC 20250–1021 or telephone (202) 720–2916, fax to (202) 720–0876, or e-mail *Robert.Curtis@fas.usda.gov.*

SUPPLEMENTARY INFORMATION: Annex 703.2 of the NAFTA provides for trade in sugar and syrup goods based on annual estimates of net production surpluses in the United States and Mexico beginning in 2001, the seventh marketing year of the agreement. To facilitate estimates of supply and demand prior to the beginning of each marketing year, Section A, paragraph 13, of the Annex provides for bilateral consultations before July 1.

In addition to duty-free access to the U.S. sugar market under NAFTA, Mexico may enter under the provisions of Additional U.S. Note 5 of chapter 17 of the HTS 2,954 metric tons, raw value, of duty-free sugar under subheadings 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10 and 2106.90.44 during a FY 2006 quota period which opened September 8, 2005.

Notice: I hereby give notice, in accordance with Annex 703.2 of the NAFTA, that an aggregate quantity of up to 250,383 metric tons, raw value, of sugar described in subheadings 1701.11.10, 1701.12.10, 1701.91.10, 1701.99.10, 1702.90.10 and 2106.90.44, of the HTS may be entered or withdrawn from warehouse for consumption during the period from October 1, 2005, through September 30, 2006. The quantity is based upon the Department's projection of Mexico's net production surplus of sugar which is available for export to the United States. The entire amount, which is authorized for duty-free entry, is accounted for by the domestic cane sugar marketing allotment that the Commodity Credit Corporation (CCC) estimates will not be filled in FY 2006. CCC is reassigning this deficit quantity to imports, pursuant to section 359e(b)(1)(D) of the Agricultural Adjustment Act of 1938, as amended (7 U.S.C. 1359ee(b)(1)(D)).

I have further determined that all entries of sugar entered from Mexico under the provisions of Annex 703.2 of the NAFTA during FY 2006 require Certificates for Quota Eligibility issued by the USDA Licensing Authority.

Signed at Washington, DC the 18th day of January, 2006.

A. Ellen Terpstra,

Administrator, Foreign Agricultural Service.

[FR Doc. E6–1030 Filed 1–26–06; 8:45 am]

BILLING CODE 3410–10–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Lewis and Clark County Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000 (Pub. L. 106–393) the Helena National Forest's Lewis and Clark County Resource Advisory Committee will meet on Monday February 27 from 3 p.m. until 6 p.m. in Helena, Montana, for a business meeting. The meeting is open to the public.

DATES: Monday, February 27, 2006.

ADDRESSES: The meeting will be held in the conference room at the Helena Chamber of Commerce, 225 Cruse Avenue, Helena, MT 59601.

FOR FURTHER INFORMATION CONTACT: Duane H. Harp, Designated Forest Official (DFO), District Ranger, Helena Ranger District, Helena National Forest, at (406) 449–5490.

SUPPLEMENTARY INFORMATION: Agenda topics for this meeting include review of projects proposed for funding and public comment as authorized under Title II of Pub. L. 106–393. If the meeting location is changed, notice will be posted in local newspapers, including the Helena Independent Record.

Dated: January 20, 2006.

Duane H. Harp,

District Ranger.

[FR Doc. E6–1028 Filed 1–26–06; 8:45 am]

BILLING CODE 3410–11–P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Notice for Requests for Proposals for Guaranteed Loans Under the Section 538 Guaranteed Rural Rental Housing Program (GRRHP) for Fiscal Year 2006

AGENCY: Rural Housing Service, USDA.

ACTION: Notice.

SUMMARY: This is a request for proposals for loan guarantees under the section 538 Guaranteed Rural Rental Housing Program (GRRHP) pursuant to 7 CFR 3565.4 for Fiscal Year (FY) 2006 subject to the availability of funding. FY 2006 funding for the section 538 program is $99 million. Applicants will submit proposals in the form of ''RESPONSES.'' The commitment of program dollars will be made to applicants of selected responses that have fulfilled the necessary requirements for obligation. The commitment of program dollars will be made to applicants of selected responses that have fulfilled the necessary requirements for obligation, to the extent an appropriation act provides funding for GRRHP for FY 2006. Expenses incurred in developing applications will be at the applicant's risk. The following paragraphs outline the timeframes, eligibility requirements, lender responsibilities, and the overall response and application processes.

The GRRHP operates under 7 CFR part 3565. The GRRHP Origination and Servicing Handbook (HB–1–3565) is available to provide lenders and the general public with guidance on program administration. HB–1–3565, which contains a copy of 7 CFR part 3565 in Appendix 1, can be found at the Rural Development Instructions Web site address *http://www.rurdev.usda.gov/regs/hblist.html#hbw6*.

Eligible lenders are invited to submit responses for the development or acquisition with rehabilitation of affordable rental housing to serve rural America. In addition, this fiscal year, guarantees will be available for the revitalization, repair, and transfer cost of existing direct section 515 housing (transfer costs are subject to Agency approval and must be an eligible use of loan proceeds as listed in 7 CFR 3565.205). In order to be considered, direct section 515 housing projects must need repairs and/or undergo revitalization of a minimum of $6,500 per unit.

The Rural Housing Service (RHS) will review responses submitted by eligible lenders, on the lender's letterhead, and signed by both the prospective borrower and lender. Although a complete application is not required in response to this Notice of Funding Availability (NOFA), eligible lenders may submit a complete application concurrently with the response. However, submitting a complete application will not have an effect on the response's score.

DATES: The RHS will review and score all responses received through June 16, 2006. Those responses that are selected that subsequently submit complete applications and meet all Federal environmental requirements will receive commitments to the extent an appropriation act provides funding for GRRHP for FY 2006 until all funds are expended. Responses received prior to June 16, 2006, that meet program criteria, but score less than 25 points or score 25 points or more but have a development cost ratio of equal to or more than 70 percent may be selected for obligation after June 16, 2006, with the highest scoring responses receiving priority as long as funds remain available. The Agency will continue to select the highest scoring NOFA responses received after June 16, 2006, notwithstanding the score, as long as the response meets program criteria and funds remain available. A notice will be placed in the **Federal Register** when all funds are committed for FY 2006.

Eligible lenders mailing a response or application must provide sufficient time to permit delivery to the ''Submission Address'' on or before the closing deadline date and time. Acceptance by

a U.S. Post Office or private mailer does not constitute delivery. Postage due responses and applications will not be accepted.

Submission Address: Eligible lenders will send responses to the Multi-Family Housing Director in the State Office where the project will be located. The lender will also send a copy of its NOFA response (copies of ''Lender Certification'' letter and ''Project Specific Data'' sheets only; do not include any application supporting documentation, *i.e.*, market studies, plans/specs, etc.) to: C.B. Alonso, Senior Loan Specialist, Guaranteed Rural Rental Housing Program, Multi-Family Housing Processing Division, U.S. Department of Agriculture, South Agriculture Building, Room 1271, STOP 0781, 1400 Independence Avenue, SW., Washington, DC 20250–0781.

Rural Development State Offices, their addresses, telephone numbers, and person to contact follows: [This information may also be found at *http://www.rurdev.usda.gov/recd_map.html*.]

Note: Telephone numbers listed are not toll-free.

Alabama State Office, Suite 601, Sterling Centre, 4121 Carmichael Road, Montgomery, AL 36106–3683. (334) 279–3455. TDD (334) 279–3495. James B. Harris.

Alaska State Office, 800 West Evergreen, Suite 201, Palmer, AK 99645. (907) 761–7740. TDD (907) 761–8905. Deborah Davis.

Arizona State Office, Phoenix Courthouse and Federal Building, 230 North First Ave., Suite 206. Phoenix, AZ 85003–1706. (602) 280–8765. TDD (602) 280–8706. Don Irby.

Arkansas State Office, 700 W. Capitol Ave., Room 3416, Little Rock, AR 72201–3225. (501) 301–3250. TDD (501) 301–3063. Gregory Kemper.

California State Office, 430 G Street, #4169, Davis, CA 95616–4169. (530) 792–5830. TDD (530) 792–5848. Stephen Nnodim.

Colorado State Office, 655 Parfet Street, Room E100, Lakewood, CO 80215. (720) 544–2923. TDD (800) 659–2656. Jamie Spakow.

Connecticut: Served by Massachusetts State Office.

Delaware and Maryland State Office, 4607 South Dupont Highway, PO Box 400, Camden, DE 19934–9998. (302) 697–4353. TDD (302) 697–4303. W. Drew Clendaniel.

Florida & Virgin Islands State Office, 4440 NW. 25th Place, Gainesville, FL 32606–6563. (352) 338–3465. TDD (352) 338–3499. Elizabeth M. Whitaker.

Georgia State Office, Stephens Federal Building, 355 E. Hancock Avenue, Athens, GA 30601–2768. (706) 546–2164. TDD (706) 546–2034. Wayne Rogers.

Hawaii State Office, (Services all Hawaii, American Samoa Guam, and Western Pacific), Room 311, Federal Building, 154 Waianuenue Avenue, Hilo, HI 96720. (808) 933–8305. TDD (808) 933–8321. Jack Mahan.

Idaho State Office, Suite A1, 9173 West Barnes Dr., Boise, ID 83709, (208) 378–5630. TDD (208) 378–5644. Roni Atkins.

Illinois State Office, 2118 West Park Court, Suite A, Champaign, IL 61821–2986. (217) 403–6222. TDD (217) 403–6240. Barry L. Ramsey.

Indiana State Office, 5975 Lakeside Boulevard, Indianapolis, IN 46278. (317) 290–3100 (ext. 423). TDD (317) 290–3343. John Young.

Iowa State Office, 210 Walnut Street Room 873, Des Moines, IA 50309. (515) 284–4666. TDD (515) 284–4858. Ambrose H. McGuire.

Kansas State Office, 1303 SW. First American Place, Suite 100, Topeka, KS 66604–4040. (785) 271–2721. TDD (785) 271–2767. Tim Rogers.

Kentucky State Office, 771 Corporate Drive, Suite 200, Lexington, KY 40503. (859) 224–7325. TDD (859) 224–7422. Paul Higgins.

Louisiana State Office, 3727 Government Street, Alexandria, LA 71302. (318) 473–7962. TDD (318) 473–7655. Yvonne R. Emerson.

Maine State Office, 967 Illinois Ave., Suite 4, PO Box 405, Bangor, ME 04402–0405. (207) 990–9110. TDD (207) 942–7331. Dale D. Holmes.

Maryland: Served by Delaware State Office.

Massachusetts, Connecticut, & Rhode Island State Office, 451 West Street, Amherst, MA 01002. (413) 253–4333. TDD (413) 253–4590. Donald Colburn.

Michigan State Office, 3001 Coolidge Road, Suite 200, East Lansing, MI 48823. (517) 324–5192. TDD (517) 337–6795. Ghulam R. Sumbal.

Minnesota State Office, 375 Jackson Street Building, Suite 410, St. Paul, MN 55101–1853. (651) 602–7782. TDD (651) 602–7830. Jackie Morris.

Mississippi State Office, Federal Building, Suite 831, 100 W. Capitol Street, Jackson, MS 39269. (601) 965–4325. TDD (601) 965–5850. Darnella Smith-Murray.

Missouri State Office, 601 Business Loop 70 West, Parkade Center, Suite 235, Columbia, MO 65203. (573) 876–0990, TDD (573) 876–9480, Anita J. Dunning.

Montana State Office, 900 Technology Blvd. Suite B, Bozeman, MT 59715. (406) 585–2565. TDD (406) 585–2562. Deborah Chorlton.

Nebraska State Office, Federal Building, Room 152, 100 Centennial Mall N, Lincoln, NE 68508. (402) 437–5594. TDD (402) 437–5093. Byron L. Fischer.

Nevada State Office, 1390 South Curry Street, Carson City, NV 89703–9910. (775) 887–1222 (ext. 25). TDD (775) 885–0633. William Brewer.

New Hampshire State Office, Concord Center, Suite 218, Box 317, 10 Ferry Street, Concord, NH 03301–5004. (603) 223–6046. TDD (603) 229–0536. Robert McDonald.

New Jersey State Office, 5th Floor North Suite 500, 8000 Midlantic Dr., Mt. Laurel, NJ 08054. (856) 787–7740. TDD (856) 787–7784. George Hyatt, Jr.

New Mexico State Office, 6200 Jefferson St., NE., Room 255, Albuquerque, NM 87109. (505) 761–4944. TDD (505) 761–4938. Walter Taylor.

New York State Office, The Galleries of Syracuse, 441 S. Salina Street, Suite 357 5th Floor, Syracuse, NY 13202. (315) 477–6419. TDD (315) 477–6447. George N. Von Pless.

North Carolina State Office, 4405 Bland Road, Suite 260, Raleigh, NC 27609. (919) 873–2066. TDD (919) 873–2003. William Hobbs.

North Dakota State Office, Federal Building, Room 208, 220 East Rosser, PO Box 1737, Bismarck, ND 58502. (701) 530–2049. TDD (701) 530–2113. Donald L. Warren.

Ohio State Office, Federal Building, Room 507, 200 North High Street, Columbus, OH 43215–2477. (614) 255–2418. TDD (614) 255–2554. Gerald Arnott.

Oklahoma State Office, 100 USDA, Suite 108, Stillwater, OK 74074–2654. (405) 742–1070. TDD (405) 742–1007. Anita Kinyon.

Oregon State Office, 101 SW Main, Suite 1410, Portland, OR 97204–3222. (503) 414–3325. TDD (503) 414–3387. Jillene Davis.

Pennsylvania State Office, One Credit Union Place, Suite 330, Harrisburg, PA 17110–2996. (717) 237–2281. TDD (717) 237–2261. Frank Wetherhold.

Puerto Rico State Office, 654 Munoz Rivera Avenue, IBM Plaza, Suite 601, Hato Rey, PR 00918. (787) 766–5095 (ext. 249). TDD (787) 766–5332. Pedro Gomez.

Rhode Island: Served by Massachusetts State Office.

South Carolina State Office, Strom Thurmond Federal Building, 1835 Assembly Street, Room 1007, Columbia, SC 29201. (803) 253–3432. TDD (803) 765–5697. Larry D. Floyd.

South Dakota State Office, Federal Building, Room 210, 200 Fourth Street, SW., Huron, SD 57350. (605) 352–1132. TDD (605) 352–1147. Roger Hazuka or Pam Reilly.

Tennessee State Office, Suite 300, 3322 West End Avenue, Nashville, TN 37203–1084. (615) 783–1375. TDD (615) 783–1397. Don Harris.

Texas State Office, Federal Building, Suite 102, 101 South Main, Temple, TX 76501. (254) 742–9758. TDD (254) 742–9712. Gayle Ledyard.

Utah State Office, Wallace F. Bennett Federal Building, 125 S. State Street, Room 4311, Salt Lake City, UT 84147–0350. (801) 524–4325. TDD (801) 524–3309. David E. Brown.

Vermont State Office, City Center, 3rd Floor, 89 Main Street, Montpelier, VT 05602. (802) 828–6021. TDD (802) 223–6365. Robert McDonald.

Virgin Islands: Served by Florida State Office.

Virginia State Office, Culpeper Building, Suite 238, 1606 Santa Rosa Road, Richmond, VA 23229. (804) 287–1596. TDD (804) 287–1753. Eileen Nowlin.

Washington State Office, 1835 Black Lake Blvd., Suite B, Olympia, WA 98512. (360) 704–7730. TDD (360) 704–7760. Robert Lund.

Western Pacific Territories: Served by Hawaii State Office.

West Virginia State Office, Federal Building, 75 High Street, Room 320, Morgantown, WV 26505–7500. (304) 284–4872. TDD (304) 284–4836. David Cain.

Wisconsin State Office, 4949 Kirschling Court, Stevens Point, WI 54481. (715) 345–7615 (ext. 151). TDD (715) 345–7614. Peter Kohnen.

Wyoming State Office, PO Box 11005, Casper, WY 82602. (307) 233–6715. TDD (307) 233–6733. Alan Brooks.

FOR FURTHER INFORMATION CONTACT: C.B. Alonso, Senior Loan Specialist, Guaranteed Rural Rental Housing Program, Multi-Family Housing Processing Division, U.S. Department of Agriculture, South Agriculture Building, Room 1271, STOP 0781, 1400 Independence Avenue, SW., Washington, DC 20250–0781. Email: *cb.alonso@wdc.usda.gov.* Telephone: (202) 720–1624. This number is not toll-free. Hearing or speech-impaired persons may access that number by calling the Federal Information Relay Service toll-free at (800) 877–8339.

Eligibility of Prior Year Selected Notices of Funding Availability Responses: NOFA response selections prior to FY 2005 that did not develop into a complete application or where funds were not obligated have been cancelled. A new NOFA response for the project may be submitted subject to the conditions of this NOFA.

FY 2005 NOFA responses that were selected by the Agency, and a complete application (including all Federal environmental documents required by 7 CFR part 1940, subpart G, a Form RD 3565–1, and the $2,500 application fee) was submitted by the lender within 90 days from the date of notification of response selection (unless an extension was granted by the State office), will be eligible for FY 2006 program dollars and will compete in the FY 2006 priority scoring without having to complete a FY 2006 NOFA response.

General Program Information

Program Purpose: The purpose of the GRRHP is to increase the supply of affordable rural rental housing, through the use of loan guarantees that encourage partnerships between the RHS, private lenders, and public agencies.

Responses Must Be Submitted by: The Agency will only accept responses from GRRHP eligible or approved lenders as described in 7 CFR 3565.102 and 3565.103 respectively.

Qualifying Properties: Qualifying properties include new construction for multi-family housing units or the acquisition of existing structures with a minimum per unit rehabilitation expenditure requirement in accordance with 7 CFR 3565.252.

In addition, this fiscal year, guarantees will be available for the revitalization, repair and transfer cost of existing direct section 515 housing (transfer costs are subject to Agency approval and must be an eligible use of loan proceeds as listed in 7 CFR 3565.205). In order to be considered, direct section 515 housing projects must need repairs and/or undergo revitalization of a minimum of $6,500 per unit.

Eligible Financing Sources: Any form of Federal, state, and conventional sources of financing can be used in conjunction with the loan guarantee, including Home Investment Partnership Program (HOME) grant funds, tax exempt bonds, and low income housing tax credits.

Maximum Guarantee: The Agency can guarantee the ''permanent'' portion or both the ''construction and permanent'' portions of a construction/permanent loan. The Agency cannot, however, guarantee only the ''construction'' portion of a construction/permanent loan.

The maximum guarantee for a permanent loan will be 90 percent of the unpaid principal and interest up to default and accrued interest 90 calendar days from the date the liquidation plan is approved by the Agency, as defined in 7 CFR 3565.452. Penalties incurred as a result of default are not covered by the guarantee. The Agency may provide a lesser guarantee based upon its evaluation of the credit quality of the loan. The Agency liability under any guarantee will decrease or increase, in proportion to any increase or decrease in the amount of the unpaid portion of the loan, up to the maximum amount specified in the Loan Note Guarantee.

The maximum guarantee of construction advances will not at any time exceed the lesser of 90 percent of the amount of principal and interest up to default advanced for eligible uses of loan proceeds or 90 percent of the original principal amount and interest up to default of the loan. Penalties incurred as a result of default are not covered by the guarantee. The Agency may provide a lesser guarantee based upon its evaluation of the credit quality of the loan.

Reimbursement of Losses: Any losses will be split on a pro-rata basis between the lender and the RHS from the first dollar lost.

Interest Rate: RHS will accept the best rate negotiated between the lender and prospective borrower. The lender is not required to provide the interest rate in the response unless applying for interest credit. The interest rate must be fixed over the term of the loan.

Interest Credit: For at least 20 percent of the loans made during each fiscal year, the Agency will provide assistance in the form of interest credit, to the extent necessary to reduce the agreed-upon rate of interest to the Long Term Monthly Applicable Federal Rate (AFR) as such term is used in section 42(I)(2)(D) of the Internal Revenue Code of 1986, 26 U.S.C. 7805, Sec. 1.42–1T. The interest credit will be paid following the January 1st of the year in which the project has reached occupancy standards, and the permanent loan note guarantee is issued. If 20 percent of the loans have not received interest credit by June 16, 2006, then RHS will award interest credit to those loans that initially requested interest credit and have the highest interest credit priority score until at least 20 percent of the loans have received interest credit. Requests for interest credit must be made in the response. When interest credit assistance is requested, lenders must state in the response the maximum basis points above the Long Term Monthly AFR that will be used to calculate the interest rate. Priority points will be given for basis points equal to or less than 250 above the Long Term Monthly AFR. Lenders are not permitted to make requests for interest credit after the selection process has taken place.

Due to limited funding and in order to distribute interest credit assistance as broadly as possible, the Agency has decided to limit the interest credit to $1.5 million per loan. For example, if an eligible request were made for interest credit on a loan of $2.5 million, up to $1.5 million of the loan would receive interest credit. Interest credit is not available for construction loans. Interest credit is only available for permanent loans. Lenders with projects that are viable with or without interest credit are encouraged to submit a response reflecting financial and market feasibility under both funding options. Responses requesting consideration under both options will not affect interest credit selection. Due to limited interest credit funds and the responsibility of RHS to target and give priority to rural areas most in need, responses requesting interest credit must score a minimum of 55 points under the criteria established in this NOFA. In the event of ties, selection between responses will be by lot.

Surcharges for Guarantee of Construction Advances: There is no surcharge for the guarantee of construction advances for FY 2006.

Program Fees for FY 2006: As a condition of receiving a loan guarantee, the Agency will charge the following guarantee fees to the lender.

(1) *Initial guarantee fee.* The Agency will charge an initial guarantee fee equal to one percent of the guarantee amount. For purposes of calculating this fee, the guarantee amount is the product of the percentage of the guarantee times the

initial principal amount of the guaranteed loan.

(2) Annual guarantee fee. An annual guarantee fee of at least 50 basis points (one-half percent) of the outstanding principal amount of the loan as of December 31 will be charged each year or portion of a year that the guarantee is in effect.

(3) There is a non-refundable application fee of $2,500 when the application is submitted.

(4) There is a flat fee of $500 when a lender requests RHS to extend the term of a guarantee commitment.

(5) There is a flat fee of $500 when a lender requests RHS to reopen an application when a commitment has expired.

(6) There is a flat fee of $1,250 when a lender requests RHS to approve the transfer of property and assumption of the loan to an eligible prospective borrower.

(7) There is no lender application fee for lender approval in FY 2006.

Eligible Lenders: An eligible lender for the section 538 GRRHP as required by 7 CFR 3565.102 must be a licensed business entity or Housing Finance Agency (HFA) in good standing in the state or states where it conducts business. Lender eligibility requirements are contained in 7 CFR 3565.102. Below is a list of some of the eligible lender criteria under 7 CFR 3565.102:

(1) Licensed business entity that meets the qualifications and has the approval of the Secretary of Housing and Urban Development (HUD) to make multi-family housing loans that are insured under the National Housing Act. A complete list of HUD approved lenders can be found on the HUD Web site at *http://www.hud.gov*.

(2) A licensed business entity that meets the qualifications and has the approval of the Ginnie Mae or Freddie Mac or Fannie Mae corporations to make multi-family housing loans that are sold to the same corporations. A complete list of Freddie Mac approved lenders can be found in Freddie Mac's Web site at *http://www.freddiemac.com*. Fannie Mae approved lenders are found at *http://www.fanniemae.com*. For a list of Ginnie Mae issuers, contact Ginnie Mae at *http://www.ginniemae.gov*.

(3) A state or local HFA with a top-tier rating from Moody's or Standard & Poors, or member of the Federal Home Loan Bank system, and the demonstrated ability to underwrite, originate, process, close, service, manage, and dispose of multi-family housing loans in a prudent manner.

(4) Be a GRRHP approved lender, defined as an entity with a current executed multi-family housing Lender's Agreement with RHS.

(5) Lenders that can demonstrate the capacity to underwrite, originate, process, close, service, manage, and dispose of multi-family housing loans in a prudent manner. In order to be approved the lender will have to have an acceptable level of financial soundness as determined by a lender rating service. The submission of materials demonstrating capacity will be required if the lender's response is selected. Lenders who are otherwise ineligible may become eligible if they maintain a correspondent relationship with an eligible lender that does have the capacity to underwrite, originate, process, close, service, manage, and dispose of multi-family housing loans in a prudent manner. In this case, the eligible lender must submit the response and application. All contractual and legal documentation will be signed between RHS and the lender that submitted the response and application.

GRRHP Lender Approval Application: Lenders whose responses are selected will be notified by the RHS to submit a request for GRRHP lender approval application within 30 days of notification. Lenders who request GRRHP approval must meet the standards in the 7 CFR 3565.102 and 103. Lenders that have received GRRHP lender approval in the past and are in good standing do not need to reapply for GRRHP lender approval.

Submission of Documentation For GRRHP Lender Approval: All lenders that have not yet received GRRHP lender approval must submit a complete lender application to: Director, Multi-Family Housing Processing Division, Rural Housing Service, U.S. Department of Agriculture, Room 1263, STOP 0781, 1400 Independence Avenue, SW., Washington, DC 20250–0781. Lender applications must be identified as ''Section 538 Guaranteed Rural Rental Housing Program'' on the envelope.

As RHS does not have a formal application form, a complete application consists of a cover letter requesting GRRHP lender approval and the following documentation:

(1) Request for GRRHP lender approval on the lender's letterhead;

(2) Lenders who are HUD, Ginnie Mae, Freddie Mac or Fannie Mae multi-family approved lenders are required to show evidence of this status, such as a copy of a letter designating the distinction;

(3) The lender's Loan Origination, Loan Servicing, and Portfolio Management Handbooks. These handbooks should detail the lender's policies and procedures on loan origination through termination for multi-family loans;

(4) Portfolio performance data;

(5) Copies of standard documents that will be used in processing GRRHP loans;

(6) Resumes and qualifications of key personnel that will be involved in the GRRHP;

(7) Identification of standards and processes that deviate from those outlined in the GRRHP Origination and Servicing Handbook (HB–1–3565) found at *http://www.rurdev.usda.gov/regs/hblist.html#hbw6;*

(8) A copy of the most recent audited financial statements;

(9) Lender specific information including: (a) Legal name and address, (b) list of principal officers and their responsibilities, (c) certification that the officers and principals of the lender have not been debarred or suspended from Federal programs, (d) Form AD 1047, (e) certification that the lender is not in default or delinquent on any Federal debt or loan, or possesses an outstanding finding of deficiency in a federal housing program, and (f) certification of the lender's credit rating; and

(10) Documentation on bonding and insurance.

Additional Construction Lender Requirements

The Agency can guarantee the ''permanent'' portion or both the ''construction and permanent'' portions of a construction/permanent loan. The Agency will not, however, guarantee only the ''construction'' portion of a construction/permanent loan.

A lender making a construction loan must demonstrate an ability to originate and service construction loans, in addition to meeting the other requirements of 7 CFR part 3565, subpart C. A lender who originates and services construction/permanent loans must agree to manage the construction and draw activities in the manner described in Chapter 5 of HB–1–3565. Lenders must meet either the basic or the demonstrated eligibility test in paragraphs 2.4 and 2.5 of HB–1–3565 and the lender approval requirements set forth in paragraph 2.6 of HB–1–3565. Lenders must clearly identify policies and processes for multifamily construction lending. Lenders must also provide a summary of their multifamily construction lending activity in the same form as specified in paragraph 2.5 of HB–1–3565. The Agency may, at its discretion, consider other types of construction loans—such as those for commercial development—as a

substitute for multifamily construction experience.

Lender Responsibilities: Lenders will be responsible for the full range of loan origination, underwriting, management, servicing, compliance issues, and property disposition activities associated with their projects. The lender will be expected to provide guidance to the prospective borrower on the RHS requirements during the application phase. Once the guarantee is issued, the lender is expected to service each loan it underwrites or contract these services to another capable entity.

Discussion of NOFA

Content of NOFA Responses: All responses require lender information and project specific data. Incomplete responses will not be considered for funding. Lenders will be notified of incomplete responses. Complete responses are to include a signed cover letter from the lender on the lender's letterhead and the following information:

(1) *Lender certification*—The lender must certify that the lender will make a loan to the prospective borrower for the proposed project, under specified terms and conditions subject to the issuance of the GRRHP guarantee. Lender certification must be on the lender's letterhead and signed by both the lender and the prospective borrower.

(2) *Project specific data*—The lender must submit the project specific data below on the lender's letterhead, signed by both the lender and the prospective borrower.

Lender Name	Insert the lender's name.
Lender Tax ID #	Insert lender's tax ID #.
Lender Contact Name	Name of the lender contact for loan.
Mailing Address	Lender's complete mailing address.
Phone #	Phone # for lender contact.
Fax #	Insert lender's fax #.
E-mail Address	Insert lender contact e-mail address.
Borrower Name and Organization Type	State whether borrower is a Limited Partnership, Corporation, Indian Tribe, etc.
Tax Classification Type	State whether borrower is for profit, not for profit, etc.
Borrower Tax ID #	Insert borrower's tax ID #.
Borrower Address, including County	Insert borrower's address and county.
Borrower Phone #	Insert borrower's phone #.
Principal or Key Member for the Borrower	Insert name and title.
Borrower Information and Statement of Housing Development Experience	Attach relevant information.
New Construction, Acquisition With Rehabilitation, or the Revitalization, Repair, and Transfer Cost of Existing Direct Section 515 Housing	State whether the project is new construction or acquisition with rehabilitation. Transfer costs are subject to Agency approval and must be an eligible use of loan proceeds listed in 7 CFR 3565.205.
Project Location Town or City	Town or city in which the project is located.
Project County	County in which the project is located.
Project State	State in which the project is located.
Project Zip Code	Insert zip code.

Project Congressional District	Congressional District for project location.
Project Name	Insert project name.
Project Type	Family, senior (all residents 55 years or older), or mixed.
Property Description and Proposed Development Schedule	Provide as an attachment.
Total Project Development Cost	Enter amount for total project.
# of Units	Insert the # of units in the project.
Ratio of 3–5 bedroom units to total units	Insert percentage of 3–5 bedroom units to total units.
Cost Per Unit	Total development cost divided by # of units.
Rent	Proposed rent structure.
Median Income for Community	Provide median income for the community.
Evidence of Site Control	Attach relevant information.
Description of Any Environmental Issues	Attach relevant information.
Loan Amount	Insert the loan amount.
Interest Credit (IC)	Is interest credit requested for this loan? (Yes or No)
Basis Points over the Long Term Monthly Applicable Federal Rate	Lenders seeking interest credit must provide the maximum basis points above the Long Term Monthly AFR that will be used to calculate the interest rate. Priority points will only be given for basis points equal to or less than 250 above the Long Term Monthly AFR.
If Above Is Yes, Should Proposal Be Considered Under Non-Interest Credit Selection If Scoring Does Not Meet the Minimum Point Threshold of 55 Points for an Interest Credit Award?	If Yes, proposal must show financial feasibility for Non-IC consideration.
Borrower's Proposed Equity	Insert amount.
Tax Credits	Will the project be allocated tax credits? How much? What is the estimated value of the tax credits awarded?
Other Sources of Funds	List all funding sources other than tax credits and amounts for each source.
Loan to Total Development Cost	Guaranteed loan divided by the total development costs of project.
Debt Coverage Ratio	Net Operating Income divided by debt service payments.
Percentage of Guarantee	Percentage guarantee requested.
Collateral	Attach relevant information.

Empowerment Zone (EZ) or Enterprise Community (EC), Colonia or Tribal Lands	Yes or No. Is the project in a recognized EZ or EC, Colonia or on an Indian Reservation?
Population	Must be within the 20,000 population limit set for the program.
Is a Guarantee for Construction Being Requested? Are Advances Being Requested?	State yes or no. The Agency can guarantee the ''permanent'' portion or both the ''construction and permanent'' portions of a construction/permanent loan. The Agency will not, however, guarantee only the ''construction'' portion of a construction/permanent loan.
Loan Term	Up to a 40-year amortized loan. Balloon mortgages with a minimum 25-year term are eligible.

Scoring of Priority Criteria for Selection of Projects: All 2006 NOFA responses will be scored based on the criteria set forth below to establish their priority for obligation of funds. Per 7 CFR 3565.5 (b), priority will be given to projects: in smaller rural communities, in the most needy communities having the highest percentage of leveraging, having the lowest interest rate, having the highest ratio of 3–5 bedroom units to total units, or located in Empowerment Zones/Enterprise Communities or on tribal lands. In addition, the Agency may, at its sole discretion, set aside assistance for or rank projects that meet important program goals.

In order to meet program goals, the Agency will award additional points to Fiscal Year 2006 NOFA responses for the revitalization, repair, and transfer cost of existing direct Section 515 housing.

Prior to June 16, 2006, projects with an overall score of 25 points and a loan to development cost ratio less than 70 percent will be processed and, when ready, obligated on a first-come-first-serve basis, provided funds are available. Projects that score less than 25 points, and projects that score 25 points or more and do not have a loan to development cost ratio less than 70 percent, may be processed up to the point of obligation, but they will not be obligated until after June 16, 2006. Each month after June 16, 2006, the Agency will select the highest scoring proposals, in light of the remaining funding, until all funds are expended. A notice will be placed in the **Federal Register** when all funds are committed for FY 2006.

Subject to available funding, all projects scoring 55 points or more on the seven priority criteria below, and that request and demonstrate a need for an interest credit subsidy, will receive interest credit awards.

The seven priority criteria for projects are listed below.

Priority 1—Projects located in eligible rural communities with the lowest populations will receive the highest points.

Population size	Points
0–5,000 people	15
5,001–10,000 people	10
10,001–15,000 people	5
15,001–20,000 people	0

Priority 2—The most needy communities as determined by the median income from the most recent census data will receive points. The RHS will allocate points to projects located in communities having the lowest median income. Points for median income will be awarded as follows:

Median income (dollars)	Points
Less than $35,000	20
$35,000–less than $45,000	15
$45,000–less than $55,000	10
$55,000–less than $65,000	5
$65,000 or more	0

Priority 3—Projects that demonstrate partnering and leveraging in order to develop the maximum number of units and promote partnerships with state and local communities will also receive points. Points will be awarded as follows:

Loan to total development cost ratio (percentage %)	Points
90–100	0
Less than 90–70	15
Less than 70–50	20
Less than 50	30

Priority 4—The development of projects on Tribal Lands, or in an Empowerment Zone or Enterprise Community will receive points. The RHS will attribute 20 points to projects that are developed in any of the locations described in this priority. The development of projects in a Colonia or in a place identified in the State's Consolidated Plan or State Needs Assessment as a high need community for multi-family housing will receive points. The RHS will attribute 20 points to projects that are developed in any of the locations described in this priority.

Priority 5—The RHS will award points to projects with the highest ratio of 3–5 bedroom units to total units as follows:

Ratio of 3–5 bedroom units to total units	Points
More than 50%	6
21%–50%	5
Less than 21%–more than 0%	1

Priority 6—RHS will award points for basis points above the long term monthly AFR used to calculate the interest rate. The score for basis points is as follows:

Basis points	Points
More than 250 basis points	−20
200 to 250 basis points, inclusive	10
100 to 199 basis points, inclusive	15
0 to 99 basis points, inclusive	20

Priority 7—NOFA responses for the revitalization, repair, and transfer cost of existing direct section 515 housing (transfer costs are subject to Agency approval and must be an eligible use of loan proceeds listed in 7 CFR 3565.205) will receive an additional 20 points.

Notifications: Responses will be reviewed for completeness and eligibility. The RHS will notify those lenders whose responses are selected via letter. The RHS will request lenders without GRRHP lender approval to apply for GRRHP lender approval within 30 days upon receipt of notification of selection. For information regarding GRRHP lender approval, please refer to the section entitled ''SUBMISSION OF

DOCUMENTATION FOR GRRHP LENDER APPROVAL'' in this NOFA.

Lenders will also be invited to submit a complete application and the required application fee of $2,500 to the Rural Development State Office where the project is located.

Submission of GRRHP Applications: Notification letters will instruct lenders to contact the Rural Development State Office immediately following notification of selection to schedule required agency reviews.

Rural Development State Office staff will work with lenders in the development of an application package. In response to the NOFA, lenders must submit a NOFA response to the office address identified in the NOFA for the scoring and ranking of a proposed GRRHP project. The lender must provide the requested information concerning the project, to establish the purpose of the proposed project, its location, and how it meets the established priorities for funding. The Agency will determine the highest ranked responses based on priority criteria and a threshold score.

NOFA responses will at least include the following [but the Agency, at its sole discretion, may request additional information]:

(1) The Project

(a) A brief description of the proposed location of the project, including town, county, state, and congressional district.

(b) A description of the property and improvements, including lot size, number of units, building type, type of construction, *etc.,* including preliminary drawings, if available.

(c) The proposed development schedule.

(d) Total project development cost.

(e) The proposed rent structure and area median income (HUD published area median incomes can be found online at *http://www.huduser.org*).

(f) Evidence of site control by the proposed borrower or a purchase option.

(g) Description of any environmental issues that may affect the project.

(h) Amount of loan to be guaranteed.

(i) Type of project (*e.g.* elderly or family).

(2) The Proposed Financing

(a) Proposed loan amount and the proposed borrower's equity.

(b) Proposed use of interest credit—If the lender proposes to use interest credit, this section should include the maximum basis points the lender will charge the borrower for the project. The interest rate may not be lower than the published Long Term Monthly AFR at the closing of the lender's loan. Selection and scoring criteria that the project must meet to receive interest credit will be published in the NOFA.

(c) Estimated development budget (total and cost/unit) and the proposed sources and uses of funds. This information should include all proposed financing sources—the amount, type, rates and terms of loans, tax credits, or grant funds. Letters of application and commitment letters should be included, if available.

(d) Estimated loan-to-development cost ratio for the guaranteed loan.

(e) Proposed Agency guarantee percentage for guaranteed loan (under no condition can the percentage exceed 90 percent of the loan amount).

(f) Collateral—all security, in addition to the real property, proposed to secure the loan.

(3) The Proposed Borrower

(a) The name of the borrower and the type of ownership entity. List the general partners if a limited partnership, officers if a corporation or members of an Limited Liability Corporation.

(b) Borrower's contact name, mailing address, phone and fax numbers, and e-mail address.

(c) Evidence that the borrower or principals of the ownership are not barred from participating in Federal housing programs and are not delinquent on any Federal debt.

(d) Borrower's unaudited or audited financial statements.

(e) Statement of borrower's housing development experience.

(4) Lender Eligibility and Approval Status

Evidence that the lender is either an approved lender for the purposes of the GRRHP or that the lender is eligible to apply for approved lender status. The lender's application for approved lender status can be submitted with the NOFA response but must be submitted to the National Office within 45 calendar days of the lender's receipt of the ''notice to proceed with application processing'' letter.

(5) Competitive Criteria

Information that shows how the proposal is responsive to the selection criteria specified in the NOFA.

(6) Lender Certification

A commitment letter signed by the lender, on the lender's letterhead, indicating that the lender will make a loan to the borrower for the proposed project, under specified terms and conditions subject only to the issuance of a guarantee by the Agency.

The deadline for the submission of a complete application and application fee is 90 days from the date of notification of response selection. If the application and fee are not received by the appropriate State Office within 90 days from the date of notification, the selection is subject to cancellation, thereby allowing another response that is ready to proceed with processing to be selected.

Obligation of Program Funds: The RHS will only obligate funds to projects that meet the requirements for obligation, including undergoing a satisfactory environmental review in accordance with the National Environmental Protection Act (NEPA) and lenders who have submitted the $2,500 application fee and completed Form RD 3565–1 for the selected project.

Conditional Commitment: Once required documents for obligation and the application fee are received and all NEPA requirements have been met, the Rural Development State Office will issue a conditional commitment, which stipulates the conditions that must be fulfilled before the issuance of a guarantee, in accordance with 7 CFR 3565.303.

Issuance of Guarantee: The RHS State Office will issue a guarantee to the lender for a project in accordance with 7 CFR 3565.303. No guarantee can be issued without a complete application, review of appropriate certifications, satisfactory assessment of the appropriate level of environmental review, and the completion of any conditional requirements.

Dated: January 18, 2006.

David J. Villano,

Acting Administrator, Rural Housing Service.

[FR Doc. E6–1054 Filed 1–26–06; 8:45 am]

BILLING CODE 3410–XV–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletion

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete a product previously furnished by such agencies.

Comments Must Be Received on or Before: February 26, 2006.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a) (2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

End of Certification

The following products and services are proposed for addition to Procurement List for production by the nonprofit agencies listed:

Products

Product/NSNs: Specimen Container
6550–00–NIB–0009—¼ turn cap, sterile individually wrapped;
6550–00–NIB–0010—¼ turn cap, sterile;
6550–00–NIB–0011—¼ turn cap, non-sterile;
6550–00–NIB–0013—full turn cap, non-sterile
NPA: Alphapointe Association for the Blind, Kansas City, Missouri
Contracting Activity: Veterans Affairs National Acquisition Center, Hines, Illinois

Services

Service Type/Location: Document Destruction.
NISH, Vienna, Virginia (PRIME CONTRACTOR). Performance to be allocated to the Nonprofit Agencies identified at the following locations:
Internal Revenue Service, 1700 Palm Beach Lakes Boulevard, West Palm Beach, Florida
7410 South U.S. Highway One, Port St. Lucie, Florida.
NPA: Association for Retarded Citizens of Indian River County, Vero Beach, Florida.
Internal Revenue Service,
2201 Cantu Court, Sarasota, Florida,
2891 Center Point Drive, Fort Myers, Florida,
300 Lock Road, Deerfield Beach, Florida,
51 SW First Avenue, Miami, Florida,
7850 SW 6th Court, Plantation, Florida,
Royal Palm One, Suite 34, 1000 South Pine Island Road, Plantation, FL.
NPA: Goodwill Industries of South Florida, Inc., Miami, Florida
Contracting Activity: U.S. Treasury, IRS, Chamblee, Georgia.

Deletion

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action may result in authorizing small entities to furnish the product to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the product proposed for deletion from the Procurement List.

End of Certification

The following product is proposed for deletion from the Procurement List:

Product

Product/NSNs: Cloth, Abrasive.
5350–00–187–6296—Cloth, Abrasive.
NPA: Louisiana Association for the Blind, Shreveport, Louisiana.
Contracting Activity: GSA, Southwest Supply Center, Fort Worth, Texas.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E6–1026 Filed 1–26–06; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Additions and Deletions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from Procurement List.

SUMMARY: This action adds to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List products previously furnished by such agencies.

DATES: *Effective Date:* February 26, 2006.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, Telephone: (703) 603–7740, Fax: (703) 603–0655, or e-mail *SKennerly@jwod.gov*.

SUPPLEMENTARY INFORMATION:

Additions

On November 25, and December 2, 2005, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (70 FR 71084, and 27788) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and services and impact of the additions on the current or most recent contractors, the Committee has determined that the products and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or

other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. The action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products and services are added to the Procurement List:

Products

Product/NSNs: Battery, Nonrechargeable (Silver Oxide).
6135–01–110–9470—Battery, Button, Silver Oxide.
6135–01–106–7740—Battery, Button, Silver Oxide, Miniature.
Product/NSNs: Battery, Nonrechargeable (Size N).
6135–01–031–0862—Battery, Size N, Alkaline-Manganese Dioxide.
NPA: Eastern Carolina Vocational Center, Inc., Greenville, North Carolina.
Contracting Activity: Defense Supply Center Richmond, Richmond, Virginia.
Product/NSNs: Paper or Stationer's Shears (GSA Global Supply Only).
5110–00–161–6912—9'' Shears have 4⅝'' length of cut.
Product/NSNs: Straight Trimmer's Shears (GSA Global Supply Only).
5110–00–293–9199—7'' Shears have 3'' length of cut.
NPA: Winston-Salem Industries for the Blind, Winston-Salem, North Carolina.
Contracting Activity: GSA, Hardware & Appliances Center, Kansas City, Missouri.

Services

Service Type/Location: Custodial Services.
Cliffside Gas Field Facility, 15 Miles NW of Amarillo, Amarillo, Texas.
NPA: World Technical Services, Inc., San Antonio, Texas.
Contracting Activity: Bureau of Land Management, Albuquerque, New Mexico.
Service Type/Location: Grounds Maintenance.
USDA, Agriculture Research Service, Weslaco Center, 2413 E. Highway 83, Weslaco, Texas.
NPA: World Technical Services, Inc., San Antonio, Texas.
Contracting Activity: USDA, Agriculture Research Service, College Station, Texas.

Deletions

On December 2, 2005, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (70 FR 72289) of proposed deletions to the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action may result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products are deleted from the Procurement List:

Products

Product/NSNs: Gloves, Patient Examining.
6515–01–411–4796—Gloves, Patient Examining.
6515–01–441–6103—Gloves, Patient Examining.
6515–01–373–8306—Gloves, Patient Examining.
NPA: Bosma Industries for the Blind, Inc., Indianapolis, Indiana.
Contracting Activity: Department of Veterans Affairs, Washington, DC.

Sheryl D. Kennerly,

Director, Information Management.

[FR Doc. E6–1027 Filed 1–26–06; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–801, A–428–801, A–475–801, A–588–804, A–559–801, A–412–801]

Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Reviews

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 27, 2006.

FOR FURTHER INFORMATION CONTACT: Janis Kalnins or Richard Rimlinger, AD/CVD Operations, Office 5, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–1392 and (202) 482–4477, respectively.

SUPPLEMENTARY INFORMATION:

Background

At the request of interested parties, the Department of Commerce (the Department) initiated administrative reviews of the antidumping duty orders on antifriction bearings and parts thereof from France, Germany, Italy, Japan, Singapore, and the United Kingdom for the period May 1, 2004, through April 30, 2005. See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 70 FR 37749 (June 30, 2005). On October 21, 2005, we published a notice of rescission and partial rescission of the antidumping duty administrative reviews of ball bearings and parts thereof from Singapore, the United Kingdom, and Japan and of spherical plain bearings from France (70 FR 61251). The preliminary results of the reviews still underway are currently due no later than January 31, 2006.

Extension of Time Limit for Preliminary Results of Antidumping Duty Administrative Reviews

Section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), requires the Department to make a preliminary determination within 245 days after the last day of the anniversary month of an order for which a review is requested and a final determination within 120 days after the date on which the preliminary determination is published. If it is not practicable to complete the review within these time periods, section 751(a)(3)(A) of the Act allows the Department to extend the time limit for the preliminary determination to a maximum of 365 days after the last day of the anniversary month.

We determine that it is not practicable to complete the preliminary results of these reviews within the original time limit because of the number of respondents in these reviews and the complexity of the issues under analysis. Therefore, we are extending the time period for issuing the preliminary results of these reviews by 30 days until March 2, 2006.

This notice is published in accordance with section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2).

Dated: January 23, 2005.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E6–1056 Filed 1–26–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–838]

Carbazole Violet Pigment 23 from India: Notice of Initiation of Antidumping Duty New Shipper Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

EFFECTIVE DATE: January 27, 2006.

SUMMARY: On September 22, 2005, the Department of Commerce received a request to conduct a new shipper review of the antidumping duty order on carbazole violet pigment 23 from India. In accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended, and 19 CFR 351.214(d) (2005), we are initiating a new shipper review.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov or Minoo Hatten at (202) 482–0665 and (202) 482–1690, respectively, Office 5, AD/CVD Operations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

The notice announcing the antidumping duty order on carbazole violet pigment 23 from India was published on December 29, 2004. See *Notice of Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Carbazole Violet Pigment 23 from India*, 69 FR 77988 (December 29, 2004). On September 22, 2005, the Department of Commerce (the Department) received a timely request for a new shipper review of the antidumping duty order on carbazole violet pigment 23 from India from Gharda Chemicals, Ltd. (Gharda). On January 17, 2006, Gharda submitted additional information to supplement its new shipper review request in response to our January 10, 2006, letter requesting that Gharda correct certain deficiencies in its new shipper review request. Gharda is both the Indian producer and exporter of the subject merchandise to the United States on which its request for a new shipper review is based. Gharda Polymers USA, its U.S. subsidiary, is an importer of the subject merchandise.

As required by 19 CFR 351.214(b)(2)(i) and (iii)(A), Gharda certified that it did not export carbazole violet pigment 23 to the United States during the period of investigation (POI) and that, since the initiation of the investigation, it has never been affiliated with any exporter or producer that exported carbazole violet pigment 23 to the United Stated during the POI.[1]

In addition, pursuant to 19 CFR 351.214(b)(2)(iv), the company submitted documentation establishing the following: (1) the date on which it first shipped the subject merchandise for export to the United States and the date on which its subject merchandise was first entered, or withdrawn from warehouse, for consumption in the United States; (2) the volume of its first shipment and the volume of subsequent shipments[2]; and (3) the date of its first sale to an unaffiliated customer in the United States.

Initiation of Review

In accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(d)(1) we are initiating a new shipper review for shipments of carbazole violet pigment 23 from India produced and exported by Gharda. The period of review is December 1, 2004, through November 30, 2005. See 19 CFR 351.214(g)(1)(i)(A). We intend to issue the preliminary results of this new shipper review no later than 180 days after initiation of this review. We intend to issue final results of this review no later than 90 days after the date on which the preliminary results are issued. See 19 CFR 351.214(i).

We will instruct U.S. Customs and Border Protection to allow, at the option of the importer, the posting, until the completion of the review, of a bond or security in lieu of a cash deposit for each entry of the subject merchandise produced and exported by Gharda Chemicals Ltd. in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Gharda has certified that it both produced and exported the subject merchandise on which it based the request for a new shipper review. Therefore, we will apply the bonding option only to entries of the subject merchandise that were both produced and exported by Gharda.

[1] See Gharda's Request for New Shipper Review, dated September 22, 2005, and Gharda's Supplemental Submission, dated January 17, 2006.

[2] In its September 22, 2005, Request for New Shipper Review, Gharda stated that it had no subsequent shipments.

Interested parties that need access to proprietary information in this new shipper review should submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are in accordance with section 751(a)(2)(B) of the Act, 19 CFR 351.214(d), and 19 CFR 351.221(c)(1)(i).

Dated: January 23, 2006.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E6–1055 Filed 1–26–06; 8:45 am]

BILLING CODE 3510–DS–S

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Advanced Technology Program (ATP) Advisory Committee

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of renewal.

In accordance with the provisions of the Federal Advisory Committee Act, 5 U.S.C. App. 2, and the General Services Administration (GSA) rule on Federal Advisory Committee Management, 41 CFR part 101–6, and after consultation with GSA, the Secretary of Commerce has determined that the renewal of the Advanced Technology Program Advisory Committee is in the public interest in connection with the performance of the duties imposed on the Department by law.

The Committee was first established in July 1999 to advise ATP regarding their programs, plans, and policies. During the next two years, the Committee is expected to provide advice on ATP programs, plans, and policies; review ATP's efforts to assess the economic impact of the program; and report on the general health of the program and its effectiveness in achieving its legislatively mandated mission.

The Committee will consist of 6 to 12 members to be appointed by the Director of the National Institute of Standards and Technology to assure a balanced membership that will reflect the wide diversity of technical disciplines and industrial sectors represented in ATP projects.

The Committee will function solely as an advisory body and in compliance with the provisions of the Federal Advisory Committee Act. Copies of the

Committee's revised charter will be filed with the appropriate committees of the Congress and with the Library of Congress.

Inquiries or comments may be directed to Janet Brumby, Advanced Technology Program, National Institute of Standards and Technology, 100 Bureau Drive, Stop 4710, Gaithersburg, Maryland 20899–4710; telephone: 301–975–3189.

Dated: January 19, 2006.

William Jeffrey,

Director, NIST.

[FR Doc. E6–1047 Filed 1–26–06; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

Public User ID Badging

ACTION: Proposed collection; comment request.

SUMMARY: The United States Patent and Trademark Office (USPTO), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: Written comments must be submitted on or before March 28, 2006.

ADDRESSES: You may submit comments by any of the following methods:

E-mail: *Susan.Brown@uspto.gov.* Include ''0651–0041 comment'' in the subject line of the message.

Fax: 571–273–0112, marked to the attention of Susan Brown.

Mail: Susan K. Brown, Records Officer, Office of the Chief Information Officer, Architecture, Engineering and Technical Services, Data Architecture and Services Division, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

Federal e-Rulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information regarding online access cards or user training should be directed to Diane Lewis, Manager, Public Search Facilities, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–8714; or by electronic mail at *Diane.Lewis@uspto.gov.*

Requests for additional information regarding security identification badges should be directed to J.R. Garland, Director, Security Office, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–6247; or by electronic mail at *Calib.Garland@uspto.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The United States Patent and Trademark Office (USPTO) is required by 35 U.S.C. 41(i)(1) to maintain a Public Search Facility to provide patent and trademark collections for searching and retrieval of information. The Public Search Facilities are maintained for public use with paper and electronic search files and trained staff to assist searchers. The USPTO also offers training courses to assist the public with using the advanced electronic search systems available at the facilities.

In order to manage the patent and trademark collections that are available to the public, the USPTO issues online access cards to customers who wish to use the electronic search systems at the Public Search Facility. Customers may obtain an online access card by completing the application at the Public Search Facility reference desk and providing proper identification. The plastic online access cards include a bar-coded user number and an expiration date. Users may renew their cards by validating and updating the required information and may obtain a replacement for a lost card by providing proper identification.

Under the authority provided in 41 CFR Part 102–81, the USPTO issues security identification badges to members of the public who wish to use the facilities at the USPTO. Public users may apply for a security badge in person at the USPTO Office of Security by providing the necessary information and presenting a valid form of identification with photograph. The security badges include a color photograph of the user and must be worn at all times while at the USPTO facilities.

The USPTO is updating this information collection to include the renewal of security identification badges for public users. The security badges must be renewed annually and there is no fee. The USPTO is also deleting the previous $15 fee for obtaining a replacement online access card from this collection because that fee has been eliminated. Finally, the USPTO is revising the estimated annual responses for this collection to reflect current submissions related to online access cards, training courses, and security badges for users of the Public Search Facilities.

II. Method of Collection

The applications for online access cards and security identification badges are completed on site and handed to a USPTO staff member for issuance. User training application forms may be mailed, faxed, or hand delivered to the USPTO.

III. Data

OMB Number: 0651–0041.

Form Number(s): PTO–2030, PTO–2224.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households; businesses or other for-profits; not-for-profit institutions; farms; the Federal Government; and state, local or tribal governments.

Estimated Number of Respondents: 11,369 responses per year.

Estimated Time Per Response: The USPTO estimates that it will take the public approximately five to 10 minutes (0.08 to 0.17 hours) to complete the information in this collection, including gathering the necessary information, preparing the appropriate form, and submitting the completed request.

Estimated Total Annual Respondent Burden Hours: 1,097 hours per year.

Estimated Total Annual Respondent Cost Burden: $163,453 per year. The USPTO estimates that approximately ⅓ of the users responding to this collection are attorneys and ⅔ are paraprofessionals. Using ⅓ of the professional rate of $286 per hour for associate attorneys in private firms and ⅔ of the paraprofessional rate of $81 per hour, the estimated rate for respondents to this collection is approximately $149 per hour.

Item	Estimated time for response (minutes)	Estimated annual responses	Estimated annual burden hours
Application for Public User ID (Online Access Card) (PTO–2030)	5	2,951	236
Issue Online Access Card	10	1,975	336
Renew Online Access Card	5	1,975	158

Item	Estimated time for response (minutes)	Estimated annual responses	Estimated annual burden hours
Replace Online Access Card	5	70	6
User Training Application Forms	10	98	17
Security Identification Badges for Public Users (PTO–2224)	5	1,000	80
Renew Security Identification Badges for Public Users	5	3,200	256
Replace Security Identification Badge	5	100	8
Total		11,369	1,097

Estimated Total Annual Non-hour Respondent Cost Burden: $4,152. There are no capital start-up, maintenance, or recordkeeping costs associated with this information collection. However, this collection does have annual (non-hour) costs in the form of filing fees and postage costs.

There are no application or renewal fees for online access cards or security identification badges. However, there is a $15 fee for issuing a replacement security identification badge. The previous $15 fee for obtaining a replacement online access card has been eliminated. The USPTO estimates that it will reissue approximately 100 security badges annually that have been lost or need to be replaced, for a total of $1,500 per year in replacement fees.

There are registration fees for the user training courses offered at the Public Search Facilities. The regular cost for a public course is $25 per class, and individual instruction may also be arranged for $120 per class. The USPTO estimates that it will receive 96 registrations for public courses and 2 registrations for individual instruction per year, for a total of $2,640 in training registration fees. Therefore, this collection has a total of $4,140 per year in filing fees in the form of security badge replacement fees and training registration fees.

Item	Estimated annual responses	Fee amount	Estimated annual fee costs
Application for Public User ID (Online Access Card) (PTO–2030)	2,951	$0.00	$0.00
Issue Online Access Card	1,975	0.00	0.00
Renew Online Access Card	1,975	0.00	0.00
Replace Online Access Card	70	0.00	0.00
User Training Application Forms (Public Course)	96	25.00	2,400.00
User Training Application Forms (Individual Course)	2	120.00	240.00
Security Identification Badges for Public Users (PTO–2224)	1,000	0.00	0.00
Renew Security Identification Badges for Public Users	3,200	0.00	0.00
Replace Security Identification Badge	100	15.00	1,500.00
Total	11,369		4,140.00

Users may incur postage costs when submitting a user training application form to the USPTO by mail. The USPTO expects that approximately 30 of the estimated 98 training forms received per year will be submitted by mail. The USPTO estimates that the average first-class postage cost for a mailed training form will be 39 cents, for a total postage cost of approximately $12 per year for this collection.

The total annual (non-hour) respondent cost burden for this collection in the form of filing fees and postage costs is estimated to be $4,152 per year.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, *e.g.*, the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: January 23, 2006.

Susan K. Brown,

Records Officer, USPTO, Office of the Chief Information Officer, Architecture, Engineering and Technical Services, Data Architecture and Services Division.

[FR Doc. E6–1025 Filed 1–26–06; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Notice of Availability of the Draft Programmatic Environmental Impact Statement for DTRA Activities on White Sands Missile Range, New Mexico

AGENCY: Office of the Under Secretary of Defense for Acquisition, Technology, and Logistics, Defense Threat Reduction Agency, DoD.

ACTION: Notice of availability.

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Act (NEPA), 42 U.S.C. 4321–4370, as implemented by the Council of Environmental Quality Regulations (40 CFR parts 1500–1508), the Defense Threat Reduction Agency (DTRA) announces the availability of the Draft Programmatic Environmental Impact Statement (PEIS) for DTRA activities on White Sands Missile Range (WSMR), New Mexico. As a major cooperating agency, WSMR has participated in the

preparation of the PEIS. Future development of DTRA's testing facilities and program, and its scope require a PEIS to adequately address potential environmental impacts.

ADDRESSES: Written comments may be forwarded to the Defense Threat Reduction Agency, ATTN: WSMR PEIS Comments, 1680 Texas St., SE., Kirtland AFB, NM 87117–5669; faxed to (505) 853–1793; or emailed to *WSMR_PEIS_Comments@abq.dtra.mil.*

FOR FURTHER INFORMATION CONTACT: DTRA Public Affairs at (703) 767–5870 or (800) 701–5096.

SUPPLEMENTARY INFORMATION: White Sands Missile Range covers approximately 8,288 km² (3,200 mi²) of south-central New Mexico. Proposed DTRA activities at WSMR have the potential to significantly impact certain natural, social, cultural, and economic resources in the region. The study area for environmental analyses includes the Hard Target Defeat Test bed (HTDT), Permanent High Explosive Test Site (PHETS), Seismic hardrock In Situ Test site (SHIST), Alternate SHIST, and Large Blast/Thermal Simulator (LBTS). The objective has been to provide a thorough, comprehensive and PEIS that will serve as a planning and decision-making tool, a public information source, and a reference for mitigation tracking concerning DTRA future activities.

Alternatives consist of modifications of specific activities; variations in type and toxicity of simulants; and the No Action alternative. These alternatives were developed during preparation of the Draft PEIS as a result of environmental analyses of the activities and public input.

Significant Issues: Certain biologically diverse areas on White Sands Missile Range utilized by the Defense Threat Reduction Agency serve as habitat or potential habitat for protected floral and faunal (plant and animal) species. To date, several locations in the areas studied have been identified as important cultural resources. The most significant are Ground Zero and McDonald Ranch House, part of Trinity Site National Historic Landmark located within the Permanent High Explosive Test Site boundaries.

Significant issues that are addressed in the Draft PEIS include:

1. The continued operation and maintenance of various test structures used as targets for weapon system evaluations.

2. Construction of new test structures, enlargement of existing test beds, and possible development of new test beds.

3. Testing, operations and maintenance activities at tunnel targets in the Capitol Canyon area (HTDT).

4. The use of chemical and biological simulants in collateral damage tests.

5. Planned improvements to the DTRA Administrative Park within the PHETS boundaries.

Public hearings will be held on Tuesday, February 28, 2006, at the Civic Center in Alamogordo, NM (800 East First Street, Alamagordo, NM); on Wednesday, March 1, 2006, at the Ramada Palms in Las Cruces, NM (201 E University Ave., Las Cruces, NM); and on Thursday, March 2, 2006, at the New Mexico Institute of Mining and Technology, Macey Center, in Socorro, NM (801 Leroy Place, Socorro, NM) to facilitate public input to the PEIS.

All hearings will begin at 5 p.m. with a 2-hour open house session for the public to ask questions of subject matter experts. These sessions will be followed by the public hearings, beginning at 7 p.m. in order to receive public comments.

Please note any changes to the times, dates, and locations for the hearings will be published in local newspapers and on the PEIS Web site at *www.dtra.mil/Toolbox/Directorates/TD/programs/dpeis/index.cfm.*

For those that cannot attend the public hearings, written comments via mail or e-mail are encouraged. Comments should clearly identify and describe the specific issue(s) or topics that the PEIS should address.

To be considered in the Final PEIS, comments and suggestions must be postmarked no later than 60 days following this **Federal Register** announcement.

Dated: January 23, 2006.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 06–815 Filed 1–26–06; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF DEFENSE

Office of the Secretary

Meeting of the Defense Department Advisory Committee on Women in the Services (DACOWITS)

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a), Public Law 92–463, as amended, notice is hereby given of a forthcoming meeting of the Defense Department Advisory Committee on Women in the Services (DACOWITS). The purpose of the Committee meeting is to introduce new members and conduct orientation training. The meeting is open to the public, subject to the availability of space.

Interested persons may submit a written statement for consideration by the Committee and make an oral presentation of such. Persons desiring to make an oral presentation or submit a written statement to the Committee must notify the point of contact listed below no later than 5 p.m., 17 February 2006. Oral presentations by members of the public will be permitted only on Wednesday, 22 February 2006 from 4:45 p.m. to 5 p.m. before the full Committee. Presentations will be limited to two minutes. Number of oral presentations to be made will depend on the number of requests received from members of the public. Each person desiring to make an oral presentation must provide the point of contact listed below with one (1) copy of the presentation by 5 p.m., 17 February 2006 and bring 35 copies of any material that is intended for distribution at the meeting. Persons submitting a written statement must submit 35 copies of the statement to the DACOWITS staff by 5 p.m. on 17 February 2006.

DATES: 22 February 2006, 8:30 a.m.–5 p.m., 23 February 2006, 8:30 a.m.–5 p.m., 24 February 2006, 8:30 a.m.–5 p.m.

Location: Double Tree Hotel Crystal City National Airport, 300 Army Navy Drive, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: MSgt Gerald Posey, USA DACOWITS, 4000 Defense Pentagon, Room 2C548A, Washington, DC 20301–4000. Telephone (703) 697–2122. Fax (703) 614–6233.

SUPPLEMENTARY INFORMATION: Meeting agenda.

Wednesday, 22 February 2006, 8:30 a.m.–5 p.m.

Welcome & Administrative Remarks.

New Member Orientation.

Public Forum.

Thursday, 23 February 2006, 8:30 a.m.–5 p.m.

New Member Orientation.

Friday, 24 February 2006, 8:30 a.m.–5 p.m.

New Member Orientation.

Note: Exact order may vary.

Dated: January 23, 2006.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. 06–786 Filed 1–26–06; 8:45 am]

BILLING CODE 5001–06–M

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before February 27, 2006.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Rachel Potter, Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10222, New Executive Office Building, Washington, DC 20503 or faxed to (202) 395–6974.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, *e.g.* new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: January 23, 2006.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer.

Federal Student Aid

Type of Review: Extension.

Title: Federal Direct Stafford/Ford Loan and Federal Direct Unsubsidized Stafford/Ford Loan Master Promissory Note.

Frequency: On Occasion.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 723,650.

Burden Hours: 361,825.

Abstract: This form is the means by which a student borrower agrees to repay a Federal Direct Stafford/Ford Loan and/or a Federal Direct Unsubsidized Stafford/Ford Loan.

Requests for copies of the information collection submission for OMB review may be accessed from *http://edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2935. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC_DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC_DocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–1052 Filed 1–26–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before March 28, 2006.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: January 23, 2006.

Angela C. Arrington,

IC Clearance Official, Regulatory Information Management Services, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.

Title: Annual Protection and Advocacy of Individual Rights (PAIR) Program Performance Reports.

Frequency: Annually.

Affected Public: Individuals or household.

Reporting and Recordkeeping Hour Burden:

Responses: 57.
Burden Hours: 912.

Abstract: Form RSA–509 will be used to analyze and evaluate the Protection and Advocacy of Individuals Rights (PAIR) Program administered by eligible systems in states. These systems provide services to eligible individuals with disabilities to protect their legal and human rights.

Requests for copies of the proposed information collection request may be accessed from *http://www.edicsweb.ed.gov,* by selecting the ''Browse Pending Collections'' link and by clicking on link number 2976. When you access the information collection, click on ''Download Attachments'' to view. Written requests for information should be addressed to U.S. Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to *IC_DocketMgr@ed.gov* or faxed to 202–245–6623. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be electronically mailed to the e-mail address *IC_DocketMgr@ed.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. E6–1053 Filed 1–26–06; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–174–000]

Dominion Transmission, Inc.; Notice of Proposed Changes in FERC Gas Tariff

January 20, 2006.

Take notice that on January 13, 2006, Dominion Transmission, Inc. (DTI) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, the following tariff sheets, to become effective February 13, 2006:

Second Revised Sheet No. 103;
Third Revised Sheet No. 212A;
Second Revised Sheet No. 653;
Second Revised Sheet No. 1008;
Second Revised Sheet No. 1009;
Second Revised Sheet No. 1010;
Second Revised Sheet No. 1043;
Third Revised Sheet No. 1088.

DTI states that the purpose of this filing is to change the penalty provisions for violations of curtailment or interruption orders or operational flow orders in DTI's FERC Gas Tariff from the existing fixed price penalties to the higher of its fixed price penalties or multiples of daily indexed prices.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of § 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E6–1000 Filed 1–26–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER05–1482–000; ER05–1482–001]

Electric Energy, Inc.; Notice of Issuance of Order

January 20, 2006.

Electric Energy, Inc. (EEInc) filed an application for market-based rate authority, with an accompanying rate tariff. The proposed rate tariff provides for wholesale sales of capacity and energy at market-based rates. EEInc. also requested waiver of various Commission regulations. In particular, EEInc. requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by EEInc.

On December 8, 2005, the Commission granted the request for blanket approval under Part 34, subject to the following:

Any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by EEInc. should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211, 385.214 (2004).

Notice is hereby given that the deadline for filing motions to intervene or protests, is February 8, 2006.

Absent a request to be heard in opposition by the deadline above, EEInc. is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of EEInc., compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of EEInc.'s issuances of securities or assumptions of liability.

Copies of the full text of the Commission's Order are available from the Commission's Public Reference Room, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Commission's Web site at *http://www.ferc.gov*, using the eLibrary link. Enter the docket number excluding the last three digits in

the docket number filed to access the document. Comments, protests, and interventions may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages electronic filings.

Magalie R. Salas,

Secretary.

[FR Doc. E6–1002 Filed 1–26–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–94–001]

Garden Banks Gas Pipeline, LLC; Notice of Compliance Filing

January 20, 2006.

Take notice that on January 5, 2006, Garden Banks Gas Pipeline, LLC (Garden Banks) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets to become effective December 15, 2005:

Substitute Second Revised Sheet No. 15
Substitute Second Revised Sheet No. 25
Substitute Third Revised Sheet No. 34

Garden Banks states that the purpose of the filing is to comply with the Commission instruction to file redlined copies of the proposed tariff sheets.

Any person desiring to protest this filing must file in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). Protests to this filing will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Such protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing a protest must serve a copy of that document on all the parties to the proceeding.

The Commission encourages electronic submission of protests in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Magalie R. Salas,

Secretary.

[FR Doc. E6–998 Filed 1–26–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP06–175–000]

Gas Transmission Northwest Corporation; Notice of Petition for Limited Waiver

January 20, 2006.

Take notice that on January 17, 2006, Gas Transmission Northwest Corporation (GTN) petitions the Commission for the grant of a limited waiver, to the extent required, of the Right-of-First-Refusal (ROFR) provisions of GTN's tariff in order to facilitate the restructuring of Duke Energy Marketing America's (DEMA) FTS–1 contracts.

GTN states that the filing has been served upon each person designated on the official service list.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed in accordance with the provisions of Section 154.210 of the Commission's regulations (18 CFR 154.210). Anyone filing an intervention or protest must serve a copy of that document on the Applicant. Anyone filing an intervention or protest on or before the intervention or protest date need not serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov*. Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible online at *http://www.ferc.gov*, using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov*, or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on January 27, 2006.

Magalie R. Salas,

Secretary.

[FR Doc. E6–1001 Filed 1–26–06; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 620]

NorQuest Seafood Inc.; Notice of Authorization for Continued Project Operation

January 20, 2006.

On October 3, 2003, NorQuest Seafood, Inc., licensee for the Chignik Hydroelectric Project No. 620, filed an application for a new or subsequent license pursuant to the Federal Power Act (FPA) and the Commission's regulations there under. Project No. 620 is located on Indian Creek in Chignik, Alaska.

The license for Project No. 620 was issued for a period ending October 31, 2005. Section 15(a)(1) of the FPA, 16 U.S.C. 808(a)(1), requires the Commission, at the expiration of a license term, to issue from year to year an annual license to the then licensee under the terms and conditions of the prior license until a new license is issued, or the project is otherwise disposed of as provided in section 15 or any other applicable section of the FPA. If the project's prior license waived the applicability of section 15 of the FPA, then, based on section 9(b) of the Administrative Procedure Act, 5 U.S.C. 558(c), and as set forth at 18 CFR 16.21(a), if the licensee of such project has filed an application for a subsequent license, the licensee may continue to operate the project in accordance with the terms and conditions of the license

after the minor or minor part license expires, until the Commission acts on its application. If the licensee of such a project has not filed an application for a subsequent license, then it may be required, pursuant to 18 CFR 16.21(b), to continue project operations until the Commission issues someone else a license for the project or otherwise orders disposition of the project.

If the project is subject to section 15 of the FPA, notice is hereby given that an annual license for Project No. 620 is issued to NorQuest Seafood Inc., for a period effective November 1, 2005 through October 31, 2006, or until the issuance of a new license for the project or other disposition under the FPA, whichever comes first. If issuance of a new license (or other disposition) does not take place on or before October 1, 2006, notice is hereby given that, pursuant to 18 CFR 16.18(c), an annual license under section 15(a)(1) of the FPA is renewed automatically without further order or notice by the Commission, unless the Commission orders otherwise.

If the project is not subject to section 15 of the FPA, notice is hereby given that NorQuest Seafood Inc. is authorized to continue operation of the Chignik Hydroelectric Project No. 620 until such time as the Commission acts on its application for subsequent license.

Magalie R. Salas,

Secretary.

[FR Doc. E6–999 Filed 1–26–06; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OECA–2005–0026; FRL–8025–7]

Agency Information Collection Activities; Submission for OMB Review and Approval; Comment Request; NSPS for Grain Elevators (Renewal), ICR Number 1130.08, OMB Number 2060–0082

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act, this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on April 30, 2006. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

DATES: Additional comments may be submitted on or before February 27, 2006.

ADDRESSES: Submit your comments, referencing docket ID number EPA–HQ–OECA–2005–0026, to (1) EPA online using *http://www.regulations.gov* (our preferred method), by email to *docket.oeca@epa.gov,* or by mail to: EPA Docket Center (EPA/DC), Environmental Protection Agency, Enforcement and Compliance Docket and Information Center, Mail Code 2201T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Learia Williams, Compliance Assessment and Media Programs Division, Office of Compliance, (Mail Code 2223A), Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone number: (202) 564–4113; fax number: (202) 564–0050; e-mail address: *williams.learia@epa.gov.*

SUPPLEMENTARY INFORMATION: EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On May 6, 2005 (70 FR 24020), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. EPA–HQ–OECA 2005–0026, which is available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center Docket is: (202) 566–1752. An electronic version of the public docket is available at *http://www.regulations.gov.* Use *http://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select ''search,'' then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in *http://www.regulations.gov* as EPA receives them and without change, unless the comment contains copyrighted material, Confidential Business Information (CBI), or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in *http://www.regulations.gov.* The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in *http://www.regulations.gov.* For further information about the electronic docket, go to *http://www.regulations.gov.*

Title: NSPS for Grain Elevators (Renewal).

Abstract: The New Source Performance Standards (NSPS) for grain elevators were proposed on January 18, 1977 and promulgated on August 3, 1978. These standards apply to each affected facility at any grain terminal elevator or any grain storage elevator. The facilities are each truck unloading station, truck loading station, barge and ship loading station, railcar loading station, railcar unloading station, grain dryer and all grain handling operations that commenced construction, modification or reconstruction after August 3, 1978.

Owners or operators of the affected facilities must make the following one-time-only reports: notification of the date of construction or reconstruction; notification of the actual date of startup; notification of any physical or operational change to an existing facility that may increase the rate of emission of the regulated pollutant; notification of initial performance test; and results of initial performance test. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction, or any period during which the monitoring system is inoperative. Performance tests are the Agency's records of a source's initial capability to comply with emissions

standards and not the operating conditions under which compliance was achieved. An annual summary report is also required.

Any owner or operator subject to the provisions of this subpart must maintain a file of these measurements, and retain the file for at least two years following the collection of such measurements, maintenance reports, and records. All reports are sent to the delegated state or local authority. In the event that there is no such delegated authority, the reports are sent directly to the EPA regional office.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB Control Number. The OMB Control Numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15, and are identified on the form and/or instrument, if applicable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 10.35 hours per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Owners or operators of each grain terminal elevator or any grain storage elevator.

Estimated Number of Respondents: 200.

Frequency of Response: On occasion, initially and annually.

Estimated Total Annual Hour Burden: 2,070 hours.

Estimated Total Annual Costs: $167,108, which includes $0 Capital/startup expense, $0 Operations and Maintenance costs, and $167,108 Respondent Labor costs.

Changes in the Estimates: There was an increase of 1,811 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. The increase in burden hours from the most recently approved ICR is due primarily to a more accurate accounting of existing sources, an annual summary report that was inadvertently left out, a revised labor rate, and the fact that we are presently accounting for management and clerical person hours per year, which was not shown in the previous ICR.

After a thorough analysis by the National Grain and Feed Association, they arrived at two hundred as the number of sources that are subject to subpart DD, as compared to one hundred and thirty-two in the previous ICR.

There are no capital or operations and maintenance costs since there is no continuous monitoring.

Dated: December 5, 2005.

Oscar Morales,

Director, Collection Strategies Division.

[FR Doc. E6–1041 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER—FRL–6671–7]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at 202–564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the **Federal Register** dated April 1, 2005 (70 FR 16815).

Draft EISs

EIS No. 20050340, ERP No. D–AFS–J65451–UT, West Fork Blacks Fork Allotment Management Plan, Proposes to Authorize Continued Livestock Grazing, Township 1 North, Range 11 East, Salt Lake Principle Meridan, Evanston Ranger District, Wasatch-Cache National Forest, Summit County, UT

Summary: EPA expressed concerns about adverse impacts from sheep grazing to soils and vegetation. Rating EC2.

EIS No. 20050400, ERP No. D–BLM–K65291–00, Lake Havasu Field Office Resource Management Plan, Implementation, Colorado River, Davis Dam in the north and south to Park Dam, CA and AZ

Summary: EPA does not object to the proposed project. Rating LO.

EIS No. 20050405, ERP No. D–NPS–K39094–NV, Clean Water Coalition Systems Conveyance and Operations Program, Construction, Operation and Maintenance, City of Las Vegas, City County, NV

Summary: EPA expressed concerns about potential impacts to water quality and requested additional information on wastewater discharge permit requirements, details on water and air quality mitigation, criteria for effluent allocation between Las Vegas Wash and Boulder Basin, measures to conserve, reuse, and recycle water, and measures to reduce wastewater production. Rating EC2.

EIS No. 20050424, ERP No. D–NPS–K39095–CA, Furnace Creek Water Collection System, Reconstruction, Death Valley National Park, Implementation, Inyo County, CA

Summary: EPA expressed environmental concerns about the proposed discharge of more than 120,000 gallons per day of reverse osmosis brine into the Furnace Creek Wash alluvium, which could affect surface water and groundwater quality. EPA requested that other disposal alternatives be considered. Rating EC2.

EIS No. 20050436, ERP No. D–NPS–F61022–MI, Isle Royale National Park Wilderness and Backcounty Management Plan, Implementation, MI

Summary: EPA does not object to the proposed project. Rating LO.

EIS No. 20050446, ERP No. D–USN–E11059–00, Undersea Warfare Training Range (USWTR), Installation and Operation, Preferred Site (in the Cherry Point Operating Area) and the Alternate Sites (within the Virginia Capes and Jacksonville Operating Areas), NC, VA and FL

Summary: EPA does not object to the proposed project. Rating LO.

Final EISs

EIS No. 20050391, ERP No. F–AFS–K65284–CA, Creeks Forest Health Recovery Project, To Develop a Network of Defensible Fuel Profile Zones (DFPZs), Group-Selection Timber Harvest, Individual Tree Selection, Lassen National Forest, Almanor Ranger District, Plumas County, CA

Summary: EPA's previous concerns about the potential impacts to water and air quality, environmental justice and tribal consultation have been adequately addressed; therefore, EPA does not object to the proposed action.

EIS No. 20050423, ERP No. F–BLM–K65439–NV, Sloan Canyon National Conservation Area, Resource Management Plan, Implementation, Cities of Las Vegas and Henderson, Clark County, NV

Summary: EPA does not object to the proposed project.

EIS No. 20050479, ERP No. F–SFW–A65171–00, Resident Canada Goose Management Plan, Evaluate Alternatives Strategies to Reduce, Manage, and Resident Canada Goose Population, Implementation, within the Conterminous U.S.

Summary: No formal comment letter was sent to the preparing agency.

EIS No. 20050508, ERP No. F–NPS–F65057–IN, Lincoln Boyhood National Memorial General Management Plan, Implementation, Lincoln City Spencer County, IN

Summary: EPA does not object to the proposed project.

EIS No. 20050522, ERP No. F–NPS–G02014–TX, Big Thicket National Preserve Oil and Gas Management Plan, Implementation, Hardin, Jefferson, Orange, Liberty, Tyler, Jasper and Polk Counties, TX

Summary: No formal comment letter was sent to the preparing agency.

Dated: January 24, 2006.

Ken Mittelholtz,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. E6–1042 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6671–6]

Environmental Impacts Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7167 or *http://www.epa.gov/compliance/nepa/.* Weekly receipt of Environmental Impact Statements Filed 01/16/2006 through 01/20/2006 pursuant to 40 CFR 1506.9.

EIS No. 20060019, Final EIS, FHW, NY, Willis Avenue Bridge Reconstruction, Proposing Reconstruction of 100-year-old Willis Avenue Bridge over the Harem River between Manhattan and the Bronx, New York and Bronx Counties, NY, Wait Period Ends: 02/27/2006, Contact: Robert Arnold 518–431–4125.

EIS No. 20060020, Final EIS, COE, NC, Fort Bragg Headquarters for XVII Airborne Corps and Army Special Operations Command, To Determine the Level of Training on the Overhills Tract Program, Cumberland and Harnett Counties, NC, Wait Period Ends: 02/27/2006, Contact: Ms. Julie Morgan 888–893–0678. Ext 258.

EIS No. 20060021, Final EIS, AFS, UT, Quitchupah Creek Road Project, Public Road Construction to Provide Access from UT–10 to the Acord Lakes Road, Application for Right-of-Way Grant, Fishlake National Forest, Sevier County Special Services District (SSD), Sevier and Emery Counties, UT, Wait Period Ends: 02/27/2006, Contact: Rod Lee 435–896–1500.

EIS No. 20060022, Draft EIS, FTA, WA, South Valley Corridor Project, Improvement to Existing Urban Transportation System, Light Rail Transit (LRT), Right-of-Way Grant, City of Liberty Lake, Spokane County, WA, Comment Period Ends: 03/13/2006, Contact: John Witmer 206–220–7954.

EIS No. 20060023, Draft EIS, IBR, 00 Upper Rio Grande Basin Water Operations Review, To Develop an Integrated Plan for Water Operations at the Existing Facilities, NM, CO and TX, Comment Period Ends: 03/21/2006, Contact: Valda Terauds 505–462–3584, U.S. Department of the Interior's Bureau of Reclamation and the U.S. Department of Army Corps of Engineers are Joint Lead Agencies for the above project.

EIS No. 20060024, Draft Supplement, AFS, WI, McCaslin Project, Vegetation Management Activities that are Consistent with Direction in the Nicolet Forest Plan, New Information to Address Inadequate Disclosure of the Cumulative Effect Analysis for Six Animal and Eight Plant Species, Lakewood/Lasna District, Chequamegaon-Nicolet National Forest, Oconto and Forest Counties, WI, Comment Period Ends: 03/13/2006, Contact: Brian Quinn 715–762–5176.

EIS No. 20060025, Draft Supplement, AFS, WI, Northwest Howell Vegetation Management Project, New Information to Address Inadequate Disclosure of the Cumulative Effects Analysis for Six Animal and Two Plant Species, Eagle River-Florence Ranger District, Chequamegon-Nicole National Forest, Florence and Forest Counties, WI, Comment Period Ends: 03/13/2006, Contact: Brian Quinn 715–762–5176.

EIS No. 20060026, Draft EIS, AFS, AK, Whistle Stop Project, Provide Access to Backcountry Recreation Area on National Forest, System (NFS) Lands, on the Kenai Peninsula between Portage and Moose Pass, Chugach National Forest, Kenai Peninsula Borough, AK, Comment Period Ends: 03/13/2006, Contact: Adam McClory 907–754–2352.

EIS No. 20060027, Draft EIS, AFS, CA, Kings River Project, Proposal to Restore Historical Pre-1850 Forest Conditions, Implementation, High Sierra Ranger District, Sierra National Forest, Fresno County, CA, Comment Period Ends: 03/13/2006, Contact: Ross Peckinpah 559–855–5355.

EIS No. 20060028, Draft EIS, DOD, NM, PROGRAMMATIC—Defense Threat Reduction Agency (DTRA) Activities on White Sands Missile Range (WSMR), Implementation, NM, Comment Period Ends: 03/28/2006, Contact: Linda Woestendiek 505–846–5396.

EIS No. 20060029, Final EIS, NOA, WA, Washington State Forest Habitat Conservation Plan, Propose Issuance of Multiple Species Incidental Take Permit of 4(d) Rules, NPDES Permit, U.S. Army COE Section 10 and 404 Permits, WA, Wait Period Ends: 02/27/2006, Contact: Sally Butt 360–753–5832.

Amended Notices

EIS No. 20050448, Draft EIS, BLM, MT, Upper Missouri River Breaks National Monument Resource Management Plan, Implementation, Blaine, Chouteau, Fergus and Phillips Counties, MT, Comment Period Ends: 04/26/2006, Contact: Jerry Majerus 406–538–1924, Revision of **Federal Register** Notice Published on 10/28/2005: Comment Period has been Extended from 01/26/2006 to 04/26/2006.

EIS No. 20050516, Draft Supplement, DOI, 00, Upper Mississippi River National Wildlife and Fish Refuge, Comprehensive Conservation Plan, A New Alternative E: Modified Wildlife and Integrated Public Use, Implementation, MN, WI, IL and IA, Comment Period Ends: 03/06/2006, Contact: Don Hultman 507–452–4232 This document is available on the Internet at: *http://www.fws.gov/midwest/planning/uppermiss/index.html* Revision of **Federal Register** Notice Published 12/16/2005: Comment Period has been extended from 02/03/2006 to 03/06/2006.

EIS No. 20050534, Draft EIS, AFS, WA, The Summit at Snoqualmie Master Development Plan (MPD), Proposal to Ensure Long-Term Economic Viability, Mt. Baker-Snoqualmie/Okanogan-Wenatchee National Forests, King County, WA, Comment Period Ends: 02/21/2006, Contact: Larry Donovan 425–744–3403,

Revision of **Federal Register** Notice Published 12/16/2005; CEQ Comment Date has been extended from 02/06/2006 to 02/21/2006.

EIS No. 20050554, Draft EIS, IBR, ND, Red River Valley Water Supply Project, Development and Delivery of a Bulk Water Supply to meet Long-Term Water Needs of the Red River Valley, Implementation, ND, Comment Period Ends: 02/28/2006, Contact: Signe Snortland 701–250–4242, ext. 3619 Revision of **Federal Register** Notice Published on 01/06/2006: Correction to Comment Period from 02/21/2006 to 02/28/2006.

Dated: January 24, 2006.

Ken Mittelholtz,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. E6–1043 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP–2004–0292; FRL–7758–8]

Notice of Filing of a Pesticide Petition for the Amendment of a Regulation for the Fungicide Pyraclostrobin and Its Metabolite in or on Almond Hulls

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the amendment of a regulation for residues of the fungicide pyraclostrobin, carbamic acid, [2–[[[1–(4–chlorophenyl)–1H-pyrazol–3–yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolite methyl-N-[[[1–(4–chlorophenyl) pyrazol–3–yl]oxy]-o-tolyl] carbamate (BF 500–3); expressed as parent compound in or on almond hulls.

DATES: Comments must be received on or before February 27, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP–2004–0292 and pesticide petition number (PP) 5F6906, by one of the following methods:

- *http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *E-mail*: *opp.docket@epa.gov*.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number EPA-HQ-OPP–2004–0292. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305–5805. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP–2004–0292. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/docket.htm/*.

Docket: All documents in the docket are listed in the www.regulation.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Tony Kish, Registration Division, (7505C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; (703) 308–9943; e-mail: *kish.tony@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the

public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

EPA is printing a summary of a pesticide petition received under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment or amendment of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. EPA has determined that this pesticide petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petition. Additional data may be needed before EPA rules on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition included in this notice, prepared by the petitioner along with a description of the analytical method available for the detection and measurement of the pesticide chemical residues is available on EPA's Electronic Docket at *http://www.regulations.gov/*. To locate this information on the home page of EPA's Electronic Docket, select ''Quick Search'' and type the OPP docket ID number. Once the search has located the docket, clicking on the ''Docket ID'' will bring up a list of all documents in the docket for the pesticide including the petition summary.

Amendment to Existing Tolerance

PP 5F6906. BASF Corporation, 26 Davis Drive, P.O. Box 13528, Research Triangle Park, NC 17709, proposes to amend the tolerances in 40 CFR 180.582 for residues of the fungicide pyraclostrobin carbamic acid, [2–[[[1–(4–chlorophenyl)–1H-pyrazol–3–yl]oxy]methyl]phenyl]methoxy-, methyl ester and its metabolite methyl-N-[[[1–(4–chlorophenyl) pyrazol–3–yl]oxy]o-tolyl] carbamate (BF 500–3); expressed as parent compound in or on the food commodity almond, hulls at 7.0 parts per million (ppm). In plants, the method of analysis is aqueous organic solvent extraction, column clean up and quantitation by liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS). In animals, the method of analysis involves base hydrolysis, organic extraction, column clean up and quantitation by LC/MS/MS or derivatization (methylation) followed by quantitation by gas chromatography/mass spectrometry (GC/MS).

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 19, 2006.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 06–758 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2006–0053; FRL–7759–1]

Notice of Filing of a Pesticide Petition for the Amendment of a Regulation for the Insecticide Imidacloprid and Its Metabolites in or on Oats and Rye Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the amendment of a regulation for residues of the insecticide imidacloprid (1–[(6–chloro–3–pyridinyl)methyl]-N-nitro–2–imidazolidinimine) and its metabolites containing the 6–chloropyridinyl moiety, all expressed as 1–[(6–chloro–3–pyridinyl)methyl]-N-nitro–2–imidazolidinimine in or on oats and rye commodities.

DATES: Comments must be received on or before February 27, 2006.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2006–0053 and pesticide petition number (PP) 5F7020, by one of the following methods:

- *http://www.regulations.gov/*. Follow the on-line instructions for submitting comments.
- *E-mail*: *opp.docket@epa.gov*.
- *Mail*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Hand Delivery*: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID numberEPA–HQ–OPP–2006–0053. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305–5805. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2004–0539. EPA's policy is that all comments received will be included in the public docket without change and may be made available on-line at *http://www.regulations.gov/*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be captured automatically and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD ROM

you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at*http://www.epa.gov/epahome/docket.htm/*.

Docket: All documents in the docket are listed in the www.regulation.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. The docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the docket facility is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Dan Kenny, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; (703) 305–7546; e-mail: *kenny.dan@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

II. What Action is the Agency Taking?

EPA is printing a summary of a pesticide petition received under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, proposing the establishment or amendment of regulations in 40 CFR part 180 for residues of the insecticide imidacloprid (1–[(6–chloro–3–pyridinyl)methyl]-N-nitro–2–imidazolidinimine) and its metabolites containing the 6–chloropyridinyl moiety, all expressed as 1–[(6–chloro–3–pyridinyl)methyl]-N-nitro–2–imidazolidinimine in or on oats and rye commodities. EPA has determined that this pesticide petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petition. Additional data may be needed before EPA rules on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition prepared by the petitioner along with a description of the analytical method available for the detection and measurement of the pesticide chemical residues is available on EPA's Electronic Docket at *http://www.regulations.gov/*. To locate this information on the home page of EPA's Electronic Docket, select ''Quick Search'' and type OPP docket ID number ''EPA–HQ–OPP–2006–0539.'' Once the search has located the docket, clicking on the ''Docket ID'' will bring up a list of all documents in the docket for the pesticide including the petition summary.

Amendment to Existing Tolerance

PP 5F7020. Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709, proposes to amend the tolerances in 40 CFR 180.472 for residues of the insecticide imidacloprid (1–[(6–chloro–3–pyridinyl)methyl]-N-nitro–2–imidazolidinimine) and its metabolites containing the 6–chloropyridinyl moiety, all expressed as 1–[(6–chloro–3–pyridinyl)methyl]-N-nitro–2–imidazolidinimine in or on the food commodities oats, forage at 2.0 parts per million (ppm); oats, grain at 0.5 ppm; oats, hay at 6.0 ppm; oats, straw at 3.0 ppm; rye, forage at 2.0 ppm; rye, grain at 0.5 ppm; rye, hay at 6.0 ppm; and rye, straw at 3.0 ppm. The analytical method for determining residues is the conversion to 6–CAN and derivatization before injection onto a gas chromatograph equipped with mass selective detection. The limit of quantitation is 0.05 ppm.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 20, 2006.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. E6–1044 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal (0121); Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comments concerning the following continuing collection of information titled: Certification of Compliance with Mandatory Bars to Employment (3064–0121).

DATES: Comments must be submitted on or before March 28, 2006.

ADDRESSES: Interested parties are invited to submit written comments by any of the following methods. All comments should refer to the name and number of the collection:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *E-mail: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Gary A. Kuiper (202.942.3824), Counsel, Federal Deposit Insurance Corporation, PA 1730–3000, 550 17th Street, NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 550 17th Street Building (located on F Street), on business days between 7 a.m. and 5 p.m.

A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Mark Menchik, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 3208, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper, at the address identified above.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collection of information:

Title: Certification of Compliance with Mandatory Bars to Employment.

OMB Number: 3064–0121.

Form Number: FDIC 2120/16.

Frequency of Response: On occasion.

Affected Public: Applicants for employment with the FDIC.

Estimated Number of Respondents: 200.

Estimated Time per Response: 10 minutes.

Total Annual Burden: 33.3. hours.

General Description of Collection: Prior to an offer of employment, job applicants to the FDIC must sign a certification that they have not been convicted of a felony or been in other circumstances that prohibit persons from becoming employed by or providing services to the FDIC.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the collection should be modified prior to submission to OMB for review and approval. Comments submitted in response to this notice also will be summarized or included in the FDIC's requests to OMB for renewal of these collections. All comments will become a matter of public record.

Dated at Washington, DC, this 23rd day of January, 2006.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 06–767 Filed 1–26–06; 8:45 am]

BILLING CODE 6714–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center Web site at *http://www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 23, 2006.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) P.O. Box 55882, Boston, Massachusetts 02106-2204:

1. Merrimack Bancorp MHC, Concord, New Hampshire; to become a bank holding company by acquiring 100 percent of the voting shares of Merrimack County Savings Bank, Concord, New Hampshire.

B. Federal Reserve Bank of Richmond (A. Linwood Gill, III, Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. American National Bankshares Inc., Danville, Virginia; to merge with Community First Financial Corporation, Lynchburg, Virginia, and thereby indirectly acquire Community First Bank, Lynchburg, Virginia.

C. Federal Reserve Bank of Chicago (Patrick M. Wilder, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414:

1. Wintrust Financial Corporation, Lake Forest, Illinois; to acquire 100 percent of the voting shares of Old Plank Trail Community Bank, National

Association, New Lenox, Illinois (in organization).

Board of Governors of the Federal Reserve System, January 24, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E6–1051 Filed 1–26–06; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–855]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Enrollment Application; *Form No.:* CMS–855 (OMB #0938–0685); *Use:* This application is currently required of all health care providers/suppliers who wish to enroll in the Medicare program. It is submitted when an applicant chooses to enroll into the Medicare program or when an enrolled provider or supplier reports a change to their Medicare information. The application is used by a Medicare fee-for-service contractor to collect data to assure the applicant meets all Federal and State requirements to provide health care services to Medicare beneficiaries. This application also allows a Medicare fee-for-service contractor to ensure that the provider/supplier is not sanctioned from the Medicare program, or debarred, suspended or excluded from any other Federal agency or program.; *Frequency:* Reporting—Other—; *Affected Public:* Business or other for-profit, Individuals or Households, Not-for-profit institutions; *Number of Respondents:* 400,000; *Total Annual Responses:* 400,000; Total Annual Hours: 1,200,000.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB Desk Officer at the address below, no later than 5 p.m. on February 27, 2006.

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 20, 2006.

Michelle Shortt,

Acting Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 06–749 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–1557, CMS–R–0074, CMS–416, CMS–437A and 437B]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form Clinical Laboratory Improvement Amendments (CLIA) and supporting regulations under 42 CFR 493.1–493.2001; *Form Number:* CMS–1557 (OMB#: 0938–0544); *Use:* This form is used by the State agency to determine a laboratory's compliance with CLIA. This information is needed for a laboratory's CLIA certification and recertification; *Frequency:* Recordkeeping and Reporting—Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal, State, Local or Tribal Government; *Number of Respondents:* 25,000; *Total Annual Responses:* 12,500; Total Annual Hours: 6,250.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Income and Eligibility Verification System Reporting in Section 1137 of the Social Security Act and Supporting Regulations in 42 CFR 431.17, 431.306, 435.910, 435.920, 435.940–435.960; *Form Number:* CMS–R–0074 (OMB#: 0938–0467); *Use:* This information is used to verify the income and eligibility of Medicaid applicants and recipients as required by Section 1137 of the Social Security Act; *Affected Public:* Individuals or Households and State, Local or Tribal Government; *Number of Respondents:* 54; *Total Annual Responses:* 54; Total Annual Hours: 124,054.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Annual Early and Periodic Screening, Diagnostic and Treatment Services (EPSDT) Participation Report; *Form No.:* CMS–416 (OMB #0938–0354); *Use:* States are required to submit an annual report on the provision of EPSDT services to CMS pursuant to section 1902(1)(43)(D) of the Social Security Act. These reports provide CMS with data necessary to assess the effectiveness of State EPSDT programs, to determine a state's results in achieving its participation goal, and to respond to inquiries; *Frequency:*

Annually; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 56; *Total Annual Responses:* 56; Total Annual Hours: 1,568.

4. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Rehabilitation Unit Criteria Work Sheet and Rehabilitation Hospital Criteria Work Sheet and Supporting Regulations at 42 CFR 488.26; *Form Number:* CMS–437A and CMS–437B (OMB#: 0938–NEW—NOTE: These instruments are currently approved under 0938–0358 but are being carved out into a separate collection as they are updated more frequently.); *Use:* The rehabilitation hospital and rehabilitation unit criteria work sheets are necessary to verify that these facilities/units comply and remain in compliance with the exclusion criteria for the Medicare prospective payment system; *Frequency:* Annually; *Affected Public:* Business or other-for-profit, Not-for-profit institutions, and State, Local, or Tribal Government; *Number of Respondents:* 1227; *Total Annual Responses:* 1227; Total Annual Hours: 306.75.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB Desk Officer at the address below, no later than 5 p.m. on February 27, 2006. OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 12, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 06–605 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10173]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Agency: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Individuals Authorized Access to the CMS Computer Services; *Form Number:* CMS–10173 (OMB#: 0938–NEW); *Use:* The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the Individuals Authorized to Customer Service Application for Access to CMS Computer Systems. CMS has planned to provide a centralized user provisioning and administration service that supports the creation, deletion, and lifecycle management of enterprise identities. This service creates accounts, supports Role Based Access Control (RBAC), the form flow approval process and enterprise identity audit and recertification, and provides business application integration points. An application integration point allows business application owners to use the form flow process of the user provisioning service to approve or deny requests for access to business applications. The primary purpose of this system is to implement a unified framework for managing user information and access rights, for those individuals who apply for and are granted access across multiple CMS systems and business contexts. Information in this system will also be used to: (1) Support regulatory and policy functions performed within the Agency or by a contractor or consultant; (2) support constituent requests made to a Congressional representative; and (3) to support litigation involving the Agency related to this system.; *Frequency:* Other—As required; *Affected Public:* Business or other-for-profit, Individuals or Households, Not-for-profit institutions, Federal government, and State, local, or tribal government; *Number of Respondents:* 60,000,000; *Total Annual Responses:* 60,000,000; *Total Annual Hours:* 15,000,000.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web Site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB Desk Officer at the address below, no later than 5 p.m. on February 27, 2006. OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: January 18, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 06–717 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–2228–PN]

Medicare and Medicaid Programs; Application by the TÜV Healthcare Specialists for Deeming Authority for Hospitals

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Proposed notice.

SUMMARY: This proposed notice acknowledges the receipt of an application from the TÜV Healthcare

Specialists for deeming authority for hospitals that wish to participate in the Medicare and Medicaid programs. Section 1865(b)(3)(A) of the Social Security Act requires that within 60 days of receipt of an organization's complete application, we publish a notice that identifies the national accrediting body making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: We will consider comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on February 27, 2006.

ADDRESSES: In commenting, please refer to file code CMS–2228–PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.) (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2228–PN, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2228-PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call Yolanda Hayes at telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, *see* the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Amber Wolfe, (410) 786–6773.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2228–PN.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/regulations/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospital provided certain requirements are met. The regulations specifying the Medicare conditions of participation (CoPs) for hospitals are located in 42 CFR part 482. These conditions implement section 1861(e) of the Social Security Act (the Act), which specifies services covered as hospital care and the requirements that a hospital must meet in order to participate in the Medicare program. Regulations concerning provider agreements are at 42 CFR part 489, and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488.

Generally, in order to enter into an agreement with CMS, a hospital must first be certified by a State survey agency as complying with the CoPs set forth in part 482 of our regulations. Thereafter, the hospital is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by State agencies.

Section 1865(b)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accreditation organization that all applicable Medicare conditions are met or exceeded, we will ''deem'' those provider entities as having met the requirements.

If an accreditation organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accreditation organization applying for approval of deeming authority under part 488, subpart A must provide us with reasonable assurance that the accreditation organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare CoPs. Accreditation by an accreditation organization is voluntary and is not required for Medicare participation.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the American Osteopathic Association (AOA) are currently the only approved national accreditation organizations for hospitals.

II. Approval of Deeming Organizations

Section 1865(b)(2) of the Act and our regulations at § 488.8(a) require that our findings concerning review and approval of a national accrediting organization's requirements consider, among other factors, the applying accreditation organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or

requirements; and ability to provide us with the necessary data for validation.

Section 1865(b)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accreditation body making the request, describing the nature of the request, and providing at least a 30-day public comment period. We have 210 days from our receipt of a completed application to publish approval or denial of the application.

The purpose of this proposed notice is to inform the public of our consideration of the TÜV Healthcare Specialists' (TÜVHS') request to become a national accreditation organization for hospitals. This notice also solicits public comment on the ability of TÜVHS requirements to meet or exceed the Medicare CoPs for hospitals.

III. Evaluation of Deeming Authority Request

On December 2, 2005, the TÜV Healthcare Specialists (TÜVHS) submitted all the necessary materials to enable us to make a determination concerning its request for approval as a deeming organization for hospitals. Under section 1865(b)(2) of the Act and our regulations at § 488.8 (Federal review of accreditation organizations), our review and evaluation of TÜVHS will be conducted in accordance with, but not necessarily limited to, the following factors:

- The equivalency of TÜVHS' standards for hospitals as compared with our comparable hospital CoPs.
- TÜVHS' survey process to determine the following:

—The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

—The comparability of TÜVHS' processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

—TÜVHS' processes and procedures for monitoring providers or suppliers found out of compliance with TÜVHS' program requirements. These monitoring procedures are used only when TÜVHS identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at § 488.7(d).

—TÜVHS' capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

—TÜVHS' capacity to provide us with electronic data in ASCII comparable code, and reports necessary for effective validation and assessment of the organization's survey process.

—The adequacy of TÜVHS' staff and other resources, and its financial viability.

—TÜVHS' capacity to adequately fund required surveys.

—TÜVHS' policies with respect to whether surveys are announced or unannounced.

—TÜVHS' agreement to provide us with a copy of the most current ac creditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

V. Response to Public Comments and Notice Upon Completion of Evaluation

Because of the large number of comments we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed notice.

Upon completion of our evaluation, including evaluation of comments received as a result of this proposed notice, we will publish a final notice in the **Federal Register** responding to the public comments and announcing the result of our evaluation.

VI. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this proposed notice was not reviewed by the Office of Management and Budget.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 20, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. 06–748 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–3144–FN]

0938–ZA49

Medicare Program; Approval of Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: In this final notice we respond to public comments on our September 30, 2005 notice with comment period and announce our decision concerning an application submitted by Advanced Medical Optics (AMO) to adjust the Medicare payment amounts for certain intraocular lenses (IOLs) on the basis that they are new technology intraocular lenses (NTIOLs).

This is the third of three statutorily required **Federal Register** documents. On May 27, 2005, we published a notice in the **Federal Register** entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 30731) that solicited interested parties to submit requests for review of the appropriateness of the payment amount for an IOL furnished by an ambulatory surgical center. On September 30, 2005, we published a notice with comment period entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 57297) acknowledging timely receipt of one application. In this final notice, we announce our decision to approve the NTIOL application submitted by Advanced Medical Optics (AMO) for Tecnis® (model numbers Z9000, Z9001, and Z9003).

EFFECTIVE DATE: This notice is effective on February 27, 2006.

FOR FURTHER INFORMATION CONTACT: Michael Lyman, (410) 786–6938.

SUPPLEMENTARY INFORMATION:

I. Background

On October 31, 1994, the Social Security Act Amendments of 1994 (SSAA 1994) (Pub. L. 103–432) were enacted. Section 141(b)(1) of SSAA 1994 required us to develop and implement

a process under which interested parties may request a review of the appropriateness of the payment amount for intraocular lenses furnished by ASCs under section 1833(i)(2)(A)(iii) of the Social Security Act (the Act) on the basis that those lenses constitute a class of new technology intraocular lenses.

On June 16, 1999, we published a final rule in the **Federal Register** entitled ''Adjustment in Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers'' (64 FR 32198), which added subpart F to 42 CFR part 416. The June 16, 1999 final rule established a process for adjusting payment amounts for NTIOLs furnished by ambulatory surgical centers (ASCs), defined the terms relevant to the process, and established an initial flat rate payment adjustment of $50 for IOLs that we determine are NTIOLs. The payment adjustment applies for a 5-year period that begins when we recognize a payment adjustment for the first IOL in a new class of technology, as explained below. Any subsequent IOLs having the same characteristics as the first IOL recognized for a payment adjustment will receive the same adjustment for the remainder of the 5-year period established by the first recognized NTIOL. In accordance with the payment review process specified in § 416.185, after July 16, 2002, the $50 adjustment amount can be modified through proposed and final rulemaking in connection with ASC services. To date, we have made no changes to the payment amount and have opted not to change the adjustment for calendar year 2005 (CY 2005).

II. NTIOL Applications Submitted for Calendar Year 2005

On May 27, 2005 we published a notice in the **Federal Register** entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses (NTIOLs) Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 30731) that solicited interested parties to submit requests for review of the appropriateness of the payment amount for an IOL furnished by an ambulatory surgical center. In response to the May 27, 2005 notice, we received one timely request for review:

1. Manufacturer: Advanced Medical Optics (AMO); Model Numbers: Tecnis® (model numbers Z9000, Z9001, and Z9003). Tecnis® Models Z9000 and Z9001 are made from silicone material. The Tecnis® Model Z9003 is made from acrylic material. All three lenses provide the same functionality, differing only in material. Accordingly, we are treating these lenses as the same lens.

On September 30, 2005 we published in the **Federal Register** a notice with comment period entitled ''Medicare Program; Calendar Year 2005 Review of the Appropriateness of Payment Amounts for New Technology Intraocular Lenses Furnished by Ambulatory Surgical Centers (ASCs)'' (70 FR 57297) acknowledging timely receipt of one application.

III. Criteria and Process for NTIOL Determination

We will classify an IOL as an NTIOL if the lens meets the definition of a ''new technology IOL'' in § 416.180, which incorporates section 141(b)(2) of SSAA 1994. Under that section, a ''new technology IOL'' is defined as ''an IOL that CMS determines has been approved by the FDA for use in labeling and advertising the IOL's claims of specific clinical advantages and superiority over existing IOLs with regard to reduced risk of intraoperative or postoperative complication or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.''

The process we use for evaluating requests for NTIOL designation and reviewing the appropriateness of the payment amount for a NTIOL furnished by ASCs is described in our regulations at part 416, subpart F and in the September 30, 2005 **Federal Register** notice.

This process includes—

- Publishing a public notice in the **Federal Register** identifying requirements and the deadline for submitting a request;
- Processing requests to review the appropriateness of the payment amount for an IOL;
- Compiling a list of the requests we receive that identify the IOL manufacturer, IOL model number under review, name of the requester, and a summary of the request for review of the appropriateness of the IOL payment amount;
- Publishing an annual public notice in the **Federal Register** that lists the requests and provides for a public comment period;
- Reviewing the information submitted with the applicant's request for review, and requesting confirmation from the FDA about labeling applications that have been approved on the IOL model under review. We also request the FDA's recommendations as to whether or not the IOL model submitted represents a new class of technology that sets it apart from other IOLs. Using a baseline of the date of the last determination of a new class of IOLs, the FDA states an opinion based on proof of superiority over existing lenses of the same type of material or over lenses providing specific clinical advantages and superiority over existing IOLs as described in the preceding paragraph;
- Determining which lenses meet the criteria to qualify for the payment adjustment based on clinical data and evidence submitted for review, the FDA's analysis, public comments on the lenses, and other available information;
- Designating a type of material or a predominant characteristic of an NTIOL that sets it apart from other IOLs to establish a new class;
- Publishing a notice in the **Federal Register** announcing the IOLs that we have determined are ''new technology'' IOLs. These NTIOLs qualify for a $50 payment adjustment (or other amount announced through notice and comment rulemaking); and
- Adjusting payments effective 30 days after the publication of the final notice announcing our determinations described in the preceding paragraph of this section.

In accordance with our NTIOL application review procedures, we asked the FDA to review the AMO application to determine whether the manufacturer's claims of specific clinical advantages and superiority over existing IOLs had been approved for labeling and advertising purposes. Our regulations require the FDA's approval of a requestor's claims for advertising and labeling in order for an IOL to be classified as a NTIOL.

IV. Analysis of and Responses to Public Comments

We received 12 timely public comments in response to the September 30, 2005 notice with comment period on the NTIOLs under review. Eleven were from ophthalmologists in support of NTIOL status for the Tecnis® lenses. One comment was received from another manufacturer who makes an IOL with similar aspheric optic design characteristics. The comments we received and our responses are as follows:

Comments: The commenting ophthalmologists strongly supported NTIOL designation for the Tecnis® lenses. Most of these commenters reported positive experiences from patients in whom they implanted the Tecnis® lenses during cataract surgery. The commenters reported improved contrast vision, reduced overall ocular spherical aberration, improved

functional vision, and significantly better contrast sensitivity and contrast acuity. One stated that surgeons should not use substandard lenses when better lenses are available. Another commenter provided a research article concluding the Tecnis® lens provided improved visual acuity and functional acuity contrast testing compared to conventional spherical silicone and acrylic IOLs. This article had been previously submitted by AMO in its 2004 and 2005 calendar year NTIOL submissions.

We also received a comment supporting NTIOL status for the Tecnis® lenses that suggested they be classified as ''Aspheric Optic'' NTIOLs. The commenter also requested that one of its IOL products having aspheric optic design characteristics, as well as an IOL of another manufacturer, be placed in this newly created ''Aspheric Optic'' NTIOL class.

We agree with the commenters in their support of the Tecnis® lenses. We do not agree with the comment that the Tecnis® lenses be classified as ''Aspheric Optic'' NTIOLs. NTIOL classes are defined by clinical outcomes which provide benefits to Medicare beneficiaries. The two previously created NTIOL classes are ''Multifocal'' and ''Reduction in Preexisting Astigmatism.'' We disagree with the commenter's suggestion to create a new ''Aspheric Optic'' NTIOL class as this class would not be based upon clinical outcome. We recommend that the commenter who claimed that one of its IOLs has aspheric optic design characteristics submit an application with evidence showing clinical benefits of its lenses during the 2006 NTIOL application period. We appreciate all commenters' interest in the NTIOL process.

V. NTIOL Decision—Approval of Advanced Medical Optics Application

AMO Tecnis® Lenses; Models Z9000, Z9001, and Z9003

In CY 2004, AMO applied for NTIOL designation for the Tecnis® lenses. As part of the 2004 NTIOL review, CMS requested FDA review of AMO's NTIOL application. FDA's review confirmed that the clinical trial performed by AMO demonstrated that results under several conditions tested were statistically significantly better with the Tecnis® lens than with the control acrylic IOL. However, we denied AMO's CY 2004 NTIOL application for the Tecnis® lenses due to the lack of evidence that the Tecnis® design improvements provided clinical benefits to patients.

AMO resubmitted its NTIOL request in CY 2005 and provided additional information on the clinical relevance of reduced postoperative spherical aberration and increased contrast sensitivity. In the CY 2005 application, AMO provided additional peer-reviewed published studies, a meta-analysis, and a justification of the choice of comparator lens, none of which were included in the CY 2004 application. To demonstrate clinical superiority, AMO submitted journal articles and AMO-sponsored research reporting improved functional vision resulting from compensation for corneal spherical aberration. We reviewed the additional literature submitted by AMO in its CY 2005 application and found it to be acceptable and supportive of our requirements.

AMO claims the Tecnis® IOLs create a new class of IOLs compensating for corneal spherical aberration. AMO states this improves contrast sensitivity, functional performance, and especially safer night driving. Based on the additional information from AMO, CMS approves AMO's claims of clinical advantages and superiority of the Tecnis® IOL for ocular spherical aberrations and simulated night driving.

We find the AMO Tecnis® Lenses Models Z9000, Z9001, and Z9003 meet the NTIOL definition and are to be given the new NTIOL classification of Reduced Spherical Aberration.

VI. Collection of Information Requirements

Because the requirements referenced in this final notice will not affect 10 or more persons on an annual basis, this notice does not impose any information collection and record keeping requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

VII. Regulatory Impact Statement

We have examined the impacts of this notice as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995(Pub. L. 104–4) and Executive Order 13132.

Executive Order 12866, (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that this final notice is not a major rule. The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this final notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a regulation may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this final notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This final notice will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State, local, or tribal governments, preempts State law, or otherwise has Federalism implications. Since this final notice does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this final notice

was not reviewed by the Office of Management and Budget.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: January 9, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare and Medicaid Services.

[FR Doc. E6–1049 Filed 1–25–06; 4:00 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3162–N]

Medicare Program; Meeting of the Medicare Coverage Advisory Committee—March 30, 2006

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a public meeting of the Medicare Coverage Advisory Committee (MCAC). The Committee generally provides advice and recommendations about whether scientific evidence is adequate to determine whether certain medical items and services are reasonable and necessary under the Medicare statute. The charter also permits the MCAC to develop recommendations about other specific issues of Medicare coverage. This meeting concerns authoritative drug compendia that may be used in determining the medically accepted indications of drugs and biologicals used in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program. Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: The public meeting will be held on Thursday, March 30, 2006 from 7:30 a.m. until 4:30 p.m. e.s.t.

Deadlines: Deadline for Presentations and Comments: Written comments and presentations must be received by February 27, 2006, 5 p.m., e.s.t.

Deadline for Registration To Attend Meeting: For security reasons, individuals wishing to attend this meeting must register by close of business on March 23, 2006.

Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to notify the Executive Secretary by March 23, 2006 (see **FOR FURTHER INFORMATION CONTACT**).

ADDRESSES: The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Blvd, Baltimore, MD 21244.

FOR FURTHER INFORMATION CONTACT: Michelle Atkinson, Executive Secretary, by telephone at 410–786–2881 or by e-mail at *Michelle.Atkinson@cms.hhs.gov.*

Web site: You may access up-to-date information on this meeting at *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage.*

Presentations and Comments: Interested persons may present data, information, or views orally or in writing on issues pending before the Committee. Please submit written comments to Michelle Atkinson, by e-mail at *Michelle.Atkinson@cms.hhs.gov* or by mail to the Executive Secretary for MCAC, Coverage and Analysis Group, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C1–09–06, Baltimore, MD 21244.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) to describe the Medicare Coverage Advisory Committee (MCAC), which provides advice and recommendations to us about clinical issues. This notice announces a public meeting of the Committee.

Meeting Topic: The Committee will discuss evidence and hear presentations and public comments regarding the desired characteristics of published authoritative compendia that may be used by CMS to determine the medically accepted indications of drugs and biologicals employed in an anti-cancer chemotherapeutic regimen under Part B of the Medicare program, section 1861(t)(2) of the Social Security Act.

Background information about this topic, including panel materials, is available on the Internet at *http://www.cms.hhs.gov/coverage/.*

II. Procedure

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. The Committee may limit the number and duration of oral presentations to the time available. If you wish to make formal presentations, you must notify the Executive Secretary named in the **FOR FURTHER INFORMATION CONTACT** section and submit the following by the *Deadline for Presentations and Comments* date listed in the **DATES** section of this notice: a brief statement of the general nature of the evidence or arguments you wish to present, the names and addresses of proposed participants, and a written copy of your presentation. Your presentation should consider the questions we have posed to the Committee and focus on the issues specific to the topic. The questions will be available on our Web site at *http://www.cms.hhs.gov/FACA/02_MCAC.asp#TopOfPage.* We require that you declare at the meeting whether or not you have any financial involvement with manufacturers of any items or services being discussed (or with their competitors).

After the public and CMS presentations, the Committee will deliberate openly on the topic. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15 minute unscheduled open public session for any attendee to address issues specific to the topic. At the conclusion of the day, the members will vote, and the Committee will make its recommendation.

III. Registration Instructions

The Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register by contacting Maria Ellis at 410–786–0309, mailing address: Coverage and Analysis Group, OCSQ; Centers for Medicare & Medicaid Services; 7500 Security Blvd, Mailstop: C1–09–06; Baltimore, MD 21244, or by e-mail at *Maria.Ellis@cms.hhs.gov.* Please provide your name, address, organization, telephone and fax number, and e-mail address.

You will receive a registration confirmation with instructions for your arrival at the CMS complex. You will be notified if the seating capacity has been reached.

This meeting is located on Federal property; therefore, for security reasons, any individuals wishing to attend this meeting must register by close of business on March 23, 2006.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal Government building; therefore, Federal security measures are applicable. In planning your arrival time, we

recommend allowing additional time to clear security.

In order to gain access to the building and grounds, individuals must present photographic identification to the Federal Protective Service or Guard Service personnel before being allowed entrance.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all individuals entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Parking permits and instructions will be issued upon arrival.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting.

The public may not enter the building earlier than 30 to 45 minutes prior to the convening of the meeting.

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 12, 2005.

Barry M. Straube,

Acting Chief Medical Officer and Acting Director, Office of Clinical Standards and Quality, Centers for Medicare and Medicaid Services.

[FR Doc. E6–704 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–1328–N]

Medicare Program; February 15, 2006 Town Hall Meeting on the Practice Expense Methodology Including the Proposal From the Physician Fee Schedule Proposed Rule for Calendar Year 2006

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting on our methodology for establishing practice expense (PE) values for services paid under the physician fee schedule (PFS). The purpose of this meeting is to: (1) Clarify our proposed revisions to the PE methodology contained in the PFS calendar year (CY) 2006 proposed rule; and (2) receive comments and opinions from individuals of the medical community regarding ideas for the CY 2007 PFS proposed rule. This meeting is open to the public, but attendance is limited to space available.

DATES: The Town Hall meeting is scheduled for Tuesday, February 15, 2006 from 1:30 p.m. to 4:30 p.m. e.s.t.

ADDRESSES: The Town Hall meeting will be held at the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850 in the auditorium in the central building.

Meeting Registration: Persons wishing to attend this meeting must register by contacting Debbie Cooley at Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop C4–03–06, Baltimore, MD 21244–1850, or, by FAX at 410–786–4490 to the attention of Debbie Cooley. Please include the name of the attendee and the organization he or she represents, if applicable. This information must be received by 5 p.m., e.s.t, on Friday, February 10, 2006.

This meeting will be held in a Federal Government building, the Centers for Medicare and Medicaid Services; therefore, persons attending this meeting will be required to show a government-issued photo identification and a copy of their confirmation of registration for the meeting. Access may be denied to persons without proper identification. In planning your arrival time, we recommend allowing additional time to clear security.

Security measures include: Inspection of vehicles, inside and out, at the entrance to the grounds; passing through a metal detector; and, the inspection of all items brought into the building. Laptops and other computer equipment must be registered with the security desk upon entry. Please note that CMS headquarters is a smoke-free complex.

FOR FURTHER INFORMATION CONTACT: Debbie Cooley, (410)786–0007 or Dorothy Shannon, (410)786–3396.

SUPPLEMENTARY INFORMATION:

I. Background

Since January 1, 1992, Medicare has paid for services of physicians and other practitioners under a physician fee schedule. This schedule sets payment rates for 7,000 services based on the resources used to provide those services and is updated annually. To construct the fee schedule, we assign values called relative value units (RVUs) to each service. The total RVUs for a service are the sum of the work RVUs (which include the physician's time and effort); the practice expense RVUs (which cover expenses such as overhead, staff, and supplies); and the malpractice expense RVUs (which cover malpractice premiums).

In the CY 2006 PFS proposed rule (70 FR 45764), we outlined our plans to revise the practice expense (PE) methodology. There were three major parts to our proposal:

1. Changing from a ''top-down'' methodology for calculating direct PE to a ''bottom-up'' approach. Currently, on a specialty-specific basis, we derive a PE per physician hour from aggregate survey data, create a cost pool using Medicare utilization data, and then allocate the pool to all the services performed by the specialty. This methodology is complex, often not intuitive, and produces some PE values that can change significantly from year-to-year. The proposed bottom-up approach would use the sum of the typical resource costs for clinical staff, supplies, and equipment required for each service. These typical costs for each service would be determined based primarily on recommendations we reviewed and accepted from the American Medical Association's Relative Value Update Committee (RUC). We would then convert these costs into direct cost PE RVUs. We believe this methodology is easier to understand and more intuitive than the current top-down approach, and should also improve the stability of the PE RVUs over time. In addition, because most of the inputs that would be used in the bottom-up calculation have been approved by the multi-specialty RUC, the medical community has already agreed to their accuracy.

2. Accepting the supplementary PE surveys from seven specialties—allergy, dermatology, urology, gastrointestinal, cardiology, radiology, and radiation oncology—and using these in the calculation of indirect PE.

3. Calculating, on a code-specific basis, the higher of the current portion of the PE RVU for indirect costs (the indirect PE RVU) or the indirect PE RVU resulting from acceptance of the supplementary surveys.

This proposal was to have the effect of mitigating the redistributive effects of accepting the seven supplementary surveys by ensuring that, before application of PE budget neutrality, the indirect PE RVUs for each service were

no lower than the current indirect PE RVUs.

In comments on the CY 2006 PFS proposed rule, commenters indicated that they did not understand the mechanics of our proposals and that there was not enough information for specialties to analyze them. Many commenters requested a 1-year delay in implementation of our proposals to allow time for CMS to provide further information and to give other specialties an additional opportunity to submit their own supplementary survey.

After reviewing the CY 2006 PFS proposed rule comments, we determined that the proposal for revising the indirect PE was confusing to the public because the published PE values and impacts were incorrect. Therefore, in the CY 2006 PFS final rule (70 FR 70116), we withdrew the proposed PE revision for 2006 and used the 2005 PE RVUs for most services. The only exceptions were to price the codes that were new in 2006 and, as required by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L 108–173), to use the new urology PE data in the calculation of the drug administration codes used by their specialty.

As we indicated when we issued the CY 2006 PFS final rule (70 FR 70116), we intend to work with the medical community to ensure that any future proposals to change the PE methodology are understandable and informed by input from the medical community. As the initial step in this process, we are holding this Town Hall meeting to provide this opportunity.

II. Meeting Format

This meeting will begin with an overview of the objectives of the meeting along with an introduction of the topics to be discussed during the meeting which include:

- Clarifying our efforts to revise the PE methodology in the CY 2006 PFS proposed rule which include:

+ The change from a ''top-down'' methodology for calculating direct PE to a ''bottom-up'' approach utilizing the direct cost inputs;

+ The use of the accepted supplementary PE surveys from the seven specialties in the calculation of indirect PE;

+ The intended method of obtaining the indirect PE values; and

+ The elimination of the nonphysician workpool and the related impacts.

- A question and answer session that offers the meeting attendees an opportunity to clarify further the topics discussed.

- Soliciting input from individual attendees on each facet of our methodology: direct PE, indirect PE, supplementary surveys, and nonphysician workpool. The comments provided during this meeting will assist us in the preparation of the physician fee schedule proposed rule for CY 2007.

To provide a basis of understanding before the meeting we will be posting information concerning the PE methodology on our Web site at *http://www.cms.hhs.gov/PhysicianFeeSched/*. This information will include current PE values, examples for deriving PE values using the bottom-up methodology, and projected impacts of these revisions. We encourage individuals to familiarize themselves with this material before the meeting. Copies of this information will be available on the day of the meeting.

Authority

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: January 19, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06–747 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[CMS–1318–N]

Medicare Program; Meeting of the Practicing Physicians Advisory Council, March 6, 2006

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces a quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Council will meet to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary of Health and Human Services (the Secretary). This meeting is open to the public.

DATES: The Council meeting is scheduled for Monday, March 6, 2006, from 8 a.m. until 5 p.m. e.s.t.

ADDRESS: The meeting will be held in Room 705A 7th floor, in the Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

MEETING REGISTRATION: Persons wishing to attend this meeting must register by contacting Kelly Buchanan, the Designated Federal Official (DFO) by e-mail at *PPAC@cms.hhs.gov* or by telephone at (410) 786–6132, at least 72 hours in advance of the meeting. This meeting will be held in a Federal Government Building, Hubert H. Humphrey Building, and persons attending the meeting will be required to show a photographic identification, preferably a valid driver's license, and will be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting.

FOR FURTHER INFORMATION CONTACT: Kelly Buchanan, (410) 786–6132, or e-mail *PPAC@cms.hhs.gov*. News media representatives must contact the CMS Press Office, (202) 690–6145. Please refer to the CMS Advisory Committees' Information Line (1–877–449–5659 toll free), (410) 786–9379 local) or the Internet at *http://www.cms.hhs.gov/faca/ppac/default.asp* for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION: In accordance with section 10(a) of the Federal Advisory Committee Act, this notice announces the quarterly meeting of the Practicing Physicians Advisory Council (the Council). The Secretary is mandated by section 1868(a)(1) of the Social Security Act (the Act) to appoint a Practicing Physicians Advisory Council based on nominations submitted by medical organizations representing physicians. The Council meets quarterly to discuss certain proposed changes in regulations and carrier manual instructions related to physicians' services, as identified by the Secretary. To the extent feasible and consistent with statutory deadlines, the Council's consultation must occur before **Federal Register** publication of the proposed changes. The Council submits an annual report on its recommendations to the Secretary and the Administrator of the Centers for Medicare and Medicaid Services (CMS) not later than December 31 of each year.

The Council consists of 15 physicians, including the Chair. Members of the Council include both participating and nonparticipating physicians, and physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or

osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action prior to its termination.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Council members are expected to participate in all meetings. Section 1868(a)(3) of the Act provides for payment of expenses and a per diem allowance for Council members at a rate equal to payment provided members of other advisory committees. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. *The current members are:* Ronald Castellanos, M.D., Chairperson; Jose Azocar, M.D.; M. Leroy Sprang, M.D.; Rebecca Gaughan, M.D.; Peter Grimm, D.O.; Carlos R. Hamilton, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Christopher Leggett, M.D.; Barbara McAneny, M.D.; Geraldine O'Shea, D.O.; Laura B. Powers, M.D.; Gregory J. Przybylski, M.D.; Anthony Senagore, M.D.; and Robert L. Urata, M.D.

The meeting will commence with the Council's Executive Director providing a status report and the CMS responses to the recommendations made by the Council at the December 5, 2005 meeting as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- Moving Towards Pay for Performance.
- Update on Implementation of Part D Drug Program.
- Medicare Contractor Reform.
- Medicare Health Support.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues must contact the DFO by 12 noon, e.s.t., February 17, 2006, to be scheduled. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to Kelly Buchanan, DFO, no later than 12 noon, e.s.t., February 17, 2006, for distribution to Council members for review prior to the meeting. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution no later than noon, e.s.t., February 17, 2006. The meeting is open to the public, but attendance is limited to the space available.

Special Accommodations: Individuals requiring sign language interpretation or other special accommodation must contact the DFO by e-mail at *PPAC@cms.hhs.gov* or by telephone at (410) 786–6132 at least 10 days before the meeting.

Authority: Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).

Dated: January 5, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E6–702 Filed 1–26–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0314]

Determination of Regulatory Review Period for Purposes of Patent Extension; SPIRIVA HANDIHALER

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SPIRIVA HANDIHALER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product SPIRIVA HANDIHALER (tiotropium bromide monohydrate). SPIRIVA HANDIHALER is indicated for the long-term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SPIRIVA HANDIHALER (U.S. Patent No. 5,610,163) from Boehringer Ingelheim Corporation, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated

August 31, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of SPIRIVA HANDIHALER represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for SPIRIVA HANDIHALER is 3,318 days. Of this time, 2,557 days occurred during the testing phase of the regulatory review period, while 761 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: January 1, 1995. The applicant claims February 2, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was January 1, 1995, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: December 31, 2001. FDA has verified the applicant's claim that the new drug application (NDA) for Spiriva HandiHaler (NDA 21–395) was initially submitted on December 31, 2001.

3. *The date the application was approved*: January 30, 2004. FDA has verified the applicant's claim that NDA 21–395 was approved on January 30, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,421 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 28, 2006, submit to the Division of Dockets Management (see **ADDRESSES**) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 26, 2006, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E6–1050 Filed 1–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Oncologic Drugs Advisory Committee. This meeting was announced in the **Federal Register** of January 6, 2006 (71 FR 943). The amendment is being made to reflect a change in the *Date and Time* portion of the document. The date of this meeting is being changed. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Johanna Clifford, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301 827–7001, FAX: 301–827–6776, e-mail: *cliffordj@cder.fda.gov*, or the FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), code 3014512542. Please call the information line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 6, 2006, FDA announced that a meeting of the Oncologic Drugs Advisory Committee would be held on March 15, 2006, from 8 a.m. to 5 p.m. On page 943, in the 2d column, the *Date and Time* portion of the document is amended to read as follows:

Date and Time: The meeting will be held on March 13, 2006, from 8 a.m. to 5 p.m.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: January 17, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1003 Filed 1–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Peripheral and Central Nervous System Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Peripheral and Central Nervous System Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 7, 2006, from 8 a.m. to 5 p.m.

Location: Holiday Inn Gaithersburg, The Ballrooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Sohail Mosaddegh, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *mosaddeghs@cder.fda.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512543. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss TYSABRI (natalizumab) biologic license application 125104/15; Biogen Idec Inc., for an indication in patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations. The committee will discuss the risks (including progressive multifocal leukoencephalopathy) associated with TYSABRI (natalizumab) administration, its efficacy in the treatment of multiple sclerosis relapses

and/or disability, its possible return to the marketplace, and its proposed risk management plan(s).

The background material will become available no later than the day before the meeting and will be posted on FDA's Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm* under the heading ''Peripheral and Central Nervous System Drugs Advisory Committee (PCNS)'' (click on the year 2006 and scroll down to PCNS meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 28, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 28, 2006, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Sohail Mosaddegh at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 17, 2006.

Jason Brodsky,

Acting Associate Commissioner for External Relations.

[FR Doc. E6–1006 Filed 1–26–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Request for Generic Clearance To Conduct Voluntary Customer/Partner Surveys

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Voluntary Customer Satisfaction Surveys.

Type of Information Collection Request: Extension. OMB Control No. 0925–0476, with an expiration date of May 31, 2006.

Need and Use of Information Collection: Executive Order 12962 directed agencies that provide significant services directly to the public to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. Additionally, since 1994, the NLM has been a ''Federal Reinvention Laboratory'' with a goal of improving its methods of delivering information to the public. An essential strategy in accomplishing reinvention goals is the ability to periodically receive input and feedback from customers about the design and quality of the services they receive.

The NLM provides significant services directly to the public including health providers, researchers, universities, other federal agencies, state and local governments, and to others through a range of mechanisms, including publications, technical assistance, and Web sites. These services are primarily focused on health and medical information dissemination activities. The purpose of this submission is to obtain OMB's generic approval to continue to conduct satisfaction surveys of NLM's customers. The NLM will use the information provided by individuals and institutions to identify strengths and weaknesses in current services and to make improvements where feasible. The ability to periodically surveys NLM's customers is essential to continually update and upgrade methods of providing high quality service.

Frequency of Response: Annually or biennially.

Affected Public: Individuals or households; businesses or other for profit; State or local governments; Federal agencies; non-profit institutions; small businesses or organizations.

Type of Respondents: Organizations, medical researchers, physicians and other health care providers, librarians, students, and the general public. Annual reporting burden is as follows:

Title of survey	Type of survey	Number of respondents	Estimated response time	Burden hours
ClinicalTrials.gov and Protocol Registration System	Web-based	2000	.167	334
Consumer Information Health Seeking Process	Web-based	500	.5	250
Consumer Knowledge of Health-Related Concepts	Interviews/Questionnaires (in person)	200	.5	100
Comprehension of Consumer Health Materials Online	Interviews/Scenarios (in person)	40	1	40
Patient Information Seeking and Symptom Management Decision Making	Interview/Observation (in person)	150 (15 × 10 sessions)	.5	75
	18 (3 × 6 sessions)	.....	.5	9
		.....	.....	84
Evaluation of Genetics Home Reference Survey	Web-based	950 (200 + 500 + 250)	.5 .4175 .4175	100 209 104
		.....	.....	413
PubMed	Web-based	2,000	.0835	167
Entrez	Web-based	1,500	.0835	128

Title of survey	Type of survey	Number of respondents	Estimated response time	Burden hours
NCBI Web Site	Web-based	1,500	.0835	128
NLM Service Desk Survey	Interactive Voice Response telephone	400	.0835	33
NLM Electronic Mail Customer Survey	Electronic Mail	1,000	.0835	84
Exhibition Surveys (3)	Exit Interview	1500 (500 × 3 sessions)	.167	251
AIDSinfo and HIV/AIDS Web sites	Web-based	2,000	.0835	167
TOXNET and related Web sites	Web-based	2,000	.0835	167
SIS Web site	Web-based	2,000	.0835	167
NLM outreach services	Web-based	2,000	.0835	167
Total		19,758		2,680

There are no capital costs to report. There are no operating or maintenance costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request additional information on the proposed collection of information contact Carol Vogel, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call 301–402–9680 (not a toll-free number). You also may e-mail your request to *vogelc@mail.nih.gov.*

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 20, 2006.

Todd Danielson,

Executive Officer, National Library of Medicine, National Institutes of Health.

[FR Doc. 06–772 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request—National Network of Tobacco Cessation Quitlines Evaluation

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Evaluation of the HHS National Network of Tobacco Cessation Quitlines Initiative.

Type of Information Collection Request: New.

Need and Use of Information Collection: In February 2004, the U.S. Department of Health and Human Services announced plans for a national network of tobacco cessation quitlines to provide all smokers in the United States access to the support and latest information to help them quit. To provide the highest level of assistance to smokers across the country who want to quit, NCI established a new toll-free telephone number (1–800–QUIT–NOW) on November 8, 2004. The aim of the National Network of Tobacco Cessation Quitlines (NNTCQ) initiative (the Initiative) is to strengthen service delivery; provide a mechanism for integration and implementation of state, regional, and national campaigns; and increase healthcare utilization by minority and medically underserved populations. NCI, CDC, and other state, private industry, and partner organizations (the North American Quitline Consortium) have created the infrastructure and a coordinated mechanism to offer cessation services to the American public. The Initiative seeks to enhance existing state-managed quitlines and to encourage the establishment of quitlines in states without them. It is expected that successful implementation of the Initiative will foster partnerships across state quitlines for technology transfer, sharing of effective practices, and understanding patterns of use and reach to special populations, thereby ensuring a sustained level of effectiveness over time. The goal of this evaluation is to monitor the implementation of the Initiative, assess its impact on key stakeholders, and examine its implications for public health. To that end, this study will conduct a series of in-depth key informant telephone interviews and selected site visits with state tobacco control officers, quitline administrators and counseling staff. Representatives of organizations and individuals that partner with quitlines, such as community health organizations or health care providers, will also be interviewed. In addition, interviews will be conducted with Federal agency staff involved with the development and implementation of the Initiative. The findings will provide valuable information concerning the development and implementation of the NNTQC initiative as a potential model for Federal-State partnerships, the impact on building and enhancing state quitline capacity, and implications for the state tobacco control community.

The annual reporting burden is presented in exhibit 1, below.

Frequency of Response: On occasion.

Affected Public: State agencies, businesses or other for-profit, non-profit associations. Type of Respondents: Federal and state employees, health services providers, administrators and researchers. The annual reporting burden is as follows:

Estimated Number of Respondents: 266;

Estimated Number of Responses per Respondent: 1;

Average Burden Hours Per Response: .9624; and

Estimated Total Annual Burden Hours Requested: 256.

There is no annualized cost to respondents. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

EXHIBIT 1

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Interviews with State tobacco control officers, quitline administrators, cessation counseling staff	125	1	1	125
Interviews with State partners	100	1	.5	50
Site visits to State tobacco control staff	20	1	1.5	30
Interviews with North American Quitline Consortium staff	6	1	1	6
Interviews with Federal Staff	15	2	1.5	45
Total	266			256

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Candace Deaton, M.P.A., Project Officer, National Cancer Institute, Cancer Information Service, 6116 Executive Blvd., Rockville, MD 20892 or call non-toll-free number (301) 594–9072 or e-mail your request, including your address to: *deatonc@mail.nih.gov*.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: January 19, 2006.

Rachelle Ragland-Greene,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E6–1020 Filed 1–26–06; 8:45 am]

BILLING CODE 4101–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Board of Scientific Advisors.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Board of Scientific Advisors.

Date: March 13–14, 2006.

Time: March 13, 2006, 8 a.m. to 10:30 a.m.

Agenda: Joint meeting of the NCI Board of Scientific Advisors and NCI Board of Scientific Counselors; Report of the Director, NCI; Legislative Update; and Ethics Overview.

Place: National Institutes of Health, Building 31, C Wing, 6 Floor, 9000 Rockville Pike, Conference Room 10, Bethesda, MD 20892.

Time: March 13, 2006, 10:30 a.m. to 6 p.m.

Agenda: Ongoing and New Business; Reports of Program Review Group(s); and Budget Presentation; Reports of Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, C Wing, 6 Floor, 9000 Rockville Pike, Conference Room 10, Bethesda, MD 20892.

Time: March 14, 2006, 8:30 a.m. to 1 p.m.

Agenda: Reports Special Initiatives; RFA and RFP Concept Reviews; and Scientific Presentations.

Place: National Institutes of Health, Building 31, C Wing, 6 Floor, 9000 Rockville Pike, Conference Room 10, Bethesda, MD 20892.

Contact Person: Paulette S. Gray, PhD, Executive Secretary, Director, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Rm. 8001, Bethesda, MD 20892, 301–496–5147, *grayp@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/bsa.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: January 20, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–779 Filed 1–26–05; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; ADIPOGENIC.

Date: February 13–14, 2006.

Time: 6 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD 20814.

Contact Person: Bita Nakhai, PhD, Scientific Review Administrator, Scientific Review Office, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, ''Low Magnitude Mechanical Stimulation to Improve BMD.''

Date: February 15, 2006.

Time: 4 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NIA, Bethesda Gateway Building, 7201 Wisconsin Avenue, Suite 2C–212, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alicja L. Markowska, PhD, DSC, Scientific Review Office, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov.*

Name of Committee: National Institute on Aging Initial Review Group, Behavior and Social Science of Aging Review Committee.

Date: March 2–3, 2006.

Time: 6 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Jon E. Rolf, PhD, Scientific Review Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue/Room 2C212, Bethesda, MD 20814, (301) 402–7703, *rolfj@nia.nih.gov.*

Name of Committee: National Institute on Aging Initial Review Group, Clinical Aging Review Committee.

Date: March 2–3, 2006.

Time: 6:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center (7400 Wisconsin Avenue), Bethesda, MD 20892.

Contact Person: Alicja L. Markowska, PhD, DSC, National Institute on Aging, National Institutes of Health, Gateway Building 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *markowsa@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, ''ACTIVE.''

Date: March 3, 2006.

Time: 11 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency, One Bethesda Metro Center, Bethesda, MD 20814 (Telephone Conference Call).

Contact Person: Jon E. Rolf, PhD, Scientific Review Administrator, Scientific Review Office, National Institutes of Health, National Institute on Aging, 7201 Wisconsin Avenue, Room 2C212, Bethesda, MD 20814, (301) 402–7703, *rolfj@nia.nih.gov.*

Name of Committee: National Institute on Aging Initial Review Group, Neuroscience of Aging Review Committee.

Date: March 6–7, 2006.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Louise L. Hsu, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue/Suite 2C212, Bethesda, MD 20892, (301) 496–7705, *hsul@exmur.nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, Alzheimer's Disease Core Center.

Date: March 15–17, 2006.

Time: 6 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Crowne Plaza Silver Spring, 8777 Georgia Avenue, Silver Spring, MD 20910.

Contact Person: William Cruce, PhD, Health Scientist Administrator, Scientific Review Office, National Institute on Aging, National Institutes of Health, Room 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7704, *crucew@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–770 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, From Intervention Development to Services: Exploratory Research Grants (R34).

Date: February 15, 2006.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: A. Roger Little, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6157, MSC 9609, Rockville, MD 20852–9609, 301–402–5844, *alittle@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Review of Conte Centers for Depression and Anxiety.

Date: February 21–22, 2006.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Clarion Bethesda Park, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: A. Roger Little, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6157, MSC 9609, Rockville, MD 20852–9609, 301–402–5844, *alittle@mail.nih.gov.*

Dated: January 20, 2006.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–771 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Estrogen Receptors and Lactotrophs.

Date: February 8, 2006.

Time: 5 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Barbara A. Woynarowska, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 754, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 402–7172, *woynarowskab@niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–773 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel MARC Post-Baccalaureate Research Education Program (PREP).

Date: February 17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Helen R. Sunshine, PhD, Chief, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN12F, Bethesda, MD 20892, 301–594–2881, *sunshinh@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–774 Filed 1–26–06; 8:45 am]

BILLING CODE 1140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disorders, Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2) notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes. The outcome of the evaluation will be a decision whether NIDDK should support the request and make available contract resources for development of the potential therapeutic to improve the treatment or prevent the development of type 1 diabetes and its complications. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Disorders Special Emphasis Panel, Type 1 Diabetes—Rapid Access to Intervention Development.

Date: February 1, 2006.

Time: 10 a.m.–11 a.m.

Agenda: To evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes and its complications.

Place: 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dr. Myrlene Staten, Senior Advisor, Diabetes Translation Research, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, NIH, 6707 Democracy Boulevard, Bethesda, MD 20892–5460, 301 402–7886.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 98.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy

[FR Doc. 06–775 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–1–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Disorders; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2) notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes. The outcome of the evaluation will be a decision whether NIDDK should support the request and make available contract resources for development of the potential therapeutic to improve the treatment or prevent the development of type 1 diabetes and its complications. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Disorders Special Emphasis Panel, Type 1 Diabetes—Rapid Access to Intervention Development.

Date: January 25, 2006.

Time: 10 a.m.—12:30 p.m.

Agenda: To evaluate requests for preclinical development resources for potential new therapeutics for type 1 diabetes and its complications.

Place: 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dr. Myrlene Staten, Senior Advisor, Diabetes Translation Research, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK, NIH, 6707 Democracy Boulevard, Bethesda, MD 20892–5460. 301 402–7886.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 98.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–776 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

This meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: February 16–17, 2006.

Open: February 16, 2006, 8:30 a.m. to 5 p.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: February 17, 2006, 8:30 a.m. to 9:30 a.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: February 17, 2006, 9:30 a.m. to 1 p.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Anne P Sassaman, Ph.D., Director, Division of Extramural Research and Training, National Institute of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233, Research Triangle Park, NC 27709. 919/541–7723.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance into the building by non-government employees. Persons without a government I.D. will need to show a photo I.D. and sign-in at the security desk upon entering the building.

Information is also available on the Institute's/Center's home page: *http://www.niehs.nih.gov/dert/c-agenda.htm*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National institutes of Health, HHS).

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–777 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Minority Programs Review Committee, MARC Review Subcommittee A.

Date: February 16, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Helen R. Sunshine, PhD, Chief, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 3AN12F, Bethesda, MD 20892, 301–594–2881, *sunshinh@nigms.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical

Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–778 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Skeletal Biology Structure and Regeneration Study Section.

Date: February 6–7, 2006.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Mehrdad M. Tondravi, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4108, MSC 7814, Bethesda, MD 20892, 301–435–1173, *tondravm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Pathogenic Eukaryotes-Quorum.

Date: February 9–10, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.

Contact Person: Robert Freund, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3200, MSC 7848, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bioengineering Research Partnerships—Imaging.

Date: February 10, 2006.

Time: 8:30 a.m. to 11:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Drive, San Diego, CA 92109.

Contact Person: Eileen W. Bradley, DSC, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5100, MSC 7854, Bethesda, MD 20892, 301–435–1179, *bradleye@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Ultrasound Exploratory Studies.

Date: February 11, 2006.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Drive, San Diego, CA 92109.

Contact Person: Lee Rosen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, 301–435–1171, *rosenl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Ultrasound.

Date: February 11, 2006.

Time: 5 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Bahia Resort Hotel, 998 West Mission Bay Drive, San Diego, CA 92109.

Contact Person: Lee Rosen, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5116, MSC 7854, Bethesda, MD 20892, (301) 435–1171, *rosenl@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Fellowship—Minority and Disability Programs.

Date: February 12–13, 2006.

Time: 6 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Lindon Suite, Washington, DC 20037.

Contact Person: Abdelouahab Aitouche, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2183, MSC 7818, Bethesda, MD 20892, 301–435–2365, *abdelouahaba@csr.nih.gov.*

Name of Committee: Oncological Sciences Integrated Review Group, Cancer Etiology Study Section.

Date: February 13–15, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel, 1515 Rhode Island Ave., Washington, DC 20005.

Contact Person: Victor A. Fung, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6178, MSC 7804, Bethesda, MD 20892, 301–435–3504, *fungv@csr.nih.gov.*

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group, Pregnancy and Neonatology Study Section.

Date: February 13–14, 2006.

Time: 8 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Michael Knecht, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6176, MSC 7892, Bethesda, MD 20892, (301) 435–1046, *knechtm@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, Bioengineering Research Applications—Respiratory.

Date: February 13, 2006.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Everett E. Sinnett, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2178, MSC 7818, Bethesda, MD 20892, 301–435–1016, *sinnett@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel, High End Mass Spectrometers.

Date: February 14, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: David R. Jollie, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7806, Bethesda, MD 20892, (301) 435–1722, *jollieda@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Macromolecular Structure and Function B Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Churchill Hotel, 1914 Connecticut Avenue, NW., Washington, DC 20009.

Contact Person: Nancy Lamontagne, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4170, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *lamontan@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review

Group, Language and Communication Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street, NW., Washington, DC 20036.

Contact Person: Weijia Ni, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3190, MSC 7848, (for overnight mail use room # and 20817 zip), Bethesda, MD 20892, (301) 435–1507, *niw@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Clinical and Integrative Diabetes and Obesity.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

Contact Person: Nancy Sheard, SCD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6046–E, MSC 7892, Bethesda, MD 20892, (301) 435–1154, *sheardn@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Immunity and Host Defense.

Date: February 16–17, 2006.

Time: 8 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Washington, Pennsylvania Ave at 15th Street, NW., Washington, DC 20004.

Contact Person: Patrick K. Lai, PhD., Scientific Review Administrator, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, 301–435–1052, *laip@csr.nih.gov.*

Name of Committee: Health of the Population Integrated Review Group, Cardiovascular and Sleep Epidemiology Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: J. Scott Osborne, PhD., MPH, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4114, MSC 7816, Bethesda, MD 20892, (301) 435–1782, *osbornes@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowships.

Date: February 16, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Select Bethesda, 8120 Wisconsin Ave, Bethesda, MD 20814.

Contact Person: Khalid Masood, PhD., Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5095H, MSC 7854, Bethesda, MD 20892, 301–402–3962, *masoodk@csr.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group, Cellular Mechanisms in Aging and Development Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: James P. Harwood, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5168, MSC 7840, Bethesda, MD 20892, 301–435–1256, *harwoodj@csr.nih.gov.*

Name of Committee: Hematology Integrated Review Group, Hematopoiesis Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Robert T. Su, PhD, Scientific Review Administrator, Cener for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4134, MSC 7802, Bethesda, MD 20892, (301) 435–1195, *sur@csr.nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review Group, Development—1 Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The River Inn, 924 25th Street, NW., Washington, DC 20037.

Contact Person: Sherry L. Dupere, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5136, MSC 7843, Bethesda, MD 20892, (301) 435–1021, *duperes@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics C Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Barbara Whitmarsh, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2206, MSC 7890, Bethesda, MD 20892, (301) 435–4511, *whitmarshb@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Neurobiology of Learning and Memory Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: George Washington University Inn, 824 New Hampshire Ave., NW., Washington, DC 20037.

Contact Person: Bernard F. Driscoll, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5184, MSC 7844, Bethesda, MD 20892, 301–435–1242, *driscolb@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group, Nuclear Dynamics and Transport.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndham Washington, DC, 1400 M Street, NW., Washington, DC 20005.

Contact Person: Charles R. Dearolf, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301–435–1024, *dearolfc@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group, Hypersensitivity, Autoimmune, and Immune-mediated Diseases.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Jurys Washington Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: Bahiru Gametchu, DVM, MS, PhD, Scientific Review Administrator, Center for Scientific Review, National Institute of Health, 6701 Rockledge Drive, Room 4204, MSC 7812, Bethesda, MD 20892, 301–435–1225, *gametchb@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Neurotoxicology and Alcohol Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Hilton Washington Embassy Row, 2015 Massachusetts Ave., NW., Washington, DC 20036.

Contact Person: Joseph G. Rudolph, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5186, MSC 7844, Bethesda, MD 20892, 301–435–2212, *josephru@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Biobehavioral Mechanisms of Emotion, Stress and Health Study Section.

Date: February 16–17, 2006.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Maribeth Champoux, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7759, Bethesda, MD 20892, 301–594–3163, *champoum@csr.nih.gov.*

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group, Adult Psychopathology and Disorders of Aging Study Section.

Date: February 16–17, 2006.
Time: 8:30 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC, 20036.
Contact Person: Mariela Shirley, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0913, *shirleym@csr.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neurogenesis and Cell Fate Study Section.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Melrose Hotel, 2430 Pennsylvania Ave., NW., Washington, DC, 20037.
Contact Person: Lawrence Baizer, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4152, MSC 7850, Bethesda, MD 20892, 301–435–1257, *baizerl@csr.nih.gov*.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Biophysics of Synapses, Channels, and Transportation Study Section.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Little America Hotel, 500 South Main Street, Salt Lake City, UT 84101.
Contact Person: Michael A. Lang, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4140, MSC 7850, Bethesda, MD 20892, 301–435–1265, *langm@csr.nih.gov*.

Name of Committee: Health of the Population Integrated Review Group, Nursing Science: Children and Families Study Section.
Date: February 16, 2006.
Time: 8:30 a.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.
Contact Person: Fungai F. Chanetsa, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3028B, MSC 7770, Bethesda, MD 20892, 301–435–1262, *chanetsaf@csr.nih.gov*.

Name of Committee: Hematology Integrated Review Group, Hemostasis and Thrombosis Study Section.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 10 a.m.
Agenda: To review and evaluate grant applications.
Place: Bethesda Marriott, 5151 Pooks Hills Road, Bethesda, MD 20814.
Contact Person: Chhanda L. Ganguly, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7802, Bethesda, MD 20892, 301–435–1729, *gangulyc@csr.nih.gov*.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics B Study Section.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: One Washington Circle Hotel, One Washington Circle, Washington, DC 20037.
Contact Person: Richard A. Currie, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5128, MSC 7840, Bethesda, MD 20892, 301–435–1219, *currieri@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromulecular Biophysics Integrated Review Group, Synthetic and Biological Chemistry B Study Section.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: Holiday Inn Georgetown, 2101 Wisconsin Avenue, NW., Washington, DC 20007.
Contact Person: Mike Radtke, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4176, MSC 7806, Bethesda, MD 20892, 301–435–1728, *radtkem@csr.nih.gov*.

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group, Enabling Bioanalystical and Biophysical Technologies Study Section.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.
Contact Person: Noni Byrnes, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4180, MSC 7806, Bethesda, MD 20892, (301)–435–1217, *byrnesn@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Kidney, Nutrition, Obesity and Diabetes (KNOD) Epidemiology.
Date: February 16–17, 2006.
Time: 8:30 a.m. to 5 p.m.
Agenda: To review and evaluate grant applications.
Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Christopher T. Sempos, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3146, MSC 7770, Bethesda, MD 20892, (301) 451–1329, *semposch@csr.nih.gov*.

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group, Biological Rhythms and Sleep Study Section.
Date: February 16, 2006.
Time: 8:30 a.m. to 4:30 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Michael Selmanoff, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892–7844, 301–435–1119, *mselmanoff@scr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Cell Biology R01 Review.
Date: February 16, 2006.
Time: 11 a.m. to 12 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Alexandra M. Ainsztein, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5144, MSC 7840, Bethesda, MD 20892, 301–451–3848, *ainsztea@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Genetics of Complex Diseases.
Date: February 16, 2006.
Time: 3 p.m. to 6 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Barbara J. Thomas, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2220, MSC 7890, Bethesda, MD 20892, 301–435–0603, *bthomas@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Malaria.
Date: February 16, 2006.
Time: 3 p.m. to 4 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.
Contact Person: Fouad A. El-Zaatari, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3206, MSC 7808, Bethesda, MD 20814–9692, 301–435–1149, *elzaataf@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Biobehavioral Mechanisms in Psychopathology, Sleep, and Eating Disorders.
Date: February 17, 2006.
Time: 1 p.m. to 2 p.m.
Agenda: To review and evaluate grant applications.
Place: Beacon Hotel and Corporate Quarters, 1615 Rhode Island Avenue, NW., Washington, DC 20036.
Contact Person: Mariela Shirley, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7848, Bethesda, MD 20892, 301–435–0913, *shirleym@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Member Conflicts: Auditory Processes.
Date: February 17, 2006.
Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Christine L. Melchior, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5176, MSC 7844, Bethesda, MD 20892, 301–435–1713, *melchioc@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: January 19, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06–780 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Toxicology Program (NTP), NTP Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM); Nomination To Hold a Workshop on Alternative Methods To Replace the Mouse LD_{50} Assay for Botulinum Toxin Potency Testing: Request for Comments, Nominations of Experts, and Submission of In Vivo and In Vitro Data

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

ACTION: Request for comments, nominations of scientific experts, and submission of data.

SUMMARY: In October 2005, the Humane Society of the United States (HSUS) submitted a nomination to NICEATM requesting that alternative test methods to the mouse LD_{50} assay for botulinum toxin potency testing be assessed and prioritized for prevalidation and validation efforts. The nomination proposed that an initial key step in this process would be for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to organize a workshop on this topic. ICCVAM considered the nomination and supports with a high priority the concept of a workshop to discuss alternative methods and approaches that might reduce, refine, or replace the use of animals for botulinum potency testing. The Scientific Advisory Committee on Alternative Toxicological Methods (SACATM) considered the nomination and the ICCVAM proposal at its meeting on December 12, 2005, and agreed that the proposed activity should have a high priority. At this time, NICEATM requests (1) information on development and/or validation activities relevant to reduction, refinement (less pain and distress), and/or replacement alternatives for botulinum toxin potency testing, (2) public comments on the appropriateness and relative priority of proceeding with a workshop on this topic, (3) the nomination of scientific experts who might participate if a workshop occurs, and (4) the submission of data from mouse LD_{50} botulinum potency testing and *ex vivo* and *in vitro* test methods used for botulinum toxin potency testing. The HSUS nomination is available at *http://iccvam.niehs.nih.gov/* see ''Nominations and Submissions.''

DATES: Comments, nominations of expert scientists, and data submissions should be received by March 13, 2006.

ADDRESSES: Correspondence should be sent by mail, fax, or e-mail to Dr. William S. Stokes, NICEATM Director, NIEHS, P.O. Box 12233, MD EC–17, Research Triangle Park, NC 27709, (phone) 919–541–2384, (fax) 919–541–0947, (e-mail) *niceatm@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Background

In October 2005, the HSUS submitted a nomination to NICEATM to organize a workshop to evaluate the state-of-the-science for potential alternatives to the mouse LD_{50} assay for botulinum toxin potency testing. The HSUS nomination is available at *http://iccvam.niehs.nih.gov/* see ''Nominations and Submissions.'' ICCVAM considered the nomination and supports the concept of a workshop to discuss alternative methods and approaches that might reduce, refine, or replace the use of animals for botulinum potency testing with a high priority. The SACATM discussed this nomination at its meeting on December 12, 2005, and advised NICEATM and ICCVAM that they consider the development and validation of alternatives to the mouse LD_{50} assay for botulinum toxin potency testing a high priority. SACATM also suggested that prior to convening a workshop that ICCVAM and NICEATM find out what efforts toward developing or validating alternatives might already be underway by companies that conduct botulinum potency testing. NICEATM now seeks (1) information on any activities directed at the development and/or validation of alternatives to the mouse LD_{50} assay for botulinum toxin potency testing, (2) input from the public on this nomination for a workshop, (3) the nomination of scientific experts who might participate in any future workshop on this topic should it occur, as well as (4) data from mouse LD_{50} botulinum potency testing and *ex vivo* and *in vitro* test methods used for botulinum toxin potency testing. NICEATM and ICCVAM will consider this information and determine how to best move forward with this nomination.

Request for Comments, Nominations of Scientific Experts and Request for Data

NICEATM requests information on the status of any efforts to develop alternatives to the mouse LD_{50} assay for botulinum toxin potency testing, as well as public comments on the appropriateness and relative priority of the proposed workshop activity. In addition, NICEATM requests the nomination of scientists with relevant knowledge and experience to potentially participate in the workshop should it be held. Areas of relevant expertise include, but are not limited to: neurophysiology, neuropharmacology, neurotoxicity, immunology, potency testing of toxins and other biologicals in animals and *in vitro* systems, development and use of *in vitro* methodologies, and biostatistical data analysis. Each nomination should include the person's name, affiliation, contact information (*i.e.*, mailing address, e-mail address, telephone and fax numbers), and a brief summary of relevant experience and qualifications.

NICEATM invites the submission of data from *in vivo* botulinum toxin potency testing, including clinical observations and corresponding time-course information, and information and data from *ex vivo* and *in vitro* test methods being used as potential alternatives to the mouse assay for botulinum toxin potency testing. Submitted data will be used to further evaluate the usefulness and limitations of *in vitro* potency test methods and may be included in future NICEATM and ICCVAM reports and publications as appropriate. The data will also be included in a NICEATM database to support the investigation of alternative test methods for assessing potency of botulinum toxin.

When submitting chemical and protocol information/test data, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, e-mail, and sponsoring organization, as applicable).

NICEATM prefers data to be submitted as copies of pages from study

notebooks and/or study reports, if available. Raw data and analyses available in electronic format may also be submitted. Each submission should preferably include the following information, as appropriate:

- Specific type of botulinum neurotoxin tested (*e.g., Clostridium botulinum* neurotoxin type A)
- *In vivo* potency test protocol used.
- *In vivo* potency test results.
- Individual animal responses, including time of onset of specific clinical signs and death.
- Alternative *ex vivo* or *in vitro* test protocol used.
- Alternative *ex vivo* or *in vitro* test results.
- The extent to which the study complied with national or international Good Laboratory Practice (GLP) guidelines.
- Date of the study.
- The organization that conducted the study.

Although public comments and data can be accepted at any time, information submitted by the deadline listed in this notice would be most useful for determining whether a workshop is the appropriate next step in pursuing an alternative to the mouse LD_{50} assay for botulinum toxin potency testing. In addition, submitting information by this date ensures its availability to workshop participants if a workshop is held.

Background Information on ICCVAM, NICEATM, and SACATM

ICCVAM is an interagency committee composed of representatives from 15 Federal regulatory and research agencies that use or generate toxicological information. ICCVAM conducts technical evaluations of new, revised, and alternative methods with regulatory applicability and promotes the scientific validation and regulatory acceptance of toxicological test methods that more accurately assess the safety and hazards of chemicals and products and that refine, reduce, or replace animal use. The ICCVAM Authorization Act of 2000 (Pub. L. 106–545) establishes ICCVAM as a permanent interagency committee of the NIEHS under the NICEATM. NICEATM administers the ICCVAM and provides scientific and operational support for ICCVAM-related activities. NICEATM and ICCVAM work collaboratively to evaluate new and improved test methods applicable to the needs of Federal agencies. Additional information about ICCVAM and NICEATM can be found at the following Web site: *http://www.iccvam.niehs.nih.gov*.

The SACATM, established January 9, 2002, is a federally chartered advisory committee composed of scientists from the public and private sectors (**Federal Register**: March 13, 2002: Vol. 67, No. 49, page 11358). The SACATM provides advice to the Director of the NIEHS, ICCVAM, and NICEATM regarding statutorily mandated duties of ICCVAM and activities of NICEATM. Additional information about SACATM, including the charter, roster, and records of past meetings, can be found at *http://ntp.niehs.nih.gov/*, see ''Advisory Board & Committees.''

Dated: January 17, 2006.

Samuel H. Wilson,

Deputy Director, National Institute of Environmental Health Sciences.

[FR Doc. E6–1019 Filed 1–26–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–23665]

Collection of Information Under Review by Office of Management and Budget: OMB Control Numbers 1625–0009, 1625–0014, 1625–0038, and 1625–0039

AGENCY: Coast Guard, DHS.

ACTION: Request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the U.S. Coast Guard intends to seek the approval of OMB for the renewal of four Information Collection Requests (ICRs). The ICRs are: (1) 1625–0009, Oil Record Book for Ships; (2) 1625–0014, Request for Designation and Exemption of Oceanographic Research Vessels; (3) 1625–0038, Plan Approval and Records for Tank, Passenger, Cargo and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels, Oceanographic Research Vessels and Electrical Engineering ? 46 CFR Subchapters D, H, I, I–A, J, R, and U; and (4) 1625–0039, Declaration of Inspection Before Transfer of Liquid Cargo in Bulk. Before submitting the ICRs to OMB, the Coast Guard is inviting comments on them as described below.

DATES: Comments must reach the Coast Guard on or before March 28, 2006.

ADDRESSES: To make sure that your comments and related material do not enter the docket [USCG–2006–23665] more than once, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility, U.S. Department of Transportation (DOT), room PL–401, 400 Seventh Street, SW., Washington, DC 20590–0001.

(2) By delivery to room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(3) By fax to the Docket Management Facility at 202–493–2251.

(4) Electronically through the Web Site for the Docket Management System at *http://dms.dot.gov*.

The Docket Management Facility maintains the public docket for this notice. Comments and material received from the public, as well as documents mentioned in this notice as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at *http://dms.dot.gov*.

Copies of the complete ICRs are available through this docket on the Internet at *http://dms.dot.gov*, and also from Commandant (CG–611), U.S. Coast Guard Headquarters, room 6106 (Attn: Mr. Arthur Requina), 1900 Half Street, SW., Washington, DC 20593–0001. The telephone number is 202–475–3523.

FOR FURTHER INFORMATION CONTACT: Mr. Arthur Requina, Office of Information Management, telephone 202–475–3523, or fax 202–475–3529, for questions on these documents; or telephone Ms. Renee V. Wright, Program Manager, Docket Operations, 202–493–0402, for questions on the docket.

SUPPLEMENTARY INFORMATION: Public participation and request for comments.

We encourage you to respond to this request for comments by submitting comments and related materials. We will post all comments received, without change, to *http://dms.dot.gov*; they will include any personal information you have provided. We have an agreement with DOT to use the Docket Management Facility. Please see the paragraph on DOT's ''Privacy Act Policy'' below.

Submitting comments: If you submit a comment, please include your name and address, identify the docket number [USCG–2006–23665], indicate the specific section of the document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but

please submit them by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change the documents supporting this collection of information or even the underlying requirements in view of them.

Viewing comments and documents: To view comments, as well as documents mentioned in this notice as being available in the docket, go to *http://dms.dot.gov* at any time and conduct a simple search using the docket number. You may also visit the Docket Management Facility in room PL–401 on the Plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: Anyone can search the electronic form of all comments received in dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the Privacy Act Statement of DOT in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://dms.dot.gov*.

Information Collection Request

1. *Title:* Oil Record Book for Ships.
OMB Control Number: 1625–0009.
Summary: The Act to Prevent Pollution from Ships (APPS), 33 U.S.C. 1901–1911, and the International Convention for Prevention of Pollution from Ships, 1973, as modified by the 1978 Protocol relating thereto (MARPOL 73/78), require that information about oil cargo or fuel operations be entered into an Oil Record Book (CG–4602A). The requirement is contained in 33 CFR 151.25.
Need: This information is used to verify sightings of actual violations of the APPS to determine the level of compliance with MARPOL 73/78 and as a means of reinforcing the discharge provisions.
Respondents: Operators of vessels.
Frequency: On occasion.
Burden Estimate: The estimated burden has decreased from 29,048 hours to 26,993 hours a year.

2. *Title:* Request for Designation and Exemption of Oceanographic Research Vessels.
OMB Control Number: 1625–0014.
Summary: Title 46 U.S.C. 2113 authorizes the Secretary of Homeland Security to exempt Oceanographic Research Vessels, by regulation, from provisions of Subtitle II, of Title 46, Shipping, of the United States Code, concerning maritime safety and seaman's welfare laws.
Need: This information is necessary to ensure a vessel qualifies for the designation.
Respondents: Owners or operators of vessels.
Frequency: On occasion.
Burden Estimate: The estimated burden has increased from 21 hours to 51 hours a year.

3. *Title:* Plan Approval and Records for Tank, Passenger, Cargo and Miscellaneous Vessels, Mobile Offshore Drilling Units, Nautical School Vessels, Oceanographic Research Vessels and Electrical Engineering ? 46 CFR Subchapters D, H, I, I–A, J, R, and U.
OMB Control Number: 1625–0038.
Summary: This information collection requires the shipyard, designer or manufacturer for the construction of a vessel to submit plans, technical information and operating manuals to the Coast Guard.
Need: Under 46 U.S.C. 3301, 3306, and 3307, the Coast Guard is responsible for enforcing regulations promoting the safety of life and property in marine transportation. The Coast Guard uses this information to ensure that a vessel meets the applicable standards for construction, arrangement and equipment.
Respondents: Shipyards, designers, and manufacturers of certain vessels.
Frequency: On occasion.
Burden Estimate: The estimated burden has increased from 8,835 hours to 13,790 hours a year.

4. *Title:* Declaration of Inspection Before Transfer of Liquid Cargo in Bulk.
OMB Control Number: 1625–0039.
Summary: A Declaration of Inspection (DOI) documents the transfer of oil and hazardous materials, to help prevent spills and damage to a facility or vessel. Persons-in-charge of the transfer operations must review and certify compliance with procedures specified by the terms of the DOI.
Need: 33 U.S.C. 1231 authorizes the Coast Guard to establish regulations to prevent the discharge of oil and hazardous material from vessels and facilities. The DOI regulations appear at 33 CFR 156.150 and 46 CFR 35.35–30.
Respondents: Persons-in-charge of transfers.
Frequency: On occasion.
Burden Estimate: The estimated burden has increased from 66,223 hours to 68,534 hours a year.

Dated: January 20, 2006.

R.T. Hewitt,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Command, Control, Communications, Computers and Information Technology.

[FR Doc. E6–1013 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2004–19842]

Ballast Water Management for Vessels Entering the Great Lakes That Declare No Ballast Onboard; Environmental Assessment and Finding of No Significant Impact

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of the Final Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) that evaluated the potential environmental impacts resulting from the implementation of the policy on ballast water management for vessels entering the Great Lakes declaring no ballast onboard (NOBOB). The purpose of this policy is to prevent the introductions of aquatic nonindigenous species (NIS) into the Great Lakes.

ADDRESSES: Comments and material received from the public as well as documents mentioned in this notice as being available in the docket, are part of Coast Guard docket number USCG–2004–19842 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, room PL–401, 400 Seventh Street, SW., between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. You may also find this docket on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: For information concerning this project, call Mr. Bivan Patnaik, Project Manager, Environmental Standards Division, U.S. Coast Guard, telephone 202–267–1744 or via e-mail: *bpatnaik@comdt.uscg.mil*. If you have any questions on viewing or submitting material to the docket, call Ms. Andrea M. Jenkins, Program Manager, Docket Operations, Department of Transportation, telephone 202–366–0271.

SUPPLEMENTARY INFORMATION: In accordance with the National Environmental Policy Act of 1969 (Section 102(2)(c)), as implemented by

the Council of Environmental Quality regulations (40 CFR parts 1500–1508) and Coast Guard Policy for Considering Environmental Impacts (COMDTINST M16475.1D), the Coast Guard prepared a Final EA and FONSI for implementing the policy on best management practices for NOBOB vessels.

Response to Comments

The Coast Guard requested comments on the Draft EA when the Notice of policy; availability of Draft EA was published on August 31, 2005 (70 FR 51831). The Coast Guard received 11 comments; however, only 2 out of the 11 comments specifically addressed the Draft EA. Therefore, the Coast Guard will only respond to those comments that addressed the Draft EA.

One commenter agreed that the policy on best management practices for NOBOB vessels will have no adverse or beneficial significant impacts on the environment. The Coast Guard partially agrees with this comment. As the EA and FONSI discuss we agree that there will be no significant adverse impact; however, we do believe that beneficial impacts to the environment will occur if NOBOB vessels conduct the recommended best management practices. These practices are intended to prevent NIS from being introduced into the Great Lakes.

One commenter expressed disappointment that the Draft EA did not analyze mandatory best management practices as one of the alternatives.

The Coast Guard has been evaluating NOBOB vessels with residual water and sediments with the National Oceanic and Atmospheric Administration's (NOAA) Great Lakes Environmental Research Laboratory (GLERL), and other partners as part of the NOAA/GLERL NOBOB Research Project. Although the NOAA/GLERL NOBOB Report published in April 2005, suggests that saltwater flushing (one of the Coast Guard's recommended best management practices) would be an effective practice to protect the Great Lakes from NIS in fresh and/or brackish residual waters, the practice has never been validated for efficacy or feasibility. We are working with NOAA/GLERL and other partners to evaluate both the efficacy and feasibility of saltwater flushing. The Coast Guard is also monitoring the level of participation of vessels conducting the recommended best management practices through record checks and sampling since vessels may not always be able to conduct these practices due to vessel/crew safety concerns and other operational requirements. These evaluations will determine if further refinements to the program are necessary.

The Coast Guard is developing a ballast water discharge standard for all vessels including vessels which enter the Great Lakes because ballast water exchange and similar practices are interim measures. This standard will be more effective in preventing invasions than mandatory best management practices.

Environmental Assessment

The Final EA identified and examined those reasonable alternatives needed to effectively prevent NIS introductions into the Great Lakes via NOBOB vessels. The Final EA analyzed the no action alternative and one action alternative that could fulfill the purpose and need of establishing best management practices for NOBOB vessels to reduce NIS introductions into the Great Lakes. Specifically, the Final EA considered potential effects to the natural and human environments by incorporating environmental analyses previously conducted for establishing ballast water management regulations for U.S. waters.

Dated: January 19, 2006.

T.H. Gilmour,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention.

[FR Doc. E6–1014 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5045–N–04]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Kathy Ezzell, room 7266, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Where property is described as for ''off-site use only'' recipients of the property will be required to relocate the building to their own site at their own expense. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to John Hicks, Division of Property Management, Program Support Center, HHS, room 5B–17, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time,

HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *GSA:* Mr. John Kelly, Acting Deputy Assistant Commissioner, General Services Administration, Office of Property Disposal, 18th and F Streets, NW., Washington, DC 20405; (202) 501–0084; *Navy:* Mr. Warren Meekins, Department of the Navy, Real Estate Services, Naval Facilities Engineering Command, Washington Navy Yard, 1322 Patterson Ave., SE., Suite 1000, Washington, DC 20374–5065; (202) 685–9305; (These are not toll-free numbers).

Dated: January 19, 2006.

Mark R. Johnston,

Acting Deputy Assistant Secretary for Special Needs.

Title V, Federal Surplus Property Program, Federal Register Report for 1/27/2006

Suitable/Available Properties

Buildings (by State)

Washington

Vancouver Chapel
1601 E. 4th Plain Blvd.
Vancouver Co: Clark WA 98661–
Landholding Agency: GSA
Status: Excess
Comment: 2906 sq. ft., asbestos siding, off-site use only
GSA Number: 9–V–WA–1230

Suitable/Unavailable Properties

Buildings (by State)

Texas

Federal Center
Bldgs. 1–4, 40
501 West Felix Street
Fort Worth Co: Tarrant TX 76115–
Landholding Agency: GSA
Property Number: 54200610002
Status: Excess
Comment: Requires substantial repairs, easements, restrictive, covenants required
GSA Number: 7–G–TX–07672

Unsuitable Properties

Buildings (by State)

California

Naval Security Group
Skaggs Island
Sonoma Co: CA
Landholding Agency: GSA
Property Number: 54200610005
Status: Excess
Reason: Isolated area
GSA Number: 9–N–CA–1488

Bldg. 325
Naval Base
Port Hueneme Co: Ventura CA 93043–
Landholding Agency: Navy
Property Number: 77200610001
Status: Unutilized
Reasons: Within airport runway clear zone; Secured Area; Extensive deterioration

Hawaii

Bldg. 346
Naval Station
Pearl Harbor Co: HI 96860–
Landholding Agency: Navy
Property Number: 77200610002
Status: Excess
Reason: Extensive deterioration

Bldgs. 86, 589
Pearl City Peninsula
Pearl Harbor Co: Honolulu HI 96860–
Landholding Agency: Navy
Property Number: 77200610003
Status: Excess
Reason: Secured Area

5 Bldgs.
Pearl City Peninsula
590, 595, 596, 597, 598
Pearl Harbor Co: Honolulu HI 96860–
Landholding Agency: Navy
Property Number: 77200610004
Status: Excess
Reason: Secured Area

Bldg. 5798
Pearl City Peninsula
Pearl Harbor Co: Honolulu HI 96860–
Landholding Agency: Navy
Property Number: 77200610005
Status: Excess
Reason: Secured Area

Bldg. 776
Pearl City Peninsula
Pearl Harbor Co: Honolulu HI 96860–
Landholding Agency: Navy
Property Number: 77200610006
Status: Excess
Reason: Secured Area

Virginia

Bldg. U63
Naval Amphibious Base
Little Creek Co: Norfolk VA 23521–
Landholding Agency: Navy
Property Number: 77200610007
Status: Excess
Reason: Extensive deterioration

Bldg. 3660
Naval Amphibious Base
Little Creek Co: Norfolk VA 23521–
Landholding Agency: Navy
Property Number: 77200610008
Status: Excess
Reason: Extensive deterioration

Bldg. 3830
Naval Amphibious Base
Little Creek Co: Norfolk VA 23521–
Landholding Agency: Navy
Property Number: 77200610009
Status: Excess
Reason: Extensive deterioration

Land (by State)

Ohio

7100 Block
Olde Eight Road
Boston Heights Co: OH 44235–
Landholding Agency: GSA
Property Number: 54200610001
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 1–D–Oh–828

Wisconsin

Parcel No 17–10267–50
600 Fisherman Road
LaCrosse Co: WI 54603–
Landholding Agency: GSA
Property Number: 54200610004
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material
GSA Number: 1–I–WI–605

[FR Doc. 06–668 Filed 1–26–06; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection To Be Sent to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act; Research To Support Analysis and Management of Carrying Capacity at Lake Umbagog National Wildlife Refuge

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (Fish and Wildlife Service) plan to request that OMB approve our information collection associated with research to support analysis and management of the carrying capacity at Lake Umbagog National Wildlife Refuge in Errol, New Hampshire. We will request that OMB approve this information collection for a 1-year term.

DATES: You must submit comments on or before March 28, 2006.

ADDRESSES: Send your comments on the information collection to Hope Grey, Information Collection Clearance

Officer, Fish and Wildlife Service, MS 222–ARLSQ, 4401 N. Fairfax Drive, Arlington, VA 22203 (mail); *hope_grey@fws.gov* (e-mail); or (703) 358–2269 (fax).

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection requirements, explanatory information, or related material, contact Hope Grey, Information Collection Clearance Officer, at the above addresses or by telephone at (703) 358–2482.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). Federal agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Lake Umbagog National Wildlife Refuge contains significant natural and recreational resources. We estimate that the area accommodates over 50,000 visits per year, and this can result in significant resource and social impacts. We propose to gather information that will help support application of visitor carrying capacity at Lake Umbagog National Wildlife Refuge. Study objectives will focus on three elements of carrying capacity frameworks that can benefit the most from empirical data: (1) Collecting baseline data on visitor use and perceptions of associated resource and social impacts, (2) identifying indicators and standards of quality, and (3) management of visitor use to ensure that we maintain standards of quality.

Title of Collection: Research to Support Analysis and Management of Carrying Capacity at Lake Umbagog National Wildlife Refuge.

OMB Control Number: This is a new collection.

Service Form Number: None.

Frequency of Responses: One time per respondent.

Description of Respondents: Visitors to Lake Umbagog National Wildlife Refuge.

Estimated Number of Respondents: 500.

Estimated Number of Responses: 500.

Estimated Total Annual Burden Hours: 125 hours. We estimate that the reporting burden will average 15 minutes per respondent.

We invite your comments concerning this information collection on: (1) Whether or not the collection of information is necessary to properly manage visitor carrying capacity, including whether or not the information will have practical utility; (2) the accuracy of our burden estimate; (3) ways to enhance the quality, utility and clarity of the information we want to collect; and (4) ways to minimize the burden of the collection of information on respondents.

The information collections in this program are part of a system of records covered by the Privacy Act (5 U.S.C. 552a). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home addresses from the record, which we will honor to the extent allowable by law. There may also be limited circumstances in which we would withhold a respondent's identity from the administrative record, as allowable by law. If you wish us to withhold your name and/or address, you must state this clearly at the beginning of your comment. We will not consider anonymous comments. We generally make all submissions from organizations or businesses and from individuals identifying themselves as representatives or officials of organizations or businesses available for public inspection in their entirety.

Dated: January 13, 2006.

Hope Grey,

Information Collection Clearance Officer, Fish and Wildlife Service.

[FR Doc. E6–1057 Filed 1–26–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Final Comprehensive Conservation Plan and Finding of No Significant Impact for the Steigerwald Lake, Franz Lake, and Pierce National Wildlife Refuges, Located in Clark County and Skamania County, WA

AGENCY: Fish and Wildlife Service, DOI.

ACTION: Notice of decision and availability of the Finding of No Significant Impact and Final Comprehensive Conservation Plan.

SUMMARY: This notice advises the public that the U.S. Fish and Wildlife Service (Service) has prepared a Final Comprehensive Conservation Plan (Final CCP) and related Finding of No Significant Impact (FONSI) for the Steigerwald Lake, Franz Lake, and Pierce National Wildlife Refuges (Gorge Refuges). The Gorge Refuges are located in southwest Washington within the Columbia River Gorge National Scenic Area. The Final CCP was prepared pursuant to the National Wildlife Refuge System Administration Act, as amended, and in accordance with the National Environmental Policy Act of 1969 (NEPA) and its implementing regulations. The Service's Regional Director for the Pacific Region has considered a reasonable range of management alternatives and has selected Alternative B of the CCP for managing the Gorge Refuges for the next 15 years.

DATES: The Final CCP and FONSI are available now. The FONSI was signed on August 26, 2005. Implementation of the Final CCP may begin immediately.

ADDRESSES: Printed copies of the Final CCP are available for viewing at Ridgefield National Wildlife Refuge Complex Headquarters, 301 N. Third Avenue, Ridgefield, WA. These documents and other project information are also available online for viewing and downloading at *http://pacific.fws.gov/planning.* Copies of the Final CCP may be obtained by writing to the Ridgefield National Wildlife Refuge Complex, P.O. Box 457, Ridgefield, WA 98642.

FOR MORE INFORMATION CONTACT: Project Leader, Ridgefield National Wildlife Refuge Complex, P.O. Box 457, Ridgefield, WA 98642, phone (360) 887–4106.

SUPPLEMENTARY INFORMATION: The Gorge Refuges are located in Skamania and Clark Counties, Washington, in the Columbia River Gorge downstream of Bonneville Dam. The administration center for these Refuges is the Ridgefield National Wildlife Refuge Complex, located 25 miles northwest of Steigerwald Lake Refuge. Planning for the Gorge Refuges occurred simultaneously because: the Refuges are located in close proximity to one another within the Columbia River floodplain; many of the same issues and management opportunities occur at all three Refuges; and they are all part of the lower Columbia River ecosystem.

The Gorge Refuges are part of the National Wildlife Refuge System (NWRS) administered by the Service. It is Service policy to have all lands within the NWRS managed in accordance with an approved CCP. The CCP guides management decisions and identifies refuge goals, long-range objectives, and strategies for achieving refuge purposes. During the planning process for the Gorge Refuges' CCP, many elements were considered, including habitat and wildlife

management, habitat protection and acquisition, public and recreational uses, and cultural resources. Public input during this planning process was considered in the development of the CCP. The notice of availability of the Draft CCP for a 30-day public review and comment period was published in the **Federal Register** on August 20, 2004 (69 FR 51706). The Draft CCP identified and evaluated three alternatives for managing the Refuges. The Service received 18 comment letters on the Draft CCP. The comments received were incorporated, when appropriate, and responded to in the Final CCP.

With the management program described in detail in the Final CCP, the Service will focus on restoring and maintaining biological diversity with particular emphasis on the conservation targets identified in the Final CCP. The Service will continue management of existing wetlands and restore and enhance emergent wetlands on the Gorge Refuges to increase native moist soil plant composition. Approximately 191 acres of managed grasslands will be maintained to support populations of wintering Canada geese. Riparian bottomland forests, riparian scrub-shrub, and native oak communities will be expanded and restored to support conservation targets. Inventory, monitoring, and research will increase on the Gorge Refuges. Working with partners, the Service will seek to remove barriers to fish passage within Gibbons Creek, Indian Mary Creek, and Hardy Creek watersheds. The Service will participate in ongoing efforts to clean up Gibbons Creek and prevent contaminants from entering Steigerwald Lake Refuge. The Service will work with partners to secure additional wetland habitat and develop a waterfowl hunt program that is compatible and consistent with the establishing purpose and goals for Steigerwald Lake Refuge. Opportunities for wildlife viewing and photography and environmental education and interpretation will increase, and the Service will officially open the portion of the Columbia Dike Trail on Steigerwald Lake Refuge to bicycling, horseback riding, jogging, and leashed pets.

The Service is furnishing this notice to advise other agencies and the public of the availability of the Final CCP, to provide information on the desired conditions for the Gorge Refuges, and to detail how the Service will implement management strategies. Based on the review and evaluation of the information contained in the environmental assessment, the Regional Director has determined that implementation of the Final CCP does not constitute a major Federal action that would significantly affect the quality of the human environment within the meaning of Section 102(2)(c) of the NEPA. Therefore, an Environmental Impact Statement will not be prepared. Future site-specific proposals discussed in the Final CCP will be addressed in separate planning efforts with full public involvement.

Dated: January 20, 2006.

Cynthia U. Barry,

Acting Regional Director, Region 1, Portland, Oregon.

[FR Doc. E6–1024 Filed 1–26–06; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 122205B]

Notice of Availability of a Final Environmental Impact Statement and Final Habitat Conservation Plan

AGENCIES: Fish and Wildlife Service (FWS), Interior; National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of final environmental impact statement.

SUMMARY: The U.S. Fish and Wildlife Service and the National Marine Fisheries Service (Services) announce the availability for public review of a final Environmental Impact Statement (EIS), final Habitat Conservation Plan (HCP), and final Implementing Agreement (IA), related to an application by the State of Washington for Endangered Species Act (ESA) Incidental Take Permits (ITPs). The final documents reflect changes made to the draft documents resulting from comments received during the 90-day public comment period. Responses to comments received from the public are included in the EIS. This notice provides an opportunity for the public to review the final documents and responses to public comments. The EIS addresses the proposed issuance of ITPs by both Services under the ESA, to the Washington Department of Natural Resources, on behalf of the State of Washington (State), for forest practices activities conducted according to the Washington Forest Practices Rules (forest practices). The proposed ITPs would authorize incidental take of aquatic species (16 listed fish species, 54 unlisted fish species, 7 unlisted amphibian species), by covered forest practices implemented under the forest practices rules. The EIS also addresses a proposed limit to the ESA section 9 prohibition against take of listed species under the ESA, such that the prohibition would not apply to forest practices regulated by the State of Washington on non-Federal and non-tribal lands.

DATES: Consistent with 40 CFR 1506.10, the Services will not make a decision on the proposed action until at least February 27, 2006.

ADDRESSES: Send comments to Sally Butts, Project Manager, FWS, 510 Desmond Drive SE, Suite 102, Lacey, WA 98503, facsimile (360)753–9518; or Laura Hamilton, Project Manager, NMFS, 510 Desmond Drive SE, Suite 103, Lacey, WA 98503, facsimile (360)753–9517.

FOR FURTHER INFORMATION CONTACT: The final documents are posted on the Internet at: *http://www.fws.gov/westwafwo/consplan/docs.html*. For further information, or to receive the documents on CD ROM, please contact Sally Butts, Project Manager, FWS, (360)753–5832; or Laura Hamilton, Project Manager, NMFS, (360)753–5820.

SUPPLEMENTARY INFORMATION:

Background

Section 9 of the ESA (16 U.S.C. 1538) and implementing regulations prohibit the ''taking'' of a species listed as endangered or threatened. The term take is defined under the ESA (16 U.S.C. 1532(19)) as to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct. ''Harm'' is defined by FWS regulation to include significant habitat modification or degradation where it actually kills or injures wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, and sheltering (50 CFR 17.3, 50 CFR 222.102). NMFS' definition of harm includes significant habitat modification or degradation where it actually kills or injures fish or wildlife by significantly impairing essential behavioral patterns, including breeding, feeding, spawning, migrating, rearing, and sheltering (64 FR 60727).

Section 10 of the ESA and implementing regulations specify requirements for the issuance of ITPs to non-Federal landowners for the take of endangered and threatened species. Any proposed take must be incidental to otherwise lawful activities, not appreciably reduce the likelihood of the survival and recovery of the species in

the wild, and minimize and mitigate the impact of such take to the maximum extent practicable. In addition, an applicant must prepare a habitat conservation plan describing the impact that will likely result from such taking, the strategy for minimizing and mitigating the incidental take, the funding available to implement such steps, alternatives to such taking, and the reasons such alternatives are not being implemented. FWS regulations governing permits for federally endangered and threatened species are promulgated in 50 CFR 13.21. NMFS regulations governing permits for federally endangered and threatened species are promulgated under 50 CFR 222.307.

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*) requires that Federal agencies conduct an environmental analysis of their proposed actions to determine if the actions may significantly affect the human environment. Under NEPA, a reasonable range of alternatives to a proposed project must be developed and considered in the Service's environmental review. Alternatives considered in an environmental analysis may include variations in the scope of covered activities; variations in the location, amount and type of conservation; variations in permit duration; or, a combination of these elements.

As a result of the listing under the ESA of several salmon species and bull trout in Washington State in the mid to late 1990s, stakeholder groups including Federal agencies, state and local government agencies, Tribes, and large and small private forest landowners, collaborated to develop a science-based plan known as the Forests and Fish Report to improve water quality and habitat for aquatic species on non-Federal and non-Tribal forestland, while maintaining an economically viable timber industry in Washington State. The Forests and Fish Report was endorsed by the State legislature which amended the Revised Code of Washington with respect to the Washington Forest Practices Act (RCW 76.09). Subsequently, the Washington Forest Practices Board amended the Washington Administrative Code with respect to the Washington Forest Practices Rules (WAC 222) to be consistent with the Forest and Fish Report. These rules, and other non-regulatory commitments, are incorporated in the State's HCP.

The Washington Department of Natural Resources, on behalf of the State of Washington, applied to the Services to: (1) obtain ITPs, pursuant to section 10(a)(1)(B) of the ESA for endangered, threatened, and unlisted species; and, (2) request from the Services a limitation on the application of the prohibition against take, pursuant to section 4(d) of the ESA for identified threatened species only, for forest practices activities in compliance with the State forest practices rules and administrative program. The forest practices rules, administrative program, and other provisions are described in the HCP and serve as documentation by the State that the HCP meets the requirements of section 4(d) as well as section 10. Each of these actions is represented as an alternative in the EIS.

Forest practices activities proposed for coverage under the ITPs or for a limitation on the application of the prohibition against take include the following: (1) timber harvesting (including final and intermediate harvesting, and pre-commercial thinning activities), (2) road construction, (3) road maintenance and abandonment, (4) site preparation and reforestation of harvested areas (including piling and or burning harvest debris and mechanical scarification), and (5) adaptive management (including research and monitoring to determine the effectiveness of the forest practices rules in protecting habitat for aquatic species).

Each of the alternatives described and analyzed in the EIS, covers approximately 9.1 million acres of non-Federal and non-Tribal forest land across the State of Washington, (i.e., covered lands defined in the EIS).

The proposed ITPs, under section 10, would authorize the take of the following federally endangered species incidental to otherwise lawful activities: Upper Columbia River spring-run chinook salmon (*Oncorhynchus tshawytscha*), Snake River sockeye salmon (*O. nerka*), and Upper Columbia River steelhead (*O. mykiss*).

The proposed ITPs would also authorize the take of the following federally threatened species incidental to otherwise lawful activities: Puget Sound chinook salmon (*Oncorhynchus tshawytscha*), Lower Columbia River chinook salmon (*O. tshawytscha*), Upper Willamette River chinook salmon (*O. tshawytscha*), Snake River spring/summer chinook salmon (*O. tshawytscha*), Snake River fall chinook salmon (*O. tshawytscha*), Columbia River chum salmon (*O. keta*), Hood Canal summer-run chum salmon (*O. keta*), Ozette Lake sockeye salmon (*O. nerka*), Lower Columbia River steelhead (*O. mykiss*), Middle Columbia River steelhead (*O. mykiss*), Snake River steelhead (*O. mykiss*), Upper Willamette River steelhead (*O. mykiss*), and bull trout (*Salvelinus confluentus*)—the Columbia River Distinct Population Segment and the Coastal-Puget Sound Distinct Population Segment.

The state is also seeking incidental take permit coverage for 54 currently unlisted fish species (including anadromous and resident fish) and 7 currently unlisted stream-associated amphibian species under specific provisions of the ITPs, should these species be listed in the future.

The proposed duration of the ITPs and HCP would be 50 years, though many aspects of the plan's conservation strategy are intended to benefit aquatic species and their habitat long into the future.

Rules adopted under section 4(d) of the ESA are limited by the statute to threatened species. NMFS has issued a 4(d) rule for most threatened salmon that occur in Washington State (65 FR 42421, July 10, 2000). Subsection (b)13 (Limit 13) of the rule pertains to forest practices in the State of Washington and provides a limit from take prohibitions pursuant to section 9 of the ESA for certain threatened salmonids provided that NMFS finds after public review and comment that certain specified requirements are met by the State of Washington. These requirements include, in part, that actions comply with forest practice regulations adopted and implemented by the Washington Forest Practices Board and that they are determined by NMFS to be at least as protective of habitat functions as the regulatory elements of the Forests and Fish Report. The FWS does not have a similar 4(d) rule for the federally threatened bull trout that applies to forest practices in the State of Washington. Since there is no comparable ESA 4(d) rule for bull trout, the FWS would have to develop a 4(d) rule to exempt take of bull trout in order to fulfill the State's request. If this alternative were to be selected as the preferred alternative, FWS would consider rule-making to initiate this action. Any 4(d) rule proposed by FWS would include a public review and comment period prior to a final rule being established.

The Services formally initiated an environmental review of the project, as required under NEPA, through publication of a Notice of Intent to prepare an Environmental Impact Statement in the **Federal Register** on March 17, 2003 (68 FR 12676). That notice also announced a public scoping period during which interested parties were invited to provide written comments expressing their issues or concerns relating to the proposal and to

attend one of four public scoping meetings held throughout the State.

Based on public scoping comments, the Services prepared a Draft Environmental Impact Statement (DEIS) to analyze the effects of alternatives on the human environment. The DEIS, draft HCP, and draft Implementation Agreement were made available to the public for a 90-day public comment period through a Notice of Availability in the **Federal Register** on February 11, 2005 (70 FR 7245). Comments received on the draft documents and responses to those comments are included in the EIS. Changes to the draft HCP and DEIS resulting from the comments received during the public comment period are reflected in the final HCP and EIS. Implementation of the State's HCP, including issuance of associated ITPs from the Services for endangered, threatened and covered species (should they become listed) is Alternative 2 in the EIS. Three other alternatives are analyzed in the EIS including: Alternative 1, no action, in that neither ITPs nor section 4(d) limits on the application of the prohibition against take would be issued to the state; Alternative 3, amend and implement the conservation plan and issue section 4(d) limits on the application of the prohibition against take for those threatened species identified in the existing NMFS 4(d) rule, and through a new rule that would be developed by FWS for the threatened bull trout; and Alternative 4, ITPs would be issued based on more restrictive forest practices rules that would be incorporated into the State's proposed conservation plan.

This notice is provided pursuant to the ESA and NEPA regulations. The Services will evaluate the applications, associated documents, and comments submitted thereon to determine whether the applications meet the requirements of the ESA and NEPA. The Services' decisions whether to issue ITPs or limits on the application of the prohibition against take will be made based on the EIS, the associated Record of Decision, and the Services' ESA decision documents.

Dated: January 24, 2006.

David J. Wesley,

Deputy Regional Director, Fish and Wildlife Service, Region 1, Portland, Oregon.

Dated: January 24, 2006.

Susan Pultz,

Acting Chief, Endangered Species Division, Office of Protected Resource, National Marine Fisheries Service.

[FR Doc. E6–1058 Filed 1–26–06; 8:45 am]

BILLING CODES 3510–22–S; 4310–55–S

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–534]

In the Matter of Certain Color Television Receivers and Color Display Monitors and Components Thereof; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation on the Basis of Two Settlement Agreements

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ's'') initial determination (''ID'') granting a joint motion to terminate the above-captioned investigation on the basis of two settlement agreements.

FOR FURTHER INFORMATION CONTACT: Steven Crabb, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–5432. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted by the Commission based on a complaint filed by Thomson Licensing S.A. and Thomson Licensing Inc. *See* 70 FR 15883 (March 29, 2005). The complaint alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, the sale for importation, and the sale in the United States after importation of certain color television receivers and color display monitors and components thereof by reason of infringement of claims 1 and 3 of U.S. Patent No. 4,836,651, claim 1 of U.S. Patent No. 5,041,888, claims 1, 5, and 7 of U.S. Patent No. 5,153,754, claims 1, 3, 5, and 6 of U.S. Patent No. 5,389,893, and claims 1 and 2 of U.S. Patent No. 5,452,195. The complaint named as respondents, BenQ Corp. of Taoyuan 33 of Taiwan; BenQ Optronics (Suzhou) Co., Ltd. of China; BenQ America Corp. of Irvine, California; and AU Optronics Corp. of Hsinchu, Taiwan.

On December 9, 2005, the private parties filed a joint motion to terminate the investigation on the basis of two settlement agreements. On December 14, 2005, the Commission investigative attorney filed a response in support of the parties' joint motion to terminate the investigation.

On December 20, 2005, the ALJ issued an ID (Order No. 45) granting the joint motion to terminate the investigation on the basis of the settlement agreements. The ALJ found no indication that such termination of the investigation would adversely impact the public interest. No party filed a petition to review the subject ID.

The Commission has determined not to review the ALJ's ID. Accordingly, the above-referenced investigation is hereby terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in §§ 210.21(b), and 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.21, 210.42).

By order of the Commission.

Issued: January 23, 2006.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–1037 Filed 1–26–06; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–542]

In the Matter of Certain DVD/CD Players and Recorders, Color Television Receivers and Monitors, and Components Thereof; Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation on the Basis of Two Settlement Agreements

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review the presiding administrative law judge's (''ALJ's'') initial determination (''ID'') granting a joint motion to terminate the above-captioned

investigation on the basis of two settlement agreements.

FOR FURTHER INFORMATION CONTACT: Steven Crabb, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 708–5432. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: This investigation was instituted by the Commission based on a complaint filed by BenQ Corporation of Taiwan and BenQ America Corporation of Irvine, California. *See* 70 FR 35453 (June 20, 2005). The complaint alleged violations of section 337 of the Tariff Act of 1930 in the importation into the United States, the sale for importation, and the sale in the United States after importation of certain DVD/CD players and recorders, color television receivers and monitors, and components thereof by reason of infringement of claims 7–11 and 13–15 of U.S. Patent No. 5,270,821, and claims 1, 2, 4, and 5 of U.S. Patent No. 6,683,842. The complaint named Thomson Inc. of Indianapolis, Indiana as the respondent.

On December 9, 2005, the private parties filed a joint motion to terminate the investigation on the basis of two settlement agreements. On December 14, 2005, the Commission investigative attorney filed a response in support of the parties' joint motion to terminate the investigation.

On December 21, 2005, the ALJ issued an ID (Order No. 16) granting the joint motion to terminate the investigation on the basis of the settlement agreements. The ALJ found no indication that such termination of the investigation would adversely impact the public interest. No party filed a petition to review the subject ID.

The Commission has determined not to review the ALJ's ID. Accordingly, the above-referenced investigation is hereby terminated.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in sections 210.21(b), and 210.42 of the Commission's Rules of Practice and Procedure (19 CFR 210.21, 210.42).

By order of the Commission.

Issued: January 23, 2006.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E6–1038 Filed 1–26–06; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[USITC SE–06–009]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: February 8, 2006 at 11 a.m.

PLACE: Room 101, 500 E Street, SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meetings: none.
2. Minutes.
3. Ratification List.
4. Inv. No. 731–TA–1089 (Final)(Certain Orange Juice from Brazil)—briefing and vote. (The Commission is currently scheduled to transmit its determination and Commissioners' opinions to the Secretary of Commerce on or before February 21, 2006.)
5. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: January 25, 2006.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 06–866 Filed 1–25–06; 3:48 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Importer of Controlled Substances; Notice of Application

Pursuant to 21 U.S.C. 958(i), the Attorney General shall, prior to issuing a registration under this Section to a bulk manufacturer of a controlled substance in Schedule I or II and prior to issuing a regulation under 21 U.S.C. 952(a)(2)(B) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with 21 CFR 1301.34(a), this is notice that on August 17, 2005, Cerilliant Corporation, 811 Paloma Drive, Suite A, Round Rock, Texas 78664, made application by renewal to the Drug Enforcement Administration (DEA) to be registered as an importer of the basic classes of controlled substances listed in Schedule I and II:

Drug	Schedule
Cathinone (1235)	I
Methcathinone (1237)	I
N-Ethylamphetamine (1475)	I
Gamma hydroxybutyric acid (2010).	I
Ibogaine (7260)	I
Tetrahydrocannabinols (7370)	I
Mescaline (7381)	I
4-Bromo-2,5-dimethoxyamphetamine (7391).	I
4-Bromo-2,5-dimethoxyphenethylamine (7392).	I
4-Methyl-2,5-dimethoxyamphetamine (7395).	I
2,5-Dimethoxyamphetamine (7396).	I
3,4-Methylenedioxyamphetamine (7400).	I
3,4-Methylenedioxymethamphetamine (7404).	I
3,4-Methylenedioxymethamphetamine (7405).	I
4-Methoxyamphetamine (7411)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Etorphine (9056)	I
Heroin (9200)	I
Pholcodine (9314)	I
Amphetamine (1100)	II
Methamphetamine (1105)	II
Methylphenidate (1724)	II
Amobarbital (2125)	II
Pentobarbital (2270)	II
Cocaine (9041)	II
Codeine (9050)	II
Dihydrocodeine (9120)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Benzoylecgonine (9180)	II
Ethylmorphine (9190)	II
Meperidine (9230)	II
Methadone (9250)	II
Dextropropoxyphene, bulk (non-dosage forms) (9273).	II
Morphine (9300)	II
Thebaine (9333)	II
Levo-alphacetylmethadol (9648)	II
Oxymorphone (9652)	II

The company plans to import small quantities of the listed controlled

substances for the manufacture of analytical reference standards.

Any manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances may file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR 1301.43 and in such form as prescribed by 21 CFR 1316.47.

Any such written comments or objections being sent via regular mail may be addressed, in quintuplicate, to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative, Liaison and Policy Section (ODL); or any being sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, Virginia 22301; and must be filed no later than February 27, 2006.

This procedure is to be conducted simultaneously with and independent of the procedures described in 21 CFR 1301.34(b), (c), (d), (e) and (f). As noted in a previous notice published in the **Federal Register** on September 23, 1975, (40 FR 43745–46), all applicants for registration to import a basic class of any controlled substance listed in Schedule I or II are, and will continue to be required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 U.S.C. 958(a), 21 U.S.C. 823(a), and 21 CFR 1301.34(b), (c), (d), (e) and (f) are satisfied.

Dated: January 20, 2006.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

[FR Doc. E6–1023 Filed 1–26–06; 8:45 am]

BILLING CODE 4410–09–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meetings of Humanities Panel

AGENCY: The National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92–463, as amended), notice is hereby given that the following meetings of Humanities Panels will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

FOR FURTHER INFORMATION CONTACT: Michael McDonald, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone (202) 606–8322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on (202) 606–8282.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by the grant applicants. Because the proposed meetings will consider information that is likely to disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential and/or information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated July 19, 1993, I have determined that these meetings will be closed to the public pursuant to subsections (c) (4), and (6) of section 552b of Title 5, United States Code.

1. *Date:* February 1, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Scholarly Editions in American and British Literature and Cultural History, submitted to the Division of Research Programs at the November 1, 2005 deadline.

2. *Date:* February 2, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Collaborative Research in American Studies, submitted to the Division of Research Programs at the November 1, 2005 deadline.

3. *Date:* February 2, 2006.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review applications for Colleges and Universities, submitted to the Office of Challenge Grants at the November 1, 2005 deadline.

4. *Date:* February 3, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Scholarly Editions in American History, submitted to the Division of Research Programs at the November 1, 2005 deadline.

5. *Date:* February 6, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Collaborative Research in Literature and the Arts, submitted to the Division of Research Programs at the November 1, 2005 deadline.

6. *Date:* February 7, 2006.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review applications for History Organizations, submitted to the Office of Challenge Grants at the November 1, 2005 deadline.

7. *Date:* February 8, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Scholarly Editions in Classical, Medieval, and Early Modern Texts, submitted to the Division of Research Programs at the November 1, 2005 deadline.

8. *Date:* February 9, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Collaborative Research in European Studies, submitted to the Division of Research Programs at the November 1, 2005 deadline.

9. *Date:* February 10, 2006.
Time: 8:30 a.m. to 5 p.m.
Room: 315.
Program: This meeting will review applications for Collaborative Research in Africa and Asia, submitted to the Division of Research Programs at the November 1, 2005 deadline.

10. *Date:* February 28, 2006.
Time: 9:00 a.m. to 5 p.m.
Room: 415.
Program: This meeting will review applications for Stabilization I, submitted to the Division of Preservation and Access at the October 1, 2005 deadline.

Michael McDonald,

Advisory Committee Management Officer.

[FR Doc. E6–1031 Filed 1–26–06; 8:45 am]

BILLING CODE 7536–01–P

NUCLEAR REGULATORY COMMISSION

Request To Amend a License for the Export of Radioactive Waste

Pursuant to 10 CFR 110.70(b)(4) ''Public notice of receipt of an

application,'' please take notice that the Nuclear Regulatory Commission has received the following request for an export license. Copies of the request can be accessed through the Public Electronic Reading Room (PERR) link *http://www.nrc.gov/reading-rm/adams.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

In its review of the application for a license to export radioactive waste as defined in 10 CFR Part 110 and noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the material to be exported. The information concerning the application follows.

NRC APPLICATION TO AMEND LICENSE FOR THE EXPORT OF RADIOACTIVE WASTE

Name of applicant, Date of application Date received, application number, docket number	Description of material		End use	Country of destination
	Material type	Total quantity (Qty)		
Diversified Scientific Services, Inc., (DSSI), December 21, 2005. December 28, 2005, XW002/03, 11004983.	Class A Radioactive Mixed Waste—(in solid form).	A maximum total quantity not to exceed 30 curies (and not more than 10 curies per year) of Class A radioactive mixed waste (primarily mixed fission product radionuclides) contained in baghouse salts and ash, which result from processing liquid waste received from Ontario Power under NRC import license IW004.	Amendment to extend the expiration date from 12/31/05 to 12/31/07.	Canada.

Dated this 20th day of January, 2006, at Rockville, Maryland.

For the Nuclear Regulatory Commission.

Margaret M. Doane,

Deputy Director, Office of International Programs.

[FR Doc. E6–1040 Filed 1–26–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–271]

Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc., Vermont Yankee Nuclear Power Station; Final Environmental Assessment and Finding of No Significant Impact Related to the Proposed License Amendment To Increase the Maximum Reactor Power Level

AGENCY: U.S. Nuclear Regulatory Commission (NRC or the Commission).

SUMMARY: The NRC has prepared a final Environmental Assessment as its evaluation of a request by Entergy Nuclear Vermont Yankee, LLC and Entergy Nuclear Operations, Inc. (Entergy or the licensee) for a license amendment to increase the maximum thermal power at Vermont Yankee Nuclear Power Station (VYNPS) from 1593 megawatts-thermal (MWt) to 1912 MWt. This represents a power increase of approximately 20 percent for VYNPS. As stated in the NRC staff's position paper dated February 8, 1996, on the Boiling-Water Reactor Extended Power Uprate (EPU) Program, the NRC staff will prepare an environmental impact statement if it believes a power uprate will have a significant impact on the human environment. The NRC staff did not identify any significant impact from the information provided in the licensee's EPU application for VYNPS or the NRC staff's independent review; therefore, the NRC staff is documenting its environmental review in an environmental assessment. The final environmental assessment and finding of no significant impact is being published in the **Federal Register**.

The NRC published a draft environmental assessment and finding of no significant impact on the proposed action for public comment in the **Federal Register** on November 9, 2005 (70 FR 68106). Two sets of comments were received as discussed below.

The licensee provided three comments in a letter dated December 8, 2005 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML053500122). The first comment clarified operation of the three modes of operation of the circulating water system. Based on this comment, the NRC revised the description of the system in the ''Plant Site and Environs'' and ''Water Use Impacts'' sections of the final environmental assessment. The second comment clarified that transmission lines are owned and operated by different transmission operators, rather than Entergy as was indicated in the draft environmental assessment. Based on this comment, the NRC revised the ''Transmission Facility Impacts'' section of the final environmental assessment. The third comment provided information regarding replacement of 21 of the 22 cooling tower fan motors with higher horsepower motors. Since Entergy indicated that the conclusions in the draft environmental assessment regarding cooling tower operation (including noise) were correctly stated, no changes were made based on this comment.

Mr. David L. Deen of the Connecticut River Watershed Council (CRWC) provided three comments in an e-mail dated December 9, 2005 (ADAMS Accession No. ML053500124). The first comment raised concerns that the current National Pollutant Discharge Elimination System (NPDES) permit for VYNPS places no upper bound on the temperature of the river at which the licensee must stop adding waste heat through its cooling tower discharge and that a draft amendment to this permit fails to address this shortcoming. The CRWC proposed that Entergy should not raise the ambient water temperature beyond 85 °F at any point within the

Connecticut River. This comment exceeds the scope of the NRC's review of the proposed EPU amendment. The purpose of the NRC's environmental assessment is to evaluate the potential impact of the proposed action (i.e., the change due to the proposed EPU). As discussed in the NRC's draft environmental assessment, Entergy has requested that the State of Vermont issue an amendment to the current NPDES permit which would allow a one-degree increase in the thermal discharge limits, for certain river water temperature ranges. Entergy stated that the NPDES permit amendment is not necessary for the proposed EPU and the licensee will comply with the current NPDES permit thermal discharge limits if the permit amendment is not granted. The current NPDES permit represents the upper bound on the current impact on the river water temperatures in the vicinity of the discharge. The NRC's draft environmental assessment found that any discharge impacts for the proposed action will be the same as the current impacts from plant operation and, as such, the NRC concluded that there will be no significant impact on the Connecticut River from VYNPS discharge due to the EPU. The CRWC comment pertains to concerns regarding lack of an upper bound temperature limit in the NPDES permit. The ''upper bound'' referenced in the NRC's draft environmental assessment refers to an upper bound on the impact of the proposed EPU. Since the CRWC comment focuses on issues regarding the NPDES permit and does not provide any information regarding the impact of the proposed EPU, no changes were made to the final environmental assessment based on this comment.

The second comment from the CRWC stated that if the NPDES permit thermal discharge limits are increased, there would be harm to specific aquatic species (*i.e.*, American shad, Atlantic salmon, spottail shiner, smallmouth bass, yellow perch, walleye, largemouth bass, fallfish, white sucker, and white perch). Similar to the first comment, since the CRWC comment focuses on issues regarding the proposed amendment to the NPDES permit and does not provide any information regarding the impact of the proposed EPU, no changes were made to the final environmental assessment based on this comment.

The third comment from the CRWC questioned the NRC's draft environmental assessment statement that there are no threatened and endangered aquatic species in the Connecticut River. The CRWC stated that the dwarf wedge mussel was listed as endangered under the Endangered Species Act in 1990, and that in 1993, the U.S. Fish and Wildlife Service approved a recovery plan to attempt to reestablish populations of the dwarf wedge mussel throughout its historical range including the Connecticut River. The CRWC stated that reestablishing the population in or near VYNPS would require the presence of one of its host species, the tessellated darter. The CRWC stated that although the nearest population of the wedge mussel is relatively far north of VYNPS, since the species is endangered and depends on the tessellated darter for its survival, the tessellated darter should be included in the threatened and endangered species review for the proposed EPU.

According to the U.S. Fish and Wildlife Service's 1993 recovery plan, the dwarf wedge mussel (*Alasmidonta heterodon*) is an endangered species located in the Connecticut River system. To assess the impact of the proposed action, the aquatic species evaluated in the draft environmental assessment were those in the vicinity of the VYNPS intake and discharge structures. The dwarf wedge mussel is not located in Windham County, Vermont and, therefore, was not included in the draft environmental assessment. The dwarf wedge mussel larvae attach to a host species for survival. One host species for the dwarf wedge mussel is the tessellated darter (*Etheostoma olmstedi*), which is also found in the Connecticut River system. The tessellated darter is not threatened or endangered and, therefore, was not included in the draft environmental assessment for the VYNPS EPU.

As noted above, the proposed EPU does not require an increase in discharge temperature limits. Further, following implementation of the EPU, the flow rate of water being withdrawn from the Connecticut River through the intake structure would not increase, and there would not be a configuration change to the intake structure to support the EPU. Therefore, the EPU would not change existing impacts on the tessellated darter. In addition, according to Ecological Studies of the Connecticut River—Vernon, Vermont—Report 32, dated May 2003, the quantity of tessellated darters impinged on the VYNPS traveling screens is small compared to other impinged species. Impingement from the VYNPS intake does not significantly impact the tessellated darter population. The intergovernmental Environmental Advisory Committee (comprised of certain Vermont, New Hampshire, Massachusetts, and federal agencies) established limits for impingement of American shad (*Alosa sapidissima*) and Atlantic salmon (*Salmo salar*), and because VYNPS has not approached the impingement limits set for these species, the Vermont Agency of Natural Resources (ANR) concluded that the impingement of other species at VYNPS meets applicable laws. Entrainment of all aquatic species was monitored for over a decade beginning in 1972 and determined to be insignificant by the Environmental Advisory Committee. Entrainment was subsequently removed from the VYNPS NPDES permit. Therefore, the staff concludes that there would be no significant impact from impingement or entrainment to the tessellated darter or the dwarf wedge mussel associated with the proposed action.

Environmental Assessment

Plant Site and Environs

The EPU will apply to the facilities at the site of VYNPS located on the west shore of the Connecticut River in the town of Vernon, Vermont. Vernon is approximately four miles north of the Massachusetts state line. Vernon is located in Windham County.

The VYNPS site is located on Vernon Pond on the Connecticut River, about two-thirds of a mile upstream of the Vernon Hydroelectric Dam, at Connecticut River mile 138.3. Vernon Pond is the portion of the Connecticut River above Vernon Hydroelectric Dam. The site is surrounded by the Connecticut River on the east, by farm and pasture land mixed with wooded areas on the north and south, and by the town of Vernon on the west. The elevation of the VYNPS site is approximately 76 meters (250 feet) above mean sea level.

Northeast of the site, the Pisgah Mountain range rises to 457 meters (1500 feet). To the west and northwest of the site, mountains and hills rise to 549 meters (1800 feet). Approximately 13 kilometers (km) (8 miles (mi)) southeast of the site are Warwick State Forest and Northfield State Forest. Colrain State Forest is approximately 29 km (18 mi) southwest of Vernon. Green Mountain National Forest is located approximately 48 km (30 mi) west of Vernon.

VYNPS is a single-unit boiling-water reactor designed by General Electric, with a maximum reactor core power level output of 1593 MWt. Plant cooling is provided by either an open-cycle system, a closed-cycle cooling system, or a hybrid-cycle system. The mode of operation is selected to limit the heat discharged to the Connecticut River. The closed-cycle cooling system is

equipped with a cooling tower that dissipates heat primarily to the atmosphere. After passing through the condenser, circulating water rejects waste heat to the atmosphere utilizing the cooling tower. Remaining waste heat is discharged in the form of blowdown from the circulating water system into the Connecticut River. In the open-cycle mode, no water passes through the cooling towers. Water is removed from the Connecticut River for cooling and discharged back to the Connecticut River downstream of the intake structure. In the hybrid-cycle mode, all of the circulating water flow is cycled through the cooling towers, but only a portion is discharged to the river while the remainder is recycled.

Identification of the Proposed Action

By letter dated September 10, 2003, Entergy proposed an amendment to the operating license for VYNPS to increase the maximum thermal power level by approximately 20 percent, from 1593 MWt to 1912 MWt. The change is considered an EPU because it would raise the reactor core power level more than 7 percent above the original licensed maximum power level. This amendment would allow the heat output of the reactor to increase, which would increase the flow of steam to the turbine. This would result in the increase in production of electricity and the amount of waste heat delivered to the condenser, and an increase in the temperature of the water being discharged into the Connecticut River. This is the first request by Entergy for a power uprate at VYNPS; no other power uprates have previously been requested or granted for this site.

The Need for the Proposed Action

Entergy estimates that the EPU will result in an additional 100 to 110 megawatts-electric being generated. This additional electricity generation can power approximately 110,000 extra homes, reducing the need to obtain electricity from other sources. The EPU would not cause the environmental impacts that would occur if construction of a new power generation facility were sought to meet the region's electricity needs.

Environmental Impacts of the Proposed Action

At the time of issuance of the operating license for VYNPS, the NRC staff noted that any activity authorized by the license would be encompassed by the overall action evaluated in the Final Environmental Statement (FES) for the operation of VYNPS, which was issued in July 1972. This environmental assessment summarizes the radiological and non-radiological impacts on the environment that may result from the currently proposed action.

Non-Radiological Impacts

Land Use Impacts

The potential impacts associated with land use for the proposed action include impacts from construction and plant modifications. The impacts from construction due to the proposed EPU are minimal. No expansion of roads, parking lots, equipment storage or laydown areas, or transmission line rights-of-way is anticipated to support the proposed action. The only new construction required to support the EPU is the installation of temporary office space using modular units. This resulted in minor soil disturbance due to trenching, setting foundation columns, hook-up of water, sewer, telephone, and electricity.

In addition, a few modifications to plant equipment will take place to support the EPU. The most significant modifications include replacement of the high-pressure turbine steam path, rewinding the main generator, replacement of four high-pressure heaters, and replacement of the main transformer. The plant modifications will not result in any changes in land use and historic and archeological resources should not be affected by the proposed EPU. The proposed EPU would not modify land use at the site significantly over that described in the FES. Therefore, the staff concludes that the environmental land use impacts of the proposed EPU are bounded by the impacts previously evaluated in the FES.

Cooling Tower Impacts

The potential impacts associated with increased cooling tower operation for the proposed action include aesthetic impacts due to the increased moisture content of the air. VYNPS has cooling towers that are currently used to reduce the heat output to the environment. The cooling towers are not currently used during the ''winter period'' of October 15 through May 15, but following the EPU, the cooling towers may be required for this period in order to meet the water discharge thermal limits set forth in the NPDES permit. The operation of the cooling towers during the ''winter period'' will result in a visible plume. However, heat rejection rates during this period are less than during the ''summer period'' of May 16 to October 14, so the visible plume size will not be larger than during the remainder of the year. The cooling tower plume dimensions during the ''summer period'' will increase following the EPU. The dimensions will increase by approximately 100 meters in length, 20 to 30 meters in width, and up to 50 meters in height. The increase in plume dimensions during the ''summer period'' and the presence of a plume during the ''winter period'' will not cause a significant aesthetic impact because similar plumes have been present in the area of VYNPS since 1972, and industrial plumes are a common feature to the Connecticut River Valley.

No significant fogging or icing due to cooling tower operation is predicted for the EPU. The Seasonal/Annual Cooling Tower Impact Program evaluation determined that there is no predicted ground-level fogging or icing during the year. The evaluation was performed for NPDES ''summer period'' and ''winter period'' thermal discharge limits.

No significant increase in noise is anticipated for cooling tower operation following the EPU. A study performed on the VYNPS cooling tower resulted in sound increases of less than one decibel for the increased cooling tower operation.

The aesthetic impacts associated with increased cooling tower operation for the proposed action will not change significantly over the aesthetic impacts associated with current cooling tower operation. Plume dimensions will increase, but will remain consistent with the current aesthetic impacts in the VYNPS environment. No significant fogging or icing is predicted, and no significant increase in noise level is predicted for the increased cooling tower operation. Therefore, the staff concludes that there are no significant aesthetic or atmospheric impacts associated with increased cooling tower operation for the proposed action.

Transmission Facility Impacts

The potential impacts associated with transmission facilities for the proposed action could include changes in transmission line corridor right-of-way maintenance and electric shock hazards due to increased current. The proposed EPU would not require any physical modifications to the transmission lines. Transmission line right-of-way maintenance practices, including the management of vegetation growth, would not change. There will be no change to operating voltage or transmission line rights-of-way. Transmission line clearances will remain unchanged. Modifications to onsite transmission equipment are necessary to support the EPU, including

installation of capacitor banks to maintain system voltage requirements.

The National Electric Safety Code (NESC) provides design criteria that limit hazards from steady-state currents. The transmission lines currently meet the applicable shock prevention provisions of the NESC. There will be an increase in current passing through the transmission lines associated with the increased power level of the proposed EPU. The increased electrical current passing through the transmission lines will cause an increase in electromagnetic field strength in the transmission line corridors. The licensee provided an evaluation of the transmission line loadings based on the approximately 20-percent power uprate which concluded that there will be no significant increase in the risk of shock under the transmission lines. Based on this information, the staff concludes that adequate protection will be provided against hazards from electric shock even with the slight increase in current attributable to the EPU.

The impacts associated with transmission facilities for the proposed action will not change significantly over the impacts associated with current plant operation. There are no physical modifications to the transmission lines, transmission line right-of-way maintenance practices will not change, there are no changes to transmission line rights-of-way or vertical clearances, and electric current passing through the transmission lines will increase only slightly. Therefore, the staff concludes that there are no significant impacts associated with transmission facilities for the proposed action.

Water Use Impacts

Potential water use impacts from the proposed action include hydrological alterations to the Connecticut River and changes to plant water supply. VYNPS uses cooling water from Vernon Pond on the Connecticut River, and discharges heated water back to the Connecticut River. Vernon Pond is the portion of the Connecticut River above Vernon Hydroelectric Dam. VYNPS can be operated in one of three modes: The open-cycle mode, the closed-cycle mode, or the hybrid-cycle mode. Each of the modes is discussed previously under ''Plant Site and Environs.''

The NPDES permit limits the amount of heat discharged to the Connecticut River from the operation of VYNPS. The thermal limit set in the NPDES permit will not change with the EPU. In order to comply with the NPDES thermal limit following the EPU, Entergy plans to operate the cooling towers more often to dissipate heat to the atmosphere rather than the river.

Due to the large flow rate of the Connecticut River, heated water discharged to the Connecticut River will begin to mix immediately with the river water and cool. A hydrological-biological study of Vernon Pond conducted in 1974–1977 included a thermal study. This study concluded that during periods of low flow in the Connecticut River, the thermal plume from the VYNPS discharge extends outward into the river channel before being swept downstream. During periods of high flow in the Connecticut River, the strong river currents shear the thermal plume and force the plume to flow along the Vermont shore. Due to these flow patterns in the Connecticut River and the thermal limits set in the NPDES permit, the EPU should not cause hydrological alterations to the Connecticut River.

The EPU would not involve any configuration change to the intake structure. The pump capacity will not change, so that there will not be an increase in the rate of withdrawal of water from the Connecticut River. There would be a slight increase in the amount of Connecticut River water consumed as a result of the EPU under all cooling modes of operation due to increased evaporative losses. During the NPDES summer period (May 16 to October 14), the increased water consumption will be less than 0.1% of the average monthly river flow. During the NPDES winter period (October 15 to May 15), the increased water consumption will be less than 0.2% of the average monthly river flow. Therefore, the increased loss is insignificant relative to the flow in the Connecticut River. On this basis, the staff concludes that there is no significant impact to the hydrological pattern on the Connecticut River, and there is no significant impact due to water consumption as a result of the proposed action.

Discharge Impacts

Potential impacts to the Connecticut River from the VYNPS discharge could include increased turbidity, scouring, erosion, and sedimentation. These discharge-related impacts apply to open-cycle flow due to the large volume of water discharged to the river. However, since the EPU will not result in any significant change in the amount of water withdrawn from the Connecticut River during open-cycle operation there will be no significant change in the discharge volume or velocity; therefore, there will be no changes in turbidity, scouring, erosion, or sedimentation related to the EPU.

Surface water and wastewater discharges at VYNPS are regulated by the State of Vermont via a NPDES permit (NPDES No. VT0000264). The NPDES permit is periodically reviewed and renewed by the Vermont ANR, Department of Environmental Conservation in Waterbury, Vermont. The EPU would cause an increase in the temperature of the water discharged to the Connecticut River, but the temperature of the water discharged will remain within thermal limits specified in the NPDES permit. The blowdown from the increased usage of the cooling towers would also be discharged to the Connecticut River. There is no significant additional impact to the Connecticut River expected from the increased operation of the cooling towers because cooling tower blowdown will increase only slightly due to minor increased usage of the cooling towers.

Entergy is requesting an amendment to the NPDES permit to allow a one-degree increase in the thermal discharge limit, for certain river water temperature ranges, for the ''summer period'' as shown in Table 1.

TABLE 1.—PROPOSED SUMMER NPDES PERMIT CHANGE

Upstream river temperature	Existing delta-temperature increase limit	Proposed delta-temperature increase limit
Above 78 °F	2 °F	2 °F
Greater than 63 °F, Less than or equal to 78 °F	2 °F	3 °F
Greater than 59 °F, Less than or equal to 63 °F	3 °F	4 °F
Greater than or equal to 55 °F, Less than or equal to 59 °F	4 °F	5 °F
Below 55 °F	5 °F	5 °F

The NPDES permit amendment is not necessary for the EPU, and VYNPS will continue to operate under the current thermal discharge limits (under either the current NRC license or the EPU) if the NPDES permit amendment is not granted.

VYNPS has been operating within the current NPDES limits; therefore, these thermal limits represent an upper bound of the current impact on the river water temperatures in the vicinity of the discharge. The proposed one-degree increase in the current NPDES thermal discharge limit similarly represents the expected upper bound of the impact on the river water temperatures during the EPU. VYNPS will comply with the current thermal limits in the NPDES permit following the EPU if the NPDES permit amendment request is not granted, and any discharge impacts for the proposed action will be the same as the current impacts from plant operation. Therefore, the staff concludes that there will be no significant impact on the Connecticut River from VYNPS discharge for the proposed action.

Chemicals and concentrations released from VYNPS into the Connecticut River are regulated by the State of Vermont through the NPDES permit. VYNPS will continue to operate within the current NPDES permit limits following the power uprate.

Since there will be no significant increase in the VYNPS staffing levels during operations as a result of the power uprate, there will also be no increase in sanitary waste.

Impacts on Aquatic Biota

The potential impacts to aquatic biota from the proposed action include impingement, entrainment, thermal discharge effects, and impacts due to transmission line right-of-way maintenance. The VYNPS has intake and discharge structures on the Connecticut River. The aquatic species evaluated in this environmental assessment are those in the vicinity of the intake and discharge structures.

VYNPS does entrain and impinge aquatic species. Entrainment and impingement of aquatic species are covered in the NPDES permit under Section 316(b) of the Clean Water Act. Entrainment was monitored for over a decade beginning in 1972, and determined to be insignificant by the inter-governmental Environmental Advisory Committee. The Environmental Advisory Committee is made up of Vermont Department of Environmental Conservation, Vermont Department of Fish and Wildlife, New Hampshire Fish and Game Department, New Hampshire Department of Environmental Services, Massachusetts Office of Watershed Management, Massachusetts Division of Fisheries and Wildlife, and the Coordinator of the Connecticut River Anadromous Fish restoration program of the U.S. Fish and Wildlife Service. The Vermont ANR concluded that no further entrainment sampling was required following historical studies conducted during the same time period, and dropped entrainment from the NPDES permit. Entrainment is no longer monitored at VYNPS. The ANR determined that entrainment sampling should be replaced with alternative biological monitoring of species in the Connecticut River. Therefore, since the 1980's, the licensee has conducted extensive monitoring as required by the ANR to determine if there are any potential impacts to aquatic species in the VYNPS intake and discharge areas. These procedures are not expected to change following the EPU.

Impingement is monitored annually and is considered low. Ecological studies of the Connecticut River—Vernon, Vermont—Report 32, dated May 2003, describes how Entergy meets the requirements of the NPDES permit through impingement sampling. During 2002, 27 species of fish were collected, and all fish species collected were typical of the Connecticut River drainage. The Environmental Advisory Committee has established limits for impingement of American shad and Atlantic salmon, and VYNPS has never approached the impingement limits set for these species. Since VYNPS has never approached the impingement limits set for American shad and Atlantic salmon, the ANR has concluded that impingement of other species at VYNPS meets applicable laws. The flow rate of water being withdrawn from the Connecticut River through the intake structure will not increase following the EPU, and there will not be any configuration change to the intake structure to support the EPU. Therefore, no increase in the impingement of fish or shellfish, or in the entrainment of planktonic organisms would be expected following the EPU.

On July 9, 2004, the Environmental Protection Agency (EPA) published a final rule in the **Federal Register** (69 FR 41575) addressing cooling water intake structures at existing power plants whose flow levels exceed a minimum threshold value of 50 million gallons per day. The rule is Phase II in EPA's development of Section 316(b) regulations that establish national requirements applicable to the location, design, construction, and capacity of cooling water intake structures at existing facilities that exceed the threshold value for water withdrawals. The national requirements, which are implemented through NPDES permits, minimize the adverse environmental impacts associated with the continued use of the intake systems. Licensees are required to demonstrate compliance with the Phase II performance standards at the time of renewal of their NPDES permit. Licensees may be required, as part of the NPDES renewal, to alter the intake structure, redesign the cooling system, modify station operation, or take other mitigative measures as a result of this regulation. The new performance standards are designed to reduce significantly impingement and entrainment losses due to plant operation. Any site-specific mitigation would result in less impact due to continued plant operation.

The NPDES permit limits the amount of heat discharged to the Connecticut River from the operation of VYNPS. An analysis conducted in accordance with the NPDES permit on fish and aquatic species in 2002 concluded that there is no significant negative relationship between these species and the thermal discharge. Actually, a larger community of aquatic species was found to colonize near the VYNPS discharge. The thermal limits specified in the NPDES permit will not change with the EPU. Because Entergy will continue to meet the thermal discharge limit set by the NPDES permit following the EPU, there should be no additional thermal discharge effects on aquatic species for the proposed action.

As discussed in the transmission facility impacts section of this environmental assessment, transmission line right-of-way maintenance practices will not change for the proposed action. Therefore, the staff concludes that there are no significant impacts to aquatic biota associated with transmission line right-of-way maintenance for the proposed action.

In conclusion, there will be no increase in the impacts of entrainment or impingement because there will be no increase in the flow rate of water being withdrawn from the Connecticut River, and the amount of heat discharged to the Connecticut River will remain within the thermal limit specified by the NPDES permit following the EPU. There are no changes in transmission line right-of-way maintenance associated with the proposed action. Therefore, the staff concludes that there are no significant impacts to aquatic biota for the proposed action.

Impacts on Terrestrial Biota

The potential impacts to terrestrial biota from the proposed action include impacts due to construction activities and transmission line right-of-way maintenance. As discussed in the transmission facility impacts section of this environmental assessment, transmission line right-of-way maintenance practices will not change for the proposed action. Similarly, as discussed above, apart from the construction of temporary office space using modular units, construction activities due to the EPU will not disturb land on the VYNPS site. Therefore, the staff concludes that there are no significant impacts to terrestrial plant or animal species associated with construction activities or transmission line right-of-way maintenance for the proposed action.

Impacts on Threatened and Endangered Species

Potential impacts to threatened and endangered species from the proposed action include the impacts assessed in the aquatic and terrestrial biota sections of this environmental assessment. These impacts include impingement, entrainment, thermal discharge effects, and impacts due to transmission line right-of-way maintenance for aquatic species, and impacts due to transmission line right-of-way maintenance for terrestrial species.

There are three species listed as threatened or endangered under the Federal Endangered Species Act within Windham County, Vermont. These are the Bald Eagle (*Haliaeetus leucocephalus*), Indiana Bat (*Myotis sodalis*), and Northeastern Bulrush (*Scirpus ancistrochaetus*). There are no records of any of these species on the VYNPS site. However, no formal surveys have been conducted by Entergy or the State of Vermont on the VYNPS site. Critical habitat has been designated for the Indiana Bat (*M. sodalis*), but not in the State of Vermont. Critical habitat has not been designated for the Bald Eagle (*H. leucocephalus*) or the Northeastern Bulrush (*S. ancistrochaetus*). There is a Bald Eagle (*H. leucocephalus*) nest downstream of the VYNPS site, on Stebbins Island in New Hampshire, and Bald Eagles (*H. leucocephalus*) have been observed flying over the VYNPS site. However, the Bald Eagle (*H. leucocephalus*) should not be impacted by the EPU because there are no Bald Eagles (*H. leucocephalus*) on the site and the NPDES permit includes provisions for protection of the Bald Eagle (*H. leucocephalus*) habitat.

Ecological Studies of the Connecticut River—Vernon, Vermont—Report 32, dated May 2003, describes how Entergy meets the requirements of the NPDES permit through impingement sampling. An analysis of this report determined that no Federally-listed threatened or endangered species were collected.

The Vermont Nongame and Natural Heritage Program, associated with the Vermont ANR, reviewed the EPU project and found no undue adverse impact to nongame resources or natural areas from the proposed action. There are no Federally-listed threatened and endangered species recorded on the VYNPS site, and there is no critical habitat in the state of Vermont for the three listed species in Windham County. Therefore, the staff concludes that there is no effect to threatened and endangered species associated with the proposed action.

Social and Economic Impacts

Potential social and economic impacts due to the proposed action include changes in tax revenue for Windham County and changes in the size of the workforce at VYNPS. The NRC staff has reviewed the information provided by the licensee regarding socioeconomic impacts. Entergy is a major employer in the community with approximately 670 full-time employees and contractors. Entergy is also a major contributor to the local tax base, but does not remit tax revenues directly to Windham County. Entergy personnel indirectly contribute to the tax base by paying sales and property taxes, state income taxes, and hotel and meal taxes which are paid by Entergy contractors while working at VYNPS. VYNPS pays a State Education Tax which is based on the level of generation of electrical power. The additional electrical power generated from the EPU will result in a proportional increase in taxes. The Tax Stabilization Contract, entered into by the Town of Vernon, Vermont and the owners of VYNPS, determines Entergy's contribution to the remaining local tax base. The contract specifies a Total Listed Value to be used for assessing Municipal Services property tax through 2010. The Total Listed Value applies to all real and personal property owned on April 1, 2000, and acquired thereafter, which is used in connection with the generation of electrical power through the nuclear fission process.

The proposed EPU would not significantly affect the size of the VYNPS labor force and would not have a material effect upon the labor force required for future outages after all stages of the modifications needed to support the EPU are complete. Entergy completed all major modifications in the Spring 2004 refueling outage, which required approximately 425 additional workers. Normally, less than 700 additional personnel are required for refueling outages; the Spring 2004 refueling outage required approximately 1125 additional personnel. Additional modifications needed to support the EPU were completed during the Fall 2005 refueling outage. The remaining modifications were less significant than those implemented during the Spring 2004 refueling outage and required less than 100 additional workers to supplement typical refueling outage staffing levels.

It is expected that the proposed EPU will increase the economic viability of VYNPS and lower the probability of early plant retirement. With the increased likelihood that VYNPS will remain operational at least through the end of the current license term, local employment opportunities will remain available. Early plant retirement would be expected to have a negative impact on the local economy and the community as a whole by reducing tax revenues and limiting local employment opportunities, although these effects could be mitigated by decommissioning activities in the short term.

The Vermont Public Service Board has determined that the EPU will not greatly interfere with the development of the region and will have a minimal impact outside the immediate area of VYNPS. Entergy has not identified any negative socioeconomic impacts associated with the EPU. Therefore, the staff concludes that there are no significant social or economic impacts associated with the proposed action.

Summary

The proposed EPU would not result in a significant change in non-radiological impacts in the areas of land use, water use, waste discharges, cooling tower operation, terrestrial and aquatic biota, transmission facility operation, or social and economic factors. No other non-radiological impacts were identified or would be expected. Table 2 summarizes the non-radiological environmental impacts of the proposed EPU at VYNPS.

TABLE 2.—SUMMARY OF NON-RADIOLOGICAL ENVIRONMENTAL IMPACTS

Land Use	No significant land use modifications; installed temporary office space to support EPU.
Cooling Tower	No significant aesthetic impact, slightly larger plume size; no significant increase in noise; no significant fogging or icing.
Transmission Facilities	No physical modifications to transmission lines; lines meet shock safety requirements; no changes to right-of-ways; small increase in electrical current would cause small increase in electromagnetic field around transmission lines.
Water Use	No configuration change to intake structure; no increased rate of withdrawal; slight increase in water consumption due to increased evaporation; no water use conflicts.
Discharge	Increase in water temperature discharged to Connecticut River; will meet thermal discharge limits in current NPDES permit following EPU; no change in chemical or sanitary waste discharges.
Aquatic Biota	No additional impact expected on aquatic biota.
Terrestrial Biota	Vermont Nongame and Natural Heritage Program found no adverse impact from EPU; no additional impact on terrestrial plant or animal species.
Threatened and Endangered Species	Three Federally-listed species in Windham County; EPU will have no effect on species.
Social and Economic	No significant change in size of VYNPS labor force required for plant operation or future refueling outages; increased production of tax revenues.

Radiological Impacts

Radioactive Waste Stream Impacts

VYNPS uses waste treatment systems designed to collect, process, and dispose of gaseous, liquid, and solid wastes that might contain radioactive material in a safe and controlled manner such that discharges are in accordance with the requirements of Title 10 of the Code of Federal Regulations (10 CFR) Part 20, ''Standards for Protection Against Radiation'', and 10 CFR Part 50, ''Domestic Licensing of Production and Utilization Facilities'', Appendix I. These radioactive waste streams are discussed in the FES. The proposed EPU would not result in changes in the operation or design of equipment in the gaseous, liquid, or solid waste systems.

Gaseous Radioactive Waste and Offsite Doses

During normal operation, the gaseous effluent treatment systems process and control the release of gaseous radioactive effluents to the environment, including small quantities of noble gases, halogens, tritium, and particulate material. The gaseous waste management systems include the offgas system and various building ventilation systems. Entergy estimates that gaseous radioactive effluents will increase following the EPU but will remain within regulatory limits. In the past three years, the peak dose from gaseous effluents at VYNPS was less than 1 millirem (mrem) per year. The increase in gaseous effluents following the EPU is not expected to be more than 20 percent of the current gaseous effluent release, consistent with the EPU. If there were a 20 percent increase from the peak dose of less than 1 mrem per year, the projected dose would still remain well below the dose design objectives of Appendix I to 10 CFR Part 50. Therefore, the increase in offsite dose due to gaseous effluent release following the EPU would not be significant.

Liquid Radioactive Waste and Offsite Doses

During normal operation, the liquid effluent treatment systems process and control the release of liquid radioactive effluents to the environment, such that the doses to individuals offsite are maintained within the limits of 10 CFR Part 20 and 10 CFR Part 50, Appendix I. The liquid radioactive waste systems are designed to process the waste and then recycle it within the plant as condensate, reprocess it through the radioactive waste system for further purification, or discharge it to the environment as liquid radioactive waste effluent in accordance with State and Federal regulations. Entergy estimates that the volume of liquid radioactive waste generated would increase by 1.2 percent of the current total, following the EPU. This is an increase in the volume of liquid radioactive waste that will require processing, and not an increase in liquid radioactive effluent. The increased volume of liquid radioactive waste is due to the increased frequency of reactor water cleanup filter demineralizer and condensate demineralizer backwashes. The demineralizer backwashes will increase due to an increase in conductivity of the reactor water cleanup system and an increase in feedwater flow following the EPU. Entergy indicated that the percentage increase in liquid radioactive waste generated due to the EPU is within the designed system total volume capacity. There is a very small increase in the volume of liquid radioactive waste generated due to the EPU, but no liquid radioactive waste discharges are expected. Therefore, there would not be a significant environmental impact from the additional volume of liquid radioactive waste generated following the EPU.

Solid Radioactive Wastes

The solid radioactive waste system collects, processes, packages, and temporarily stores radioactive dry and wet solid wastes prior to shipment offsite and permanent disposal. The largest volume of solid radioactive waste at VYNPS is low-level radioactive waste; sources of this include spent ion exchanger resins, filter sludges, air filters, and miscellaneous papers and rags. In 2001, which represents a year of peak solid waste generation, Entergy generated 37 cubic meters (1291 cubic feet) of solid waste. The proposed EPU is expected to increase the amount of reactor water cleanup and condensate demineralizer resins due to increased flow rates for the steam, feedwater, and condensate systems. This is the only expected waste increase. Entergy estimates that the volume of this solid waste could increase by as much as 17.8 percent over the volume of solid waste generated in 2001. Even with such an increase, the expected volume of low-level radioactive waste would be well below the value in the FES.

The proposed EPU would also result in a greater percentage of fuel assemblies being removed from the reactor core and replaced with new fuel assemblies during each refueling outage. Entergy expects the number of fuel assemblies consumed each cycle to increase by 28 percent following the EPU for the remaining term of the license. The additional amount of fuel assemblies consumed will result in greater storage of spent fuel at VYNPS. Entergy estimates that VYNPS can operate to the Fall 2008 refueling outage before exhausting its full-core discharge capability and reaching the capacity of the spent fuel pool, if the plant does not implement the proposed EPU.

Assuming the proposed EPU is implemented, Entergy estimates that VYNPS would exhaust its full core discharge capability one cycle earlier (i.e., by the Spring 2007 refueling outage). Regardless of the EPU, Entergy plans to utilize dry cask storage at VYNPS in the near future (pending Vermont Public Service Board approval), to permit continued operations for the full term of the current license. Dry cask storage at VYNPS will be necessary regardless of the EPU, subject to State approval separate from the EPU application, and would not involve a significant increase in the total number of spent fuel assemblies requiring storage over the term of the current license. Accordingly, the NRC staff concludes that there will be no significant environmental impact resulting from storage of the additional fuel assemblies.

In-Plant Radiation Doses

The proposed EPU would result in the production of more radioactive material and higher radiation dose rates in some areas at VYNPS. For most areas, radiation doses are unchanged due to the ample margin in the radiation shielding design. Area dose rates inside shielded cubicles can increase as much as 20 percent. However, these areas are not normally occupied during plant operation. Entergy estimates that there will be higher radiation levels in and around the turbine, due to increased steam flow and velocity following the EPU, which will lead to shorter travel times to the turbine and less time for radioactive decay in transit. Therefore, Entergy estimates that the overall increase in radiation level could be as high as 26 percent in those areas with higher steam flow.

The VYNPS FES does not contain an estimate for annual collective occupational radiation dose. The collective occupational dose at VYNPS in 2001 and 2002 was 142 person-rem and 150 person-rem, respectively. The potentially higher dose rates due to the EPU are not expected to increase the annual collective occupational dose by more than 20 percent. Therefore, the annual average collective occupational dose after the EPU is implemented may increase by approximately 30 person-rem.

Individual worker exposure is maintained within acceptable limits by the VYNPS ''as low as reasonably achievable'' (ALARA) program which controls access to radiation areas. Procedural controls compensate for increased radiation levels to ensure that worker exposure remains ALARA and that the normal operation radiation zones are labeled and controlled for access in accordance with the requirements of 10 CFR Part 20 related to allowable worker exposure and access control. Accordingly, occupational doses after the EPU is implemented will remain within acceptable levels and will not result in a significant environmental or radiological dose impact.

Direct Radiation Doses Offsite

Direct radiation emitted skyward from radionuclides (mainly nitrogen-16) in the main steam system components in the turbine building is scattered back to ground level by molecules in the air and provides another offsite public dose pathway (skyshine) from an operating boiling-water reactor. The licensee routinely monitors whole body dose rate offsite using high purity germanium detectors, pressurized ion chambers, and thermoluminescent dosimeters. Based on measurements of radiation, the highest direct radiation dose offsite was found at the west side boundary. Entergy estimates that approximately 90 percent of the direct radiation dose at the west side boundary is due to skyshine. The highest annual dose at the west side boundary is 13.4 mrem from skyshine. Following the EPU, skyshine is expected to increase by 26 percent due to the expected increase in the nitrogen-16 source in the turbine building. Assuming a 26-percent increase in direct radiation dose offsite due to skyshine following the EPU, the direct radiation dose offsite at the site boundary would be 16.9 mrem from skyshine. The total maximum direct radiation dose offsite at the site boundary would be 18.6 mrem (16.9 mrem from nitrogen-16 skyshine plus 1.7 mrem from miscellaneous radwaste stored on site).

The annual whole body dose equivalent to a member of the public beyond the site boundary is limited to 25 mrem (0.25 mSv) by 40 CFR Part 190. The projected maximum direct radiation dose offsite at VYNPS is within this limit. The licensee will continue to perform surveys as the EPU is implemented to ensure continued compliance with 40 CFR Part 190. Therefore, the impact of the EPU on direct radiation dose offsite would not be significant.

Postulated Accident Doses

As a result of implementation of the proposed EPU, there is an increase in the source term used in the evaluation of some of the postulated accidents in the FES. The inventory of radionuclides in the reactor core is dependent upon power level; therefore, the core inventory of radionuclides could increase by as much as 20 percent. The concentration of radionuclides in the reactor coolant may also increase by as much as 20 percent; however, this concentration is limited by the VYNPS Technical Specifications. This coolant concentration is part of the source term considered in some of the postulated accident analyses. Some of the radioactive waste streams and storage systems evaluated for postulated accidents may contain slightly higher quantities of radionuclides than is present under current operations. For those postulated accidents where the source term has increased, the calculated potential radiation dose to individuals at the site boundary (the exclusion area) and in the low population zone would be increased over values presented in the FES, but would be within the doses calculated by the licensee and approved by the NRC staff in a separate license amendment dated March 29, 2005, as discussed below.

In support of the EPU, the licensee submitted a separate license amendment request which proposed a full-scope implementation of an alternative source term (AST) methodology pursuant to 10 CFR 50.67. The licensee performed the radiological analyses that support the AST amendment assuming a reactor power of 1950 MWt which is approximately 102 percent of the proposed EPU power level of 1912 MWt. The NRC approved the AST amendment request on March 29, 2005. As discussed in the safety evaluation for the AST amendment, the NRC staff concluded that the doses, for postulated design-basis accidents under EPU conditions, would meet the acceptance criteria of 10 CFR 50.67 and the guidance in Regulatory Guide 1.183. Therefore, the NRC staff concludes that any increased environmental impact under EPU conditions, in terms of potential increased radiological doses from postulated accidents, would not be significant.

Fuel Cycle and Transportation Impacts

The environmental impacts of the fuel cycle and transportation of fuels and wastes are described in Tables S–3 and S–4 of 10 CFR 51.51 and 10 CFR 51.52, respectively. An additional NRC generic Environmental Assessment (53 FR 30355, dated August 11, 1988, as corrected by 53 FR 32322, dated August 24, 1988) evaluated the applicability of Tables S–3 and S–4 to higher burnup cycle and concluded that there is no significant change in environmental impact from the parameters evaluated in Tables S–3 and S–4 for fuel cycles with

uranium enrichments up to 5 weight percent Uranium-235 and burnups less than 60,000 megawatt (thermal) days per metric ton of Uranium-235 (MWd/MTU). Entergy has concluded that the fuel enrichment at VYNPS will increase to approximately 4.6 weight percent Uranium-235 as a result of the EPU. Entergy states that the expected core average exposure for the EPU is 35,000 MWd/MTU and the maximum bundle exposure is 58,000 MWd/MTU. The fuel enrichment for the EPU will not exceed 5 weight percent Uranium-235, and the rod average discharge burnup will not exceed 60,000 MWd/MTU. Therefore, the environmental impacts of the EPU will remain bounded by the impacts in Tables S–3 and S–4 and are not significant.

Summary

The proposed EPU would not result in a significant increase in occupational or public radiation exposure, would not significantly increase the potential doses from postulated accidents, and would not result in significant additional fuel cycle environmental impacts. Accordingly, the Commission concludes that there are no significant radiological environmental impacts associated with the proposed action. Table 3 summarizes the radiological environmental impacts of the proposed EPU at VYNPS.

TABLE 3.—SUMMARY OF RADIOLOGICAL ENVIRONMENTAL IMPACTS

Gaseous Effluents and Doses	Up to 20% increase in dose due to gaseous effluents; doses to individuals offsite will remain within NRC limits.
Liquid Effluents and Doses	Volume of liquid effluent generated expected to increase by 1.2%; slight increase in the amount of radioactive material in liquid effluent; no discharge of liquid effluent expected, no increase in dose to public.
Solid Radioactive Waste	Volume of solid waste expected to increase by 17.8% due to demineralizer resins; within FES estimate; increase in amount of spent fuel assemblies to be stored onsite.
In-plant Dose	Occupational dose could increase by 20% overall; will remain within acceptable limits under the VYNPS ALARA program.
Direct Radiation Dose	Up to 26% increase in dose rate offsite due to skyshine; expected annual dose continues to meet NRC/EPA limits.
Postulated Accidents	Licensee using Alternative Source Term; doses are within NRC limits.
Fuel Cycle and Transportation	Increase in bundle average enrichment and burnup; impacts stated in Tables S–3 and S–4 in 10 CFR Part 51 are bounding.

Alternatives to Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed EPU (i.e., the ''no-action'' alternative). Denial of the application would result in no change in the current environmental impacts. However, if the EPU were not approved, other agencies and electric power organizations may be required to pursue other means of providing electric generation capacity to offset future demand. Such alternatives could include construction of fossil fuel or other generating capacity, or purchase of power from generating facilities outside the service area; such alternatives, however, would likely result in environmental impacts comparable to or greater than those involved in the EPU. For example, fossil fuel plants routinely emit atmospheric pollutants, causing impacts in air quality that are larger than if VYNPS were to provide the same amount of electric generation. Construction and operation of a fossil fuel plant also creates impacts in land use and waste management.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in the 1972 FES for operation of the VYNPS.

Agencies and Persons Consulted

In accordance with its stated policy, on September 2, 2005, the NRC staff consulted with the Vermont State official, William K. Sherman, of the Department of Public Service, regarding the environmental impact of the proposed action. The State official had no comments.

Finding of No Significant Impact

On the basis of the environmental assessment, the Commission concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed action.

For further details with respect to the proposed action, see the licensee's application dated September 10, 2003, as supplemented on October 1, and October 28 (2 letters), 2003; January 31 (2 letters), March 4, May 19, July 2, July 27, July 30, August 12, August 25, September 14, September 15, September 23, September 30 (2 letters), October 5, October 7 (2 letters), December 8, and December 9, 2004; February 24, March 10, March 24, March 31, April 5, April 22, June 2, August 1, August 4, September 10, September 14, September 18, September 28, October 17, October 21 (2 letters), October 26, and October 29, November 2, November 22, and December 2, 2005; and January 10, 2006. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible electronically from the ADAMS Public Electronic Reading Room on the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC PDR Reference staff at 1–800–397–4209, or 301–415–4737, or send an e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 20th day of January 2006.

For the Nuclear Regulatory Commission.

Richard B. Ennis,

Senior Project Manager, Plant Licensing Branch I–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. E6–1035 Filed 1–26–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–8905]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for Rio Algom Mining LLC, Ambrosia Lake, NM

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: Michael G. Raddatz, Project Manager, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–6334; fax number: (301) 415–5955; e-mail: *mgr@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) is issuing a license amendment to Source Materials License No. SUA–1473 issued to Rio Algom Mining LLC (the licensee), to authorize Alternate Concentration Limits (ACLs) at its uranium mill tailings site in Ambrosia Lake, New Mexico. NRC has prepared an Environmental Assessment (EA) in support of this amendment in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this Notice.

II. EA Summary

The purpose of the proposed amendment is to authorize ACLs at the licensee's Ambrosia Lake facility. Specifically, ACLs have been approved for hazardous constituents gross alpha, lead-210, molybdenum, nickel, radium-226 & –228, selenium, thorium-230, and natural uranium and nonhazardous constituents chloride, nitrate, sulfate, and Total Dissolved Solids (TDS). On February 15, 2000, May 30, 2001, and July 7, 2005, Rio Algom Mining LLC requested that NRC approve the proposed amendment. The licensee's request for the proposed change was previously noticed in the **Federal Register** on June 29, 2000, (65 FR 40144) with a notice of an opportunity to request a hearing and an opportunity to provide comments on the amendment and its environmental impacts.

The staff has prepared the EA in support of the proposed license amendment. The staff considered impacts to ground water, surface water, socioeconomic conditions, threatened and endangered species, transportation, land use, public and occupational health, and historic and cultural resources. The EA supports a FONSI because this licensing action does not involve any land disturbance; therefore, impacts to socioeconomic conditions, threatened and endangered species, transportation, land use, public and occupational health, and historic and cultural resources would not occur. In addition, reviews of ground water flow, fate and transport, and exposure models indicate that the ACLs are protective of human health and the environment at the point of exposure because hydrogeologic conditions, natural attenuation processes, and aquifer class of use near the facility would preclude human exposures and environmental impacts.

III. Finding of No Significant Impact

On the basis of the EA, NRC has concluded that there are no significant environmental impacts from the proposed amendment and has determined not to prepare an environmental impact statement.

IV. Further Information

Documents related to this action, including the application for amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are as follows:

Document	ADAMS accession No.	Date
Quivira Mining Company, Corrective Action Program and Alternate Concentration Limits Petition for Uppermost Bedrock Units, Ambrosia Lake Uranium Mill Facility Near Grants, New Mexico, Grants, New Mexico	ML003687843	2/15/2000
Rio Algom Mining, LLC, Ground Water Modeling and Feasibility Analysis for the Application of Alternate Concentration Limits	ML003737960	7/21/2000
Quivira Mining Company, Application for Alternate Concentration Limits in the Alluvial Materials at Quivira Mill Facility, Ambrosia Lake, New Mexico, Grants, New Mexico	ML011690068	5/20/2001
U.S. Nuclear Regulatory Commission, Rio Algom Mining LLC, Ground Water Alternate Concentration Limits, Request for Additional Information	ML030170464	1/16/2003
Rio Algom Mining LLC, Response to Request for Additional Information for the Rio Algom Mining LLC's January 16, 2003, Application for Alternate Concentration Limits	ML031080523	4/11/2003
Rio Algom Mining LLC, 2004a, Response to Agreements Reached During August 12, 2003, Meeting With the Nuclear Regulatory Commission, Oklahoma City, Oklahoma	ML040430419	2/9/2004
U.S. Fish and Wildlife Service, letter to J. Caverly	ML042780480	9/20/2004
New Mexico Environment Department, letter to Gary S. Janosko transmitting comments on the draft environmental assessment	ML050800062	2/21/2005
Rio Algom Mining LLC, Response to U.S. Nuclear Regulatory Commission's February 10, 2005, Request for Additional Information To Incorporate Nonhazardous Constituents as Part of the Site Alternate Concentration Limit Petition	ML051990088	7/7/2005
U.S. Nuclear Regulatory Commission, Rio Algom Mining LLC, Nonhazardous Constituent Alternate Concentration Limits, Request for Additional Information	ML052770173	10/31/2005
Rio Algom Mining LLC, 2005b. Response to October 31, 2005, Request for Additional Information	ML053480214	12/7/2005
Environmental Assessment for Amendment of Source Materials License SUA–1473 for Ground Water Alternate Concentration Limits, Rio Algom Mining, LLC, Ambrosia Lake, New Mexico	ML060130097	1/20/2006

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

These documents may also be viewed electronically on the public computers located at the NRC's PDR, O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland this 23rd day of January, 2006.

For the Nuclear Regulatory Commission.

Michael G. Raddatz,

Project Manager, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E6–1036 Filed 1–26–06; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–0299]

Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for Umetco Minerals Corporation, East Gas Hills, WY

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of availability.

FOR FURTHER INFORMATION CONTACT: Paul Michalak, Project Manager, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–7612; fax number: (301) 415–5955; e-mail: *pxm2@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The Nuclear Regulatory Commission (NRC) proposes to issue a license amendment for License Condition 35 (alternate concentration limit (ACL) for ground water compliance monitoring), to Materials License SUA–648, for the Umetco Minerals Corporation (Umetco), East Gas Hills, Wyoming uranium mill site. The purpose of this amendment is to increase the Lead-210 (Pb-210) ACL from 46.7 pCi/L to 189 pCi/L in the Southwestern Flow Regime (SWFR). NRC has prepared an Environmental Assessment (EA) in support of this amendment in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this Notice.

II. EA Summary

The staff has prepared the EA in support of the proposed license amendment. Much of the information relied upon in preparation of the EA was obtained from the licensee's ACL application and from two previous EAs for Umteco site activities related to their revised soil decommissioning plan and a recent application for several ACLs. Since this action relates to ground water, the primary focus of the evaluation of potential environmental impacts relates to ground water. In particular, current and future ground water use, and predicted concentrations of Pb-210 at the designated point of exposure were considered in the analysis. Staff has concluded that there would be no effect to the following resources: Visual resources, vegetation and soils, ambient air quality, and transportation. Staff has also determined that the proposed action is not the type of activity that has the potential to cause effects on cultural or historic resources.

III. Finding of No Significant Impact

On the basis of the EA, NRC has concluded that there are no significant environmental impacts from the proposed amendment and has determined not to prepare an environmental impact statement.

IV. Further Information

Documents related to this action, including the application for amendment and supporting documentation, are available electronically at the NRC's Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html.* From this site, you can access the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession numbers for the documents related to this notice are as follows:

Document	ADAMS accession No.	Date
NRC's EA for Umteco's Revised Soil Decommissioning Plan	ML010460319	2/23/2001
NRC's EA for Umteco's ACLs Application	ML020840234	3/24/2002
Umetco's ACL Amendment Request	ML051780369	6/17/2005
NRC's EA for ACL Amendment Request	ML060200288	1/20/2006

If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

These documents may also be viewed electronically on the public computers located at the NRC's PDR, O1 F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents for a fee.

Dated at Rockville, Maryland this 23rd day of January, 2006.

For the Nuclear Regulatory Commission.

Paul Michalak,

Project Manager, Fuel Cycle Facilities Branch, Division of Fuel Cycle Safety and Safeguards, Office of Nuclear Material Safety and Safeguards.

[FR Doc. E6–1045 Filed 1–26–06; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of January 30, 2006:

An open meeting will be held on Monday, January 30, 2006 at 10 a.m. in Room L–002, the Auditorium.

Commissioner Atkins as duty officer determined that no earlier notice thereof was possible.

The subject matter of the open meeting scheduled for Monday, January 30, 2006 will be:

The Commission will hear oral argument on an appeal by Vladlen ''Larry'' Vindman and the Division of Enforcement from the decision of an administrativelaw judge. The law judge found that Vindman engaged in a scheme to inflate artificially the demand for and price of the stock of Marx Toys & Entertainment Corp. (''Marx''), a penny stock, in violation of Section 17(a) of the Securities Act of 1933, Section 10(b) of the Securities Exchange Act of 1934, and Exchange Act Rule

10b–5. The law judge imposed a cease-and-desist order on Vindman and barred him from participating in an offering of penny stock. She also imposed a third-tier civil money penalty in the amount of $20,000. In imposing the penalty, the law judge found that the $120,000 penalty requested by the Division, the maximum third-tier penalty allowed by statute for each act or omission found, was consistent with Commission precedent, but she reduced the penalty to $20,000, which she found took into account both the need for deterrence and record evidence bearing on Vindman's ability to pay. Vindman appeals from the law judge's findings of violation and the sanctions she imposed. The sole issue pressed in the Division's appeal is the amount of the civil penalty imposed.

Among the issues likely to be argued are:

1. Whether Vindman violated antifraud provisions by manipulating the market in Marx stock.

2. If violations are found, what, if any, sanctions are warranted.

3. If a civil penalty is warranted, whether and what amount Vindman is able to pay.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact:

The Office of the Secretary at (202) 551–5400.

Dated: January 24, 2006.

Nancy M. Morris,

Secretary.

[FR Doc. 06–835 Filed 1–25–06; 11:34 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–53166; File No. SR–Phlx–2006–05]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Notice of Filing and Order Granting Accelerated Approval to a Proposed Rule Change and Amendment No. 1 Thereto Relating to the Phlx XL Risk Monitor Mechanism

January 23, 2006.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on January 13, 2006, the Philadelphia Stock Exchange, Inc. (''Phlx'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. On January 19, 2006, the Exchange filed Amendment No. 1 to the proposed rule change.[3] The Commission is publishing this notice to solicit comments on the proposed rule change, as amended, from interested persons. In addition, the Commission is granting accelerated approval of the proposed rule change, as amended.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to adopt Phlx Rule 1093, Phlx XL Risk Monitor Mechanism, to provide Exchange specialists, Streaming Quote Traders (''SQTs''),[4] Remote Streaming Quote Traders (''RSQTs''),[5] and non-SQT ROTs[6] who are required to submit continuous two-sided electronic quotations pursuant to Phlx Rule 1014(b)(ii)(E)[7] (collectively, ''Phlx XL participants'') protection from the unreasonable risk associated with the execution of an excessive number of contracts resulting from near simultaneous executions in a single option issue. Such protection would be provided by way of the implementation of a Risk Monitor Mechanism. The Exchange also proposes conforming changes to Phlx Rule 1017, Openings in Options, and to Phlx Rule 1082, Firm Quotations, to describe the Exchange's disseminated quotation when the disseminated size is exhausted and the specialist has not yet revised its quotation. The text of the proposed rule change, as amended, is below. Proposed new language is in *italics*; proposed deletions are in [brackets].

Phlx XL Risk Monitor Mechanism

Rule 1093. (a) The Phlx XL system (the ''system'') will maintain a counting program (''counting program'') for each specialist, SQT, RSQT, and non-SQT ROT who is required to submit continuous two-sided electronic quotations pursuant to Rule 1014(b)(ii)(E) (collectively, ''Phlx XL participants'') assigned in a particular option. The counting program will count the number of contracts traded in such an option by each Phlx XL participant within a specified time period, not to exceed 15 seconds, established by each Phlx XL participant (the ''specified time period''). The specified time period will commence for an option when a transaction occurs in any series in such option.

(b)(i) Risk Monitor Mechanism. The system will engage the Risk Monitor Mechanism in a particular option when the counting program has determined that a Phlx XL participant has traded a Specified Engagement Size (as defined below) established by such Phlx XL participant during the specified time period. When such Phlx XL participant has traded the Specified Engagement Size during the specified time period, the Risk Monitor Mechanism will automatically remove such Phlx XL participant's quotations from the Exchange's disseminated quotation in all series of the particular option.

(ii) Specified Engagement Size. The Specified Engagement Size is determined by the following: (A) For each series in an option, the counting program will determine the percentage that the number of contracts executed in that series represents relative to the disseminated size in that series (''series percentage''); (B) The counting program will determine the sum of the series percentages in the option issue (''issue percentage''); (C) Once the counting program determines that the issue percentage equals or exceeds a percentage established by the Phlx XL participant, not less than 100% (''Specified Percentage''), the number of executed contracts in the option issue equals the Specified Engagement Size. For example, if a Phlx XL participant is quoting in four series of a particular option issue, and sets its Specified Percentage at 100%, the Specified Engagement Size would be determined as follows:

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 corrected certain technical errors in the text of the proposed rule change.

[4] An SQT is an Exchange Registered Options Trader (''ROT'') who has received permission from the Exchange to generate and submit option quotations electronically through the Exchange's Automated Options Market (''AUTOM'') in eligible options to which such SQT is assigned. An SQT may only submit such quotations while such SQT is physically present on the floor of the Exchange. *See* Phlx Rule 1014(b)(ii)(A).

[5] An RSQT is an ROT that is a member or member organization with no physical trading floor presence who has received permission from the Exchange to generate and submit option quotations electronically through AUTOM in eligible options to which such RSQT has been assigned. An RSQT may only submit such quotations electronically from off the floor of the Exchange. *See* Phlx Rule 1014(b)(ii)(B).

[6] A non-SQT ROT is an ROT who is neither an SQT nor an RSQT. *See* Phlx Rule 1014(b)(ii)(C).

[7] Phlx Rule 1014(b)(ii)(E) requires non-SQT ROTs who transact more than 20% of their contract volume in an option electronically versus in open outcry during a particular calendar quarter to submit proprietary electronic quotations in such an option during the subsequent calendar quarter for a certain number of series in such option, depending on the percent of total volume transacted electronically versus in open outcry on the Exchange in such option.

Example I

Series	Size	Number of contracts executed	Percentage
Series 1	100	40	40
Series 2	50	20	40
Series 3	200	20	10
Series 4	150	15	10
Total	500	95	100

In this example the Specified Engagement Size is 95 contracts, which is the aggregate number of contracts executed among all series during the specified time period that represents an issue percentage equal to the Specified Percentage of 100%.

Example II

Series	Size	Number of contracts executed	Percentage
Series 1	100	0	0
Series 2	50	0	0
Series 3	200	0	0
Series 4	150	150	100
Total	500	150	100

In this example the Specified Engagement Size is 150 contracts, which is the aggregate number of contracts executed among all series during the specified time period that represents an issue percentage equal to the Specified Percentage of 100%.

If a Phlx XL participant is quoting in four series of a particular option, and sets its Specified Percentage at 200%, the Specified Engagement Size would be determined as follows:

Example III

Series	Size	Number of contracts executed	Percentage
Series 1	100	80	80
Series 2	50	40	80
Series 3	200	40	20
Series 4	150	30	20
Total	500	190	200

In this example the Specified Engagement Size is 190 contracts, which is the aggregate number of contracts executed among all series during the specified time period that represents an issue percentage equal to the Specified Percentage of 200%. The Specified Engagement Size will be automatically offset by a number of contracts that are executed on the opposite side of the market in the same option issue during the specified time period (the ''Net Offset Specified Engagement Size''). For example, a Phlx XL participant that buys calls and also sells calls or buys puts in the same option during the specified time period would have a Net Offset Specified Engagement Size as follows:

Example IV

Series	Size	Buy call	Sell call/buy put	Net offset size	Percentage
Series 1	100	60	20	40	40
Series 2	50	100	80	20	40
Series 3	200	150	130	20	10
Series 4	150	75	60	15	10
Total	500	385	290	95	100

The Net Offset Specified Engagement Size for each series is determined by offsetting the number of contracts executed on the opposite side of the market for each series during the specified time period. The Risk Monitor Mechanism shall be engaged once the Net Offset Specified Engagement Size is for a net number of contracts executed among all series in an option issue during the specified time period that

represents an issue percentage equal to or greater than the Specified Percentage.

(c) Any marketable orders, or quotes that are executable against a Phlx XL participant's disseminated quotation that are received prior to the time the Risk Monitor Mechanism is engaged will be automatically executed at the disseminated price up to the Phlx XL participant's disseminated size, regardless of whether such an execution results in executions in excess of the Phlx XL participant's Specified Engagement Size.

(d) In the event that the specialist's quote is removed by the Risk Monitor Mechanism and there are no other Phlx XL participants quoting in the particular option, the system will automatically provide two-sided quotes that comply with the Exchange's rules concerning quote spread parameters on behalf of the specialist until such time as the specialist revises the quotation. All quotations generated by the Exchange on behalf of a specialist shall be considered ''firm quotations'' and shall be the obligation of the specialist.

(e) The system will automatically reset the counting program and commence a new specified time period when:

(i) A previous counting period has expired and a transaction occurs in any series in such option; or

(ii) The Phlx XL participant refreshes his/her quotation, in a series for which an order has been executed (thus commencing the specified time period) prior to the expiration of the specified time period.

* * * * *

Obligations and Restrictions Applicable to Specialists and Registered Options Traders

Rule 1014. (a) No change.

(b) ROT. (i) No change.

(ii) (A)–(C) No change.

(D) Market Making Obligations Applicable in Streaming Quote Options. In addition to the other requirements for ROTs set forth in this Rule 1014, an SQT and an RSQT shall be responsible to quote continuous, two-sided markets in not less than 60% of the series in each Streaming Quote Option (as defined in Rule 1080(k)) in which such SQT or RSQT is assigned, provided that a Directed SQT or RSQT (as defined in Rule 1080(l)(i)(C)) shall be responsible to quote continuous, two-sided markets in not less than [100] *99*% of the series in each Streaming Quote Option in which they receive Directed Orders (as defined in Rule 1080(l)(i)(A)). The specialist shall be responsible to quote continuous, two-sided markets in not less than [100] *99*% of the series in each Streaming Quote Option in which such specialist is assigned.

(E) No change.

(c)–(h) No change.

Commentary: No change.

* * * * *

Openings in Options

Rule 1017. (a) No change.

(b) The system will calculate an Anticipated Opening Price (''AOP'') and Anticipated Opening Size (''AOS'') when a quote or trade has been disseminated by the primary market for the underlying security, and under the conditions set forth below. The specialist assigned in the particular option must enter opening quotes not later than one minute following the dissemination of a quote or trade by the primary market for the underlying security. An AOP may only be calculated if: (i) the Exchange has received market orders, or the book is crossed (highest bid is higher than the lowest offer) or locked (highest bid equals the lowest offer); and (ii) either (A) the specialist's quote has been submitted; (B) the quotes of at least two Phlx XL participants that are required to submit continuous, two-sided quotes in [100] *99*% of the series in all option issues in which such Phlx XL participant is assigned (''[100] *99*% participants''), have been submitted within two minutes of the opening trade or quote on the primary market for the underlying security (or such shorter time as determined by the Options Committee and disseminated to membership via Exchange Circular); or (C) if neither the specialist's quote nor the quotes of two [100] *99*% participants have been submitted within two minutes of the opening trade or quote on the primary market for the underlying security (or such shorter time as determined by the Options Committee and disseminated to membership via Exchange circular), one [100] *99*% participant has submitted their quote.

In situations where an AOP may be calculated and there is an order/quote imbalance, the system will immediately send an imbalance notice indicating the imbalance side (buy or sell) and the AOP and AOS (an ''Imbalance Notice'') to Phlx XL participants provided that the primary market for the underlying security has disseminated the opening quote or trade. Phlx XL participants that have not submitted opening quotes will then submit their opening quotes, and Phlx XL participants that have submitted opening quotes may submit revised opening quotes; thereafter the system will disseminate an updated Imbalance Notice every five seconds (or such shorter period as determined by the Options Committee and disseminated to membership via Exchange Circular) until the series is open. If no imbalance exists, no Imbalance Notice will be sent, and the system will establish an opening price as described in paragraph (c) below.

(c)–(d) No change.

(e) The system will not open a series if one of the following conditions is met:

(i) there is no quote from the specialist or a [100] *99*% participant;

(ii)–(iii) No change.

(f)–(j) No change.

Commentary: No change.

* * * * *

Firm Quotations

Rule 1082. (a) (i) No change.

(ii) (A)–(B) No change.

(C)(1) If an SQT or RSQT's (other than a Directed SQT or RSQT) quotation size in a particular series in a Streaming Quote Option is exhausted *or removed by the Risk Monitor Mechanism*, such SQT or RSQT's quotation shall be deleted from the Exchange's disseminated quotation until the time the SQT or RSQT revises his/her quotation.

(2) If the Exchange's disseminated size in a particular series in a Streaming Quote Option is exhausted at that particular price level, and no specialist, SQT or RSQT has revised their quotation immediately following the exhaustion of the Exchange's disseminated size at such price level, the Exchange shall automatically [disseminate the specialist's most recent disseminated price prior to the time of such exhaustion] *provide two-sided quotes that comply with the Exchange's rules concerning quote spread parameters on behalf of the specialist until such time as the specialist revises the quotation,* with a size of one contract.

(iii)–(iv) No change.

(b)–(d) No change.

Commentary: No change.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The Phlx has prepared summaries, set forth in Sections A, B, and C below, of the

most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to provide Phlx XL participants protection from the unreasonable risk of multiple nearly simultaneous executions. The risk to Phlx XL participants is not limited to a single series in an option issue; Phlx XL participants have exposure in all series of a particular option issue, requiring them to offset or hedge their overall position in an option issue.

Phlx XL participants submit proprietary electronic quotations in options in which they are assigned based on proprietary pricing models that rely on various factors such as the price and market volatility of the underlying security. The Phlx XL participant's pricing model and automated quotation system will continuously enter updated quotations in all series of an option based on changes in the various factors included in its pricing models. In addition to the Phlx XL participant's own proprietary quoting system, the Risk Monitor Mechanism would provide an additional tool to the Phlx XL participant to help manage the risk associated with providing liquidity in a large number of series across an option in which it is assigned.

Specialists trading on Phlx XL, together with SQTs and RSQTs that receive Directed Orders [8] are currently required to submit continuous, two-sided quotations in 100% of the series in each option in which they are assigned.[9] SQTs and RSQTs that do not receive Directed Orders are required to submit continuous, two-sided quotations in 60% of the series in each option in which they are assigned.[10] Phlx XL participants are thus exposed to the possibility of near-simultaneous executions that can create large, unintended principal positions that expose the Phlx XL participant to unnecessary market risk. Consequently, Phlx XL participants may be more likely to widen their quotations, quote less aggressively, and limit their disseminated size in order to address these risks. The Risk Monitor Mechanism is intended to address these concerns by assisting Phlx XL participants in managing their market risk.

Phlx XL Risk Monitor Mechanism

The Phlx XL Risk Monitor Mechanism would begin with a counting program that would count the number of contracts traded in a particular option by each Phlx XL participant within a specified time period established by each Phlx XL participant (the ''specified time period''). The specified time period would commence for an option when a transaction occurs in any series in such option. The specified time period may not exceed 15 seconds; Phlx XL participants may, however, set the specified time period for less than 15 seconds.

The system would engage the Risk Monitor Mechanism in a particular option when the counting program has determined that a Phlx XL participant has traded a Specified Engagement Size (as defined below) established by such Phlx XL participant during the specified time period. When such Phlx XL participant has traded the Specified Engagement Size during the specified time period, the Risk Monitor Mechanism would automatically remove such Phlx XL participant's quotations from the Exchange's disseminated quotation in all series of the particular option until such Phlx XL participant submits a new, revised quotation.

Specified Engagement Size. Each Phlx XL participant would establish a Specified Engagement Size.[11] When such Phlx XL participant has traded the Specified Engagement Size during the specified time period, the Risk Monitor Mechanism would automatically remove such Phlx XL participant's quotations from the Exchange's disseminated quotation in all series of the particular option.

The Specified Engagement Size is determined as follows: For each series in an option, the counting program would determine the percentage that the number of contracts executed in that series represents relative to the disseminated size in that series (the ''series percentage''). The counting program would then determine the sum of the series percentages in the underlying option issue (the ''issue percentage''). Once the counting program determines that the issue percentage equals or exceeds a percentage established by the Phlx XL participant which may not be less than 100% (the ''Specified Percentage''), the number of executed contracts in the option issue equals the Specified Engagement Size.

For example, if a Phlx XL participant is quoting in four series of a particular option issue, and sets its Specified Percentage at 100%, the Specified Engagement Size would be determined as follows:

Example I

Series	Size	Number of contracts executed	Percentage
Series 1	100	40	40
Series 2	50	20	40
Series 3	200	20	10
Series 4	150	15	10
Total	500	95	100

[8] *See* Phlx Rule 1080(l).

[9] *See* Phlx Rule 1014(b)(ii)(D). The proposed rule change would reduce the percentage quoting requirement as described more fully below.

[10] *Id.*

[11] A Phlx XL participant could establish the Specified Engagement Size as 100% or greater of the number of contracts executed in each series during the specified time period relative to the disseminated size. For example, a Phlx XL participant could establish the Specified Engagement Size as 200%, in which case the Risk Monitor Mechanism would not be engaged until 200% of the number of contracts in each series have been executed during the specified time period relative to the disseminated size. A Phlx XL participant could also establish the Specified Engagement Size as, for example, 120%, in which case the Risk Monitor Mechanism would not be engaged until 120% of the number of contracts in each series have been executed during the specified time period relative to the disseminated size. In any event, however, a Phlx XL participant may not establish a Specified Engagement Size that is less than 100%.

In this example the Specified Engagement Size is 95 contracts, which is the aggregate number of contracts executed among all series during the specified time period that represents an issue percentage equal to the Specified Percentage of 100%.

Example II

Series	Size	Number of contracts executed	Percentage
Series 1	100	0	0
Series 2	50	0	0
Series 3	200	0	0
Series 4	150	150	100
Total	500	150	100

In this example the Specified Engagement Size is 150 contracts, which is the aggregate number of contracts executed among all series during the specified time period that represents an issue percentage equal to the Specified Percentage of 100%.

If a Phlx XL participant is quoting in four series of a particular option, and sets its Specified Percentage at 200%, the Specified Engagement Size would be determined as follows:

Example III

Series	Size	Number of contracts executed	Percentage
Series 1	100	80	80
Series 2	50	40	80
Series 3	200	40	20
Series 4	150	30	20
Total	500	190	200

In this example the Specified Engagement Size is 190 contracts, which is the aggregate number of contracts executed among all series during the specified time period that represents an issue percentage equal to the Specified Percentage of 200%.

Offset on the Opposite Side of the Market. The Risk Monitor Mechanism would calculate the number of contracts executed on one side of the market during the specified time period, and offset that number of contracts by the number of contracts executed on the opposite side of the market during the specified time period. The purpose of this provision is to account for the offset in risk of one option position created by a position in the same option issue on the opposite side of the market. Because the risk in such a situation is neutral, the Exchange believes that Phlx XL participants should continue executing contracts until the actual risk that is created by the Specified Engagement Size is realized.

The Specified Engagement Size would thus be automatically offset by a number of contracts that are executed on the opposite side of the market in the same option issue during the specified time period (the ''Net Offset Specified Engagement Size''). The Risk Monitor Mechanism would be engaged when the Net Offset Specified Engagement Size is for a number of contracts executed among all series during the specified time period that represents an issue percentage that is equal to or greater than the specified percentage. For example, a Phlx XL participant that buys calls and also sells calls or buys puts in the same option during the specified time period would have a Net Offset Specified Engagement Size as follows:

Example IV

Series	Size	Buy call	Sell call/buy put	Net offset size	Percentage
Series 1	100	60	20	40	40
Series 2	50	100	80	20	40
Series 3	200	150	130	20	10
Series 4	150	75	60	15	10
Total	500	385	290	95	100

In this example, 675 contracts have been executed during the specified time period (buy calls 385 + sell calls/buy puts 290). The Net Offset Specified Engagement Size for each series is determined by offsetting the number of contracts executed on the opposite side of the market for each series during the specified time period. The Risk Monitor Mechanism would be engaged once the Net Offset Specified Engagement Size is executed for a net number of contracts among all series during the specified time period that represents an issue percentage that is equal to or greater than the specified percentage.

Firm Quotations. In order to remain consistent with the Exchange's rules concerning Firm Quotations,[12] the proposed rule change would provide that any marketable orders, or quotes that are executable against a Phlx XL participant's disseminated quotation,

[12] *See* Phlx Rule 1082.

that are received prior to the time the Risk Monitor Mechanism is engaged would be automatically executed at the disseminated price up to the Phlx XL participant's disseminated size, regardless of whether such an execution results in executions in excess of the Phlx XL participant's Specified Engagement Size. Therefore, it is possible for a Phlx XL participant to execute a number of contracts that is greater than the Specified Engagement Size before the Risk Monitor Mechanism removes their quote from the Exchange's disseminated market.

Further, the proposed rule change would establish that, in the event that the specialist's quote is exhausted or removed by the Risk Monitor Mechanism, and there are no other Phlx XL participants quoting in the particular option, the system would automatically provide two-sided quotes that comply with the Exchange's rules concerning quote spread parameters on behalf of the specialist until such time as the specialist revises the quotation. All quotations generated by the Exchange on behalf of a specialist would be considered ''firm quotations'' and shall be the obligation of the specialist. The Exchange proposes conforming changes to Rule 1082 to reflect this situation.

The purpose of this provision is to ensure that the Exchange disseminates continuous quotations in all series traded on the Exchange, even in situations where no Phlx XL participant is disseminating its own quotations due to, for example, system malfunctions. The Exchange believes that it should ''take control'' of a Phlx XL participant's quotation only in limited circumstances (*i.e.,* only when the Exchange's failure to do so would result in no disseminated market from the Exchange), and that the Phlx XL participants then quoting should determine the Exchange's disseminated price and size.

The Exchange proposes to amend Phlx Rule 1014(b)(ii)(D) to reduce the obligation of specialists and Phlx XL participants that receive Directed Orders [13] to quote continuous, two-sided markets in not less than 100% of the series in each option in which they are assigned. The new obligation would be to quote in 99% of such series. The purpose of this proposal is to make the Exchange's rules concerning quoting requirements consistent with the Risk Monitor Mechanism's functionality (*i.e.*, the removal of individual specialist and Directed SQT and RSQT quotations from the Exchange's disseminated market). If the quoting obligation were to remain at 100% for these particular Phlx XL participants, a rule violation would occur each time the Risk Monitor Mechanism removes their quotation. Thus, the Exchange proposes to reduce this obligation so that removal of individual quotations does not result in violations of Exchange rules.

For consistency, the Exchange proposes conforming amendments to Phlx Rule 1017, Openings in Options, to change references to ''100% participants'' and re-name them ''99% participants.''

Re-Setting the Counting System. Finally, the proposed rule change provides that the system would automatically reset the counting program and commence a new specified time period when either: (i) a previous counting period has expired and a transaction occurs in any series in such option; or (ii) the Phlx XL participant refreshes his/her quotation, in a series for which an order has been executed (thus commencing the specified time period) prior to the expiration of the specified time period.

The commencement of the specified time period is event-driven, *i.e.*, upon the execution of a transaction in a particular series in an option. The system would only initiate a specified time period when such an execution occurs. If there is no activity in an option, the system would not repeatedly commence and calculate the expiration of a new specified time period for such option unnecessarily. Once an execution occurs, however, a specified time period would commence.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5) of the Act,[15] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, by assisting Phlx XL participants in managing their risk through the Risk Monitor Mechanism.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov.* Please include File Number SR–Phlx–2006–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–9303.

All submissions should refer to File Number SR–Phlx–2006–05. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 100 F Street, NE., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the Phlx. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File Number SR–Phlx–2006–05 and should be submitted on or before February 17, 2006.

[13] *See* Phlx Rule 1080(l).

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

IV. Commission's Findings and Order Granting Accelerated Approval of Proposed Rule Change

After careful review, the Commission finds that the proposed rule change, as amended, is consistent with the requirements of the Act and the rules and regulations thereunder, applicable to a national securities exchange.[16] In particular, the Commission believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires among other things, that the rules of the Exchange are designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Commission notes that the proposal does not alter the obligations of Phlx XL participants, except for the fact that it will reduce specialists and Phlx XL participants that receive directed orders continuous quoting obligation from 100% of the series in each option in which it is assigned to 99% of the series in each option in which it is assigned. The Commission notes that this reduction should provide specialists and Phlx XL participants that receive directed orders a brief amount of time to update their quotes after the Risk Monitor Mechanism removes their quotes from the Exchange's disseminated quotation. In addition, the Commission believes that the proposed rule change should provide Phlx XL participants assistance in effectively managing their quotations.

The Phlx has requested that the Commission find good cause for approving the proposed rule change prior to the thirtieth day after publication of notice thereof in the **Federal Register**. The Commission notes that similar proposals to provide protection from risk for market makers have been approved for other options exchanges.[18] The Commission believes that granting accelerated approval of the proposal should provide Phlx XL participants with similar protections from the risk associated with an excessive number of near simultaneous executions in a single options class. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[19] for approving the proposed rule change, as amended, prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[20] that the proposed rule change (SR–Phlx–2006–05) and Amendment No. 1 thereto be, and hereby are, approved on an accelerated basis.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[21]

Nancy M. Morris,

Secretary.

[FR Doc. E6–1017 Filed 1–26–06; 8:45 am]

BILLING CODE 8010–01–P

[16] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Securities Exchange Act Release Nos. 51049 (January 18, 2005), 70 FR 3756 (January 26, 2005) (SR–BSE–2004–52); 51050 (January 18, 2005), 70 FR 3758 (January 26, 2005) (SR–ISE–2004–31); and 51740 (May 25, 2005), 70 FR 32686 (June 3, 2005) (SR–PCX–2005–64).

[19] 15 U.S.C. 78s(b)(2).

[20] 15 U.S.C. 78s(b)(2).

[21] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 5284]

Culturally Significant Objects Imported for Exhibition Determinations: ''Life in the Pacific of the 1700s: The Cook/Forster Collection of the George August University of Gottingen''

SUMMARY: Notice is hereby given of the following determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.*; 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236 of October 19, 1999, as amended, and Delegation of Authority No. 257 of April 15, 2003 [68 FR 19875], I hereby determine that the objects to be included in the exhibition ''Life in the Pacific of the 1700s: The Cook/Forster Collection of the George August University of Gottingen,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at the Honolulu Academy of Arts, Honolulu, HI, from on or about February 23, 2006, until on or about May 14, 2006, and at possible additional venues yet to be determined, is in the national interest. Public Notice of these Determinations is ordered to be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the exhibit objects, contact Julianne Simpson, Attorney-Adviser, Office of the Legal Adviser, U.S. Department of State (telephone: 202/453–8049). The address is U.S. Department of State, SA–44, 301 4th Street, SW., Room 700, Washington, DC 20547–0001.

Dated: January 23, 2006.

C. Miller Crouch,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 06–842 Filed 1–26–06; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

RIN 2120–AA64

General Aviation Summit; Notice of Public Meeting

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of Public Meeting.

SUMMARY: This notice announces a public meeting on the subject of the continued airworthiness of the U.S. general aviation fleet of aircraft. The purpose of the meeting is to gather information and discuss technical issues related to problems associated with the increasing average age of the general aviation fleet. Particular emphasis will be given to actions that have potential to mitigate the inevitable effects of fatigue, corrosion, and deterioration on aging general aviation airplanes.

DATES: The public meeting will be held March 22–23, 2006, starting at 8 a.m. each day, in Kansas City, Missouri. Registration will begin at 8 a.m. on the first day of the meeting.

ADDRESSES: The public meeting will be held at the following location: Doubletree Hotel Overland Park, 10100 College Blvd., Overland Park, Kansas, United States, 66210.

Persons who are unable to attend the meeting may mail their comments to: Federal Aviation Administration, (FAA), Central Region, Small Airplane Directorate, Attention: Mr. Marv Nuss, 901 Locust, Room 301, Kansas City, Missouri 64106. Written comments regarding the subject of this meeting will receive the same consideration as statements made at the public meeting.

FOR FURTHER INFORMATION CONTACT: Mr. Marv Nuss, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone:

(816) 329–4117; facsimile: (816) 329–4090; e-mail: *marvin.nuss@faa.gov.*

SUPPLEMENTARY INFORMATION:

Participation at the Public Meeting

Submit requests to present a statement at the public meeting to Mr. Marv Nuss as listed in the section titled **FOR FURTHER INFORMATION CONTACT** above. The FAA should receive your requests to present oral statements at the public meeting no later than 10 days prior to the meeting. Include a written summary of oral remarks you would like to present and the estimated time needed for your presentation. Requests received after the date specified above will be scheduled during the meeting if time allows; however, the names of those individuals may not appear on the written agenda. The FAA will prepare an agenda of speakers available at the meeting. To accommodate as many speakers as possible, the amount of time allocated to each speaker may be less than the amount of time requested. Those persons desiring to have audiovisual equipment available should notify the FAA when they request placement on the agenda.

Background

The average airplane in the general aviation fleet of the United States is approximately 35 years old. We expect the average age to continue to rise. By the year 2020, the average general aviation airplane will be almost 50 years old. In 1991, Congress mandated that the FAA establish an Aging Aircraft Program to focus on age-related structural problems for the air carrier fleet. Congress specifically excluded general aviation (GA) aircraft from the mandate. However, the FAA determined that as the GA fleet gets older, there is also concern about ensuring the continued airworthiness of these airplanes. The diversity of the fleet makes dealing with continued airworthiness difficult. The wide variety of designs and uses poses problems unique to GA.

In 2000, the FAA held a public meeting on this subject. Ideas were exchanged and FAA worked with industry to institute several initiatives. However, since that meeting there have been GA fatal accidents caused by the effects of airplane aging. There have also been primary component failures caused by the effects of airplane aging that were discovered before catastrophic failure. The FAA is taking a more proactive role in managing the risk associated with continued airworthiness. The FAA is concerned about issues such as service difficulty experiences and reporting, modification and inspection programs, and continued field support from type certificate holders.

The FAA has determined that in the interest of the public we should hold a public meeting on this subject to share information and gather additional data. Accordingly, the FAA will conduct this public meeting in Kansas City, Missouri.

The FAA anticipates that the agency, industry, and the general public will use the public meeting as a forum to share information, resolve questions, and discuss potential solutions concerning the continued airworthiness of older general aviation airplanes.

Public Meeting Procedures

The FAA has established the following procedures for this meeting:

1. Admission and participation in the public meeting are free. The meeting will be open to all persons who have requested in advance to present statements or who register on the first day of the meeting (between 8 a.m. and 8:30 a.m.). Time availability for presentations and seating will be made according to the order of reservation.

2. Representatives from the FAA will conduct the public meeting. A technical panel of FAA personnel will discuss information presented by participants.

3. The public meeting is intended as a forum to share information and resolve questions concerning the continued airworthiness of older general aviation airplanes. Those sharing information will include industry, the general public, and operators of general aviation aircraft. Participants must limit their presentations to the issue of continued airworthiness of older general aviation airplanes.

4. All interested parties will have the opportunity to present any additional information not currently available to the FAA. The FAA will then have the opportunity to explain the methodology and technical assumptions supporting its current observations.

5. FAA personnel, industry, and public participants may engage in a full discussion of all technical material presented at the meeting. Anyone presenting conclusions will be expected to submit their supporting data to the FAA.

6. The FAA will try to accommodate all speakers. Time may be limited for each presentation.

7. Sign and oral interpretations will be made available at the meeting, including assistive listening devices, if requested 15 calendar days before the meeting.

8. A court reporter will record the meeting (except for any breakout sessions). Any person interested in purchasing a copy of the transcript should contact the court reporter directly. This information will be available at the meeting.

9. The FAA will review and consider all material presented by participants at the public meeting. Position papers or material presenting views or information related to the subject of the meeting may be accepted at the discretion of the presiding officer. The FAA requests that persons participating in the meeting provide 10 copies of all materials to be presented for distribution to the panel members; other copies may be provided to the audience at the discretion of the participant.

10. Statements made by FAA personnel are intended to facilitate discussion of the issues or to clarify issues.

11. The meeting is designed to share information and solicit public views and additional information. The meeting will be conducted in an informal and nonadversarial manner.

Issued in Kansas City, Missouri, on January 18, 2006.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E6–1021 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2005–22727]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 22 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to qualify as drivers of commercial motor vehicles (CMVs) in interstate commerce without meeting the vision standard prescribed in 49 CFR 391.41 (b)(10).

DATES: The exemptions are effective January 27, 2006.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Chief, Physical Qualifications Division, (202) 366–4001, *mgunnels@fmcsa.dot.gov*, FMCSA, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001. Office hours are from 8 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Document Management System (DMS) at *http://dmses.dot.gov*.

Background

On November 30, 2005, FMCSA published a notice of receipt of exemption applications from 22 individuals, and requested comments from the public (70 FR 71884). The 22 individuals petitioned FMCSA for exemptions from the vision requirement in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce. They are: Kerry L. Baxter, Donald J. Bierwirth, Jr., Arthur L. Bousema, Curtis F. Caddy, III, Paul D. Crouch, Matthew Daggs, Donald R. Date, Jr., Douglas M. Fuller, Michael Grzybowski, David L. Jones, John E. Kimmet, Jason L. Light, Douglas J. Mauton, Dennis L. Maxcy, Robert Mollicone, William P. Murphy, John V. Nehls, Dean B. Ponte, John P. Rodrigues, Paul D. Schmautz, Robert A. Sherry, Thomas E. Voyles, Jr.

Under 49 U.S.C. 31315 and 31136(e), FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The statute also allows the agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 22 applications on their merits and made a determination to grant exemptions to all of them. The comment period closed on December 30, 2005. One comment was received, and fully considered by FMCSA in reaching the final decision to grant the exemptions.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber (49 CFR 391.41(b)(10)).

Since 1992, the agency has undertaken studies to determine if this vision standard should be amended. The final report from our medical panel recommends changing the field of vision standard from 70 to 120 degrees, while leaving the visual acuity standard unchanged. (See Frank C. Berson, M.D., Mark C. Kuperwaser, M.D., Lloyd Pual Aiello, M.D., and James W. Rosenberg, M.D., ''Visual Requirements and Commercial Drivers,'' October 16, 1998, filed in the docket, FMCSA–98–4334.) The panel's conclusion supports the agency's view that the present visual acuity standard is reasonable and necessary as a general standard to ensure highway safety. FMCSA also recognizes that some drivers do not meet the vision standard, but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely.

The 22 exemption applicants listed in this notice fall into this category. They are unable to meet the vision standard in one eye for various reasons, including amblyopia, retinal detachment, and loss of an eye due to trauma. In most cases, their eye conditions were not recently developed. All but five of the applicants were either born with their vision impairments or have had them since childhood. The five individuals who sustained their vision conditions as adults have had them for periods ranging from 4 to 13 years.

Although each applicant has one eye which does not meet the vision standard in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV. All these applicants satisfied the testing standards for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a commercial vehicle, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 22 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 4 to 44 years. In the past 3 years, four of the drivers have had five convictions for traffic violations. Two of these convictions were for speeding, two were for seatbelt violations in a CMV, and one was for failure to obey a traffic sign. None of the applicants were involved in crashes.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the November 30, 2005 notice (70 FR 71884).

Basis for Exemption Determination

Under 49 U.S.C. 31315 and 31136(e), FMCSA may grant an exemption from the vision standard in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered not only the medical reports about the applicants' vision, but also their driving records and experience with the vision deficiency. To qualify for an exemption from the vision standard, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at docket number FMCSA–98–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively. (See 61 FR 13338, 13345, March 26, 1996.) The fact that experienced monocular drivers with good driving records in the waiver program demonstrated their ability to drive safely supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly. (See Bates and Neyman, University of California Publications in Statistics, April 1952.) Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes. (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971.) A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 22 applicants receiving an exemption, we note that the applicants have had no collisions and a total of five traffic violations among them in the last 3 years. The applicants achieved this record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision standard in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31315 and 31136(e) to the 22 applicants listed in the notice of November 30, 2005 (70 FR 71884).

We recognize that the vision of an applicant may change and affect his/her ability to operate a commercial vehicle as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 22 individuals consistent with the grandfathering provisions applied to drivers who participated in the agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

Discussion of Comments

Advocates for Highway and Auto Safety (Advocates) express continued opposition to FMCSA's policy to grant exemptions from the FMCSRs, including the driver qualification standards. Specifically, Advocates: (1) Objects to the manner in which FMCSA presents driver information to the public and makes safety determinations; (2) objects to the agency's reliance on conclusions drawn from the vision waiver program; (3) claims the agency has misinterpreted statutory language on the granting of exemptions (49 U.S.C. 31315 and 31136(e)); and finally (4) suggests that a 1999 Supreme Court decision affects the legal validity of vision exemptions.

The issues raised by Advocates were addressed at length in 64 FR 51568 (September 23, 1999), 64 FR 66962 (November 30, 1999), 64 FR 69586 (December 13, 1999), 65 FR 159 (January 3, 2000), 65 FR 57230 (September 21, 2000), and 66 FR 13825 (March 7, 2001). We will not address these points again here, but refer interested parties to those earlier discussions.

Conclusion

Based upon its evaluation of the 22 exemption applications, FMCSA exempts Kerry L. Baxter, Donald J. Bierwirth, Jr., Arthur L. Bousema, Curtis F. Caddy, III, Paul D. Crouch, Matthew Daggs, Donald R. Date, Jr., Douglas M. Fuller, Michael Grzybowski, David L. Jones, John E. Kimmet, Jason L. Light, Douglas J. Mauton, Dennis L. Maxcy, Robert Mollicone, William P. Murphy, John V. Nehls, Dean B. Ponte, John P. Rodrigues, Paul D. Schmautz, Robert A. Sherry, Thomas E. Voyles, Jr., from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31315 and 31136(e), each exemption will be valid for 2 years unless revoked earlier by the FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31315 and 31136.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: January 20, 2006.

Rose A. McMurray,

Associate Administrator, Policy and Program Development.

[FR Doc. E6–1015 Filed 1–26–06; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34806]

Susquehanna Valley Railroad Corporation—Acquisition of Control Exemption—Juniata Valley Railroad Company, Lycoming Valley Railroad Company, Nittany & Bald Eagle Railroad Company, North Shore Railroad Company, Wellsboro & Corning Railroad Company, Union County Industrial Railroad Company, and Shamokin Valley Railroad Company

Susquehanna Valley Railroad Corporation (SVRC), a new noncarrier holding company, has filed a verified notice of exemption to acquire control of seven Class III railroads: Juniata Valley Railroad Company, Lycoming Valley Railroad Company, Nittany & Bald Eagle Railroad Company, North Shore Railroad Company, Wellsboro & Corning Railroad Company, Union County Industrial Railroad Company, and Shamokin Valley Railroad Company. Mr. Richard D. Robey, a noncarrier individual, is the sole shareholder and current owner of each of these Class III railroads. In a related transaction, STB Finance Docket No. 34807, Mr. Robey has obtained an exemption to continue in control of SVRC and Stourbridge Railroad Company, a Class III railroad.

The transaction was scheduled to be consummated on or after January 6, 2006, the effective date of the exemption (7 days after the exemption was filed).[1]

SVRC states that this is a corporate family transaction that will not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with carriers outside the corporate family. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. See 49 CFR 1180.2(d)(3).

As a result of this transaction, SVRC will own and control the seven Class III railroads owned by Mr. Robey and Mr. Robey will be the sole shareholder and owner of SVRC. The purpose of the transaction is to create a noncarrier holding company that can provide consolidated administration and management of the seven shortline railroad companies to be acquired by SVRC from Mr. Robey.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under section 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34806, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on: Richard R. Wilson, Esq., 127 Lexington Ave, Ste. 100, Altoona, PA 16601.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov*.

Decided: January 20, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. 06–733 Filed 1–26–06; 8:45 am]

BILLING CODE 4915–01–P

[1] The notice erroneously indicated a consummation date of January 1, 2006. That date has been corrected here.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34816]

Dakota Northern Railroad, Inc.—Lease and Operation Exemption—Rail Lines of BNSF Railway Company

Dakota Northern Railroad, Inc. (DN), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to acquire by lease and to operate two lines of railroad from BNSF Railway Company (BNSF). The subject lines total 69.79 miles in length and are located in Walsh and Pembina Counties, ND.[1]

Specifically, DN will lease and operate: (1) BNSF's entire Walhalla Subdivision, between milepost 0.0, near Grafton, ND, and the end of the line at milepost 48.38, near Walhalla, ND, a distance of approximately 48.38 miles; and (2) a portion of BNSF's Glasston Subdivision, between the clearance point of the turnout located at milepost 38.79, near Grafton, ND, and the end of the line at milepost 60.20, near Glasston, ND, a distance of approximately 21.41 miles.

This transaction is related to STB Finance Docket No. 34817, *KBN, Inc.—Continuance in Control Exemption—Dakota Northern Railroad, Inc.,* wherein KBN, Inc. (KBN), has filed a notice of exemption to continue in control of DN upon DN's becoming a Class III rail carrier.

DN certifies that its projected revenues as a result of the transaction will not exceed those that would qualify it as a Class III carrier. The transaction was scheduled to be consummated on or about January 18, 2006.[2]

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34816, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at *www.stb.dot.gov.*

Decided: January 23, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E6–1039 Filed 1–26–06; 8:45 am]

BILLING CODE 4915–01–P

[1] On January 11, 2006, a correction was received from DN to its verified notice of exemption filed on December 30, 2005, to reflect that BNSF's Glasston Subdivision was located at milepost 60.20, not milepost 61.23, and that the total length of the two rail lines was 69.79, instead of 70.82.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 34817]

KBN, Inc.—Continuance in Control Exemption—Dakota Northern Railroad, Inc.

KBN, Inc. (KBN), a noncarrier, has filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to continue in control of Dakota Northern Railroad, Inc. (DN), upon DN's becoming a Class III rail carrier.

[2] In DN's correction received on January 11, 2006, DN indicated that the proposed lease and operation agreement would not be consummated until 7 days or more after the filing of the correction to the verified notice.

The transaction was scheduled to be consummated on or after January 18, 2006.[1]

This transaction is related to a concurrently filed verified notice of exemption in STB Finance Docket No. 34816, *Dakota Northern Railroad, Inc.—Lease and Operation Exemption—BNSF Railway Company.* In that proceeding, DN seeks to acquire by lease from BNSF Railway Company (BNSF) and operate approximately 69.79 miles of rail line in Walsh and Pembina Counties, ND, specifically: (1) The entire BNSF Walhalla Subdivision, between milepost 0.0 near Grafton, ND, and the end of the line at milepost 48.38, near Walhalla, ND, a distance of approximately 48.38 miles; and (2) a portion of BNSF's Glasston Subdivision, between the clearance point of the turnout located at milepost 38.79, near Grafton, ND, and the end of the line at milepost 60.20, near Glasston, ND, a distance of approximately 21.41 miles.[2]

KBN is a noncarrier that currently controls two Class III rail carriers: The Minnesota Northern Railroad, Inc. (MNR), and St. Croix Valley Railroad Company (SCVR). DN will operate wholly within North Dakota. MNR and SCVR presently operate wholly within Minnesota.

KBN states that: (1) The rail lines operated by MNR and SCVR do not connect with the rail lines being leased by DN; (2) the continuance in control is not part of a series of anticipated transactions that would connect the rail lines of MNR, SCVR and DN with each other or with any railroads in their corporate family; and (3) neither DN nor any of the carriers controlled by KBN are Class I or Class II rail carriers. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 11323. *See* 49 CFR 1180.2(d)(2). The purpose of the transaction is to achieve operating economies, to improve rail service to the public, and to improve the financial viability of the commonly controlled rail carriers.

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here, because all of the carriers involved are Class III carriers.

If the verified notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

An original and 10 copies of all pleadings, referring to STB Finance Docket No. 34817, must be filed with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thomas F. McFarland, Thomas F. McFarland, P.C., 208 South LaSalle Street, Suite 1890, Chicago, IL 60604.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

Decided: January 23, 2006.

By the Board, David M. Konschnik, Director, Office of Proceedings.

Vernon A. Williams,

Secretary.

[FR Doc. E6–1033 Filed 1–26–06; 8:45 am]

BILLING CODE 4915–01–P

[1] Although KBN indicated that this transaction would be consummated no earlier than 7 days after the filing of its notice of exemption, DN, in STB Finance Docket No. 34816, indicated that the lease and operating agreement would not be consummated until January 18, 2006 (7 days after DN filed a correction to its notice of exemption).

[2] By letter received on January 11, 2006, DN corrected its verified notice to reflect the mileposts listed herein.

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network; Proposed Collection; Comment Request; Suspicious Activity Report by Casinos and Card Clubs

AGENCY: Financial Crimes Enforcement Network.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, the Financial Crimes Enforcement Network invites comment on a proposed information collection contained in a revised form, ''Suspicious Activity Report by Casinos and Card Clubs, Financial Crimes Enforcement Network Form 102.'' The form will be used by casinos and card clubs to report suspicious activity to the Department of the Treasury. This request for comments is being made pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

DATES: Written comments are welcome and must be received on or before March 28, 2006.

ADDRESSES: Written comments should be submitted to: Financial Crimes Enforcement Network, Department of the Treasury, P.O. Box 39, Vienna, Virginia 22183, Attention: Paperwork Reduction Act Comments—Suspicious Activity Report by Casinos Form. Comments also may be submitted by electronic mail to the following Internet address: *regcomments@fincen.treas.gov,* again with a caption, in the body of the text, ''Attention: Paperwork Reduction Act Comments—Suspicious Activity Report by Casinos Form.''

Inspection of comments. Comments may be inspected, between 10 a.m. and 4 p.m., in the Financial Crimes Enforcement Network reading room in Washington, DC. Persons wishing to inspect the comments submitted must request an appointment by telephoning (202) 354–6400.

FOR FURTHER INFORMATION CONTACT: Regulatory Policy and Programs Division, at (800) 949–2732.

SUPPLEMENTARY INFORMATION:

Title: Suspicious Activity Report by Casinos and Card Clubs.

OMB Number: 1506–0006.

Form Number: Financial Crimes Enforcement Network Form 102.

Abstract: The statute generally referred to as the ''Bank Secrecy Act,'' Titles I and II of Public Law 91–508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, and 31 U.S.C. 5311–5331, authorizes the Secretary of the Treasury, inter alia, to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities, to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.[1] Regulations implementing Title II of the Bank Secrecy Act appear at 31 CFR Part 103. The authority of the Secretary of the Treasury to administer the Bank Secrecy Act has been delegated to the Director of the Financial Crimes Enforcement Network.

The Secretary of the Treasury was granted authority in 1992, with the enactment of 31 U.S.C. 5318(g), to require financial institutions to report suspicious transactions.

The information collected on this revised form is required to be provided pursuant to 31 U.S.C. 5318(g) and 31 CFR 103.21. This information will be

[1] Language expanding the scope of the Bank Secrecy Act to intelligence or counter-intelligence activities to protect against international terrorism was added by section 358 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001 (the ''USA Patriot Act''), Pub. L. 107–56.

made available, in accordance with strict safeguards, to appropriate criminal law enforcement and regulatory personnel for use in official performance of their duties, for regulatory purposes and in investigations and proceedings involving domestic and international money laundering, tax violations, fraud, and other financial crimes.

Reports filed by casinos required to report suspicious transactions under 31 CFR 103.21, and any reports filed voluntarily by casinos or card clubs will be subject to the protection from liability contained in 31 U.S.C. 5318(g)(3) and the provision contained in 31 U.S.C. 5318(g)(2) which prohibits notification of any person involved in the transaction that a suspicious activity report has been filed.

A number of minor changes are being made to the current Suspicious Activity Report by Casinos to clarify and shorten the form. Item 1 is revised by adding a new box 1(a) to indicate if the Suspicious Activity Report by Casinos is an updated report and by adding a new box 1(b) to indicate if the report is a jointly filed report. Part III, Law Enforcement or Regulatory Contact Information, has been deleted, and the remaining parts of the form have been renumbered accordingly. Information about law enforcement or regulatory contacts should be entered in renumbered Part V, Suspicious Activity Information—Narrative, as explained in the revised instructions to that part. Renumbered Part III, Reporting Casino or Card Club Information, has been revised to record information about a joint filing. Renumbered Part IV, Contact for Assistance, has been revised so that it no longer requires the name and title of the filer. A number of minor editorial changes have also been made to the instructions to the form, including explaining how to complete critical fields when information is not known and updating the Post Office box number to use when filing the form by mail.

The draft revised Suspicious Activity Report by Casinos is presented only for purposes of soliciting public comment on the form. The draft form should not be used at this time to report suspicious activity. A final version of the form will be made available at a later date.

Type of Review: Revision of a currently approved information collection.

Affected Public: Business or other for-profit institutions.

Frequency: As required.

Estimated Burden: Reporting average of 45 minutes per response. This burden relates to the completion of the form. The recordkeeping burden of 31 CFR 103.21 is reflected in the final rule requiring casinos and card clubs to file reports of suspicious activity.

Estimated Number of Respondents: 600.

Estimated Total Annual Responses: 6,100.

Estimated Total Annual Burden Hours: 4,575 hours.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid Office of Management and Budget control number. Records required to be retained under the Bank Secrecy Act must be retained for five years.

Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected: (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Dated: January 20, 2006.

William J. Fox,

Director, Financial Crimes Enforcement Network.

Attachment: Suspicious Activity Report by Casinos

BILLING CODE 4810–02–P

FinCEN Form 102	Suspicious Activity Report by Casinos and Card Clubs	OMB No. 1506 - 0006
April 2006 Previous editions will not be accepted after December 31, 2006	▶ Please type or print. Always complete entire report. Items marked with an asterisk * are considered critical (See instructions).	

1 ☐ Check this box only if amending or correcting a prior report. 1a ☐ Check this box if this is an updated report

1b ☐ Check this box if this report is being filed jointly with another financial institution (See instructions for restrictions on joint filing. Also note instructions for listing joint filer information).

Part I Subject Information

2 Check box (a) ☐ if more than one subject box (b) ☐ subject information unavailable

*3 Individual's last name or entity's full name	*4 First name	*5 Middle initial

*6 Also known as (AKA- individual), doing business as (DBA- entity)	7 Occupation / type of business

*8 Address	*9 City	*10 State	*11 ZIP code

*12 Country code (if not U.S.)	13 Vehicle license # / state (opt.) a. number	b. state	*14 SSN / ITIN (individual) or EIN (entity)	15 Date of birth MM DD YYYY

*16 Government issued identification (if available) a ☐ Driver's license/state ID b ☐ Passport c ☐ Alien registration
d ☐ Other _____
e Number: _____ f Issuing state or country _____

17 Phone number - work	18 Phone number - home	19 E-mail address (if available)
( ) -	( ) -	

20 Does casino/card club still have a business association and/or an employee/employer relationship with suspect?
a ☐ Yes b ☐ No If no, why? c ☐ Barred d ☐ Resigned e ☐ Terminated f ☐ Other (Specify in Part V)

21 Date action taken(20) ___/___/___ MM DD YYYY

Part II Suspicious Activity Information

*22 Date or date range of suspicious activity
From ___/___/___ To ___/___/___
MM DD YYYY MM DD YYYY

*23 Total dollar amount involved in suspicious activity
$ .00

* 24 Type of suspicious activity:

a ☐ Bribery/gratuity	g ☐ Misuse of position	m ☐ Unusual use of wire transfers
b ☐ Check fraud (includes counterfeit)	h ☐ Money laundering	n ☐ Unusual use of counter checks or markers
c ☐ Credit/debit card fraud (incl. counterfeit)	i ☐ No apparent business or lawful purpose	
d ☐ Embezzlement/theft	j ☐ Structuring	o ☐ False or conflicting ID(s)
e ☐ Large currency exchange(s)	k ☐ Unusual use of negotiable instruments (checks)	p ☐ Terrorist financing
f ☐ Minimal gaming with large transactions	l ☐ Use of multiple credit or deposit accounts	q ☐ Other (Describe in Part V)

Paperwork Reduction Act Notice:

The purpose of this form is to provide an effective means for financial institutions to notify appropriate law enforcement agencies of suspicious transactions that occur by, through, or at the financial institutions. This report is required by law, pursuant to authority contained in 31 U.S.C. 5318(g). Information collected on this report is confidential (31 U.S.C. 5318(g)). Federal securities regulatory agencies and the U.S. Departments of Justice and Treasury, and other authorized authorities may use and share this information. Public reporting and record keeping burden for this form is estimated to average 45 minutes per response, and includes time to gather and maintain information for the required report, review the instructions, and complete the information collection. Send comments regarding this burden estimate, including suggestions for reducing the burden, to the Office of Management and Budget, Paperwork Reduction Project, Washington, DC 20503 and to the Financial Crimes Enforcement Network, Attn.: Paperwork Reduction Act, P.O. Box 39, Vienna VA 22183-0039. The agency may not conduct or sponsor, and an organization (or a person) is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Part III Reporting Casino or Card Club Information 2

*25 Trade name of casino or card club This is: a ☐ Filing Institution or b ☐ Joint filer

*26 Legal name of casino or card club | *27 EIN

*28 Address | *29 City | *30 State | *31 ZIP code

32 Type of gaming institution
a ☐ State licensed casino c ☐ Card club
b ☐ Tribal authorized casino d ☐ Other (specify)_____

33 Internal control/file number(Optional)

34 Primary Federal Regulator
a ☐ Federal Reserve b ☐ FDIC c ☐ NCUA d ☐ OCC e ☐ OTS f ☐ IRS g ☐ SEC h ☐ CFTC

*35 Account number(s) affected that are related to subject listed in Part I, if any. Check "Yes" if closed.
a _____ ☐ Yes b _____ ☐ Yes
c _____ ☐ Yes d _____ ☐ Yes

36 Affiliation or relationship to casino/card club
a ☐ Customer b ☐ Agent c ☐ Junket / tour operator d ☐ Employee e ☐ Check cashing operator
f ☐ Supplier g ☐ Concessionaire h ☐ Other (Explain in Part V)

*37 Address of branch office(s) where activity occured (See instructions)

*38 City | *39 State | *40 ZIP Code | *41 Country (If not US, enter 2 digit code)

42 Address of branch office where activity occured (if required)

43 City | 44 State | 45 ZIP Code | 46 Country (If not US, enter 2 digit code)

47 Address of branch office where activity occured (if required)

48 City | 49 State | 50 ZIP Code | 51 Country (If not US, enter 2 digit code)

52 Address of branch office where activity occured (if required) ☐ Check if additional branch addresses are listed in Part V

53 City | 54 State | 55 ZIP Code | 56 Country (If not US, enter 2 digit code)

Part IV Contact for Assistance

*57 Designated contact office | *58 Designated phone number (Include area code) | *59 Date filed (See instructions) ___/___/___ MM DD YYYY

60 Agency (If not filed by a financial institution)

Special note:
If this report is being filed jointly, box 1b must be checked and Item 34 completed. A Part III and Part IV must be completed for each institution.

Send each completed SAR report to:

Detroit Computing Center
Attn: SAR-C
P.O. Box 32621
Detroit, MI 48232-0980

Part V Suspicious Activity Information - Narrative* 3

Explanation/description of suspicious activity(ies). This section of the report is **critical**. The care with which it is completed may determine whether or not the described activity and its possible criminal nature are clearly understood by investigators. The narrative should address as much of the information listed below as possible.

a. **Describe** the conduct that raised suspicion.
b. **Explain** whether the transaction(s) was completed or only attempted.
c. **Describe** supporting documentation and retain such documentation for your file for five years.
d. **Explain** who benefited, financially or otherwise, from the transaction(s), how much and how (if known).
e. **Describe and retain** any admission or explanation of the transaction(s) provided by the subject(s), witness(s), or other person(s). Indicate to whom and when it was given. Include witness or other person ID.
f. **Describe and retain** any evidence of cover-up or evidence of an attempt to deceive federal or state examiners, or others.
g. **Indicate** where the possible violation of law(s) took place (*e.g.*, branch, cage, specific gaming pit, specific gaming area).
h. **Indicate** whether the suspicious activity is an isolated incident or relates to another transaction.
i. **Indicate** whether there is any related litigation. If so, specify the name of the litigation and the court where the action is pending.
j. **Recommend** any further investigation that might assist law enforcement authorities.
k. **Indicate** whether any information has been excluded from this report; if so, state reasons.
l. **Indicate** whether any U.S. or foreign currency and/or U.S. or foreign negotiable instrument(s) were involved. If foreign, provide the amount, name of currency, and country of origin.
m. **Indicate** whether funds or assets were recovered and, if so, enter the dollar value of the recovery in whole dollars only.
n. **Indicate** any additional account number(s), and any domestic or foreign bank(s) account numbers which may be involved.
o. **Indicate** for a foreign national any available information on subject's passport(s), visa(s), and/or identification card(s). Include date, country, city of issue, issuing authority, and nationality.
p. **Describe** any suspicious activities that involve transfer of funds to or from a foreign country, or any exchanges of a foreign currency. Identify the currency, country, sources and destinations of funds.
q. **Describe** subject(s) position if employed by the casino or card club (*e.g.*, dealer, pit supervisor, cage cashier, host, *etc.*).
r. **Indicate** the type of casino or card club filing this report, if this is not clear from Part IV.
s. **Describe** the subject only if you do not have the identifying information in Part I or if multiple individuals use the same identification. Use descriptors such as male, female, age, etc.
t. **Indicate** any wire transfer in or out identifier numbers, including the transfer company's name.
u. If a law enforcement agency has been contacted, list the name of the agency, the name of any person contacted, their title, their telephone number, and when they were contacted here in Part V.
v. **If correcting** a prior report, complete the form in its entirety and note the changes here in Part V.

Information already provided in earlier parts of this form need not necessarily be repeated if the meaning is clear.

Supporting documentation should not be filed with this report. Maintain the information for your files.

Tips on SAR Form preparation and filing are available in the SAR Activity Review at www.fincen.gov/pub_reports.html

Legal disclaimers will not be included in this narrative.

FinCEN Form 102a — SAR- Casinos and Card Clubs Instructions — 1

Safe Harbor Federal law (31 U.S.C. 5318(g)(3)) provides complete protection from civil liability for all reports of suspicious transactions made to appropriate authorities, including supporting documentation, regardless of whether such reports are filed pursuant to this report's instructions or are filed on a voluntary basis. Specifically, the law provides that a financial institution, and its directors, officers, employees and agents, that make a disclosure of any possible violation of law or regulation, including in connection with the preparation of suspicious activity reports, "shall not be liable to any person under any law or regulation of the United States, any constitution, law, or regulation of any State or political subdivision of any state, or under any contract or other legally enforceable agreement (including any arbitration agreement), for such disclosure or for any failure to provide notice of such disclosure to the person who is the subject of such disclosure or any other person identified in the disclosure".

Notification Prohibited Federal law (31 U.S.C. 5318(g)(2)) provides that a financial institution, and its directors, officers, employees, and agents who, voluntarily by means of a suspicious activity report, report suspicious transactions to the government, may not notify any person involved in the transaction that the transaction has been reported.

In situations involving suspicious transactions requiring immediate attention, such as when a reportable transaction is ongoing, the financial institution shall immediately notify, by telephone, appropriate law enforcement and financial institution regulatory authorities in addition to filing a timely suspicious activity report.

When To File A Report:

1. Every casino and card club (for purposes of 31 CFR 103, a "reporting casino"), shall file with FinCEN, to the extent and in the manner required by 31 CFR 103, a report of any suspicious transaction relevant to a possible violation of law or regulation. A casino may also file with FinCEN, by using the Suspicious Activity Report by Casinos (SARC), a report of any suspicious transaction that it believes is relevant to the possible violation of any law or regulation but whose reporting is not required by 31 CFR 103.

2. A transaction requires reporting under the terms of 31 CFR 103.21 if it is conducted or attempted by, at, or through a casino, and involves or aggregates at least $5,000 in funds or other assets, and the casino knows, suspects, or has reason to suspect that the transaction (or a pattern of transactions of which the transaction is a part):

(i) Involves funds derived from illegal activity or is intended or conducted in order to hide or disguise funds or assets derived from illegal activity (including, without limitation, the ownership, nature, source, location, or control of such funds or assets) as part of a plan to violate or evade any federal law or regulation or to avoid any transaction reporting requirement under federal law or regulation;

(ii) Is designed, whether through structuring or other means, to evade any requirements of 31 CFR 103 or of any other regulations promulgated under the Bank Secrecy Act, Public Law 91-508, as amended, codified at 12 U.S.C. 1829b, 12 U.S.C. 1951-1959, and 31 U.S.C. 5311-5332;

(iii) Has no business or apparent lawful purpose or is not the sort in which the particular customer would normally be expected to engage, and the casino knows of no reasonable explanation for the transaction after examining the available facts, including the background and possible purpose of the transaction; or

(iv) Involves use of the casino to facilitate criminal activity.

3. A SARC shall be filed no later than 30 calendar days after the date of the initial detection by the reporting casino of facts that may constitute a basis for filing a SAR under this section. If no suspect is identified on the date of such initial detection, a casino may delay filing a SARC for an additional 30 calendar days to identify a suspect, but in no case shall reporting be delayed more than 60 calendar days after the date of such initial detection. In situations involving violations that require immediate attention, such as ongoing money laundering schemes, the reporting casino shall immediately notify by telephone an appropriate law enforcement authority in addition to filing timely a SARC. Casinos wishing to voluntarily report suspicious transactions that may relate to terrorist activity may call FinCEN's Financial Institutions Hotline at 1-866-556-3974 in addition to filing timely a SARC if required by 31 CFR 103.

4. Exceptions. A casino is not required to file a SARC for a robbery or burglary committed or attempted that is reported to appropriate law enforcement authorities.

5. The Bank Secrecy Act requires financial institutions to file currency transaction reports (CTRs) in accordance with the Department of the Treasury's implementing regulations (31 CFR Part 103). These regulations require a financial institution to file a CTR whenever a currency transaction exceeds $10,000. 31 CFR 103.22(b)(2) requires that all casinos and card clubs (except in Nevada) file using FinCEN form 103(CTRC). Nevada Gaming Commission Regulation 6A requires Nevada casinos to use FinCEN Form 103-N (CTRC-N). If a currency transaction exceeds $10,000 and is suspicious, the institution must file both a CTR (reporting the currency transaction) and a suspicious activity report (reporting the suspicious aspects of the transaction). If a currency transaction is $10,000 or less and is suspicious, the institution should only file a suspicious activity report. Appropriate records must be maintained in each case. See: 31 CFR Part 103.

General Instructions

A. Abbreviations and Definitions:

1. AKA--also known as
2. DBA--doing business as
3. DEA--Drug Enforcement Administration
4. EIN--Employer Identification Number
5. FBI--Federal Bureau of Investigation
6. IRS--Internal Revenue Service (AML or CI)
7. ITIN--Individual Taxpayer Identification Number
8. SSN--Social security number

B. How to Make a Report:

1. **This form should be e-filed through the Bank Secrecy Act E-filing System. Go to http://bsaefiling.fincen.treas.gov/index.jsp to register.** This form is also available for download on the Financial Crimes Enforcement Network's Web site at www.fincen.gov, or may be ordered by calling the IRS Forms Distribution Center at (800) 829-3676.

Send each completed suspicious activity report to:

Detroit Computing Center
ATTN: SARC
P.O. Box 32621
Detroit, MI 48232-5980

2. While all items should be completed fully and accuractely, items marked with an asterisk (*) are considered critical for law enforcement purposes and must be completed according to the provisions of paragraph 3 below.

3. If the information for a critical item is not known or not applicable, enter special responses "None," "Not Applicable," "Unknown," or "XX" (state/country/middle initial) as appropriate to complete the item.

4. Complete each suspicious activity report by providing as much information as possible on initial and corrected reports.

5. Do not include supporting documentation with the suspicious activity report filed. Identify and retain a copy of the suspicious activity report and all supporting documentation or business record equivalents for your files for five (5) years from the date of the suspicious activity report. All supporting documentation such as, canceled checks, confessions, credit bureau reports, credit slips/vouchers, deposit/withdrawal slips, multiple transaction logs, player rating records, slot club records, identification credentials, spreadsheets, photographs, surveillance audio and/or video recording media, and surveillance logs must be made available to appropriate authorities upon request.

6. If more than one subject is being reported, make a copy of page 1 and complete only the subject information Part I, and attach the additional page(s) behind page 1. If more space is needed to complete any other item(s), identify that item in

Part V by "item number", and provide the additional information.

7. Type or complete the report using block written letters.

8. Enter all **dates** in MM/DD/YYYY format where MM = month, DD = day, and YYYY = year. Precede any single number with a zero, *i.e.*, 01, 02, etc.

9. Enter all **telephone numbers** with (area code) first and then the seven numbers, using the format, (XXX) XXX-XXXX. List international telephone and fax numbers in Part V.

10. Always enter an **individual's name** by entering the last name, first name, and middle initial (if known). If a legal entity is listed, enter its name in the last name field.

11. Enter all **identifying numbers** (Alien registration, Driver's License/State ID, EIN, ITIN, Foreign National ID, Passport, SSN, etc.) starting from left to right. Do not include spaces, dashes or other punctuation.

12. Enter all **Post Office ZIP codes** with at least the first five numbers (all nine (ZIP+4)) if known) and listed from left to right.

13. Enter all **monetary amounts** in U.S. Dollars. Use whole dollar amounts rounded up when necessary. Use this format: $0,000,000.00. If foreign currency is involved, state name of the currency and country of origin.

14. **Addresses, general.** Enter the permanent street address, city, two letter state/territory abbreviation used by the U.S. Postal Service and ZIP code (ZIP+4 if known) of the individual or entity. A post office box number should not be used for an individual, unless no other address is available. For an individual also enter any apartment number or suite number, and road or route number. If a P.O. Box is used for an entity, enter the street name, suite number, and road or route number. If the address of the individual or entity is in a foreign country, enter the city, province or state, postal code and the name of the country. Complete any part of the address that is known, even if the entire address is not known. If from the United States, leave country box blank.

C. Specific Suspicious Activity Report Preparation Instructions:

Item 1-- *Check box, "corrects prior report", if this report is filed to correct a previously filed SARC. To correct a report, a new SARC must be completed in its entirety. Also note corrected information in Part V, (see line "v").

Item 1a-- Check this box if this is an updated report.

Item 1b-- Check this box if this is a jointly filed report with another financial institution.

Part I Subject Information

Note: Casinos and card clubs may rely upon their own internal records, including copies of federal forms, which contain verified customer information, to identify the subjects of these reports. These records may include credit, deposit, or check cashing account records; or a filed FinCEN Form 103 (CTRC), or FinCEN Form 103-N(CTRC-N), IRS Form W-2G, (Certain Gambling Winnings) (*e.g.*, pertaining to a keno or slot win), IRS form W-9 (Request for Taxpayer Identification Number and Certification), or any tax or other form containing such customer information. If casinos do not have verified identification information on the customer, they should consult whatever other sources of customer information that are available within internal records (player rating records, slot club records, etc.). If the subject is an "unknown," casinos should consider using whatever other internal sources are available to obtain customer identification (hotel registrations, show reservations, credit card numbers, riverboat casino reservation records etc.) .

Item 2a-- Check this box if more than one subject. (*e.g.*, multiple subjects or a subject and an agent). Make a copy of page 1 and fill in the data blocks for the additional subject. Make as many copies of page 1 as necessary.

Item 2b-- If no identification information about the subject is available, check box 2b. This will alert law enforcement and regulatory users of the SARC database that this information has not been inadvertently omitted.

Items 3, 4, and 5-- *Subject's name. See General Instruction B10. If box 2a is checked, see instructions for item 2a above. Attach the additional copies to the report behind page 1.

Item 6-- *also known as (AKA-individual), or doing business as (DBA-entity). If a reporting casino or card club has knowledge of a subject's separate "AKA" or an entity's DBA name, enter it in item 6.

Item 7-- Occupation/type of business. Fully identify the occupation, profession or business of the individual or entity shown in **Items 3** through **5** (*e.g.*, accountant, attorney, carpenter, truck driver, check casher, etc.). Do not use nondescript terms such as merchant, self-employed, businessman, or salesperson. If the subject's business activities can be described more fully than just by occupation, provide additional information in Part V. Indicate in **Item 7** if unknown.

Items 8, 9, 10, 11 and 12-- *Address. See General Instructions B12 and B14.

Item 13-- Vehicle license number (optional). Enter the subject's vehicle license plate number and issuing state, if known or available.

Item 14-- *SSN/ITIN (individual) or EIN (entity). See General Instruction B11 and definitions. If the subject named in **Items 3** through **5** is a U.S. Citizen or an alien with a SSN, enter his or her SSN in **Item 13**. If that individual is an alien who has an ITIN, enter that number. If the subject is an entity, enter the EIN.

Item 15-- Date of birth. See General Instruction B8. If an individual is named in **Items 3** through **5**, enter the date of birth. If the month and/or day is not available or is unknown, fill in with zeros (*e.g.*, "01/00/1969" indicates an unknown date in January, 1969).

Item 16-- *Government issued identification (if available). See General Instruction B11. Check the appropriate box(es) showing the type of document used to verify the subject's identity. If you check box "d" (Other), be sure to specify the type of document used. In box "e" list the number of the identifying document. In box "f" list the issuing state or country. If more space is required, enter the information in Part V.

Items 17, 18 and 19-- Telephone numbers and e-mail address. See General Instruction B9 (telephone). List any additional number(s) (*e.g.*, hotel, etc.) in Part V. List e-mail address if available.

Items 20 and 21-- Continuing business association and/or employer/employee relationship. If the "no" box is checked, check the appropriate box to indicate what action occurred that ended the relationship. Indicate the date that action was taken in **Item 20** (see General Instruction B8).

PART II Suspicious Activity Information*

Item 22-- *Date or date range of suspicious activity. See General Instruction B8. Enter the date of the reported activity in the "From" field. If more than one day, indicate the duration of the activity by entering the first date in the "From" field and the last date in the "To" field. If the same individual or organization conducts multiple or related activities within the 30 calendar day period after the date of initial detection, the reporting institution may consider reporting the suspicious transactions on one form but only if doing so will fully describe what has occurred. A new report must be filed for other related suspicious transactions committed after the initial detection period.

Item 23-- *Total dollar amount. See General Instruction B13. Enter the total dollar value of the funds or asset(s) involved in the suspicious activity which is conducted by the same individual or organization within the 30 calendar day period after the date of initial detection. For multiple or related suspicious transactions, show the breakdown of this aggregated total in Part V. For individual(s) with a relationship to the casino (reference **Item 36** "b" through "h"), the value of this item can be zero (0). Do not use any words, such as "thousand", "million", etc.

3

Item 24-- *Type of suspicious activity. Check the box(es), which best identify the suspicious activity. If the activity involves exchanging numerous small denomination bills for large denomination bills at the cage, after the subject engages in minimal or no gaming activity, check boxes "e" and "f". Check box "j" for Structuring when a subject acting alone, in conjunction with, or on behalf of other subjects, conducts or attempts to conduct activity designed to evade any recordkeeping or reporting requirement promulgated under the Bank Secrecy Act. Check box "o" if the ID presented does not match the individual or if multiple ID's conflict. If you check box "q" for Other, you must specify, in Part V, the type of suspicious activity that occurred not listed in **Item 24**.

Part III Reporting Casino or Card Club Information*

If this report is being filed jointly (box in item 1b checked), make a copy of page two and complete items 25 through 36 for the joint filer following the same instructions as the filer. Complete branch office information, items 37 through 56 if appropriate. Branch office's of casinos and card clubs include non-gaming office operations world wide. If there are additional joint filers, make as many copies of page two as required to record the additional joint filer information. Attach any additional pages behind page three, and indicate the total number of joint filers in Part V.

NOTE: Reports involving insider abuse may not be filed jointly.

Item 25-- *Casino or card club's trade name*. Enter the name by which the casino or card club does business and is commonly known. Do not enter a corporate, partnership, or other entity name unless such name is the one by which the casino is commonly known.

Item 26-- *Casino or card club's legal name. Enter the legal name as shown on required tax filings, only if different from the trade name shown in **Item 25**. The legal name should match the name shown on the charter or other document creating the entity, and which is identified with the casino's established employer identification number.

Item 27-- *Employer identification number. Enter the institution's nine-digit EIN.

Items 28, 29, 30, and 31-- *Address. See General Instruction B 12 & 14.

Item 32-- Type of gaming institution. -Check the appropriate box for the type of gaming institution. Check box "a" for a land-based or riverboat casino that is duly licensed by a State, Territory or Insular Possession of the United States. Check box "b" for a tribal casino (*e.g.*, a Class III type gaming operation). Check box "c" for a card club, gaming club, and card room or gaming room (including one operating on Indian lands). If you check box "d" for "**Other**", be sure to specify the type of gaming institution (*e.g.*, racino, race track).

Item 33--Internal report control/file number (optional). Enter any internal file or report number assigned by the reporting institution to track this report. This information will act as an identification aid if contact is required.

Item *34--Primary Federal Regulator. Check the appropriate box (only one).

Item 35-- *Account number(s). See General Instruction B11. Enter the number of any account in or through which the suspicious activity occurred. If an account is not affected or if no affected account is known, enter "none" in item 37a. Check the "yes" box to indicate if the account is closed. If more than four accounts are affected, provide the additional information in Part V.

Item 36-- Affiliation/relationship to casino. If box "d" (employee) is checked, indicate in Part V the subject's position (*e.g.*, dealer, pit supervisor, cage cashier, host, *etc.*) and the subject's involvement. If box "h" (other) is checked, briefly describe in Part V.

Items *37- 56--Branch Office Addresses. See General Instructions B12 & B14. Provide the addresses of up to four branch locations where the most significant portion of the suspicious activity occurred. If there are more than four branches, check the box labeled "Check if additional branch ..." in the last branch address (item 52) and list the additional locations in Part V. If there are no branch addresses involved, enter "Not Applicable" in Item 37. Branch office's of casinos and card clubs include non-gaming office operations world wide.

Part IV Contact for Assistance*

Item *57-- Designated contact office. Enter the name of the office that the casino or card club has designated to receive request for assistance with this report. This office must have an individual knowledgeable of this report available during regular business hours.

Item *58--Designated phone number. See General Instruction B9. Enter the work telephone number of the designated contact office.

Item *59--Date filed. See General Instruction B8. Enter the date this report was filed. For electronic filing, it is the date that the report was e-filed using BSA Direct. For magnetic media filing, it is the date the magnetic media was forwarded to DCC. For all other filers, it is the date the financial institution completed the final review and mailed/submitted the report to DCC.

Item 60--Agency. If this report is filed by an agency other than a casino or card club such as a regulator or OFAC, enter the name of the reporting agency in Item 61.

PART V *Suspicious Activity Information -- Narrative. See FinCEN Form 102, page 3 for instructions. Legal disclaimers will not be included in this narrative.

[FR Doc. 06–784 Filed 1–26–06; 8:45 am]
BILLING CODE 4810–02–C

Corrections

Federal Register

Vol. 71, No. 18

Friday, January 27, 2006

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF EDUCATION

Office of Postsecondary Education; Overview Information; Developing Hispanic-Serving Institutions (HSI) Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 2006

Corrections

In notice document E6–829 beginning on page 3830 in the issue of Tuesday, January 24, 2006, make the following corrections:

1. On page 3830, in the first column, under the heading **DATES**, in the third paragraph, under *Deadline for Intergovernmental Review:* ''March 27, 2006'' should read '' May 9, 2006''.

2. On page 3832, in the first column, in the fourth paragraph, under *Deadline for Intergovernmental Review:* ''March 27, 2006'' should read ''May 9, 2006''.

[FR Doc. Z6–829 Filed 1–26–06; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 9, 141, and 142

[EPA–HQ–OW–2002–0043; FRL–8012–1]

RIN 2040–AD38

National Primary Drinking Water Regulations: Stage 2 Disinfectants and Disinfection Byproducts Rule

Correction

In rule document 06–3 beginning on page 388 in the issue of Wednesday, January 4, 2006, make the following corrections:

1. On page 424, in the third column, in the last paragraph, in the second line, ''complete'' should read ''completing''.

2. On the same page, in the same column, in the same paragraph, in the 12th line, ''complete'' should read ''completing''.

3. On page 426, the table is corrected to read as set forth below:

TABLE IV.G–1.—IDSE MONITORING FREQUENCIES AND LOCATIONS

Source water type	Population size category	Monitoring periods and frequency of sampling	Distribution system monitoring locations [1]				
			Total per monitoring period	Near entry points	Average residence time	High TTHM locations	High HAA5 locations
Subpart H	<500 consecutive systems.	one (during peak historical month) [2].	2	1	.....	1	
	<500 non-consecutive systems.	.....	2	.....	.....	1	1
	500–3,300 non-consecutive systems.	four (every 90 days)	2	1	.....	1	.....
	500–3,300 consecutive systems.	.....	2	.....	.....	1	1
	3,301–9,999	.....	4	.....	1	2	1
	10,000–49,999	six (every 60 days)	8	1	2	3	2
	50,000–249,999	.....	16	3	4	5	4
	250,000–999,999	.....	24	4	6	8	6
	1,000,000–4,999,999	.....	32	6	8	10	8
	≥5,000,000	.....	40	8	10	12	10
Ground Water	<500 consecutive systems.	one (during peak historical month) [2].	2	1	.....	1	.....
	<500 non-consecutive systems.	.....	2	.....	.....	1	1
	500–9,999	four (every 90 days)	2	.....	.....	1	1
	10,000–99,999	.....	6	1	1	2	2
	100,000–499,999	.....	8	1	1	3	3
	≥500,000	.....	12	2	2	4	4

[1] A dual sample set (i.e., a TTHM and an HAA5 sample) must be taken at each monitoring location during each monitoring period.
[2] The peak historical month is the month with the highest TTHM or HAA5 levels or the warmest water temperature.

4. On page 433, in the second column, in the third full paragraph, in the sixth and seventh lines, ''2×10/b 2×10^{-4}, 10^{-4} and 10^{-6}'' should read ''2×10^{-4}''.

5. On pages 434 and 435, Table IV.K–1 is corrected to read as set forth below:

TABLE IV.K–1.—TECHNOLOGIES CONSIDERED AND PREDICTED TO BE USED IN COMPLIANCE FORECAST FOR SMALL SYSTEMS

SW Water Plants	GW Water Plants
• *Switching to chloramines as a residual disinfectant*	• *Switching to chloramines as a residual disinfectant*
• *Chlorine dioxide (not for systems serving fewer than 100 people)*	• *UV*
• *UV*	• Ozone (not for systems serving fewer than 100 people)
• Ozone (not for systems serving fewer than 100 people)	• *GAC20*
• Micro-filtration/Ultra-filtration	• Nanofiltration
• GAC20.	
• *GAC20 + Advanced disinfectants*.	
• *Integrated Membranes*.	

Note: Italicized technologies are those predicted to be used in the compliance forecast.
Source: Exhibits 5.11b and 5.14b, USEPA 2005a.

6. On page 435, in Table IV.K–2, in column H, in the second line, ''9'' should read ''0''.

7. On page 464, in Table VI.K–1, in the ''Notes:'', in the third line, ''established exposure'' should read ''established between exposure''.

§ 9.1 [Corrected]

8. On page 477, in § 9.1, in the third column, in the table National Primary Drinking Water Regulations Implementation, under ''OMB control No.'', in the first line, ''2040–0265'' should read ''2040–0205''.

§ 141.620 [Corrected]

9. On page 489, in § 141.620(c), in the table, in the first column, in entry (4), ''System serving > 10,000'' should read ''System serving < 10,000''.

[FR Doc. C6–3 Filed 1–26–06; 8:45 am]
BILLING CODE 1505–01–D

Federal Register

Friday,

January 27, 2006

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; Prospective Payment System for Long-Term Care Hospitals RY 2007: Proposed Annual Payment Rate Updates, Policy Changes, and Clarification; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS–1485–P]

RIN 0938–AO06

Medicare Program; Prospective Payment System for Long-Term Care Hospitals RY 2007: Proposed Annual Payment Rate Updates, Policy Changes, and Clarification

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). The proposed payment amounts and factors used to determine the updated Federal rates that are described in this proposed rule were determined based on the LTCH PPS rate year July 1, 2006 through June 30, 2007. The annual update of the long-term care diagnosis-related group (LTC–DRG) classifications and relative weights remains linked to the annual adjustments of the acute care hospital inpatient diagnosis-related group system, and would continue to be effective each October 1. The proposed outlier threshold for July 1, 2006, through June 30, 2007, would also be derived from the LTCH PPS rate year calculations. We are also proposing to make policy changes and clarifications.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 20, 2006.

ADDRESSES: In commenting, please refer to file code CMS–1485–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking/*. (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1485–P, P.O. Box 8012, Baltimore, MD 21244–8012.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1485–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7197 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the ''Collection of Information Requirements'' section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:
Tzvi Hefter, (410) 786–4487 (General information).
Judy Richter, (410) 786–2590 (General information, payment adjustments for special cases, and onsite discharges and readmissions, interrupted stays, co-located providers, and short-stay outliers).
Michele Hudson, (410) 786–5490 (Calculation of the payment rates, LTC–DRGs, relative weights and case-mix index, market basket, wage index, budget neutrality, and other payment adjustments).
Ann Fagan, (410) 786–5662 (Patient classification system).
Miechal Lefkowitz, (410) 786–5316 (High-cost outliers and cost-to-charge ratios).
Linda McKenna, (410) 786–4537 (Payment adjustments, interrupted stay, and transition period).
Nancy Kenly, (410) 786–7792 (Federal rate update and case-mix index).

SUPPLEMENTARY INFORMATION:

Submission of Public Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code [CMS–1485-P] and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all comments received before the close of the comment period on its public website as soon as possible after they are received. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Table of Contents

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding terms in alphabetical order below:

3M 3M Health Information Systems
AHA American Hospital Association
AHIMA American Health Information Management Association
ALOS Average length of stay
APR All patient refined
ASCA Administrative Simplification Compliance Act of 2002 (Pub. L. 107–105)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
BIPA Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)
BLS Bureau of Labor Statistics
CBSA Core-based statistical area
CC Complications and comorbidities
CCR Cost-to-charge ratio
C&M Coordination and maintenance
CMI Case-mix index
CMS Centers for Medicare & Medicaid Services
CMSA Consolidated metropolitan statistical area
COLA Cost of living adjustment
COPS Medicare conditions of participation
CPI Consumer Price Indexes
DSH Disproportionate share of low-income patients
DRGs Diagnosis-related groups
ECI Employment Cost Indexes
FI Fiscal intermediary
FY Federal fiscal year
HCRIS Hospital cost report information system
HHA Home health agency
HHS (Department of) Health and Human Services
HIPAA Health Insurance Portability and Accountability Act (Pub. L. 104–191)
HIPC Health Information Policy Council
HwHs Hospitals Within Hospitals
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification (codes)
IME Indirect medical education
I–O Input-Output
IPF Inpatient psychiatric facility
IPPS Acute Care Hospital Inpatient Prospective Payment System
IRF Inpatient rehabilitation facility
LOS Length of stay
LTC–DRG Long-term care diagnosis-related group
LTCH Long-term care hospital
MCE Medicare code editor
MDC Major diagnostic categories
MedPAC Medicare Payment Advisory Commission
MedPAR Medicare provider analysis and review file
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
MSA Metropolitan statistical area
NCHS National Center for Health Statistics
NECMA New England County metropolitan area
OPM U.S. Office of Personnel Management
O.R. Operating room
OSCAR Online Survey Certification and Reporting (System)
PIP Periodic interim payment
PLI Professional liability insurance
PMSA Primary metropolitan statistical area
PPI Producer Price Indexes
PPS Prospective payment system
QIO Quality Improvement Organization (formerly Peer Review organization (PRO))
RPL Rehabilitation psychiatric long-term care (hospital)
RTI Research Triangle Institute, International
RY Rate year (July 1 through June 30)
SNF Skilled nursing facility
SSO Short-stay outlier
TEFRA Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248)
UHDDS Uniform hospital discharge data set

I. Background

[If you choose to comment on issues in this section, please include the caption ''BACKGROUND'' at the beginning of your comments.]

A. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's

Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) provide for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Social Security Act (the Act), effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act defines a LTCH as ''a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.'' Section 1886(d)(1)(B)(iv)(II) of the Act also provides an alternative definition of LTCHs: specifically, a hospital that first received payment under section 1886(d) of the Act in 1986 and has an average inpatient length of stay (LOS) (as determined by the Secretary of Health and Human Services (the Secretary)) of greater than 20 days and has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in FY 1997.

Section 123 of the BBRA requires the PPS for LTCHs to be a per discharge system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resources and costs in LTCHs while maintaining budget neutrality.

Section 307(b)(1) of BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In a **Federal Register** document issued on August 30, 2002, we implemented the LTCH PPS authorized under BBRA and BIPA (67 FR 55954). This system uses information from LTCH patient records to classify patients into distinct long-term care diagnosis-related groups (LTC-DRGs) based on clinical characteristics and expected resource needs. Payments are calculated for each LTC-DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by a LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable cost-based payment provisions are located at 42 CFR Part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and were paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital-specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we also presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

On June 6, 2003, we published a final rule in the **Federal Register** (68 FR 34122) that set forth the 2004 annual update of the payment rates for the Medicare PPS for inpatient hospital services furnished by LTCHs. It also changed the annual period for which the payment rates are effective. The annual updated rates are now effective from July 1 through June 30 instead of from October 1 through September 30. We refer to the July through June time period as a ''long-term care hospital rate year'' (LTCH PPS rate year). In addition, we changed the publication schedule for the annual update to allow for an effective date of July 1. The payment amounts and factors used to determine the annual update of the LTCH PPS Federal rate is based on a LTCH PPS rate year. While the LTCH payment rate update is effective July 1, the annual update of the LTC–DRG classifications and relative weights are linked to the annual adjustments of the acute care hospital inpatient DRGs and are effective each October 1.

On May 6, 2005, we published the Prospective Payment System for Long-Term Care Hospitals: Annual Payment Rate Updates, Policy Changes, and Clarifications final rule (70 FR 24168) (hereinafter referred to as the RY 2006 LTCH PPS final rule). In this rule, we set forth the 2006 LTCH PPS rate year annual update of the payment rates for the Medicare PPS for inpatient hospital services provided by LTCHs. We also discussed clarification of the notification policy for colocated LTCHs and satellite facilities. The RY 2006 LTCH PPS final rule also included a provision to extend the surgical DRG exception in the 3-day or less interruption of stay policy at § 412.531 as well as a provision that clarified and modified existing notification requirements for the purpose of implementing § 412.532.

B. Criteria for Classification as a LTCH

1. Classification as a LTCH

Under the existing regulations at § 412.23(e)(1) and (e)(2)(i), which implement section 1886(d)(1)(B)(iv)(I) of the Act, to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare and must have an average Medicare inpatient LOS of greater than 25 days. Alternatively, § 412.23(e)(2)(ii) states that for cost reporting periods beginning on or after August 5, 1997, a hospital that was first excluded from the PPS in 1986 and can demonstrate that at least 80 percent of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease must have an average inpatient LOS for all patients, including both Medicare and non-Medicare inpatients, of greater than 20 days.

Section 412.23(e)(3) provides that, subject to the provisions of paragraphs (e)(3)(ii) through (e)(3)(iv) of this section, the average Medicare inpatient LOS, specified under § 412.23(e)(2)(i) is calculated by dividing the total number of covered and noncovered days of stay of Medicare inpatients (less leave or pass days) by the number of total Medicare discharges for the hospital's most recent complete cost reporting

period. Section 412.23 also provides that subject to the provisions of paragraphs (e)(3)(ii) through (e)(3)(iv) of this section, the average inpatient LOS specified under § 412.23(e)(2)(ii) is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period.

In the RY 2005 LTCH PPS final rule (69 FR 25674), we specified the procedure for calculating a hospital's inpatient average length of stay (ALOS) for purposes of classification as a LTCH. That is, if a patient's stay includes days of care furnished during two or more separate consecutive cost reporting periods, the total days of a patient's stay would be reported in the cost reporting period during which the patient is discharged (69 FR 25705). Therefore, we revised the regulations at § 412.23(e)(3)(ii) to specify that, effective for cost reporting periods beginning on or after July 1, 2004, in calculating a hospital's ALOS, if the days of an inpatient stay involve days of care furnished during two or more separate consecutive cost reporting periods, the total number of days of the stay are considered to have occurred in the cost reporting period during which the inpatient was discharged.

Fiscal intermediaries (FIs) verify that LTCHs meet the ALOS requirements. We note that the inpatient days of a patient who is admitted to a LTCH without any remaining Medicare days of coverage, regardless of the fact that the patient is a Medicare beneficiary, will not be included in the above calculation. Because Medicare would not be paying for any of the patient's treatment, data on the patient's stay would not be included in the Medicare claims processing systems. As described in § 409.61, in order for both covered and noncovered days of a LTCH hospitalization to be included, a patient admitted to the LTCH must have at least one remaining benefit day (68 FR 34123).

The FI's determination of whether or not a hospital qualified as an LTCH is based on the hospital's discharge data from the hospital's most recent complete cost reporting period (§ 412.23(e)(3)) and is effective at the start of the hospital's next cost reporting period (§ 412.22(d)). However, if the hospital does not meet the ALOS requirement as specified in § 412.23(e)(2)(i) and (ii), the hospital may provide the intermediary with data indicating a change in the ALOS by the same method for the period of at least 5 months of the immediately preceding 6-month period (69 FR 25676). Our interpretation of the current regulations at § 412.23(e)(3) was to allow hospitals to submit data using a period of at least 5 months of the most recent data from the immediately preceding 6-month period.

As we stated in the Inpatient Prospective Payment System (IPPS) final rule, published August 1, 2003, prior to the implementation of the LTCH PPS, we did rely on data from the most recently submitted cost report for purposes of calculating the ALOS. The calculation to determine whether an acute care hospital qualifies for LTCH status was based on total days and discharges for LTCH inpatients. However, with the implementation of the LTCH PPS, for the ALOS specified under § 412.23(e)(2)(i), we revised § 412.23(e)(3)(i) to only count total days and discharges for Medicare inpatients (67 FR 55970 through 55974). In addition, the ALOS specified under § 412.23(e)(2)(ii) is calculated by dividing the total number of days for all patients, including both Medicare and non-Medicare inpatients (less leave or pass days) by the number of total discharges for the hospital's most recent complete cost reporting period. As we discussed in the August 1, 2003 IPPS final rule, we are unable to capture the necessary data from our present cost reporting forms. Therefore, we have notified FIs and LTCHs that until the cost reporting forms are revised, for purposes of calculating the ALOS, we will be relying upon census data extracted from Medicare Provider Analysis and Review (MedPAR) files that reflect each LTCH's cost reporting period (68 FR 45464). Requirements for hospitals seeking classification as LTCHs that have undergone a change in ownership, as described in § 489.18, are set forth in § 412.23(e)(3)(iv).

2. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1) or section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b–1 (note)) (Statewide all-payer systems, subject to the rate-of-increase test at section 1814(b) of the Act).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

C. Transition Period for Implementation of the LTCH PPS

In the August 30, 2002 final rule, we provided for a 5-year transition period from reasonable cost-based reimbursement to a full Federal prospective payment based on 100 percent of the Federal rate for LTCHs (67 FR 56038). However, existing LTCHs and LTCHs that are not defined as new in § 412.533(d) have the option to elect to be paid based on 100 percent of the Federal prospective payment. During the 5-year period, two payment percentages are to be used to determine a LTCH's total payment under the PPS. The blend percentages are as shown in Table 1.

TABLE 1

Cost reporting periods beginning on or after	Prospective payment federal rate percentage	Reasonable cost-based reimbursement rate percentage
October 1, 2002	20	80
October 1, 2003	40	60
October 1, 2004	60	40
October 1, 2005	80	20
October 1, 2006	100	0

D. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). In the RY 2005 LTCH PPS final rule (69 FR 25676), we clarified that the discussion of beneficiary liability in the August 30, 2002 final rule was not meant to establish rates or payments for, or define Medicare-eligible expenses. Under § 412.507, as consistent with other established hospital prospective payment systems, a LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under § 409.82, § 409.83, and § 409.87 and for items and services as specified under § 489.30(a), if the Medicare payment to the LTCH is the full LTC–DRG payment amount. However, under the LTCH PPS, Medicare will only pay for days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. (See section V.A.1.a. of this preamble.) Therefore, if the Medicare payment was for a SSO case (§ 412.529) that was less than the full LTC–DRG payment amount because the beneficiary had insufficient remaining Medicare days, the LTCH could also charge the beneficiary for services delivered on those uncovered days (§ 412.507).

E. Administrative Simplification Compliance Act and Health Insurance Portability and Accountability Act Compliance

Claims submitted to Medicare must comply with both the Administrative Simplification Compliance Act (ASCA) (Pub. L. 107–105), and Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104–191). Section 3 of ASCA requires the Medicare Program, to deny payment under Part A or Part B for any expenses for items or services ''for which a claim is submitted other than in an electronic form specified by the Secretary.'' Section 1862(h) of the Act (as added by section 3(a) of ASCA) provides that the Secretary shall waive such denial in two types of cases and may also waive such denial ''in such unusual cases as the Secretary finds appropriate.'' (Also, see 68 FR 48805, August 15, 2003, implementing section 3 of ASCA.) Section 3 of ASCA operates in the context of the Administrative Simplification provisions of HIPAA, which include, among other provisions, the transactions and code sets standards requirements codified as 45 CFR parts 160 and 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including covered providers, to conduct covered electronic transactions according to the applicable transactions and code sets standards.

II. Summary of the Major Contents of This Proposed Rule

In this proposed rule, we are setting forth the proposed annual update to the payment rates for the Medicare LTCH PPS, as well as, proposing other policy changes. The following is a summary of the major areas that we are addressing in this proposed rule:

In section III of this preamble, we discuss the LTCH PPS patient classification and the relative weights which remain linked to the annual adjustments of the acute care hospital inpatient DRG system, and are based on the annual revisions to the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD–9-CM) codes effective each October 1.

In section IV.B. of this preamble, we propose to adopt the ''Rehabilitation, Psychiatric, Long Term Care (RPL)'' market basket under the LTCH PPS in place of the excluded hospital with capital market basket.

As discussed in section IV.C. of this preamble, we are proposing a zero percent update to the LTCH PPS Federal rate for the 2007 LTCH PPS rate year instead of the most recent estimate of the LTCH PPS market basket.

Also in section IV.C. of this preamble, we discuss the proposed prospective payment rate for RY 2007, and in section IV.D. we discuss the applicable adjustments to the proposed payment rates, including the proposed revisions to the wage index, the proposed cost-of-living adjustment factors, the proposed outlier threshold, and the proposed transition period budget neutrality factor for the 2007 LTCH PPS rate year. We are also proposing revisions to the cost-to-charge ratio and reconciliation provisions as they apply to LTCH outlier payment policies.

In section IV.D.1.c. of this preamble, we also discuss our proposal to revise the LTCH PPS labor-related share based on RPL market basket. Also in section IV.D. of this preamble, we are proposing to postpone the deadline for making the one-time prospective adjustment for the Federal rate at § 412.523(d)(3).

In section V.A. of this preamble, we are proposing to revise the existing payment adjustment for SSO cases by reducing the part of the current payment formula that is based on costs and adding a fourth component to the current payment formula. Also in section V.A. of this preamble, we are proposing to sunset the surgical DRG exception to the payment policy established under the 3-day or less interruption of stay regulations at § 412.531(a)(1).

In section V.B. of this preamble, for LTCH hospitals within hospitals (HwHs) and LTCH satellites, we are proposing to clarify at § 412.534(c) that under the policy for adjusting the LTCH PPS payment based on the amount that would be determined under the IPPS payment methodology, we calculate the LTCH PPS payment amount that is equivalent to what would otherwise be paid under the IPPS. We are also proposing to codify in regulations the general formula we currently use to give affect to the regulations as they pertain to calculating an amount under subpart O that is equivalent to an amount that would be determined under § 412.1(a).

In section X. of this preamble, we will discuss our on-going monitoring protocols under the LTCH PPS.

In section XI of this preamble, we will discuss the recommendations made by the Research Triangle Institute, International's (RTI) evaluation of the feasibility of adopting recommendations made in the June 2004 MedPAC Report.

In section XIII of this preamble, we analyze the impact of the proposed changes presented in this proposed rule on Medicare expenditures, Medicare-participating LTCHs, and Medicare beneficiaries.

In Appendix A of this proposed rule, we present a description of a preliminary model of an update framework under the LTCH PPS that we may propose to use in the future for purposes of the annual updating of the LTCH PPS Federal rate in future years.

III. Long-Term Care Diagnosis-Related Group (LTC-DRG) Classifications and Relative Weights

[If you choose to comment on issues in this section, please include the caption ''LTC–DRG CLASSIFICATIONS AND RELATIVE WEIGHTS'' at the beginning of your comments.]

A. Background

Section 123 of the BBRA specifically requires that the PPS for LTCHs be a per discharge system with a DRG-based patient classification system reflecting the differences in patient resources and costs in LTCHs while maintaining budget neutrality. Section 307(b)(1) of BIPA modified the requirements of section 123 of the BBRA by specifically requiring that the Secretary examine ''the feasibility and the impact of basing payment under such a system [the LTCH PPS] on the use of existing (or refined) hospital DRGs that have been modified to account for different

resource use of LTCH patients as well as the use of the most recently available hospital discharge data.''

In accordance with section 123 of the BBRA as amended by section 307(b)(1) of BIPA and § 412.515, we use information derived from LTCH PPS patient records to classify these cases into distinct LTC–DRGs based on clinical characteristics and estimated resource needs. The LTC–DRGs used as the patient classification component of the LTCH PPS correspond to the hospital inpatient DRGs in the IPPS. We assign an appropriate weight to the LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In a departure from the IPPS, we use low volume LTC–DRGs (less than 25 LTCH cases) in determining the LTC–DRG weights, since LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. In order to manage the large number of low volume DRGs (all DRGs with fewer than 25 cases), we group low volume DRGs into 5 quintiles based on average charge per discharge. (A listing of the current composition of low volume quintiles used in determining the FY 2006 LTC–DRG relative weights appears in the FY 2006 IPPS final rule (70 FR 47329 through 47332).) We also account for adjustments to payments for cases in which the stay at the LTCH is less than or equal to five-sixths of the geometric ALOS and classify these cases as SSO cases. (A detailed discussion of the application of the Lewin Group model that was used to develop the LTC–DRGs appears in the August 30, 2002 LTCH PPS final rule (67 FR 55978).)

B. Patient Classifications Into DRGs

Generally, under the LTCH PPS, Medicare payment is made at a predetermined specific rate for each discharge; that payment varies by the LTC–DRG to which a beneficiary's stay is assigned. Cases are classified into LTC–DRGs for payment based on the following six data elements:

(1) Principal diagnosis.
(2) Up to eight additional diagnoses.
(3) Up to six procedures performed.
(4) Age.
(5) Sex.
(6) Discharge status of the patient.

As indicated in the August 30, 2002 LTCH PPS final rule, upon the discharge of the patient from a LTCH, the LTCH must assign appropriate diagnosis and procedure codes from the most current version of the ICD–9–CM. HIPAA transactions and code sets standards regulations (45 CFR parts 160 and 162) require that no later than October 16, 2003, all covered entities must comply with the applicable requirements of subparts A and I through R of part 162. Among other requirements, those provisions direct covered entities that electronically transmit institutional health care claim or equivalent encounter information, for instance, to use the ASC X12N 837 Health Care Claim: Institutional, Volumes 1 and 2, version 4010, and the applicable standard medical data code sets. (See 45 CFR 162.1002 and 45 CFR 162.1102).

Medicare FIs enter the clinical and demographic information into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a DRG can be made. During this process, the following types of cases are selected for further development:

- Cases that are improperly coded. (For example, diagnoses are shown that are inappropriate, given the sex of the patient. Code 68.6, Radical abdominal hysterectomy, would be an inappropriate code for a male.)
- Cases including surgical procedures not covered under Medicare. (For example, organ transplant in a non-approved transplant center.)
- Cases requiring more information. (For example, ICD–9–CM codes are required to be entered at their highest level of specificity. There are valid 3-digit, 4-digit, and 5-digit codes. That is, code 262, Other severe protein-calorie malnutrition, contains all appropriate digits, but if it is reported with either fewer or more than 3 digits, the claim will be rejected by the MCE as invalid.)
- Cases with principal diagnoses that do not usually justify admission to the hospital. (For example, code 437.9, unspecified cerebrovascular disease. While this code is valid according to the ICD–9–CM coding scheme, a more precise code should be used for the principal diagnosis.)

After screening through the MCE, each claim will be classified into the appropriate LTC–DRG by the Medicare LTCH GROUPER software. As indicated in August 30, 2002 LTCH PPS final rule, the Medicare GROUPER software, which is used under the LTCH PPS, is specialized computer software, and is the same GROUPER software program used under the IPPS. The GROUPER software was developed as a means of classifying each case into a DRG on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). Following the LTC–DRG assignment, the Medicare FI determines the prospective payment by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for the LTCH to review the LTC–DRG assignments made by the FI and to submit additional information within a specified timeframe as specified in § 412.513(c).

The GROUPER software is used both to classify past cases in order to measure relative hospital resource consumption to establish the DRG weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible DRG classification changes and to recalibrate the DRG weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517). As discussed in greater detail in sections III.D. and E. of this preamble, with the implementation of section 503(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), there is the possibility that one feature of the GROUPER software program may be updated twice during a Federal fiscal year (FY) (October 1 and April 1) as required by the statute for the IPPS (69 FR 48954 through 48957). Specifically, as we discussed in the FY 2006 IPPS final rule, ICD–9 diagnosis and procedure codes for new medical technology may be created and added to existing DRGs in the middle of the Federal FY on April 1 (70 FR 47323). However, this policy change will have no effect on the LTC–DRG relative weights, which will continue to be updated only once a year (October 1), nor will there be any impact on Medicare payments under the LTCH PPS. The use of the ICD–9–CM code set is also compliant with the current requirements of the Transactions and Code Sets Standards regulations at 45 CFR parts 160 and 162, published in accordance with HIPAA.

C. Organization of DRGs

The DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Accordingly, the principal diagnosis determines MDC assignment. Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures

by resource intensity. The GROUPER software program does not recognize all ICD–9–CM procedure codes as procedures that affect DRG assignment, that is, procedures which are not surgical (for example, EKG), or minor surgical procedures (for example, 86.11, Biopsy of skin and subcutaneous tissue).

The medical DRGs are generally differentiated on the basis of diagnosis. Both medical and surgical DRGs may be further differentiated based on age, sex, discharge status, and presence or absence of complications or comorbidities (CC). We note that CCs are defined by certain secondary diagnoses not related to, or not inherently a part of, the disease process identified by the principal diagnosis. (For example, the GROUPER software would not recognize a code from the 800.0x series, Skull fracture, as a CC when combined with principal diagnosis 850.4, Concussion with prolonged loss of consciousness, without return to preexisting conscious level.) In addition, we note that the presence of additional diagnoses does not automatically generate a CC, as not all DRGs recognize a comorbid or complicating condition in their definition. (For example, DRG 466, Aftercare without History of Malignancy as Secondary Diagnosis, is based solely on the principal diagnosis, without consideration of additional diagnoses for DRG determination.)

In its June 2000, Report to Congress, MedPAC recommended that the Secretary ''* * * improve the hospital inpatient prospective payment system by adopting, as soon as practicable, diagnosis-related group refinements that more fully capture differences in severity of illness among patients,'' (Recommendation 3A, p. 63). In response to that recommendation, we determined at that time that it was not practical to develop a refinement to inpatient hospital DRGs based on severity due to time and resource requirements. However, this does not preclude us from development of a severity-adjusted DRG refinement in the future. That is, a refinement to the list of CCs could be incorporated into the existing DRG structure. It is also possible that a more comprehensive severity adjusted structure may be created if a new code set is adopted. That is, if ICD–9–CM is replaced by ICD–10–CM (for diagnostic coding) and ICD–10–PCS (for procedure coding) or by other code sets, a severity concept may be built into the resulting DRG assignments. Of course, any change to the code set would be adopted through the process established in the HIPAA Administrative Simplification Standards provisions.

In its March 2005 Report to Congress, ''Physician-Owned Specialty Hospitals,'' MedPAC recommended that the Secretary improve payment accuracy in the hospital IPPS by, among other things, ''refining the current DRGs to more fully capture differences in severity of illness among patients.'' (Recommendation 1, p. 93.) In the FY 2006 IPPS final rule (70 FR 47474 through 47479), we stated that we expected to make changes to the DRGs to better reflect severity of illness and we indicated that we plan to conduct a comprehensive review of the CCs list for FY 2007. We also indicated that we are considering the possibility of proposing to use the All Patient Refined (APR) DRGs under the IPPS for FY 2007. We explained that we did not propose to adopt the APR–DRGS under the IPPS for FY 2006 because it would represent a significant undertaking that could have a substantial effect on all hospitals and there was insufficient time to fully analyze a change of that magnitude. However, as an interim step to better recognize severity in the DRG system for FY 2006, until we can complete a more comprehensive analysis of the APR–DRG system and CC list as part of a complete analysis of the MedPAC recommendations that we plan to perform over the next year, we established cardiovascular DRGs 547 through 558 as described in the FY 2006 IPPS final rule (70 FR 47474 through 47478).

D. Update of LTC–DRGs

For FY 2006, the LTC–DRG patient classification system was based on LTCH data from the FY 2004 MedPAR file, which contained hospital bills data from the March 2005 update. The patient classification system consists of 526 DRGs that formed the basis of the FY 2006 LTCH PPS GROUPER program. The 526 LTC–DRGs included two ''error DRGs.'' As in the IPPS, we included two error DRGs in which cases that cannot be assigned to valid DRGs will be grouped. These two error DRGs are DRG 469 (Principal Diagnosis Invalid as a Discharge Diagnosis) and DRG 470 (Ungroupable). (See the FY 2006 IPPS final rule (70 FR 47323 through 47341)). The other 524 LTC–DRGs are the same DRGs used in the IPPS GROUPER program for FY 2006 (Version 23.0).

In the past, the annual update to the CMS DRGs was based on the annual revisions to the ICD–9–CM codes and was effective each October 1. Recently, the ICD–9–CM coding update process was revised as discussed in greater detail in the FY 2005 IPPS final rule (69 FR 48954 through 48957). Specifically, section 503(a) of the MMA includes a requirement for updating ICD–9–CM codes twice a year instead of the current process of annual updates on October 1 of each year. This requirement is included as part of the amendments to the Act relating to recognition of new medical technology under the IPPS. (For additional information on this provision, including its implementation and its impact on the LTCH PPS, refer to the FY 2005 IPPS final rule (69 FR 48952 through 48957) and the RY 2006 LTCH PPS final rule (70 FR 24172 through 24177).)

As discussed in the RY 2006 LTCH PPS final rule, with the implementation of section 503(a) of the MMA, there is the possibility that one feature of the GROUPER software program may be updated twice during a Federal FY (October 1 and April 1) as required by the statute for the IPPS (70 FR 24173 through 24175). Specifically, ICD–9–CM diagnosis and procedure codes for new medical technology may be created and added to existing DRGs in the middle of the Federal FY on April 1. No new LTC–DRGs will be created or deleted. Consistent with our current practice, any changes to the DRGs or relative weights will be made at the beginning of the next Federal FY (October 1). Therefore, there will not be any impact on Medicare payments under the LTCH PPS. The use of the ICD–9–CM code set is also compliant with the current requirements of the Transactions and Code Sets Standards regulations at 45 CFR parts 160 and 162, issued under HIPAA.

As we explained in the FY 2006 IPPS final rule, in the health care industry, historically annual changes to the ICD–9–CM codes were effective for discharges occurring on or after October 1 each year (70 FR 47323). Thus, the manual and electronic versions of the GROUPER software, which are based on the ICD–9–CM codes, were also revised annually and effective for discharges occurring on or after October 1 each year. The patient classification system used under the LTCH PPS (LTC–DRGs) is based on the DRG patient classification system used under the IPPS, which historically had been updated annually and effective for discharges occurring on or after October 1 through September 30 each year. As we also mentioned, the ICD–9–CM coding update process was revised as a result of the implementation of section 503(a) of the MMA, which includes a requirement for updating ICD–9–CM codes as often as twice a year instead of the current process of annual updates on October 1 of each year. As discussed

in the FY 2005 IPPS final rule, this requirement is included as part of the amendments to the Act relating to recognition of new medical technology under the IPPS (69 FR 48954 through 48957). Section 503(a) of the MMA amended section 1886(d)(5)(K) of the Act by adding a new paragraph (vii) which states that ''the Secretary shall provide for the addition of new diagnosis and procedure codes in [sic] April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) * * * until the FY that begins after such date.'' This requirement will improve the recognition of new technologies under the IPPS by accounting for those ICD–9–CM codes in the MedPAR claims data at an earlier date.

Despite the fact that aspects of the GROUPER software may be updated to recognize any new technology ICD–9–CM codes, there will be no impact on either LTC–DRG assignments or payments under the LTCH PPS at that time. That is, changes to the LTC–DRGs (such as the creation or deletion of LTC–DRGs) and the relative weights will continue to be updated in the manner and timing (October 1) as they are now.

Updates to the GROUPER software for both the IPPS and the LTCH PPS (for relative weights and the creation or deletion of DRGs) are made in the annual IPPS proposed and final rules and are effective each October 1. We also explained that since we do not publish a midyear IPPS rule, April 1 code updates will not be published in a midyear IPPS rule. Rather, we will assign any new diagnosis or procedure codes to the same DRG in which its predecessor code was assigned, so that there will be no impact on the DRG assignments. Any coding updates will be available through the Web sites provided in section III.E. of this preamble and through the *Coding Clinic for ICD–9–CM.* Publishers and software vendors currently obtain code changes through these sources in order to update their code books and software system. If new codes are implemented on April 1, revised code books and software systems, including the GROUPER software program, will be necessary because we must use current ICD–9–CM codes. Therefore, for purposes of the LTCH PPS, because each ICD–9–CM code must be included in the GROUPER algorithm to classify each case into a LTC–DRG, the GROUPER software program used under the LTCH PPS would need to be revised to accommodate any new codes.

In implementing section 503(a) of the MMA, there will only be an April 1 update if new technology codes are requested and approved. We note that any new codes created for April 1 implementation will be limited to those diagnosis and procedure code revisions primarily needed to describe new technologies and medical services. However, we reiterate that the process of discussing updates to the ICD–9–CM has been an open process through the ICD–9–CM Coordination and Maintenance Committee since 1995. Requestors will be given the opportunity to present the merits for a new code and make a clear and convincing case for the need to update ICD–9–CM codes for purposes of the IPPS new technology add-on payment process through an April 1 update.

Discharges between October 1, 2005, and September 30, 2006, (Federal FY 2006) are using Version 23.0 of the GROUPER software for both the IPPS and the LTCH PPS. Consistent with our current practice, any changes to the DRGs or relative weights will be made at the beginning of the Federal FY (October 1). We will notify LTCHs of any revised LTC–DRG relative weights based on the final DRGs and the applicable version of the GROUPER software program that will be effective October 1, 2006, in the annual IPPS proposed and final rules. At the September 2005 ICD–9–CM Coordination and Maintenance Committee meeting, there were no requests for an April 1, 2006 implementation of ICD–9–CM codes, and therefore, the next update to the ICD–9–CM coding system will not occur until October 1, 2006 (FY 2007). Presently, as there were no coding changes suggested for an April 1, 2006 update, the ICD–9–CM coding set implemented on October 1, 2005, will continue through September 30, 2006 (FY 2006). The next update to the LTC–DRGs and relative weights for FY 2007 will be presented in the FY 2007 IPPS proposed and final rules. Furthermore, we would notify LTCHs of any revisions to the GROUPER software used under the IPPS and LTCH PPS that would be implemented April 1, 2007.

E. ICD–9–CM Coding System

1. Uniform Hospital Discharge Data Set (UHDDS) Definitions

Because the assignment of a case to a particular LTC–DRG will help determine the amount that will be paid for the case, it is important that the coding is accurate. Classifications and terminology used in the LTCH PPS are consistent with the ICD–9–CM and the UHDDS, as recommended to the Secretary by the National Committee on Vital and Health Statistics (''Uniform Hospital Discharge Data: Minimum Data Set, National Center for Health Statistics, April 1980'') and as revised in 1984 by the Health Information Policy Council (HIPC) of HHS.

We note that the ICD–9–CM coding terminology and the definitions of principal and other diagnoses of the UHDDS are consistent with the requirements of the HIPAA Administrative Simplification Act of 1996 (45 CFR part 162). Furthermore, the UHDDS was used as a standard for the development of policies and programs related to hospital discharge statistics by both governmental and nongovernmental sectors for over 30 years. In addition, the following definitions (as described in the 1984 Revision of the UHDDS, approved by the Secretary for use starting January 1986) are requirements of the ICD–9–CM coding system, and have been used as a standard for the development of the CMS DRGs:

- Diagnoses are defined to include all diagnoses that affect the current hospital stay.
- Principal diagnosis is defined as the condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care.
- Other diagnoses (also called secondary diagnoses or additional diagnoses) are defined as all conditions that coexist at the time of admission, that develop subsequently, or that affect the treatment received or the LOS or both. Diagnoses that relate to an earlier episode of care that have no bearing on the current hospital stay are excluded.
- All procedures performed will be reported. This includes those that are surgical in nature, carry a procedural risk, carry an anesthetic risk, or require specialized training.

We provide LTCHs with a 60-day window after the date of the notice of the initial LTC–DRG assignment to request review of that assignment. Additional information may be provided by the LTCH to the FI as part of that review.

2. Maintenance of the ICD–9–CM Coding System

The ICD–9–CM Coordination and Maintenance (C&M) Committee is a Federal interdepartmental committee, co-chaired by the National Center for Health Statistics (NCHS) and CMS, that is charged with maintaining and updating the ICD–9–CM system. The C&M Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD–9–CM to

reflect newly developed procedures and technologies and newly identified diseases. The C&M Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The NCHS has lead responsibility for the ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while we have the lead responsibility for the ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures. The C&M Committee encourages participation by health-related organizations in this process and holds public meetings for discussion of educational issues and proposed coding changes twice a year at the CMS Central Office located in Baltimore, Maryland. The agenda and dates of the meetings can be accessed on our Web site at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes.*

As discussed previously in this section of the preamble, section 503(a) of the MMA includes a requirement for updating ICD–9–CM codes twice a year instead of the current process of annual updates on October 1 of each year. This requirement will improve the recognition of new technologies under the IPPS by accounting for them in the GROUPER software at an earlier date. Because this new statutory requirement could have a significant impact on health care providers, coding staff, publishers, system maintainers, and software systems, among others, we solicited comments on our proposed provisions to implement this requirement as part of the FY 2005 IPPS proposed rule (69 FR 28220 through 28221). We responded to comments and published our new policy regarding the updating of ICD–9–CM codes in the FY 2005 IPPS final rule (69 FR 48954 through 48957).

While this new requirement states that the Secretary shall not adjust the payment of the DRG classification for any codes created for use on April 1, DRG software and other systems will have to be updated in order to recognize and accept the new codes. If any coding changes were implemented on April 1, the Medicare GROUPER software program used under both the IPPS and the LTCH PPS would need to be revised to reflect the new ICD–9–CM codes because the LTC–DRGs are the same DRGs used under the IPPS. Furthermore, although the GROUPER software used under both the IPPS and the LTCH PPS would need to be revised to accommodate the new codes effective April 1, there would be no additions or deletions of DRGs nor would the relative weights used under the IPPS and the LTCH PPS, respectively, be changed until the annual update October 1 (to the extent that those changes are warranted), just as they are historically updated. As the LTCH PPS is based on the IPPS, we adopted the same approach used under the IPPS for potential April 1 ICD–9–CM coding changes. That is, we will assign any new diagnosis codes or procedure codes to the same DRG in which its predecessor code was assigned, so there will be no DRG impact in terms of potential DRG assignment until the following October 1. We will maintain the current method of publicizing any new code changes, as noted below. Current addendum and code title information is published on the CMS Web page at: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/04_addendum.asp.* Summary tables showing new, revised, and deleted code titles are also posted on the following CMS Web page: *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/07_summarytables.asp.* Information on ICD–9–CM diagnosis codes can be found at *http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/.* Information on new, revised, and deleted ICD–9–CM codes is also available in the American Hospital Association (AHA) publication Coding Clinic for ICD–9–CM. AHA also distributes information to publishers and software vendors. We also send copies of all ICD–9–CM coding changes to our contractors for use in updating their systems and providing education to providers.

If the April 1 changes are made to ICD–9–CM diagnosis or procedure codes, LTCHs will be required to obtain the new codes, coding books, or encoder updates, and make other system changes in order to capture and report the new codes. When we implemented section 503(a) of the MMA in the FY 2005 IPPS final rule, we indicated that we were aware of the additional burden this will have on health care providers.

It should be noted that any new codes created for April 1 implementation will be limited to those diagnosis and procedure code revisions primarily needed to describe new technologies and medical services. However, we reiterate that the process for discussing updates to the ICD–9–CM has been an open process through the ICD–9–CM C&M Committee since 1995. Any requestor who makes a clear and convincing case for the need to update ICD–9–CM codes for purposes of the IPPS new technology add-on payment process through an April 1 update will be given the opportunity to present the merits of their proposed new code.

At the September 2005 C&M Committee meeting, no new codes were proposed for update on April 1, 2006. While no DRG additions or deletions or changes to relative weights will occur prior to the usual October 1 update, in the event any new codes were created to describe new technologies and medical services through an April 1, 2006 update, under our policy established in the RY 2006 final rule (70 FR 24176), LTCH systems would be expected to recognize and report those new codes through the channels as described in this section.

The ICD–9–CM coding changes that have been adopted by the C&M Committee would become effective either at the beginning of each Federal FY (October 1) or, in the case of codes created to capture new technology, April 1 of each year. Coders will be expected to use the most current ICD–9–CM codes, as updated. Because we do not publish a mid-year IPPS rule, the currently accepted avenues of information dissemination will be used to inform all ICD–9–CM code users of any changes to the coding system. These avenues were described in section III.D. of this preamble and were discussed at length in the FY 2005 IPPS final rule (69 FR 48956). Coders in LTCHs using the updated ICD–9–CM coding system will be on the same schedule as the rest of the health care industry. In the past, the updated ICD–9–CM was not available for use until October 1 of each year.

Therefore, because the LTCH PPS and the IPPS use the same GROUPER software, the LTCH PPS will be directly affected by the statutory mandates directed at the IPPS as amended by section 503(a) of the MMA. (We note that there is no statutory requirement in the LTCH PPS to make additional payments for new technology.) The practical effect of this provision is that the GROUPER software must accept new ICD–9–CM codes reflecting the incorporation of new technologies into inpatient treatment at an acute care hospital prior to the scheduled annual update of the GROUPER software. Despite the fact that there are no provisions for additional payments for new technology under the LTCH PPS as there are under the IPPS, statutory compliance requires an alteration of the GROUPER software used under the IPPS, and since the LTCH PPS uses the same GROUPER software that is used under the IPPS, this consequently means that the GROUPER software used under the LTCH PPS would change.''

While DRG assignments would not change from October 1 through September 30, it is possible that there could be additional new ICD–9–CM diagnosis and procedure codes during that time, which would be assigned to predecessor DRGs. For both the IPPS and LTCH coders, it is possible that there will be ICD–9–CM codes in effect from October 1 through March 31, with additional ICD–9–CM codes in effect from April 1 through September 30. Presently, as there were no coding changes suggested for an April 1, 2006 update, the ICD–9–CM coding set implemented on October 1, 2005, will continue through September 30, 2006 (FY 2006).

Of particular note to LTCHs are the invalid diagnosis codes (Table 6C) and the invalid procedure codes (Table 6D) located in the annual proposed and final rules for the IPPS. Claims with invalid codes are not processed by the Medicare claims processing system.

3. Coding Rules and Use of ICD–9–CM Codes in LTCHs

We emphasize the need for proper coding by LTCHs. Inappropriate coding of cases can adversely affect the uniformity of cases in each LTC–DRG and produce inappropriate weighting factors at recalibration. We continue to urge LTCHs to focus on improved coding practices. Because of concerns raised by LTCHs concerning correct coding, we have asked the AHA to provide additional clarification or instruction on proper coding in the LTCH setting. The AHA will provide this instruction via their established process of addressing questions through their publication ''Coding Clinic for ICD–9–CM.'' Written questions or requests for clarification may be addressed to the Central Office on ICD–9–CM, American Hospital Association, One North Franklin, Chicago, IL 60606. A form for question(s) is available for download and can be mailed on AHA's Web site at: *www.ahacentraloffice.org.* In addition, current coding guidelines are available at the NCHS Web site: *http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/ftpicd9.htm#conv.*

In conjunction with the cooperating parties (AHA, the American Health Information Management Association (AHIMA), and NCHS), we reviewed actual medical records and are concerned about the quality of the documentation under the LTCH PPS, as was the case at the beginning of the IPPS. We fully believe that, with experience, the quality of the documentation and coding will improve, as it did for the IPPS. The cooperating parties have plans to assist their members with improvement in documentation and coding issues for the LTCHs through specific questions and coding guidelines. The importance of good documentation is emphasized in the revised ICD–9–CM Official Guidelines for Coding and Reporting: ''A joint effort between the attending physician and coder is essential to achieve complete and accurate documentation, code assignment, and reporting of diagnoses and procedures. The importance of consistent, complete documentation in the medical record cannot be overemphasized. Without this documentation, the application of all coding guidelines is a difficult, if not impossible, task.'' (Coding Clinic for ICD–9–CM, Fourth Quarter 2002, page 115)

To improve medical record documentation, LTCHs should be aware that if the patient is being admitted for continuation of treatment of an acute or chronic condition, guidelines at Section I.B.10 of the Coding Clinic for ICD–9–CM, Fourth Quarter 2002 (page 129) are applicable concerning selection of principal diagnosis. To clarify coding advice issued in the August 30, 2002 final rule (67 FR 55979), at Guideline I.B.12, Late Effects, we state that a late effect is considered to be the residual effect (condition produced) after the acute phase of an illness or injury has terminated (Coding Clinic for ICD–9–CM, Fourth Quarter 2002, page 129). Regarding whether a LTCH should report the ICD–9–CM code(s) for an unresolved acute condition instead of the code(s) for late effect of rehabilitation, we emphasize that each case must be evaluated on its unique circumstances and coded appropriately. Depending on the documentation in the medical record, either a code reflecting the acute condition or rehabilitation could be appropriate in a LTCH.

Since implementation of the LTCH PPS, our Medicare FIs have conducted training and provided assistance to LTCHs in correct coding. We have also issued manuals containing procedures as well as coding instructions to LTCHs and FIs. We will continue to conduct training and provide guidance on an as-needed basis. We also refer readers to the detailed discussion on correct coding practices in the August 30, 2002 LTCH PPS final rule (67 FR 55981 through 55983). Additional coding instructions and examples will be published in Coding Clinic for ICD–9–CM.

F. Method for Updating the LTC–DRG Relative Weights

As discussed in the August 30, 2002 LTCH PPS final rule that implemented the LTCH PPS, under the LTCH PPS, each LTCH will receive a payment that represents an appropriate amount for the efficient delivery of care to Medicare patients (67 FR 55984). The system must be able to account adequately for each LTCH's case-mix in order to ensure both a fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is more costly. Therefore, in § 412.523(c), we adjust the standard Federal PPS rate by the LTC–DRG relative weights in determining payment to LTCHs for each case.

Under this payment system, relative weights for each LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups as described in § 412.515. To ensure that Medicare patients who are classified to each LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each LTC–DRG that represents the resources needed by an average inpatient LTCH case in that LTC–DRG. For example, cases in a LTC–DRG with a relative weight of 2 will, on average, cost twice as much as cases in a LTC–DRG with a weight of 1.

As we discussed in the FY 2006 IPPS final rule, the LTC–DRG relative weights effective under the LTCH PPS for Federal FY 2006 were calculated using the March 2005 update of FY 2004 MedPAR data and Version 23.0 of the GROUPER software (70 FR 47325). We use total days and total charges in the calculation of the LTC–DRG relative weights.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients and rehabilitation and wound care. Some case types (DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. Distribution of cases with relatively high (or low) charges in specific LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, we use a hospital-specific relative value method to calculate relative weights. We believe this method removes this hospital-specific source of bias in measuring average charges. Specifically, we reduce the impact of the variation in charges across providers on any particular LTC–DRG relative weight by converting each LTCH's charge for a case to a relative value based on that LTCH's average charge. (See the FY 2006 IPPS final rule for further information on the hospital-

specific relative value methodology (70 FR 47328 through 47329).)

In order to account for LTC–DRGs with low volume (that is, with fewer than 25 LTCH cases), we grouped those low volume LTC–DRGs into 1 of 5 categories (quintiles) based on average charges, for the purposes of determining relative weights. For FY 2006 based on the FY 2004 MedPAR data, we identified 171 LTC–DRGs that contained between 1 and 24 cases. This list of low volume LTC–DRGs was then divided into 1 of the 5 low volume quintiles, each containing a minimum of 34 LTC–DRGs (171/5 = 34 with 1 LTC–DRG as a remainder). Each of the low volume LTC–DRGs grouped to a specific quintile received the same relative weight and ALOS using the formula applied to the regular LTC–DRGs (25 or more cases). (See the FY 2006 IPPS final rule for further explanation of the development and composition of each of the 5 low volume quintiles for FY 2006 (70 FR 47329 through 47332).)

After grouping the cases in the appropriate LTC–DRG, we calculated the relative weights by first removing statistical outliers and cases with a LOS of 7 days or less. Next, we adjusted the number of cases remaining in each LTC–DRG for the effect of short-stay outlier cases under § 412.529. The short-stay adjusted discharges and corresponding charges were used to calculate ''relative adjusted weights'' in each LTC–DRG using the hospital-specific relative value method. We also adjusted the LTC–DRG relative weights to account for nonmonotonically increasing relative weights. That is, we made an adjustment if cases classified to the LTC–DRG ''with complications or comorbidities (CCs)'' of a ''with CC''/''without CC'' pair had a lower average charge than the corresponding LTC–DRG ''without CCs'' by assigning the same weight to both LTC–DRGs in the ''with CC''/''without CC'' pair. (See the FY 2006 IPPS final rule for further details on the steps for calculating the LTC–DRG relative weights (70 FR 47336 through 47341).)

In addition, of the 526 LTC–DRGs in the LTCH PPS for FY 2006, based on LTCH cases in the FY 2004 MedPAR files, we identified 196 LTC–DRGs for which there were no LTCH cases in the database. That is, no patients who would have been classified to those DRGs were treated in LTCHs during FY 2004 and, therefore, no charge data were reported for those DRGs. Thus, in the process of determining the relative weights of LTC–DRGs, we were unable to determine weights for these 196 LTC–DRGs using the method described in this section of the preamble. However, since patients with a number of the diagnoses under these LTC–DRGs may be treated at LTCHs beginning in FY 2006, we assigned relative weights to each of the 196 ''no volume'' LTC–DRGs based on clinical similarity and relative costliness to one of the remaining 330 (526 − 196 = 330) LTC–DRGs for which we were able to determine relative weights, based on the FY 2004 claims data. (A list of the current no-volume LTC–DRGs and further explanation of their FY 2006 relative weight assignment can be found in the FY 2006 IPPS final rule (70 FR 47337 through 47341).)

Furthermore, for FY 2006, we established LTC–DRG relative weights of 0.0000 for heart, kidney, liver, lung, and simultaneous pancreas/kidney transplants (LTC–DRGs 103, 302, 480, 495, 512 and 513, respectively) because Medicare will only cover these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. If in the future, however, a LTCH applies for certification as a Medicare-approved transplant center, we believe that the application and approval procedure would allow sufficient time for us to propose appropriate weights for the LTC–DRGs affected. At the present time, we included these 6 transplant LTC–DRGs in the GROUPER software program for administrative purposes. As the LTCH PPS uses the same GROUPER software program for LTCHs as is used under the IPPS, removing these DRGs would be administratively burdensome.

As we noted previously, there were no new ICD–9–CM code requests for an April 1, 2006 update. Therefore, Version 23.0 of the DRG GROUPER software established in the FY 2006 IPPS final rule (70 FR 47284 through 47322) will continue to be effective until October 1, 2006. Moreover, the LTC–DRGs and relative weights for FY 2006 established in that same IPPS final rule (70 FR 47681 through 47689) will continue to be effective until October 1, 2006, (just as they would have been even if there had been any new ICD–9–CM code requests for an April 1, 2006 update). Accordingly, Table 3 in the Addendum to this proposed rule lists the LTC–DRGs and their respective relative weights, geometric mean LOS, and five-sixths of the geometric mean LOS that we will continue to use for the period of July 1, 2006 through September 30, 2006. (This table is the same as table 11 of the Addendum to the FY 2006 IPPS final rule (70 FR 47681 through 47689). The next update to the ICD–9–CM coding system will be presented in the FY 2007 IPPS proposed rule (since there will be no April 1, 2006 updates to the ICD–9–CM coding system). The final update to the ICD–9–CM coding system that would become effective October 1, 2006, and the final DRGs and GROUPER for FY 2007 that would be used for the IPPS and the LTCH PPS, effective October 1, 2006, will be presented in the IPPS FY 2007 proposed and final rule in the **Federal Register**. At that time, we will also present the next annual update to the LTC–DRG relative weights based on the final DRGs and GROUPER software version that will be established for FY 2007.

IV. Proposed Changes to the LTCH PPS Payment Rates for the 2007 LTCH PPS Rate Year

[If you choose to comment on issues in this section, please include the caption ''PROPOSED CHANGES TO LTCH PPS PAYMENT RATES FOR THE 2007 LTCH PPS RATE YEAR'' at the beginning of your comments.]

A. Overview of the Development of the Payment Rates

The LTCH PPS was effective for a LTCH's first cost reporting period beginning on or after October 1, 2002. Effective with that cost reporting period, LTCHs are paid, during a 5-year transition period, on the basis of an increasing proportion of the LTCH PPS Federal rate and a decreasing proportion of a hospital's payment under the reasonable cost-based payment system, unless the hospital makes a one-time election to receive payment based on 100 percent of the Federal rate (see § 412.533). New LTCHs (as defined at § 412.23(e)(4)) are paid based on 100 percent of the Federal rate, with no phase-in transition payments.

The basic methodology for determining LTCH PPS Federal prospective payment rates is set forth in the regulations at § 412.515 through § 412.532. Below we discuss the proposed factors that will be used to update the LTCH PPS standard Federal rate for the 2007 LTCH PPS rate year that would be effective for LTCHs discharges occurring on or after July 1, 2006 through June 30, 2007. When we implemented the LTCH PPS in the August 30, 2002 final rule (67 FR 56029 through 56031), we computed the LTCH PPS standard Federal payment rate for FY 2003 by updating the best available (FY 1998 or FY 1999) Medicare inpatient operating and capital costs per case data, using the excluded hospital market basket.

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs be budget neutral. Therefore, in

calculating the standard Federal rate under § 412.523(d)(2), we set total estimated LTCH PPS payments equal to estimated payments that would have been made under the reasonable cost-based payment methodology had the PPS for LTCHs not been implemented. Section 307(a) of BIPA specified that the increases to the hospital-specific target amounts and cap on the target amounts for LTCHs for FY 2002 provided for by section 307(a)(1) of BIPA shall not be taken into account in the development and implementation of the LTCH PPS.

Furthermore, as specified at § 412.523(d)(1), the standard Federal rate is reduced by an adjustment factor to account for the estimated proportion of outlier payments under the LTCH PPS to total estimated LTCH PPS payments (8 percent). For further details on the development of the FY 2003 standard Federal rate, see the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037), and for subsequent updates to the LTCH PPS Federal rate, refer to the following final rules: RY 2004 LTCH PPS final rule (68 FR 34134 through 34140), RY 2005 LTCH PPS final rule (69 FR 25682 through 25684), and RY 2006 LTCH PPS final rule (70 FR 24179 through 24180).

B. Proposed LTCH PPS Market Basket

Historically, the Medicare program used a market basket to account for price increases of the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. The development of the LTCH PPS standard Federal rate is discussed in further detail in the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56033).

In the August 30, 2002 final rule (67 FR 56016 through 56017 and 56030), which implemented the LTCH PPS, we established the use of the excluded hospital with capital market basket as the LTCH PPS market basket. The excluded hospital market basket was used to update the limits on LTCHs' operating costs for inflation under the former reasonable cost-based (TEFRA) payment system. We explained in that same final rule that we believe that the use of the excluded hospital market basket to update LTCHs' costs for inflation was appropriate because the excluded hospital market basket (with a capital component) measures price increases of the services furnished by excluded hospitals, including LTCHs. Since the costs of LTCHs are included in the excluded hospital market basket, this market basket index, in part, also reflects the costs of LTCHs. However, in order to capture the total costs (operating and capital-related) of LTCHs, we added a capital component to the excluded hospital market basket for use under the LTCH PPS. We refer to this index as the ''Excluded Hospital with Capital'' market basket. Currently, the excluded hospital with capital market basket used to update LTCH PPS payments is based on 1997 Medicare cost report data and includes Medicare participating psychiatric, rehabilitation, long term care, cancer, and childrens hospitals (68 FR 34137). (For further details on the development of the FY 1997-based LTCH PPS market basket, see the RY 2004 LTCH PPS final rule (68 FR 34134 through 34137)).

In the RY 2006 LTCH PPS final rule (70 FR 24179), we noted that based on our research, we did not develop a market basket specific to LTCH services. Presently, we are still unable to create a separate market basket specifically for LTCHs due to the small number of facilities and the limited data that are provided (for instance, approximately 15 percent of LTCHs reported contract labor cost data for 2002). We noted in that same final rule that we would discuss the use of the ''Rehabilitation, Psychiatric and Long-Term Care (RPL) market basket'' under the LTCH PPS, which is currently used under the IRF PPS. The RPL market basket is based on the operating and capital costs of inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs) and LTCHs. Since all IRFs are now paid under the IRF PPS Federal payment rate, nearly all LTCHs are paid 100 percent of the Federal rate under the LTCH PPS, and most IPFs are transitioning to payment based on 100 percent of the Federal per diem payment amount under the IPF PPS (payments will be based on 100 percent of the Federal rate for cost reporting periods beginning on or after January 1, 2008), under broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA to develop the LTCH PPS, we are proposing to adopt the RPL market basket as the appropriate market basket of goods and services under the LTCH PPS for discharges occurring on or after July 1, 2006. The RPL market basket would reflect the operating and capital cost structures for these hospitals. Specifically, beginning in the 2007 LTCH PPS rate year, we are proposing to adopt under the LTCH PPS the RPL market basket based on FY 2002 cost report data as it is the best available data. We choose to use the FY 2002 Medicare cost reports because these are the most recent, relatively complete cost data for IRFs, IPF, and LTCHs serving Medicare beneficiaries.

We propose to exclude childrens, cancer hospitals, and religious nonmedical healthcare institutions (RNHCIs) from the RPL market basket because their payments are based entirely on reasonable costs subject to rate-of-increase limits established under the authority of section 1886(b) of the Act, and implemented in § 413.40. Childrens and cancer hospitals are not reimbursed under a PPS. Also, based on FY 2002 data, the cost structures for childrens and cancer hospitals are noticeably different than the cost structures of the IRFs, IPFs, and LTCHs. The services offered in IRFs, IPFs, and LTCHs are typically more labor-intensive than those offered in cancer and childrens hospitals. Therefore, the compensation cost weights for IRFs, IPFs, and LTCHs are larger than those in cancer and childrens hospitals. In addition, the depreciation cost weights for IRFs, IPFs, and LTCHs are noticeably smaller than those for childrens and cancer hospitals.

Therefore, including the fact that IRFs, IPFs and LTCHs are subject to a PPS while childrens, cancer and RNCHIs continue to receive payment based on reasonable costs, we believe a market basket based on the data of IRFs, IPFs and LTCHs is appropriate to use under the LTCH PPS since it is the best available data that would reflect the cost structures of LTCHs. In the following discussion we provide a background on market baskets and describe the methodologies we propose to use under broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA to develop the LTCH PPS for purposes of determining the operating and capital portions of the FY 2002-based RPL market basket.

1. Overview of the RPL Market Basket

The proposed RPL market basket is a fixed weight, Laspeyres-type price index that is constructed in three steps. First, a base period is selected (in this case, FY 2002) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories based upon type of expenditure. Then the proportion of total operating costs that each category represents is determined. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are price levels derived from publicly

available statistical series that are published on a consistent schedule, preferably at least on a quarterly basis. Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy for a given period. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that time period.

A market basket is described as a fixed-weight index because it quantifies the cost, at another time, to purchase the same mix of goods and services purchased to provide hospital services in a base period. The effects on total expenditures resulting from changes in the quantity or mix of goods and services (intensity) purchased subsequent to the base period are not measured. In this manner, the market basket measures only pure price change. Only when the index is rebased would the quantity and intensity effects be captured in the cost weights. Therefore, we rebase the market basket periodically so that cost weights reflect changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish patient care between base periods.

The terms rebasing and revising, while often used interchangeably, actually denote different activities. Rebasing means moving the base year for the structure of costs of an input price index (for example, shifting the base year cost structure from FY 1997 to FY 2002). Revising means changing data sources, methodology, or price proxies used in the input price index. In this proposed rule, we are proposing to rebase and revise the market basket used to update the LTCH PPS. Specifically, as noted above in this section, for the 2007 LTCH PPS rate year, we are proposing to use the FY 2002-based RPL market basket, which is described in greater detail below in this section.

2. Proposed Methodology for Operating Portion of the RPL Market Basket

The proposed operating portion of the FY 2002-based RPL market basket consists of several major cost categories derived from the FY 2002 Medicare cost reports for IRFs, IPFs, and LTCHs. We choose to use the FY 2002 Medicare cost reports because these are the most recent, relatively complete cost data for IRFs, IPFs, and LTCHs serving Medicare beneficiaries. Generally, if detailed cost data are not available for these Medicare cost reports, we prefer to use the PPS hospital (IPPS) Medicare cost reports to supplement IPF, IRF, and LTCH data because this is a comprehensive source of cost data for hospitals serving Medicare beneficiaries. When the IPPS Medicare cost report data are not available, we choose the best publicly available data source, such as the Bureau of Economic Analysis Input-Output Tables.

We use the IRF, IPF, and LTCH Medicare cost reports to derive these major cost categories for the RPL market basket which include wages, drugs, professional liability insurance (PLI), and a residual ''all other.'' As stated above in this section, we propose to use FY 2002 as the base year because we believe this is the most recent, relatively complete year of Medicare cost report data. Due to insufficient Medicare cost report data for IRFs, IPFs, and LTCHs, we propose to develop cost weights for benefits, contract labor, and blood and blood products using the FY 2002-based IPPS market basket (70 FR 23384), which we explain in more detail later in this section. For example, less than 30 percent of IRF, IPF, and LTCH reported benefit cost data in FY 2002. We noticed an increase in the cost data for these expense categories over the last four years. (we note that in the future, there may be sufficient IRFs, IPFs, and LTCHs cost report data to develop the weights for these expenditure categories.

Since the cost weights for the proposed RPL market basket are based on facility costs, we are proposing to limit our sample to hospitals with a Medicare average LOS within a comparable range of the total facility ALOS. We believe this provides a more accurate reflection of the structure of costs for Medicare treatments. Our goal is to measure cost shares that are reflective of case-mix and practice patterns associated with providing services to Medicare beneficiaries.

We propose to use those cost reports for IRFs and LTCHs whose Medicare ALOS is within 15 percent (that is, 15 percent higher or lower) of the total facility ALOS for the hospital. This is the same edit applied to the FY 1992-based and FY 1997-based excluded hospital with capital market basket. Consistent with the development of the RPL market basket adopted under the IRF PPS in the FY 2006 IRF PPS final rule (70 FR 47909), we propose 15 percent because it includes those LTCHs and IRFs whose Medicare LOS is within approximately 5 days of the facility LOS. We believe this edit provides us with a representative sample of LTCHs and IRFs serving Medicare beneficiaries.

We propose to use a less stringent measure of Medicare LOS for IPFs whose ALOS is within 30 or 50 percent (depending on the total facility ALOS) of the total facility ALOS. This less stringent edit allows us to increase our sample size by over 150 reports and produce a cost weight more consistent with the overall facility. When developing the FY 1997-based excluded hospital with capital market basket, the edit we applied to IPFs was based on the best available data at the time.

The detailed cost categories under the residual (that is, the remaining portion of the market basket after excluding wages and salaries, drugs, and professional liability cost weights) are derived from the FY 2002-based IPPS market basket and the 1997 Benchmark Input-Output (I–O) Tables published by the Bureau of Economic Analysis, U.S. Department of Commerce. The FY 2002-based IPPS market basket was developed using FY 2002 Medicare hospital cost reports with the most recent and detailed cost data (70 FR 47388). The 1997 Benchmark I–O is the most recent, comprehensive source of cost data for all hospitals. The proposed RPL cost weights for benefits, contract labor, and blood and blood products were derived using the FY 2002-based IPPS market basket. For example, the ratio of the benefit cost weight to the wages and salaries cost weight in the FY 2002-based IPPS market basket was applied to the RPL wages and salaries cost weight to derive a benefit cost weight for the RPL market basket. The remaining proposed RPL operating cost categories were derived using the 1997 Benchmark I–O Tables, aged to 2002 using relative price changes. (The methodology we used to age the data involves applying the annual price changes from the price proxies to the appropriate cost categories. We repeat this practice for each year.) Therefore, using this methodology, roughly 59 percent of the proposed RPL market basket is accounted for by wages, drugs, and PLI data from FY 2002 Medicare cost report data for IRFs, LTCHs, and IPFs.

The following is a summary outlining the choice of the proxies we propose to use for the operating portion of the market basket. The price proxies for the capital portion are described in more detail in section IV.B.3. of this preamble. With the exception of the Professional Liability proxy, all the proposed price proxies for the operating portion of the proposed RPL market basket are based on Bureau of Labor

Statistics (BLS) data and are grouped into one of the following BLS categories:

• Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are preferable price proxies for goods that hospitals purchase as inputs in producing their outputs because the PPIs would better reflect the prices faced by hospitals. For example, we propose to use a special PPI for prescription drugs, rather than the Consumer Price Index (CPI) for prescription drugs because hospitals generally purchase drugs directly from the wholesaler. The PPIs that we propose to use measure price change at the final stage of production.

• Consumer Price Indexes (CPIs) measure changes in the prices of final goods and services bought by the typical consumer. Because they may not represent the price faced by a producer, we use CPIs only if an appropriate PPI were not available, or if the expenditures were more similar to those of retail consumers in general rather than purchases at the wholesale level. For example, the CPI for food purchases away from home is used as a proxy for contracted food services.

• Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. Appropriately, they are not affected by shifts in employment mix.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter.

The market baskets are updated quarterly, and therefore, it is important that the underlying price proxies be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, when possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs selected by us to be proposed in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

We note that the proxies are the same as those used for the FY 1997-based excluded hospital with capital market basket, which is currently used under the LTCH PPS, and are the same proxies as those used for the FY 2002-based excluded hospital market basket that is used to update the reasonable cost-based portion of LTCHs' blended transition payments (70 FR 47399 through 47403). Because these proxies meet our criteria of reliability, timeliness, availability, and relevance, we believe they continue to be the best measure of price changes for the cost categories. For further discussion on the FY 1997-based excluded hospital with capital market basket, see the 2004 LTCH PPS rate year final rule (68 FR 34134 through 34136). For further discussion on the FY 2002-based excluded hospital market basket, see the FY 2006 IPPS final rule (70 FR 47400 through 47403).

Table 2 sets forth the complete proposed 2002-based RPL market basket including cost categories, weights, and price proxies. For comparison purposes, the corresponding FY 1997-based excluded hospital with capital market basket, which is currently used under the LTCH PPS, is also listed.

Wages and salaries are 52.895 percent of total costs for the proposed FY 2002-based RPL market basket compared to 47.335 percent for the FY 1997-based excluded hospital with capital market basket. Employee benefits are 12.982 percent for the proposed FY 2002-based RPL market basket compared to 10.244 percent for the FY 1997-based excluded hospital with capital market basket. As a result, compensation costs (wages and salaries plus employee benefits) for the proposed FY 2002-based RPL market basket are 65.877 percent of costs compared to 57.579 percent for the FY 1997-based excluded hospital with capital market basket. Of the 8 percentage-point difference between the compensation shares, approximately three percentage points are due to the proposed new base year (FY 2002 instead of FY 1997), three percentage points are due to revised LOS edit (that is, including only IRFs and LTCHs whose Medicare ALOS is within 15 percent of the total facility ALOS for the hospital and including only IPFs whose Medicare average LOS in within 30 or 50 percent of the total facility ALOS), and the remaining two percentage points are due to the proposed exclusion of other types of IPPS-excluded hospitals (that is, only including IPFs, IRFs, and LTCHs in the market basket and excluding childrens, cancer hospitals and RNCHIs.).

TABLE 2.—PROPOSED FY 2002-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PROXIES WITH FY 1997-BASED EXCLUDED HOSPITAL WITH CAPITAL MARKET BASKET USED FOR COMPARISON

Expense categories	FY 1997-based excluded hospital with capital market basket	Proposed FY 2002-based RPL market basket	Proposed FY 2002 RPL market basket price proxies
Total	100.000	100.000	
Compensation	57.579	65.877	
Wages and Salaries *	47.335	52.895	ECI–Wages and Salaries, Civilian Hospital Workers.
Employee Benefits *	10.244	12.982	ECI–Benefits, Civilian Hospital Workers.
Professional Fees, Non-Medical	4.423	2.892	ECI–Compensation for Professional, Specialty & Technical Workers.

TABLE 2.—PROPOSED FY 2002-BASED RPL MARKET BASKET COST CATEGORIES, WEIGHTS, AND PROXIES WITH FY 1997-BASED EXCLUDED HOSPITAL WITH CAPITAL MARKET BASKET USED FOR COMPARISON—Continued

Expense categories	FY 1997-based excluded hospital with capital market basket	Proposed FY 2002-based RPL market basket	Proposed FY 2002 RPL market basket price proxies
Utilities	1.180	0.656	
Electricity	0.726	0.351	PPI–Commercial Electric Power.
Fuel Oil, Coal, etc.	0.248	0.108	PPI–Refined Petroleum Products.
Water and Sewage	0.206	0.197	CPI–U—Water & Sewage Maintenance
Professional Liability Insurance	0.733	1.161	CMS Professional Liability Premium Index.
All Other Products and Services	27.117	19.265	
All Other Products	17.914	13.323	
Pharmaceuticals	6.318	5.103	PPI Prescription Drugs.
Food: Direct Purchase	1.122	0.873	PPI Processed Foods & Feeds.
Food: Contract Service	1.043	0.620	CPI–U Food Away From Home.
Chemicals	2.133	1.100	PPI Industrial Chemicals.
Blood and Blood Products**	0.748		
Medical Instruments	1.795	1.014	PPI Medical Instruments & Equipment.
Photographic Supplies	0.167	0.096	PPI Photographic Supplies.
Rubber and Plastics	1.366	1.052	PPI Rubber & Plastic Products.
Paper Products	1.110	1.000	PPI Converted Paper & Paperboard Products.
Apparel	0.478	0.207	PPI Apparel.
Machinery and Equipment	0.852	0.297	PPI Machinery & Equipment.
Miscellaneous Products	0.783	1.963	PPI Finished Goods less Food & Energy.
All Other Services	9.203	5.942	
Telephone	0.348	0.240	CPI–U Telephone Services.
Postage	0.702	0.682	CPI–U Postage.
All Other: Labor Intensive	4.453	2.219	ECI–Compensation for Private Service Occupations.
All Other: Non-labor Intensive	3.700	2.800	CPI–U All Items.
Capital-Related Costs	8.968	10.149	
Depreciation	5.586	6.186	
Fixed Assets	3.503	4.250	Boeckh Institutional Construction 23-year useful life.
Movable Equipment	2.083	1.937	WPI Machinery & Equipment 11-year useful life.
Interest Costs	2.682	2.775	
Nonprofit	2.280	2.081	Average yield on domestic municipal bonds (source: Moody's Aaa bonds vintage).
For Profit	0.402	0.694	Average yield on Moody's AAA bonds vintage weighted (23 years).
Other Capital-Related Costs	0.699	1.187	CPI–U Residential Rent.

* Labor-related
** Blood and blood-related products are included in miscellaneous products
Note: Due to rounding, weights may not sum to total.

The following is an explanation of the proposed expense categories from Table 2.

a. Wages and Salaries

For measuring the price growth of wages in the proposed FY 2002-based RPL market basket, we propose to use the ECI for wages and salaries for civilian hospital workers as the proxy for wages in the RPL market basket.

b. Employee Benefits

The proposed FY 2002-based RPL market basket uses the ECI for employee benefits for civilian hospital workers.

c. Nonmedical Professional Fees

The ECI for compensation for professional and technical workers in private industry would be applied to this category since it includes occupations such as management and consulting, legal, accounting, and engineering services.

d. Fuel, Oil, Coal, and Gasoline.

The percentage change in the price of gas fuels as measured by the PPI (Commodity Code #0552) would be applied to this component.

e. Electricity

The percentage change in the price of commercial electric power as measured by the PPI (Commodity Code #0542) would be applied to this component.

f. Water and Sewerage

The percentage change in the price of water and sewage maintenance as measured by the CPI for all urban consumers (CPI Code #CUUR0000SEHG01) would be applied to this component.

g. Professional Liability Insurance (PLI)

The proposed FY 2002-based RPL market basket would use the percentage change in hospital PLI premiums as estimated by the CMS Hospital Professional Liability Index for the proxy of this category. In the FY 1997-based excluded hospital with capital market basket, the same proxy was used. We continue to research options for improving our proxy for PLI. This research includes exploring various options for expanding our current survey, including the identification of another entity that would be willing to work with us to collect more complete and comprehensive data. We are also exploring other options such as third party or industry data that might assist us in creating a more precise measure of PLI premiums. At this time we have not identified a preferred option, therefore no change is proposed for the proxy in this proposed rule.

h. Pharmaceuticals

The percentage change in the price of prescription drugs as measured by the PPI (PPI Code #PPI32541DRX) would be used as a proxy for this cost category.

This is a special index produced by BLS as a proxy in the 1997-based excluded hospital with capital market basket.

i. Food: Direct Purchases

The percentage change in the price of processed foods and feeds as measured by the PPI (Commodity Code #02) would be applied to this component.

j. Food: Contract Service

The percentage change in the price of food purchased away from home as measured by the CPI for all urban consumers (CPI Code #CUUR0000SEFV) would be applied to this component.

k. Chemicals

The percentage change in the price of industrial chemical products as measured by the PPI (Commodity Code #061) would be applied to this component. While the chemicals hospitals purchase include industrial as well as other types of chemicals, the industrial chemicals component constitutes the largest proportion by far. Thus we believe that Commodity Code #061 is the appropriate proxy.

l. Medical Instruments

The percentage change in the price of medical and surgical instruments as measured by the PPI (Commodity Code #1562) would be applied to this component.

m. Photographic Supplies

The percentage change in the price of photographic supplies as measured by the PPI (Commodity Code #1542) would be applied to this component.

n. Rubber and Plastics

The percentage change in the price of rubber and plastic products as measured by the PPI (Commodity Code #07) would be applied to this component.

o. Paper Products

The percentage change in the price of converted paper and paperboard products as measured by the PPI (Commodity Code #0915) would be used.

p. Apparel

The percentage change in the price of apparel as measured by the PPI (Commodity Code #381) would be applied to this component.

q. Machinery and Equipment

The percentage change in the price of machinery and equipment as measured by the PPI (Commodity Code #11) would be applied to this component.

r. Miscellaneous Products

The percentage change in the price of all finished goods less food and energy as measured by the PPI (Commodity Code #SOP3500) would be applied to this component. Using this index would remove the double-counting of food and energy prices, which are captured elsewhere in the market basket. The weight for this cost category is higher, in part, than in the 1997-based index because the weight for blood and blood products (1.188) is added to it. In the 1997-based excluded hospital with capital market basket we included a separate cost category for blood and blood products, using the BLS PPI for blood and derivatives as a price proxy. A review of recent trends in the PPI for blood and derivatives suggests that its movements may not be consistent with the trends in blood costs faced by hospitals. While this proxy did not match exactly with the product hospitals are buying, its trend over time appears to be reflective of the historical price changes of blood purchased by hospitals. However, an apparent divergence between the BLS PPI for blood and derivatives and trends in blood costs faced by hospitals over recent years led us to reevaluate whether the PPI for blood and derivatives was an appropriate measure of the changing price of blood. As discussed in both the FY 2006 IPPS and IRF PPS proposed rules, we ran test market baskets classifying blood into three separate cost categories: Blood and blood products; contained within chemicals as was done for the 1992-based excluded hospital with capital market basket; and, within miscellaneous products. These categories use as proxies the following PPIs: the PPI for blood and blood products, the PPI for chemicals, and the PPI for finished goods less food and energy, respectively. Of these three proxies, the PPI for finished goods less food and energy moved most like the recent blood cost and price trends. In addition, the impact on the overall market basket by using different proxies for blood was negligible, mostly due to the relatively small weight for blood in the market basket.

Therefore, we are proposing to use the PPI for finished goods less food and energy for the blood proxy because we believe it more appropriately proxies price changes (not quantities or required tests) associated with blood purchased by hospitals because it moved most like the recent blood cost and price trends. (We note that we would continue to evaluate this proxy for its appropriateness and, if adopted, would explore the development of alternative price indexes to proxy the price changes associated with this cost for presentation in a future proposed rule.)

s. Telephone

The percentage change in the price of telephone services as measured by the CPI for all urban consumers (CPI Code #CUUR0000SEED) would be applied to this component.

t. Postage

The percentage change in the price of postage as measured by the CPI for all urban consumers (CPI Code #CUUR0000SEEC01) would be applied to this component.

u. All Other Services, Labor Intensive

The percentage change in the ECI for compensation paid to service workers employed in private industry would be applied to this component.

v. All Other Services, Nonlabor Intensive

The percentage change in the all items component of the CPI for all urban consumers (CPI Code # CUUR0000SA0) would be applied to this component.

3. Proposed Methodology for Capital Portion of the RPL Market Basket

Unlike for the operating costs of the proposed FY 2002-based RPL market basket, we did not have IRF, IPF, and LTCH FY 2002 Medicare cost report data for the capital cost weights, due to a change in the FY 2002 reporting requirements. Rather, we propose to use these hospitals' expenditure data for the capital cost categories of depreciation, interest, and other capital expenses for FY 2001, and age the data to a FY 2002 base year using relevant price proxies. We believe this is the best approach since these data are the capital cost structures of those IRFs, IPFs and LTCHs serving Medicare beneficiaries that require inpatient hospital services.

We calculated weights for the proposed RPL market basket capital costs using the same set of Medicare cost reports used to develop the operating share for IRFs, IPFS, and LTCHs in order to use consistent expense data in developing the proposed weights for both operating and capital costs. The resulting proposed capital weight for the FY 2002 base year is 10.149 percent. This is based on FY 2001 Medicare cost report data for IRFs, IPFs, and LTCHs, aged to FY 2002 using relevant price proxies.

Lease expenses are not a separate cost category in the proposed market basket, but are distributed among the cost categories of depreciation, interest, and

other, reflecting the assumption that the underlying cost structure of leases is similar to capital costs in general. We assumed 10 percent of lease expenses are overhead and assigned them to the other capital expenses cost category as overhead. We base this assignment of 10 percent of lease expenses to overhead on the common assumption that overhead is 10 percent of costs. The remaining lease expenses were distributed to the three cost categories based on the weights of depreciation, interest, and other capital expenses not including lease expenses.

Depreciation contains two subcategories: building and fixed equipment, and movable equipment. The proposed split between building and fixed equipment and movable equipment was determined using the FY 2001 Medicare cost reports for IRFs, IPFs, and LTCHs. We believe this is the best available data source because it reflects the capital cost structures of those IRFs, IPFs and LTCHs serving Medicare beneficiaries. This methodology was also used to compute the 1997-based index (67 FR 50044).

The proposed total interest expense cost category is split between the government/nonprofit and for-profit hospitals. The 1997-based excluded hospital with capital market basket allocated 85 percent of the total interest cost weight to the government nonprofit interest, proxied by average yield on domestic municipal bonds, and 15 percent to for-profit interest, proxied by average yield on Moody's Aaa bonds.

We propose to derive the split using the relative FY 2001 Medicare cost report data for PPS hospitals on interest expenses for the government/nonprofit and for-profit hospitals. Due to insufficient Medicare cost report data for IPFs, IRFs, and LTCHs, we propose to use the same split used in the IPPS capital input price index, which is 75 percent of the total interest cost weight of the government/non-profit interest and 25 percent of for-profit interest. We believe that this split reflects the latest relative cost structure of interest expenses for hospitals because it is based on the most recent complete hospital cost report data and, therefore, we propose to use a 75–25 split to allocate interest expenses to government/nonprofit and for-profit hospitals' interest (70 FR 47408).

Since capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The vintage-weighted capital index is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the purchase patterns of building and fixed equipment and movable equipment over time. Depreciation and interest expenses are determined by the amount of past and current capital purchases. Therefore we are proposing to use the vintage weights to compute vintage-weighted price changes associated with depreciation and interest expense.

Vintage weights are an integral part of the proposed FY 2002-based RPL market basket. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on factors such as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. The capital portion of the proposed FY 2002-based RPL market basket would reflect the annual price changes associated with capital costs, and would be a useful simplification of the actual capital investment process. By accounting for the vintage nature of capital, we are able to provide an accurate, stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes. Therefore, they do not reflect the actual annual price changes for Medicare capital-related costs. The capital component of the proposed FY 2002-based RPL market basket would reflect the underlying stability of the capital acquisition process and provide hospitals with the ability to plan for changes in capital payments.

To calculate the vintage weights for depreciation and interest expenses, we needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides the best time series of capital purchases by hospitals for all of the above components of capital purchases. The early Medicare Cost Reports were not sufficiently completed to have capital data to meet this need. While the AHA Panel Survey provided a consistent database back to 1963, it did not provide annual capital purchases. However, the AHA Panel Survey provided a time series of depreciation expenses through 1997 which could be used to infer capital purchases over time. From 1998 to 2001, hospital depreciation expenses were calculated by multiplying the AHA Annual Survey total hospital expenses by the ratio of depreciation to total hospital expenses from the Medicare cost reports. Beginning in 2001, the AHA Annual Survey began collecting depreciation expenses. We note that we hope to be able to propose to use these data in proposed rebasings that would be presented in future proposed rules.

In order to estimate capital purchases from AHA data on depreciation and interest expenses, the expected life for each cost category (building and fixed equipment, movable equipment, and debt instruments) is needed. Due to insufficient Medicare cost report data for IPFs, IRFs, and LTCHs, we propose to use FY 2001 Medicare Cost Reports for IPPS hospitals to determine the expected life of building and fixed equipment and movable equipment. We believe this data source reflects the latest relative cost structure of depreciation expenses for all hospital types, including IPFs, IRFs, and LTCHs, and is the best available data at this time. The expected life of any piece of equipment can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated useful life of an asset if depreciation were to continue at current year levels, assuming straight-line depreciation. From the FY 2001 Medicare cost reports for IPPS hospitals the expected life of building and fixed equipment was determined to be 23 years, and the expected life of movable equipment was determined to be 11 years.

We also propose to use the fixed and movable weights derived from FY 2001 Medicare cost reports for IPFs, IRFs, and LTCHs to separate the depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation because this is the best available data source. By multiplying the annual depreciation amounts by the expected life calculations from the FY 2001 Medicare cost reports, year-end asset costs for building and fixed equipment and movable equipment were determined. Then, we calculated a time series back to 1963 of annual capital purchases by subtracting the previous year asset costs from the current year asset costs. From this capital purchase time series we are able to calculate the vintage weights for building and fixed equipment, movable equipment, and debt instruments. An explanation of each of these sets of vintage weights follows.

For proposed building and fixed equipment vintage weights, the real annual capital purchase amounts for building and fixed equipment derived from the AHA Panel Survey were used. The real annual purchase amount was used to capture the actual amount of the physical acquisition, net of the effect of price inflation. This real annual

purchase amount for building and fixed equipment was produced by deflating the nominal annual purchase amount by the building and fixed equipment price proxy, the Boeckh Institutional Construction Index. This is the same proxy used for the FY 1997-based excluded hospital with capital market basket. We believe this proxy continues to meet our criteria of reliability, timeliness, availability, and relevance. Since building and fixed equipment has an expected life of 23 years, the vintage weights for building and fixed equipment are deemed to represent the average purchase pattern of building and fixed equipment over 23-year periods. With real building and fixed equipment purchase estimates back to 1963, 16 23-year periods could be averaged to determine the average vintage weights for building and fixed equipment that are representative of average building and fixed equipment purchase patterns over time. Vintage weights for each 23-year period are calculated by dividing the real building and fixed capital purchase amount in any given year by the total amount of purchases in the 23-year period. This calculation is done for each year in the 23-year period, and for each of the 16 23-year periods. The average of each year across the 16 23-year periods is used to determine the 2002 average building and fixed equipment vintage weights.

For proposed movable equipment vintage weights, the real annual capital purchase amounts for movable equipment derived from the AHA Panel Survey were used to capture the actual amount of the physical acquisition, net of price inflation. This real annual purchase amount for movable equipment is calculated by deflating the nominal annual purchase amount by the movable equipment price proxy, the PPI for Machinery and Equipment. This is the same proxy used for the FY 1997-based excluded hospital with capital market basket. We believe this proxy, which meets our criteria, is the best measure of price changes for this cost category. Since movable equipment has an expected life of 11 years, the vintage weights for movable equipment are deemed to represent the average purchase pattern of movable equipment over an 11-year period. With real movable equipment purchase estimates available back to 1963, 28 11-year periods could be averaged to determine the average vintage weights for movable equipment that are representative of average movable equipment purchase patterns over time. Vintage weights for each 11-year period are calculated by dividing the real movable capital purchase amount for any given year by the total amount of purchases in the 11-year period. This calculation is done for each year in the 11-year period, and for each of the 28 11-year periods. The average of the 28 11-year periods is used to determine the proposed FY 2002 average movable equipment vintage weights.

For proposed interest vintage weights, the nominal annual capital purchase amounts for total equipment (building and fixed and movable) derived from the AHA Panel and Annual Surveys were used. Nominal annual purchase amounts were used to capture the value of the debt instrument. Since hospital debt instruments have an expected life of 23 years, the vintage weights for interest are deemed to represent the average purchase pattern of total equipment over 23-year periods. With nominal total equipment purchase estimates available back to 1963, 16 23-year periods could be averaged to determine the average vintage weights for interest that are representative of average capital purchase patterns over time. Vintage weights for each 23-year period are calculated by dividing the nominal total capital purchase amount for any given year by the total amount of purchases in the 23-year period. This calculation is done for each year in the 23-year period and for each of the 16 23-year periods. The average of the 16 23-year periods is used to determine the proposed FY 2002 average interest vintage weights. The proposed vintage weights for the index are presented in Table 3.

In addition to the proposed price proxies for depreciation and interest costs described above in the vintage weighted capital section, we propose to use the CPI–U for Residential Rent as a price proxy for other capital-related costs. Other capital-related costs are mainly composed of taxes and insurance. There is no price proxy for these specific costs; however, we believe the price changes associated with these costs would be reflected in the price changes of residential rent because rent is assumed to move with taxes and insurance on order to maintain profit margins. The price proxies for each of the capital cost categories are the same as those used for the IPPS final rule (67 FR 50044) capital input price index.

TABLE 3.—PROPOSED CMS FY 2002-BASED RPL MARKET BASKET CAPITAL VINTAGE WEIGHTS

Year	Fixed assets (23 year weights)	Movable assets (11 year weights)	Interest: capital-related (23 year weights)
1	.021	.065	.010
2	.022	.071	.012
3	.025	.077	.014
4	.027	.082	.016
5	.029	.086	.019
6	.031	.091	.023
7	.033	.095	.026
8	.035	.100	.029
9	.038	.106	.033
10	.040	.112	.036
11	.042	.117	.039
12	.045	.....	.043
13	.047	.....	.048
14	.049	.....	.053
15	.051	.....	.056
16	.053	.....	.059
17	.056	.....	.062
18	.057	.....	.064
19	.058	.....	.066
20	.060	.....	.070
21	.060	.....	.071

TABLE 3.—PROPOSED CMS FY 2002-BASED RPL MARKET BASKET CAPITAL VINTAGE WEIGHTS—Continued

Year	Fixed assets (23 year weights)	Movable assets (11 year weights)	Interest: capital-related (23 year weights)
22	.061	.....	.074
23	.061	.....	.076
Total	1.000	1.000	1.000

4. Proposed Market Basket Estimate for the 2007 LTCH PPS Rate Year

As discussed previously in this proposed rule, beginning in the 2007 LTCH PPS rate year, we are proposing to adopt the FY 2002-based RPL market basket as the appropriate market basket of goods and services under the LTCH PPS. We are proposing a zero percent update to the LTCH PPS Federal rate for the 2007 LTCH PPS rate year rather than proposing an update based solely on the most recent estimate of the proposed LTCH PPS market basket as we have done in the past. However, as we discuss in section IV.D.1.c. of this preamble, we are proposing to revise the LTCH PPS labor-related share based on the proposed RPL market basket. In Table 4, we are presenting a comparison of the most recent estimates of the increase to the current LTCH PPS market basket (that is, the FY 1997-based excluded hospital with capital market basket) and the proposed FY 2002-based RPL market basket.

Based on Global Insight's 3rd quarter 2005 forecast with history through the 2nd quarter of 2005, the most recent estimate of the RPL market basket for July 1, 2006 through June 30, 2007 (the 2007 LTCH PPS rate year) is 3.6 percent. Global Insight, Inc. is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. Using the current FY 1997-based excluded hospital with capital market basket, Global Insight's 3rd quarter 2005 forecast, with history through the 2nd quarter of 2005, for the 2007 LTCH PPS rate year would also be 3.6 percent. Table 4 compares the proposed FY 2002-based RPL market basket and the FY 1997-based excluded hospital with capital market basket percent changes. For both the historical and forecasted periods between FY 2000 and FY 2008, the difference between the two market baskets is minor with the exception of FY 2002, where the proposed FY 2002-based RPL market basket increased 3/10 of a percentage point higher than the FY 1997-based excluded hospital with capital market basket. This is primarily due to the proposed FY 2002-based RPL having a larger compensation (this is, the sum of wages and salaries and benefits) cost weight than the FY 1997-based index and the price changes associated with compensation costs increasing much faster than the prices of other market basket components. Also contributing is the ''all other nonlabor intensive'' cost weight, which is smaller in the proposed FY 2002-based RPL market basket than in the FY 1997-based index, as well as the slower price changes associated with these costs.

TABLE 4.—PROPOSED FY 2002-BASED RPL MARKET BASKET AND FY 1997-BASED EXCLUDED HOSPITAL WITH CAPITAL MARKET BASKET, PERCENT CHANGES: 2000–2008

Fiscal year (FY)	Proposed rebased FY 2002-based RPL market basket	FY 1997-based excluded hospital market basket with capital
Historical data:		
RY 2001	3.8	3.9
RY 2002	4.1	3.8
RY 2003	3.8	3.7
RY 2004	3.6	3.6
RY 2005	3.8	3.9
Average RY 2001–2005	3.8	3.8
Forecast:		
RY 2006	3.7	3.8
RY 2007	3.6	3.6
RY 2008	3.5	3.5
RY 2009	3.3	3.1
Average RY 2006–2009	3.5	3.5

Source: Global Insight, Inc. 3rd Qtr 2005, @USMACRO/CNTL0905 @CISSIM/TL0805.SIM.

C. Proposed Standard Federal Rate for the 2007 LTCH PPS Rate Year

1. Background

Under the existing regulations at § 412.523(c)(3)(ii), we update the standard Federal rate annually to adjust for the most recent estimate of the projected increases in prices for LTCH inpatient hospital services. We established this regulation in the August 30, 2002 final rule (67 FR 56030), which implemented the LTCH PPS, because at that time we believed that was the most appropriate method for updating the LTCH PPS Standard Federal rate annually for years after FY 2003. When we moved the date of the annual update of the LTCH PPS from October 1 to July 1 in the RY 2004 LTCH PPS final rule (68 FR 34138), we revised § 412.523(c)(3) to specify that for LTCH PPS rate years beginning on or after July 1, 2003, the annual update to the standard Federal rate for the LTCH prospective payment system would be equal previous rate year's Federal rate updated by the most recent estimate of increases in the appropriate market basket of goods and services included in

covered inpatient LTCH services because, at that time, we continued to believe that was the most appropriate method for updating the LTCH PPS Standard Federal rate annually for years after RY 2004. As established in the RY 2006 LTCH PPS final rule (70 FR 24179), based on the most recent estimate of the excluded hospital with capital market basket, adjusted to account for the change in the LTCH PPS rate year update cycle, the current LTCH PPS standard Federal rate which is effective from July 1, 2005 through June 30, 2006 (the 2006 LTCH PPS rate year) is $38,086.04 (70 FR 24179). In the discussion that follows, we explain how we developed the proposed standard Federal rate for the 2007 LTCH PPS rate year. Specifically, we explain our rationale, which is based on our ongoing monitoring activities, for proposing a zero percent update to the standard Federal rate for the 2007 LTCH PPS rate year rather than proposing to solely use the most recent estimate of the proposed RPL market basket as the update factor for the Federal rate for the upcoming rate year. Thus, the proposed standard Federal rate for the 2007 LTCH PPS rate year would be $38,086.04.

2. Description of a Preliminary Model of an Update Framework Under the LTCH PPS

In the August 30, 2002 final rule (67 FR 56087), which implemented the LTCH PPS, we stated that in the future we may propose to develop a framework to update payments to LTCHs that would account for other appropriate factors that affect the efficient delivery of services and care provided to Medicare patients. A conceptual basis for the proposal of developing an update framework in the future was presented in Appendix B of that same final rule (67 FR 56086). In subsequent final rules that updated the LTCH PPS standard Federal rate for years after FY 2003, we explained that we did not propose an update framework because we had not yet collected sufficient data to allow for the analysis and development of a framework under the LTCH PPS (see 68 FR 34134, 69 FR 25682, and 70 FR 24179). Since the LTCH PPS was implemented just slightly over 3 years ago (for cost reporting periods beginning on or after October 1, 2002) and due to the time lag in the availability of Medicare data, we continue to believe that we still do not yet have sufficient data to develop an update framework upon which to base the proposed update to the standard Federal rate for the 2007 LTCH PPS rate year.

Although we do not have enough complete data at this time to propose an update for RY 2007 based on an update framework, we believe that the almost 2 full years of data generated under the LTCH PPS is sufficient data to begin the discussion of the development of a potential update framework that we may propose to use in the future under the LTCH PPS for the annual update to the LTCH standard Federal rate. Therefore, although we are not proposing to employ an analytical update framework in this proposed rule to determine the proposed 2007 LTCH PPS rate year update to the standard Federal rate, in Appendix A of this proposed rule, we are presenting a preliminary model of an update framework, using the best available data and concepts, which we may propose to adopt at some time in the future.

We are soliciting comments on this preliminary update framework methodology and its application that may be proposed in the future. Also, we would appreciate comments regarding recommendations to improve it. We note that this preliminary model of an update framework for the LTCH PPS is based on the conceptual discussion of a LTCH PPS update framework that was presented in the August 30, 2002 final rule (67 FR 56086), and is similar to the update framework formerly used to develop the operating IPPS annual update recommendation (69 FR 28816 through 28817) and that which is currently used under the capital IPPS for inpatient short-term acute-care hospitals set forth at § 412.308(c)(1)(ii).

3. Proposed Update to the Standard Federal Rate for the 2007 LTCH PPS Rate Year

Currently, under § 412.523, the annual update to the LTCH PPS standard Federal rate is equal to the most recent estimate of increases in the prices of an appropriate market basket of goods and services included in covered inpatient LTCH services (that is, presently, the excluded hospital with capital market basket). As we indicated in previous LTCH PPS final rules (67 FR 56014, 68 FR 34157, 69 FR 25712, and 70 FR 24209 through 24213), we have developed a monitoring system to assist us in evaluating the LTCH PPS. We have used the results of these monitoring efforts, along with the most recently available LTCH PPS data to assess current payment adequacy under the LTCH PPS. As we discuss in greater detail, because we believe that current payments are more than adequate to account for price increases in the services furnished by LTCHs during the 2007 LTCH PPS rate year, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA to include appropriate adjustments in the establishment of the LTCH PPS, we are proposing to revise § 412.523(c)(3)(ii), to specify that, for discharges occurring on or after July 1, 2006 and on or before June 30, 2007, the standard Federal rate from the previous year would be updated by a factor of zero percent. That is, the standard Federal rate for the July 1, 2006 through June 30, 2007 rate year would remain the same as the standard Federal rate in effect during the 2006 rate year (July 1, 2005 through June 30, 2006), that is, $38,086.04.

In the August 30, 2002 final rule (67 FR 56014), we describe an on-going monitoring component of the new LTCH PPS that would enable us to evaluate the impact of the new payment policies. We stated that if our data indicate that changes to the system might be warranted, we may consider proposing revisions to these policies in the future. Since the implementation of the LTCH PPS (for cost reporting periods beginning on or after October 1, 2002), there has been tremendous growth in the number of LTCHs reimbursed by Medicare. Specifically, the number of LTCHs has almost doubled over the past 3 years from approximately 200 LTCHs in FY 2003 to 378 LTCHs at the start of FY 2005. In addition, Medicare spending for LTCHs has also grown rapidly, as noted in MedPAC's June 2004 Report to Congress (page 122). Rapid increases in LTCH growth and Medicare spending under the LTCH PPS, in conjunction with the fact that over 98 percent of LTCHs are currently paid based fully on the Federal rate (rather than choosing to be paid under a blend of the reasonable cost-based (TEFRA) payment amount and the LTCH PPS Federal rate payment amount), prompted us to examine changes in LTCHs' patient case-mix index (CMI) and margins under the LTCH PPS. Margins are defined as payment-to-cost ratios of LTCH inpatient Medicare payments to LTCH inpatient Medicare costs. We believe the proposed zero percent update factor for RY 2007 is supported by our findings regarding CMI, Medicare margins, and patient census based on the most recent complete LTCH data. The following is a discussion of our analysis of each of these factors.

A LTCH's CMI is defined as its case weighted average LTC–DRG relative weight for all its discharges in a given period. Changes in CMI consist of two components: ''real'' CMI changes and ''apparent'' CMI changes. Real CMI increase is defined as the increase in the average LTC–DRG relative weights resulting from the hospital's treatment

of more resource intensive patients. Apparent CMI increase is defined as the increase in CMI due to changes in coding practices. Observed CMI increase is defined as real CMI increase plus the increase in computed CMI due to changes in coding practices (including better documentation of the medical record by physicians and more complete coding of the medical record by coders). If LTCH patients have more costly impairments, lower functional status, or increased comorbidities, and thus require more resources in the LTCH, we would consider this a real change in case-mix. Conversely, if LTCH patients have the same impairments, functional status, and comorbidities but are coded differently, resulting in higher payment, we consider this an apparent change in case-mix. We believe that changes in payment rates should accurately reflect changes in LTCHs' true cost of treating patients (real CMI increase), and should not be influenced by changes in coding practices (apparent CMI increase). Apparent CMI increase results in a case being grouped to a LTC–DRG with a higher weight than it would be without such changes in coding practices, which results in a higher LTCH PPS payment that does not necessarily reflect the true cost of treating the patient. Therefore, under the broad discretionary authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA to include appropriate adjustments in the establishment of the LTCH PPS, we are proposing to revise the annual update to the LTCH PPS standard Federal rate set forth at § 412.523(a)(2) for the 2007 LTCH PPS rate year to adjust the payment amount for LTCH inpatient hospital services to eliminate the effect of coding or classification changes that do not reflect real changes in LTCHs' case-mix. It is important to eliminate the effect of coding or classification changes because, as discussed above in this section, they do not reflect the true cost of treating patients. We believe that the adjustment we are proposing to eliminate the effect of coding or classification changes that do not reflect real changes in LTCHs' case-mix would reduce the amount that RY 2007 LTCH PPS payments would have been absent this adjustment so that payments would become more aligned with the true costs of treating LTCH patients.

As described in our August 30, 2002 final rule, we contracted with 3M Health Information Systems (3M) to analyze LTCH data to support our efforts in developing the original LTCH PPS in 2002. We have continued our contract with 3M to assist CMS in developing potential refinements to the LTCH PPS, including some of the proposed changes presented in this proposed rule. As part of this research, we asked 3M to examine changes in case-mix and coding since the implementation of the LTCH PPS based on the most recently available data. As part of their analysis, 3M compared FY 2003 LTCH claims data from the first year of implementation of the PPS with the FY 2001 claims data (generated prior to the implementation of the LTCH PPS), which is the same LTCH claims data used to develop the LTCH PPS.

The analysis performed by 3M indicates that the observed case-mix in LTCHs increased by 5.6 percent between FY 2001 and FY 2003. The average annual CMI increase from FY 2001 to FY 2003 was 2.75 percent. Since coding of diagnoses was not a factor in determining payments under the former reasonable cost-based (TEFRA) payment system, and since payments were not directly tied to diagnosis codes, there was no incentive for LTCHs to attempt to influence payments through changes in coding practices. Therefore, it is reasonable to assume that the observed 2.75 percent change in case-mix in the years prior to the implementation of the LTCH PPS represent the value for the real CMI increase (that is, we assume that the increase in case-mix is not due to improvements in documentation or more complete coding of the medical record during this period). Using the average annual 2.75 percent observed CMI increase as a baseline, we can separate the CMI increase between FYs 2003 and 2004 into the real CMI increase, which is based on the treatment of more resource intensive patients, and the apparent CMI increase, which is due to improvements in documentation and coding practices.

The calculated observed CMI increase between FYs 2003 and 2004 was 6.75 percent. Assuming that the real CMI increase observed (on average) from FY 2001 to FY 2003 remained relatively constant into FY 2005, then the difference of 4.0 percent (6.75 percent minus 2.75 percent) represents the apparent CMI increase due to improvements in documentation and coding. This is considerably higher than the 0.34 percent behavioral offset originally estimated by CMS actuaries, which was used in the development of the FY 2003 LTCH PPS standard Federal rate (67 FR 56033). We note that the 4.0 percent apparent CMI increase is a conservative estimate when compared to the 5.35 percent apparent CMI increase that would result if we applied the information from past studies on case-mix change. Based on past studies of IPPS case-mix change by the RAND Corporation, (''Has DRG Creep Crept Up? Decomposing the Case-Mix Index Change Between 1987 and 1988'' by G.M. Carter, J.P. Newhouse, and D.A. Relles, R–4098–HCFA/ProPAC (1991)), we have assumed that real case-mix change for IPPS hospitals was a fairly steady 1.0 to 1.4 percent per year. If we apply this same assumption to LTCHs, nearly 5.35 percent (6.75 percent − 1.4 percent) of the change in case-mix during the first year of the LTCH PPS is apparent CMI and not real CMI.

We recognize that the LTCH PPS may have increased incentives for LTCHs to take patients with greater impairment, lower function, or increased comorbidities because the more complicated the patient's principle diagnosis and accompanying comorbidities, the higher the relative weight for the LTC–DRG, and the higher the resulting LTCH PPS payment. Under TEFRA, LTCHs were paid on the basis of Medicare reasonable costs limited by a hospital-specific target amount per discharge, which were based on base-year cost per case. Thus, LTCHs may have greater incentives to admit more costly patients and therefore, we expected to see an increase in the observed CMI due to the implementation of the LTCH PPS. However, we believe a significant portion of the 6.75 percent increase in CMI between FY 2003 and FY 2004 is due to changes in coding practices rather than the treatment of more resource intensive patients. In our analysis of cost per discharge, we found that while payments (revenue) per discharge increased approximately 17 percent from FY 2002 to FY 2003 (the first year of LTCH PPS), costs (expenses) per discharge increased by only 8 percent for the same period. Thus payments to LTCHs from FY 2002 to FY 2003 increased more than 2 times as much as the increase of costs during the same period. We didn't observe a large increase in cost per discharge, which we would have expected to see if the observed CMI was due to ''real'' CMI change (treating sicker patients). We would have expected to see a large increase in costs per discharge if the CMI was due to real CMI change because we expected LTCHs to admit more severely ill patients as described previously which we thought would have required more resources to treat these patients. Furthermore, review by a Medicare program safeguard contractor working with the FI sampled LTCH claims with specific diagnoses in one LTCH and determined that the majority of those patients were not ''hospital-

level'' patients. Rather, the level of care needed by these patients was more suitable for a Skilled Nursing Facility (SNF) than a LTCH. The QIO reviewed a sample of the claims that had been determined not to be hospital-level patients by the Medicare program safeguard contractor and concurred with its assessment of most of those cases. Anecdotally, we have heard of other investigations of LTCHs treating patients that do not require hospital-level care. This finding further supports the data showing that cost per discharge did not increase as rapidly as LTCHs' CMI and that the increase in LTCHs' CMI is primarily due to factors other than real CMI.

In addition, an internal CMS analysis shows high Medicare margins among LTCHs since the implementation of the LTCH PPS in FY 2003. Specifically, we calculated ''revenue-weighted'' Medicare margins, which are the sum of hospital inpatient Medicare revenue (payments) minus the sum of hospital inpatient Medicare expenses (costs) divided by the sum of hospital inpatient Medicare revenue (payments). This margin calculation, also utilized by MedPAC in its analyses, is used to evaluate the overall financial status of LTCHs. In an analysis of the latest available LTCH cost reports, we found that LTCH Medicare payments for FY 2003 (the first year of the LTCH PPS) were 8.8 percent higher than LTCHs' Medicare costs. Preliminary cost report data for FY 2004 reveal an even higher Medicare margin of 11.7 percent. For the period prior to the implementation of the LTCH PPS (that is, FY 1996 through FY 2002), we found that Medicare margins ranged between a minimum of −2.2 percent in FY 2002, and a maximum of 2.9 percent in FY 1997.

We note that MedPAC is presently engaged in an evaluation of payment adequacy for LTCHs, which upon completion, will be published in the Commission's 2006 Reports to the Congress. At the Commission's October 7, 2005 public meeting, the preliminary findings were presented. The report included the following:

- The number of LTCHs increased rapidly since the implementation of the LTCH PPS; the increase in the volume of cases was even greater; and beneficiaries' access to care has also increased;
- Medicare spending has increased more rapidly than volume.
- LTCHs have access to capital and are rapidly expanding into market areas that had no LTCHs prior to the establishment of the LTCH PPS for FY 2003, as well as in areas that already had LTCHs.
- Medicare payments under the LTCH PPS are ''attractive'' since despite the fact that LTCHs could opt to be phased-in to the fully Federal payments over 5 years, with a decreasing percentage of payments based on their former TEFRA payments, since 2004, 93 percent of LTCHs have opted to be paid 100 percent under the Federal rate.
- In evaluating adequacy of payments, it can generally be assumed that if the payments are adequate, the volume of patients will increase. This was true under the LTCH PPS, where cases increased 12 percent per year between 2001 and 2004, while Medicare spending increased 25 percent per year for the same period.
- Medicare LTCH spending increased 28 percent from 2003 to 2004.

(The transcript of the discussion of LTCH payment adequacy from the October 7, 2005 MedPAC public meeting can be found at the following web address: *http://www.medpac.gov/public_meetings/transcripts/1005_allcombined_transc.pdf* (pages 256 through 298).)

Consistent with MedPAC's most recent research, our margins analysis indicates that in spite of the estimated real increase in case-mix (severity of patients), payments to LTCHs under the LTCH PPS are generally more than adequate to cover the Medicare costs of the inpatient hospital services provided to LTCH patients. We believe this is because the large observed increase in LTCH case-mix was not accompanied by a corresponding increase in Medicare costs. This is consistent with our belief expressed earlier that a significant part of this observed increase in case-mix is ''apparent'' and not ''real.'' Therefore, under the broad discretionary authority conferred upon the Secretary in section 123(a) of the BBRA as amended by section 307(b)(1) of the BIPA to make appropriate adjustments, as explained previously, we believe that it is fiscally prudent and appropriate to propose to revise § 412.523(c)(3)(iii) to specify that the standard Federal rate for the LTCH PPS rate year July 1, 2006 through June 30, 2007, would be the standard Federal rate from the previous year be updated by a factor of zero percent. A zero percent update factor would reflect an adjustment to the market basket update to account for the increase in the apparent case-mix in the prior period. Based on our analysis of the observed LTCH case-mix increase, we estimate that 4 percent of the 6.75 percent calculated observed LTCH CMI increase is due to improvements in documentation and coding and not due to an increase in the severity of the patients being treated at LTCHs. As previously noted, the Federal payment rate was offset by 0.34 percent to reflect expected behavioral changes, including changes in coding. The recent estimate of apparent CMI increase (4 percent) indicates that an additional 3.66 percent adjustment (4 percent apparent CMI increase minus 0.34 percent behavioral offset) should be made to the Federal payment rate to account for improvements in coding. Accounting for the most recent estimate of the RPL market basket increase (3.6 percent) and the additional adjustment for improvements in coding (3.66 percent), the resulting update is within rounding error of zero percent. We are proposing a zero percent update for the 2007 LTCH PPS rate year, which would result in a proposed LTCH PPS standard Federal rate of $38,086.04 for the 2007 LTCH PPS rate year. We believe that a zero percent update for the 2007 LTCH PPS rate year is appropriate to protect the integrity of the Medicare Trust Funds by ensuring that the LTCH PPS payment rates better reflect the true costs of treating LTCH patients. Furthermore, based on the sizeable Medicare margins among LTCHs, we believe that the proposed standard Federal rate for the 2007 LTCH PPS rate year would not affect beneficiary access to LTCH services since LTCHs would continue to be paid adequately to reflect the cost of resources needed to treat Medicare beneficiaries.

As discussed in section IV.B.4. of this preamble, the most recent estimate of the proposed LTCH PPS market basket is 3.6 percent for the 2007 LTCH PPS rate year. If we were not proposing to revise § 412.523(c)(3) to provide a zero percent update to the standard Federal rate for the 2007 LTCH PPS rate year to account for changes in coding that do not reflect real changes in the severity and cost of LTCH patients presented in this proposed rule, under existing § 412.523(c)(3)(ii) the proposed update would have been 3.6 percent.

We note that the proposed revision to § 412.525(c)(3) would only address an update to the LTCH PPS Federal rate through the 2007 LTCH PPS rate year. We intend to propose future revisions to § 412.525(c)(3) to address future proposed updates to the LTCH PPS Federal rates in future rate years based on an analysis of the most recent available LTCH data that would be presented in upcoming LTCH proposed rules. As noted previously in this proposed rule and in the August 30, 2002 final rule (67 FR 56097), we are examining the potential for developing and implementing an update framework

under the LTCH PPS. We believe an update framework, used in combination with the market basket, would enhance the methodology for updating payments by addressing factors beyond changes in pure input prices (measured by the market basket) such as case-mix, intensity, and productivity. (As noted in section IV.C.2 of this proposed rule, a preliminary model of an update framework that may be proposed at some later date for future use under the LTCH PPS is presented in Appendix A of this proposed rule.) However, we are not proposing a specific annual update framework until we have collected sufficient complete LTCH PPS data to evaluate payments and costs under the LTCH PPS.

In addition, currently as implemented in § 412.523(d)(3), we have provided for the possibility of making a one-time prospective adjustment to the LTCH PPS rates so that any significant difference from actual payments and the estimated payments for the first year of the LTCH PPS is not perpetuated in the prospective payment rates for future years. As discussed in section IV.D.5. of this proposed rule, we are not proposing an adjustment to the LTCH PPS rates under § 412.523(d)(3) in this proposed rule; however, we intend to continue to collect and interpret new data to determine if an adjustment should be proposed in the future. In addition, as also discussed in section IV.D.5. of this proposed rule, we are proposing to postpone the deadline of the possible one-time prospective adjustment to the LTCH PPS rates provided for in § 412.523(d)(3) to July 1, 2008 in order to maximize the availability of data used to conduct a comprehensive evaluation of the LTCH PPS. However, we note that the proposed zero percent update for the 2007 LTCH PPS rate year may make this one-time prospective adjustment to the LTCH PPS Federal rate unnecessary if our comprehensive analysis of the LTCH PPS determines that LTCH PPS payments and the costs for LTCH services become aligned as a result of this proposed change. We solicit comments on whether the proposed zero percent for the 2007 LTCH PPS rate year is appropriate or if an alternative percentage reduction should be applied to the standard Federal rate for the 2007 LTCH PPS rate year.

4. Proposed Standard Federal Rate for the 2007 LTCH PPS Rate Year

In the RY 2006 LTCH PPS final rule (70 FR 24180), we established a standard Federal rate of $38,086.04 for the 2006 LTCH PPS rate year that was based on the best available data and policies established in that final rule. In this proposed rule, we would revise § 412.523(c)(3) to establish a standard Federal rate based on a zero percent update as discussed in section IV. B. of this proposed rule. Therefore, based on the proposed zero percent update, the proposed standard Federal rate for RY 2007 would be $38,086.04. As we stated in the RY 2006 LTCH PPS final rule, the standard Federal rate of $38,086.04 was already adjusted for differences in case-mix, wages, cost-of-living, and high cost outlier payments. Therefore, we made additional adjustments in the RY 2006 LTCH PPS standard Federal rate for those factors (70 FR 24180). Similarly, since the proposed standard Federal rate for the 2007 LTCH PPS rate year has already been adjusted for differences in case-mix, wages, cost-of-living, and high-cost outlier payments, we would not propose to make any additional adjustments in the proposed standard Federal rate for these factors.

D. Calculation of Proposed LTCH Prospective Payments for the 2007 LTCH PPS Rate Year

The basic methodology for determining prospective payment rates for LTCH inpatient operating and capital-related costs is set forth in § 412.515 through § 412.532. In accordance with § 412.515, we assign appropriate weighting factors to each LTC–DRG to reflect the estimated relative cost of hospital resources used for discharges within that group as compared to discharges classified within other groups. The amount of the prospective payment is based on the standard Federal rate, established under § 412.523, and adjusted for the LTC–DRG relative weights, differences in area wage levels, cost-of-living in Alaska and Hawaii, high-cost outliers, and other special payment provisions (short-stay outliers (SSO) under § 412.529 and interrupted stays under § 412.531).

In accordance with § 412.533, during the 5-year transition period, payment is based on the applicable transition blend percentage of the adjusted Federal rate and the reasonable cost-based payment rate unless the LTCH makes a one-time election to receive payment based on 100 percent of the Federal rate. A LTCH defined as ''new'' under § 412.23(e)(4) is paid based on 100 percent of the Federal rate with no blended transition payments (§ 412.533(d)). As discussed in the August 30, 2002 final rule (67 FR 56038), and in accordance with § 412.533(a), the applicable transition blends are as shown in Table 5.

TABLE 5

Cost reporting periods beginning on or after	Federal rate percentage	Reasonable cost-based payment rate percentage
October 1, 2002	20	80
October 1, 2003	40	60
October 1, 2004	60	40
October 1, 2005	80	20
October 1, 2006	100	0

Accordingly, for cost reporting periods beginning during FY 2005 (that is, on or after October 1, 2004, and on or before September 30, 2005), blended payments under the transition methodology are based on 40 percent of the LTCH's reasonable cost-based payment rate and 60 percent of the adjusted LTCH PPS Federal rate. For cost reporting periods that begin during FY 2006 (that is, on or after October 1, 2005 and on or before September 30, 2006), blended payments under the transition methodology will be based on 20 percent of the LTCH's reasonable cost-based payment rate and 80 percent of the adjusted LTCH PPS Federal rate. For cost reporting periods beginning on or after October 1, 2006 (FY 2007), Medicare payment to LTCHs will be determined entirely (100 percent) under the LTCH PPS Federal rate.

1. Proposed Adjustment for Area Wage Levels

a. Background

Under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS Federal rate to account for differences in LTCH area wage levels at § 412.525(c). The labor-related share of the LTCH PPS Federal rate, currently estimated by the excluded hospital with capital market basket, is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under sections 1886(d)(8) or 1886(d)(10) of the Act. Furthermore, as we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56015), we established a 5-year transition to the full wage adjustment. The applicable wage index phase-in percentages are based on the start of a LTCH's cost reporting period as shown in Table 6.

TABLE 6

Cost reporting periods beginning on or after	Phase-in percentage of the full wage index
October 1, 2002	1/5th (20 percent).
October 1, 2003	2/5ths (40 percent).
October 1, 2004	3/5ths (60 percent).
October 1, 2005	4/5ths (80 percent).
October 1, 2006	5/5ths (100 percent).

For example, for cost reporting periods beginning on or after October 1, 2004 and on or before September 30, 2005 (FY 2005), the applicable LTCH wage index value is three-fifths of the applicable full LTCH PPS wage index value. Similarly, for cost reporting periods beginning on or after October 1, 2005 and on or before September 30, 2006 (FY 2006), the applicable LTCH wage index value will be four-fifths of the applicable full LTCH PPS wage index value. The wage index adjustment will be completely phased-in beginning with cost reporting periods beginning in FY 2007, that is, for cost reporting periods beginning on or after October 1, 2006, the applicable LTCH wage index value will be the full (five-fifths) LTCH PPS wage index value. As we established in the August 30, 2002 LTCH PPS final rule (67 FR 56018), the applicable full LTCH PPS wage index value is calculated from acute-care hospital inpatient wage index data without taking into account geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act.

In that same final rule (67 FR 56018), we stated that we would continue to reevaluate LTCH data as they become available and would propose to adjust the phase-in if subsequent data support a change. As we discussed in the RY 2006 LTCH PPS final rule (70 FR 24181), because the LTCH PPS was only recently implemented (slightly over 2 years) and because of the time lag in availability of cost report data, sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of the appropriateness of adjusting the phase-in. However, for this proposed rule, we have reviewed the most recent data (FY 2002–FY 2004) available and did not find any evidence to support a change in the 5-year phase-in of the wage index. Specifically, our statistical analysis still does not show a significant relationship between LTCHs' costs and their geographic location. Therefore, in this proposed rule, we are not proposing a change in the phase-in of the adjustment for area wage levels under § 412.525(c).

b. Geographic Classifications/Labor Market Area Definitions

As discussed in the August 30, 2002 LTCH PPS final rule, which implemented the LTCH PPS (67 FR 56015 through 56019), in establishing an adjustment for area wage levels under § 412.525(c), the labor-related portion of a LTCH's Federal prospective payment is adjusted by using an appropriate wage index based on the labor market area in which the LTCH is located. In the 2006 LTCH PPS rate year final rule (70 FR 24184 through 24185), in § 412.525(c), we revised the labor market area definitions used under the LTCH PPS effective for discharges occurring on or after July 1, 2005 based on the Office of Management and Budget's (OMB's) Core Based Statistical Area (CBSA) designations based on 2000 Census data because we believe that those new labor market area definitions will ensure that the LTCH PPS wage index adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. As set forth in § 412.525(c)(2), a LTCH's wage index is determined based on the location of the LTCH in an urban or rural area as defined in § 412.64(b)(1)(ii)(A) through (C). An urban area under the LTCH PPS is defined as is defined at § 412.64(b)(1)(ii)(A) and (B). In general, an urban area is defined as a Metropolitan Statistical Area (MSA) as defined by the OMB. (In addition, a few counties located outside of MSAs are considered urban as specified at § 412.64(b)(1)(ii)(B).) Under § 412.64(b)(1)(ii)(C), a rural area is defined as any area outside of an urban area. We note that these are the same CBSA-based designations implemented for acute care inpatient hospitals under the IPPS at § 412.64(b) effective October 1, 2004 (69 FR 49026 through 49034). For further discussion of the labor market area (geographic classification) definitions used under the LTCH PPS, see the 2006 LTCH PPS rate year final rule (70 FR 24182 through 24191).

c. Proposed Labor-Related Share

In the August 30, 2002 LTCH PPS final rule (67 FR 56016), we established a labor-related share of 72.885 percent based on the relative importance of the labor-related share of operating costs (wages and salaries, employee benefits, professional fees, postal services, and all other labor-intensive services) and capital costs of the excluded hospital with capital market basket based on FY 1992 data. In the June 6, 2003 final rule (68 FR 34142), in conjunction with our revision and rebasing of the excluded hospital with capital market basket from a FY 1992 to a FY 1997 base year, we discussed revising the labor-related share based on the relative importance of the labor-related share of operating and capital costs of the excluded hospital with capital market basket based on FY 1997 data. However, in the June 6, 2003 final rule (68 FR 34142), while we adopted the revised and rebased FY 1997-based LTCH PPS market basket as the LTCH PPS update factor for the 2004 LTCH PPS rate year, we decided not to update the labor-related share under the LTCH PPS pending further analysis of the current labor share methodology.

In LTCH PPS final rules subsequent to the FY 2003 LTCH PPS final rule in which we established the current labor-related share (68 FR 34142, 69 FR 25685 through 25686 and 70 FR 24182), we explained that the primary reason that we did not update the LTCH PPS labor-related share for the 2004, 2005 and 2006 LTCH PPS rate years was because of data and methodological concerns, which was the same reason for not updating the labor-related share under the IPPS for FY 2004 (68 FR 45467 through 45468) and FY 2005 (69 FR 49069), which are equally applicable to the LTCH PPS. We indicated that we would conduct further analysis to determine the most appropriate methodology and data for determining the labor-related share. We also stated that we would propose to update the IPPS and excluded hospital labor-related shares, if necessary, once our research is complete.

In the FY 2006 IPPS final rule, the labor-related share under the IPPS that is ''estimated by the Secretary from time to time'' as specified in section 1886(d)(3)(E) of the Act was revised and rebased based on the FY 2002-based IPPS hospital market basket for discharges occurring on or after October 1, 2005 using our established methodology of defining the labor-related share as the national average proportion of operating costs that are attributable to wages and salaries, fringe benefits, professional fees, contract labor, and labor intensive services. Therefore, the IPPS labor-related share ''estimated by the Secretary from time to time'' was calculated by adding the relative weights for these operating cost categories. In that same final rule we stated that we continue to believe, as we stated in the past, that these operating cost categories likely are related to, are influenced by, or vary with the local markets (70 FR 47392 through 47393). (We note that section 403 of the MMA

amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share under the IPPS unless this employment ''would result in lower payments than would otherwise be made.'') In that same final rule, we also revised and rebased the excluded hospital market basket, which is used to update the reasonable cost-based portion of LTCHs' blended transition payments (70 FR 47399 through 47403).

As we stated previously, once our research into the labor-related share methodology was complete, we would update the IPPS and excluded hospital labor-related shares based on that research and the best available data if necessary. In this proposed rule, we are proposing to update the LTCH PPS labor-related share based on the proposed RPL market basket as discussed in section IV.D.1.c. of this preamble. We are proposing to adopt the RPL market basket under the LTCH PPS because we believe that this market basket is developed based on the best available data that reflect the cost structures of LTCHs. Specifically, we are proposing to revise the LTCH PPS labor-related share from 72.885 percent (as established in the August 30, 2002 final rule (67 FR 56016) based on the FY 1997-based excluded hospital with capital market basket) to 75.923 percent based on the relative importance of the labor-related share of operating costs (wages and salaries, employee benefits, professional fees, and all other labor-intensive services) and capital costs of the proposed RPL market basket based on FY 2002 data, as discussed in greater detail below.

Consistent with our historical practice, the labor-related share is determined by identifying the national average proportion of operating costs that are related to, influenced by, or varies with the local labor market. Using our current definition of labor-related, the labor-related share is the sum of the relative importance of wages and salaries, fringe benefits, professional fees, labor-intensive services, and a portion of the capital share from an appropriate market basket. We are proposing to use the proposed FY 2002-based RPL market basket costs to determine the proposed labor-related share for the LTCH PPS effective for discharges occurring on or after July 1, 2006 as it is based on the most recent available data. The proposed labor-related share for the 2007 LTCH PPS rate year would be the sum of the relative importance of each labor-related cost category, and would reflect the different rates of price change for these cost categories between the base year (FY 2002) and the 2007 LTCH PPS rate year. Based on the most recent available data, the sum of the proposed relative importance for 2007 LTCH PPS rate year for operating costs (wages and salaries, employee benefits, professional fees, and labor-intensive services) would be 71.845, as shown in Table 7. The portion of capital that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage used in the 1997-based excluded hospital with capital market basket currently used under the LTCH PPS. Since the relative importance for capital would be 8.866 percent of the proposed FY 2002-based RPL market basket for the 2007 LTCH PPS rate year based on the latest available data, we are proposing to multiply the estimated portion of capital influenced by the local labor market (46 percent) by the relative importance for capital of the proposed FY 2002-based RPL market basket (8.866 percent) to determine the proposed labor-related share of capital for the 2007 LTCH PPS rate year. The result would be 4.078 percent (0.46 × 8.866 percent), which we propose to add to 71.845 percent for the operating cost amount to determine the total proposed labor-related share for the 2007 LTCH PPS rate year. Thus, based on the latest available data, we are proposing to use a labor-related share of 75.923 percent under the LTCH PPS for the 2007 LTCH PPS rate year. This proposed labor-related share is determined using the same methodology as employed in calculating the current LTCH labor-related share (67 FR 56016). If more recent data become available before the publication of the final rule and if we revise the LTCH PPS labor-related share based on the proposed FY 2002-based RPL market basket, we propose that we would use that data to determine the labor-related share for the 2007 LTCH PPS rate year in the final rule.

Table 7 shows the proposed 2007 LTCH PPS rate year relative importance labor-related share using the proposed 2002-based RPL market basket and the current relative importance labor-related share using the FY 1997-based excluded hospital with capital market basket.

TABLE 7.—TOTAL LABOR-RELATED SHARE-RELATIVE IMPORTANCE FOR THE 2007 FOR THE PROPOSED RPL MARKET BASKET AND THE EXCLUDED HOSPITAL WITH CAPITAL MARKET BASKET

Cost category	Proposed FY 2002-based RPL market basket relative importance (percent) for the 2007 LTCH PPS rate year	FY 1997-based excluded hospital with capital market basket relative importance (percent currently used under the LTCH PPS)
Wages and salaries	52.761	50.381
Employee benefits	14.008	11.525
Professional fees	2.903	2.059
Postal Services*	.....	0.244
All other labor-intensive services**	2.173	5.219
Subtotal	71.845	69.428
Labor-related share of capital costs	4.078	3.457
Total	75.923	72.885

* No longer considered labor related.

** Other labor intensive services includes landscaping services, services to buildings, detective and protective services, repair services, laundry services, advertising, auto parking and repairs, physical fitness facilities, and other government enterprises.

d. Proposed Wage Index Data

In the RY 2006 LTCH PPS final rule (70 FR 24190 through 24191), we established LTCH PPS wage index values for the 2006 LTCH PPS rate year calculated from the same data (generated in cost reporting periods beginning during FY 2000) used to compute the FY 2005 acute care hospital inpatient wage index data without taking into account geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act because that was the best available data at that time. The LTCH wage index values applicable for discharges occurring on or after July 1, 2005 through June 30, 2006 are shown in Table 1 (for urban areas) and Table 2 (for rural areas) in the Addendum to the RY 2006 LTCH PPS final rule. Acute care hospital inpatient wage index data are also used to establish the wage index adjustment used in the IRF PPS, HHA PPS, and SNF PPS. As we discussed in the August 30, 2002 LTCH PPS final rule (67 FR 56019), since hospitals that are excluded from the IPPS are not required to provide wage-related information on the Medicare cost report and because we would need to establish instructions for the collection of this LTCH data in order to establish a geographic reclassification adjustment under the LTCH PPS, the wage adjustment established under the LTCH PPS is based on a LTCH's actual location without regard to the urban or rural designation of any related or affiliated provider.

In this proposed rule, under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA to determine appropriate adjustments under the LTCH PPS, we are proposing that, for the 2007 LTCH PPS rate year, the same data (generated in cost reporting periods beginning during FY 2002) used to compute the FY 2006 acute care hospital inpatient wage index data without taking into account geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act would be used to determine the applicable wage index values under the LTCH PPS because these data (FY 2002) are the most recent complete data. We are proposing to continue to use IPPS wage data as a proxy to determine the proposed LTCH wage index values for the 2007 LTCH PPS rate year because both LTCHs and acute-care hospitals are required to meet the same certification criteria set forth in section 1861(e) of the Act to participate as a hospital in the Medicare program and they both compete in the same labor markets, and therefore experience similar wage-related costs. These data are the same FY 2002 acute care hospital inpatient wage data that were used to compute the FY 2006 wage indices currently used under the IPPS, SNF PPS and HHA PPS.

The proposed LTCH wage index values that would be applicable for discharges occurring on or after July 1, 2006 through June 30, 2007, are shown in Table 1 (for urban areas) and Table 2 (for rural areas) in the Addendum to this proposed rule.

As discussed above in section IV.D.1.a. of this preamble, the applicable wage index phase-in percentages are based on the start of a LTCH's cost reporting period beginning on or after October 1st of each year during the 5-year transition period. Thus, for cost reporting periods beginning on or after October 1, 2004 and before October 1, 2005 (FY 2005), the labor portion of the standard Federal rate is adjusted by three-fifths of the applicable LTCH wage index value. For cost reporting periods beginning on or after October 1, 2005 and before October 1, 2006 (FY 2006), the labor portion of the standard Federal rate is adjusted by four-fifths of the applicable LTCH wage index value. Specifically, for a LTCH's cost reporting period beginning during FY 2006, for discharges occurring on or after July 1, 2006 through June 30, 2007, the applicable wage index value would be four-fifths of the full FY 2006 acute care hospital inpatient wage index data, without taking into account geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act (shown in Tables 1 and 2 in the Addendum to this proposed rule).

Because the phase-in of the wage index does not coincide with the LTCH PPS rate year (July 1st through June 30th), most LTCHs will experience a change in the wage index phase-in percentages during the LTCH PPS rate year. For example, during the 2007 LTCH PPS rate year, for a LTCH with a January 1st FY, the four-fifths wage index will be applicable for the first 6 months of the 2007 LTCH PPS rate year (July 1, 2006 through December 31, 2006) and the full (five-fifths) wage index will be applicable for the second 6 months of the 2007 LTCH PPS rate year (January 1, 2007 through June 30, 2007). We also note that some providers will still be in the third year of the 5-year phase-in of the LTCH wage index (that is, those LTCHs who entered the 5-year phase-in during their cost reporting periods that began between July 1, 2003 and September 30, 2003). For the remainder of those LTCHs' FY 2005 cost reporting periods that will coincide with the first 3 months of RY 2007, the applicable wage index value would be three-fifths of the full FY 2006 acute care hospital inpatient wage index data, without taking into account geographic reclassification under sections 1886(d)(8) and (d)(10) of the Act (as shown in Tables 1 and 2 in the Addendum to this proposed rule). Since there are no longer any LTCHs in their cost reporting period that began during FYs 2003 and 2004 (the first and second years of the 5-year wage index phase-in), we are no longer showing the 1/5th and 2/5ths wage index values in Tables 1 and 2 in the Addendum to this proposed rule.

2. Proposed Adjustment for Cost-of-Living in Alaska and Hawaii

In the August 30, 2002 final rule (67 FR 56022), we established, under § 412.525(b), a cost-of-living adjustment (COLA) for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. In the RY 2006 LTCH PPS final rule (70 FR 24191), for the 2006 LTCH PPS rate year, we established that we make a COLA to payments for LTCHs located in Alaska and Hawaii by multiplying the standard Federal payment rate by the appropriate factor listed in Table I. of that same final rule.

Similarly, in this proposed rule, under broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA to determine appropriate adjustments under the LTCH PPS, for the 2007 LTCH PPS rate year we are proposing to make a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the proposed standard Federal payment rate by the proposed factors listed in Table 8 because these are currently the most recent available data. These proposed factors are obtained from the U.S. Office of Personnel Management (OPM) and are currently used under the IPPS. In addition, we propose that if OPM releases revised COLA factors before March 1, 2006, we would use them for the development of the payments for the 2007 LTCH rate year and publish them in the LTCH PPS final rule.

TABLE 8.—PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE 2007 LTCH PPS RATE YEAR

Alaska:	
All areas	1.25
Hawaii:	
Honolulu County	1.25
Hawaii County	1.165
Kauai County	1.2325

TABLE 8.—PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII HOSPITALS FOR THE 2007 LTCH PPS RATE YEAR—Continued

Maui County	1.2375
Kalawao County	1.2375

3. Proposed Adjustment for High-Cost Outliers

a. Background

Under the broad authority conferred upon the Secretary by section 123 of the BBRA as amended by section 307(b) of BIPA, in the regulations at § 412.525(a), we established an adjustment for additional payments for outlier cases that have extraordinarily high costs relative to the costs of most discharges. Providing additional payments for outliers strongly improves the accuracy of the LTCH PPS in determining resource costs at the patient and hospital level. These additional payments reduce the financial losses that would otherwise be caused by treating patients who require more costly care and, therefore, reduce the incentives to underserve these patients. We set the outlier threshold before the beginning of the applicable rate year so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. Outlier payments under the LTCH PPS are determined consistent with the IPPS outlier policy.

Under § 412.525(a), we make outlier payments for any discharges if the estimated cost of a case exceeds the adjusted LTCH PPS payment for the LTC–DRG plus a fixed-loss amount. The fixed-loss amount is the amount used to limit the loss that a hospital will incur under the outlier policy for a case with unusually high costs. This results in Medicare and the LTCH sharing financial risk in the treatment of extraordinarily costly cases. Under the LTCH PPS high cost outlier policy, the LTCH's loss is limited to the fixed-loss amount and a fixed percentage of costs above the marginal cost factor. We calculate the estimated cost of a case by multiplying the overall hospital cost-to-charge ratio (CCR) by the Medicare allowable covered charge. In accordance with § 412.525(a)(3), we pay outlier cases 80 percent of the difference between the estimated cost of the patient case and the outlier threshold (the sum of the adjusted Federal prospective payment for the LTC–DRG and the fixed-loss amount).

Under the LTCH PPS, we determine a fixed-loss amount, that is, the maximum loss that a LTCH can incur under the LTCH PPS for a case with unusually high costs before the LTCH will receive any additional payments. We calculate the fixed-loss amount by estimating aggregate payments with and without an outlier policy. The fixed-loss amount will result in estimated total outlier payments being projected to be equal to 8 percent of projected total LTCH PPS payments. Currently, MedPAR claims data and CCRs based on data from the most recent provider specific file (PSF) (or to the applicable Statewide average CCR if a LTCH's CCR data are faulty or unavailable) are used to establish a fixed-loss threshold amount under the LTCH PPS.

b. Cost-to-Charge Ratios (CCRs)

In determining outlier payments, we calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case.

As we discussed in greater detail in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34506 through 34516), because the LTCH PPS high-cost outlier policy (§ 412.525) is modeled after the IPPS outlier policy, we believed that it and the short-stay outlier (SSO) policy (§ 412.529) are susceptible to the same payment vulnerabilities that became evident under the IPPS and therefore, merited revision. Thus, we revised the high-cost outlier policy at § 412.525(a) and short-stay policy at § 412.529 in that same final rule for the determination of LTCHs' CCRs and the reconciliation of outlier payments.

Under the LTCH PPS, a single prospective payment per discharge is made for both inpatient operating and capital-related costs, and therefore, we compute a single ''overall'' or ''total'' CCR for LTCHs based on the sum of their operating and capital costs (as described in Chapter 3, section 150.24, of the Medicare Claims Processing Manual (CMS Pub. 100–4) as compared to total charges. Specifically, a LTCH's CCR is calculated by dividing a LTCH's total Medicare costs (that is, the sum of its operating and capital inpatient routine and ancillary costs) divided by its total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges). (Instructions regarding the changes established in the June 9, 2003 IPPS high cost outlier final rule for both LTCHs and IPPS hospitals can be found in Transmittal A–03–058 (Change Request 2785; July 3, 2003).)

As a result of the changes established in the June 9, 2003 IPPS high cost outlier final rule, as we discussed in previous LTCH PPS final rules ((RY 2004, 68 FR 34144 through 34146); (RY 2005, 69 FR 25687 through 25690); and (RY 2006, 70 FR 24192 through 24194)), under our current policy a LTCH is assigned the applicable Statewide average CCR if, among other things, a LTCH's CCR is found to be in excess of the applicable maximum CCR threshold (that is, the combined IPPS operating and capital CCR ceiling). As we explained in that same final rule (68 FR 34507), CCRs above this threshold are most likely due to faulty data reporting or entry, and therefore, these CCRs should not be used to identify and make payments for outlier cases. Such data are clearly errors and should not be relied upon. Thus, under our established policy, if a LTCH's CCR is above the applicable ceiling, the applicable combined IPPS Statewide average CCR is assigned to the LTCH instead of the CCR computed from its most recent (settled or tentatively settled) cost report data.

As we explained in the RY 2006 LTCH PPS final rule (70 FR 24192), we believe it is appropriate to use the combined IPPS operating and capital CCR ceiling and the applicable combined IPPS Statewide average CCRs in determining LTCHs' CCRs because LTCHs' cost and charge structures are similar to that of IPPS acute-care hospitals. For instance, LTCHs are certified as acute care hospitals, as set forth in section 1861(e) of the Act to participate as a hospital in the Medicare program, and these hospitals, in general, are paid as LTCHs only because their Medicare ALOS is greater than 25 days (see § 412.23(e)). Furthermore, as also explained in that same final rule, prior to qualifying as a LTCH under § 412.23(e)(2)(i), a hospital generally is paid as an acute-care hospital under the IPPS during the period in which it demonstrates that it has an ALOS of greater than 25 days. In addition, since there are less than 400 LTCHs, which are unevenly geographically distributed throughout the United States, there may not be sufficient LTCH CCR data to determine an appropriate LTCH PPS CCR ceiling using LTCH data.

As noted previously in this proposed rule, under the LTCH PPS, there is a single prospective payment per discharge for both inpatient operating and capital-related costs, and therefore, we compute a single ''overall'' or ''total'' CCR for LTCHs based on the sum of their Medicare operating and capital costs and charges. However, under the IPPS, Medicare per discharge payments to acute-care hospitals for the costs of inpatient operating services are made under the ''Operating IPPS'' and per discharge payments to acute-care hospitals for inpatient capital-related

costs are made under the ''Capital IPPS.'' Because separate payments are made to acute-care hospitals under the IPPS for operating and capital costs, separate operating and capital CCRs are calculated and used in determining IPPS high cost outlier payments. Accordingly, under the IPPS a separate ''operating'' CCR ceiling and a ''capital'' CCR ceiling are determined annually. As we explained previously in this proposed rule and as stated in annual instructions (see Transmittal A–02–093 (Change Request 2288; September 27, 2002); Transmittal A–03–073 (Change Request 2891; August 22, 2003); Transmittal 309 (Change Request 3459; October 1, 2004); and Transmittal 692 (Change Request 4046; September 30, 2005)), under our current policy, if a LTCH's CCR is above the applicable ''combined'' IPPS operating and capital ceiling (that is, adding the separate IPPS operating and capital CCR ceiling together), the applicable Statewide average CCR is assigned to the LTCH. Because, LTCHs have a single ''total'' CCR (rather than separate operating and capital CCRs), under the broad authority of section 123 of the BBRA and section 307(b)(1) of BIPA, we are proposing to revise § 412.525(a)(4) to specify that, for discharges occurring on or after October 1, 2006, if, among other things, a LTCH's CCR is in excess of the LTCH CCR ceiling (which would be calculated as 3 standard deviations above the corresponding national geometric mean CCR), established and published annually by CMS), the FI may use a Statewide average CCR (also established annually by CMS).

This proposed change is similar to our existing policy (established in the June 9, 2003 IPPS high cost outlier final rule as previously discussed in this proposed rule). Under proposed revised § 412.525(a)(4)(iv)(C)(*2*), for discharges occurring on or after October 1, 2006, we are proposing that we would determine the single ''total'' CCR ceiling, based on IPPS CCR data, by first calculating the total (that is, operating and capital) CCR for each hospital and then determining the average total CCR for all hospitals. The ceiling would then be established at 3 standard deviations from the mean total CCR rather than determining the LTCH total CCR ceiling by adding the separate IPPS operating CCR and capital CCR ceilings as we do under our current policy. Specifically, under this proposed policy we would use the same IPPS CCR data that we currently use to annually determine the separate IPPS operating CCR and capital CCR ceilings (that we add together under our current policy to determine the annual CCR ceiling for LTCHs) to compute IPPS hospital-specific total CCRs that would be used to determine the single LTCH total CCR ceiling. We believe that determining a LTCH CCR ceiling based on IPPS total (operating and capital) Medicare costs and charges rather than adding the separate IPPS CCR ceilings determined from operating CCRs and capital CCRs, respectively, would be more consistent with the LTCH PPS single payment, which does not differentiate payments between operating and capital costs.

As explained previously in this proposed rule, there is a single LTCH PPS Federal rate rather than a separate operating standardized amount and a capital Federal rate, as there is under the IPPS. (We note, as discussed in greater detail below in this section, in conjunction with this proposed change in the calculation of the LTCH CCR ceiling, we are also proposing a change in our methodology for calculating the applicable Statewide average CCRs under the LTCH PPS to be based on hospital-specific ''total'' CCRs.) Our rationale for proposing to continue to use IPPS data to determine the LTCH CCR ceiling annually continues to be the same as the one stated above. We note that we are proposing that the proposed refinement to our methodology for determining the annual CCR ceiling under the LTCH PPS at proposed revised § 412.525(a)(4)(iv)(C)(*2*) would be effective for discharges occurring on or after October 1, 2006 rather than July 1, 2006 because, we are proposing to continue to use the same IPPS data used to determine the individual IPPS operating and capital CCR ceilings established and published annually in the IPPS proposed and final rules. Since both the separate IPPS operating and capital CCRs ceilings and the LTCH ''total'' CCR ceiling would be determined using the same data, we believe it would be administratively expedient to continue to establish the LTCH CCR ceiling to be effective for discharges occurring on or after October 1 of each year. (As stated previously, this is consistent with our current policy, where the LTCH CCR ceiling is updated annually on October 1.) Therefore, under this proposal, the public should continue to consult the annual IPPS proposed and final rules for changes to the LTCH CCR ceiling that would be effective for discharges occurring on or after October 1, 2006 (since, under this proposal, the current LTCH CCR ceiling, established for discharges occurring on or after October 1, 2005 in the FY 2006 IPPS final rule, would remain in effect for discharges occurring on or before September 30, 2006).

Also in the June 9, 2003 IPPS high cost outlier final rule, we established our existing policy that, for discharges occurring on or after August 8, 2003, that in addition to assigning the applicable Statewide average CCR to a LTCH whose CCR is above the ceiling, the FI may use the applicable Statewide average CCR for LTCHs for whom data with which to calculate a CCR is not available (for example, missing or faulty data) or new LTCHs that have not yet submitted their first Medicare cost report (for this purpose, a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter). (We note that consistent with our current policy, either CMS or the hospital may request the use of a different (higher or lower) CCR based on substantial evidence that such a CCR more accurately reflects the hospital's actual costs and charges. This applies to new (as defined above) as well. For instance, CMS may determine that the applicable Statewide average CCR should not be applied to hospitals that convert from acute-care IPPS hospitals to LTCHs (and receive a new LTCH provider number). Rather, the cost and charge data from the IPPS hospital's cost report (even if it is more or less than a 12-month cost reporting period) would be used to determine the LTCH's CCR.)

Thus, in addition to proposing to revise our methodology for determining the annual CCR ceiling under the LTCH PPS for discharges occurring on or after October 1, 2006, under the broad authority of section 123 of the BBRA and section 307(b)(1) of BIPA, we are also proposing to revise § 412.525(a)(4), for discharges occurring on or after October 1, 2006, to codify in subpart O of part 42 of the CFR the remaining LTCH PPS high cost policy changes that were established in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34506 through 34513), including proposed modifications and editorial clarifications to those existing policies established in that final rule, which are discussed in greater detail below in this section. We are proposing these additional revisions to § 412.525(a)(4), as discussed in greater detail below in this section, because we believe that a position such as this would more precisely describe the application of those policies as they relate to the determination of LTCH CCRs because these proposed changes would be consistent with the proposed changes to the calculation of the LTCH CCR ceiling

discussed above in this section. Specifically, similar to our current policy, we are proposing in § 412.525(a)(4)(iv)(C) to specify that the FI may use a Statewide average CCR, which would be established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following three circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH would be defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling (that is, 3 standard deviations above the corresponding national geometric mean total CCR, as discussed in greater previously in this proposed rule); and (3) other LTCHs for whom data with which to calculate a CCR is not available (for example, missing or faulty data). Also similar to our current practice, under proposed § 412.525(a)(4)(iv)(C), for discharges occurring on or after October 1, 2006, we are proposing that we would annually establish Statewide average ''total'' CCRs (as explained below in this section) for use under the LTCH PPS based on IPPS data rather than assigning the combined (operating and capital) Statewide average CCRs (see Transmittal 692 (Change Request 4046; September 30, 2005)). Specifically, under this proposed policy, we would use the same IPPS CCR data that we currently use to annually establish the separate IPPS operating and capital Statewide CCRs (that we add together under our current policy to determine the applicable ''combined'' Statewide average CCR for LTCHs) to compute Statewide average total CCRs by first calculating the total (that is, operating and capital) CCR for each hospital and then determining the average total CCR for all hospitals in each State rather than adding together the separate applicable IPPS operating and capital Statewide average CCRs as we do under our current policy. We are also proposing that these Statewide average ''total'' (operating and capital) CCRs that would be used under the LTCH PPS would continue to be published annually in the IPPS proposed and final rules, and therefore, the public should continue to consult the annual IPPS proposed and final rules for changes to the applicable Statewide average total CCRs that would be effective for discharges occurring on or after October 1, 2006 (since, under this proposal, the current applicable Statewide average operating and capital CCRs, established for discharges occurring on or after October 1, 2005, would remain in effect for discharges occurring on or before September 30, 2006). Our rationale for proposing to establish Statewide average ''total'' CCRs (as described above in this section) based on IPPS data under proposed § 412.525(a)(4)(iv)(C) is the same as the one stated above for proposing to use IPPS data to determine a ''total'' LTCH CCR ceiling.

Similar to our current policy, we are also proposing to specify under proposed § 412.525(a)(4)(iv)(B), that for discharges occurring on or after October 1, 2006, the CCR applied at the time a claim is processed would be based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period. Furthermore, we are proposing under proposed § 412.525(a)(4)(iv)(A) to state that CMS may specify an alternative to the CCR computed under proposed § 412.525(a)(4)(iv)(B), that is the CCR computed from the most recent settled cost report or the most recent tentative settled cost report, whichever is later, or a hospital may also request that its FI use a different (higher or lower) CCR based on substantial evidence presented by the hospital. These proposed revisions to our policy for determining a LTCH's CCR for discharges occurring on or after October 1, 2006 under proposed revised § 412.525(a)(4)(iv)(A) and (B) are similar to our existing policy established in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34506 through 34513).

In conjunction with the proposed revisions to § 412.525(a)(4) concerning the determination of LTCHs' CCRs discussed above in this section, we are also proposing to revise § 412.525(a)(4) to codify in subpart O of part 42 of the CFR the existing outlier reconciliation provisions, including the proposed editorial clarifications to those existing policies, which are discussed in greater detail below in section IV.D.3.d. of this preamble. Furthermore, because CCRs are also used in determining payments under the existing SSO policy (§ 412.529), as discussed in greater detail in section VI.A.1. of this preamble, we are also proposing to revise § 412.529(c), for discharges occurring on or after October 1, 2006, to make the same changes to the SSO policy. In addition, we are also proposing a technical correction to existing § 412.525(a)(3) to change the plural reference from cost-to-charge ''ratios'' to the singular reference cost-to-charge ''ratio'' because under the LTCH PPS a single (total) CCR is computed for LTCHs.

c. Establishment of the Proposed Fixed-Loss Amount

When we implemented the LTCH PPS, as discussed in the August 30, 2002 final rule (67 FR 56022 through 56026), under the broad authority of section 123 of the BBRA as amended by section 307(b) of BIPA, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. To determine the fixed-loss amount, we estimate outlier payments and total LTCH PPS payments for each case using claims data from the MedPAR files. Specifically, to determine the outlier payment for each case, we estimate the cost of the case by multiplying the Medicare covered charges from the claim by the LTCH's hospital specific CCR. Under § 412.525(a)(3), if the estimated cost of the case exceeds the outlier threshold (the sum of the adjusted Federal prospective payment for the LTC–DRG and the fixed-loss amount), we pay an outlier payment equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal prospective payment for the LTC–DRG and the fixed-loss amount).

In the RY 2006 LTCH PPS final rule (70 FR 24194), in calculating the fixed-loss amount that would result in outlier payments projected to be equal to 8 percent of total estimated payments for the 2006 LTCH PPS rate year, we used claims data from the December 2004 update of the FY 2004 MedPAR files and CCRs from the December 2004 update of the PSF, as that was the best available data at that time. As we discussed in that same final rule (70 FR 24193 through 24194), we believe that CCRs from the PSF were the best available CCR data for determining LTCHs' LTCH PPS payments during the 2006 LTCH PPS rate year because they were the most recently available CCRs (at that time) actually used to make LTCH PPS payments.

As we also discussed in the RY 2006 LTCH PPS rate year final rule (70 FR 24192 through 24193), we calculated a single fixed-loss amount for the 2006 LTCH PPS rate year based on the version 22.0 of the GROUPER, which was the version in effect as of the beginning of the LTCH PPS rate year (that is, July 1, 2005 for the 2006 LTCH PPS rate year). In addition, we applied the current outlier policy under § 412.525(a) in determining the fixed-loss amount for the 2006 LTCH PPS rate

year; that is, we assigned the applicable Statewide average CCR only to LTCHs whose CCRs exceeded the ceiling (and not when they fell below the floor). Accordingly, we used the FY 2005 IPPS combined operating and capital CCR ceiling of 1.409 (70 FR 24192). (Our rationale for using the FY 2005 combined IPPS operating and capital CCR ceiling for LTCHs stated in section IV.D.3.b. of this preamble.) As noted in that same final rule, in determining the fixed-loss amount for the 2006 LTCH PPS rate year using the CCRs from the PSF, there were no LTCHs with missing CCRs or with CCRs in excess of the current ceiling and, therefore, there was no need for us to independently assign the applicable Statewide average CCR to any LTCHs in determining the fixed-loss amount for the 2006 LTCH PPS rate year (as this may have already been done by the FI in the PSF in accordance with the established policy).

Accordingly, in 2006 LTCH PPS rate year final rule (70 FR 24194), we established a fixed-loss amount of $10,501 for the 2006 LTCH PPS rate year. Thus, we pay an outlier case 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal LTCH PPS payment for the LTC–DRG and the fixed-loss amount of $10,501).

In this proposed rule, for the 2007 LTCH PPS rate year, we used the June 2005 update of the FY 2004 MedPAR claims data to determine a proposed fixed-loss amount that would result in outlier payments projected to be equal to 8 percent of total estimated payments, based on the policies described in this proposed rule, because these data are the most recent complete LTCH data available. Furthermore, as noted previously, we determined the proposed fixed-loss amount based on the version of the GROUPER that would be in effect as of the beginning of the 2007 LTCH PPS rate year (July 1, 2006), that is, Version 23.0 of the GROUPER (70 FR 47324).

We also used CCRs from the June 2005 update of the Provider Specific File for determining the proposed fixed-loss amount for the 2007 LTCH PPS rate year as they are currently the most recent complete available data. If more recent CCR data are available, we propose to use it for determining the fixed-loss amount for the 2007 LTCH PPS rate year in the final rule. As we discussed previously in this proposed rule, we are proposing a change to our methodology for our annual determination of the applicable LTCH CCR ceiling and applicable Statewide average CCRs that would be assigned in determining a LTCH's CCR effective for discharges occurring on or after October 1, 2006. As noted above in this section, under this proposal, the current LTCH CCR ceiling and applicable Statewide average CCRs, established for discharges occurring on or after October 1, 2005, would remain in effect for discharges occurring on or before September 30, 2006. In determining the proposed fixed-loss amount for the 2007 LTCH PPS rate year, we are proposing to use the current FY 2006 applicable IPPS combined operating and capital CCR ceiling of 1.423 and Statewide average CCRs (as discussed in the FY 2006 IPPS final rule (70 FR 47496) and established in Transmittal 692 (September 30, 2005)) such that the current applicable Statewide average CCR would be assigned if, among other things, a LTCH's CCR exceeded the current ceiling (1.423). Our reason for proposing to use the existing LTCH CCR ceiling and Statewide average CCRs to determine the proposed RY 2007 fixed-loss amount even though we are proposing to change our methodology for determining the CCR ceiling and Statewide average CCRs effective for discharges occurring on or after October 1, 2006, is because, based on our analysis of the data used to determine the FY 2006 LTCH CCR ceiling, we believe that this methodology change would result in a minor change in the numerical value of the LTCH CCR ceiling, and therefore, would have a negligible effect on the LTCHs' CCRs used to determine the proposed fixed-loss amount for the 2007 LTCH PPS rate year. Moreover, we note that in determining the proposed fixed-loss amount for the 2007 LTCH PPS rate year using the CCRs from the PSF, there was no need for us to independently assign the applicable Statewide average CCR to any LTCHs in determining the proposed fixed-loss amount for the 2007 LTCH PPS rate year (as this may have already been done by the FI in the PSF in accordance with our established policy). (Currently, the applicable FY 2006 IPPS Statewide averages can be found in Tables 8A and 8B of the FY 2006 IPPS final rule (70 FR 47672).)

Accordingly, based on the data and policies described in this proposed rule, we are proposing a fixed-loss amount of $18,489 for the 2007 LTCH PPS rate year. Thus, we would pay an outlier case 80 percent of the difference between the estimated cost of the case and the proposed outlier threshold (the sum of the adjusted proposed Federal LTCH payment for the LTC–DRG and the proposed fixed-loss amount of $18,489). We note that the proposed fixed-loss amount for the 2007 LTCH PPS rate year is significantly higher than the current fixed-loss amount of $10,501. This proposed change in the fixed-loss amount would primarily be due to the projected decrease in LTCH PPS payments resulting from the proposed change in the SSO policy under § 412.529 (discussed in greater detail in section V.A.1. of this preamble) and the changes to the LTC–DRG relative weights for FY 2006 (as discussed in the FY 2006 IPPS final rule (70 FR 47355)). Because we are projecting approximately an 11 percent decrease in aggregate LTCH PPS payments in the 2007 LTCH PPS rate year (as discussed in section XIII. of this proposed rule), we believe that an increase in the proposed fixed-loss amount is appropriate and necessary to maintain the requirement that estimated outlier payments would equal 8 percent of estimated total LTCH PPS payments, as required under § 412.525(a). Maintaining the fixed-loss amount at the current level would result in high cost outlier payments that significantly exceed the current regulatory requirement that estimated outlier payments would be projected to equal 8 percent of estimated total LTCH PPS payments. We note that in the August 30, 2002 final rule (67 FR 56022 through 56024), based on our regression analysis, we established the outlier target at 8 percent of estimated total LTCH PPS payments to allow us to achieve a balance between the ''conflicting considerations of the need to protect hospitals with costly cases, while maintaining incentives to improve overall efficiency.'' In that same final rule (67 FR 56023), we also explained that our regression analysis showed that additional increments of outlier payments over 8 percent (that is, raising the outlier target to a larger percentage than 8 percent) would reduce financial risk, but by successively smaller amounts. Since outlier payments are included in budget neutrality calculations, outlier payments would be funded by prospectively reducing the non-outlier PPS payment rates by the proportion of projected outlier payments to projected total PPS payments in the absence of outlier payments; the higher the outlier target, the greater the (prospective) reduction to the base payment rate in order to maintain budget neutrality. As another alternative to the proposed reduction to the fixed-loss amount for RY 2007, we are soliciting comments on whether we should revisit the regression analysis discussed above in this section that was used to establish the existing 8 percent

outlier target, using the most recent available data to evaluate whether the current outlier target of 8 percent should be adjusted, and therefore may result in less of an increase in the fixed-loss amount for RY 2007. After revisiting this issue and an analysis of the most recent complete available data, due to the lag time in the availability of data, we now believe the most appropriate time to revisit a budget neutral policy change in the outlier policy (among other things), which would affect future LTCH PPS payment rates, would be after the conclusion of the 5-year transition period when we expect to have several years of data generated after the implementation of the LTCH PPS.

As an alternative to proposing to raise the fixed-loss amount for FY 2007, we also examined adjusting the marginal cost factor (that is, the percentage that Medicare will pay of the estimated cost of a case that exceeds the sum of the adjusted Federal prospective payment for the LTC–DRG and the fixed-loss amount for LTCH PPS outlier cases as specified in § 412.525(a)(3)), as a means of ensuring that estimated outlier payments would be projected to equal 8 percent of estimated total LTCH PPS payments. As we established in the August 30, 2002 final rule (67 FR 56022 through 56026), under the LTCH PPS high-cost outlier policy at § 412.525(a)(3), the marginal cost factor is currently equal to 80 percent. A marginal cost factor equal to 80 percent means that for an outlier case we pay the LTCH 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted Federal rate for the LTC–DRG PPS payment and the fixed-loss amount).

In addition, as we discussed in the August 30, 2002 final rule (67 FR 56023) that implemented the LTCH PPS, the marginal cost factor is designed to ensure ''a balance between the need to protect LTCHs financially, while encouraging them to treat expensive patients and maintaining the incentives of a prospective payment system to improve the efficient delivery of care.'' Decreasing the marginal cost factor from the established 80 percent, while maintaining the current fixed-loss amount ($10,501), would decrease total estimated outlier payments because we would pay a smaller percentage of the estimated costs that exceed the outlier threshold (the sum of the adjusted Federal rate for the LTC–DRG and the fixed-loss amount). For example, if we were to decrease the marginal cost factor to 65 percent without raising the fixed-loss amount, we would pay outlier cases 15 percent less (80 percent minus 65 percent) of the estimated costs that exceed the outlier threshold (the sum of the adjusted Federal rate for the LTC–DRG and the fixed-loss amount).

While this alternative could ensure that outlier payments are projected to equal 8 percent of estimated total LTCH PPS payments by reducing estimated aggregate outlier payments, it may not maintain the existing balance between providing an incentive for LTCHs to treat expensive patients and improving the efficient delivery of care because a policy such as this would reduce the financial protection currently afforded to LTCHs under the current high cost outlier policy (with an 80 percent marginal cost factor), which could result in LTCHs' inability to treat seriously ill and costly patients. This is because we believe it may be more financially difficult for LTCHs to absorb a greater share of the costs of a true high cost outlier case (that is, a case with an unusually high cost) than it would be to have a higher fixed-loss amount. Keeping the marginal cost factor at 80 percent while proposing to raise the fixed-loss amount would afford more financial protection to LTCHs than proposing to lower the fixed-loss amount and retain the current fixed loss amount. Because a relatively higher fixed-loss amount identifies fewer cases as high cost outlier cases (since the amount that the estimated cost of the case must exceed before the case qualifies as a high cost outlier case is higher), such a proposed policy better identifies LTCH patients that are truly unusually costly cases, which is consistent with our intent of the LTCH high cost outlier policy as stated when we implemented the LTCH PPS in the August 30, 2002 final rule (67 FR 56025). As we discussed in that same final rule (67 FR 56023 through 56024), our analysis of payment-to-cost ratios for outlier cases showed that a marginal cost factor of 80 percent appropriately addresses outlier cases that are significantly more expensive than nonoutlier cases, while simultaneously maintaining the integrity of the LTCH PPS.

Although proposing to raise the fixed-loss amount from $10,501 to $18,489 (based on the policies presented in this proposed rule) would increase the amount of the loss that a LTCH must incur under the LTCH PPS for a case with unusually high costs before the LTCH would receive any additional Medicare payments, as we explained previously in this proposed rule, we believe the 80 percent marginal cost factor continues to adequately maintain the LTCHs' share of the financial risk in treating the most costly patients and ensure the efficient delivery of services. As we discussed in the August 30, 2002 final rule when we established the high cost outlier policy, our analysis showed that a marginal cost factor of 80 percent appropriately addresses outlier cases that are significantly more expensive than nonoutlier cases. Accordingly, we are not proposing to adjust the marginal cost factor under the LTCH PPS high-cost outlier policy; however, we are soliciting comments on whether we should revisit the regression analysis that was used to establish the existing 80 percent marginal cost factor, using the most recent available data to evaluate whether the current marginal cost factor of 8 percent in the current high cost outlier policy should be adjusted, and therefore may result in less of an increase in the fixed-loss amount for RY 2007.

Furthermore, we note that the proposed fixed-loss amount of $18,489 is lower than the FY 2003 fixed-loss amount of $24,450 (67 FR 56023) and the 2004 LTCH PPS rate year fixed-loss amount of $19,590 (68 FR 34144), and only slightly higher than the 2005 LTCH PPS rate year fixed-loss amount of $17,864 (69 FR 25688), all of which were in effect during the time period that we are currently estimating positive Medicare margins (as discussed in greater detail in section IV.C.3 of this preamble). Therefore, we believe the proposed fixed-loss amount of $18,489 would appropriately identify unusually costly LTCH cases while maintaining the integrity of the LTCH PPS. Thus, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of BIPA, we are proposing to establish a fixed-loss amount of $18,489 based on the best available LTCH data and the policies presented in this proposed rule because, we believe a proposed increase in the fixed-loss amount is appropriate and necessary to maintain estimated outlier payments equal to 8 percent of estimated total LTCH PPS payments, as required under § 412.525(a).

d. Reconciliation of Outlier Payments Upon Cost Report Settlement

In the June 9, 2003 high-cost outlier final rule (68 FR 34508 through 34512), we established a policy for LTCHs that provided that effective for LTCH PPS discharges occurring on or after August 8, 2003, any reconciliation of outlier payments will be based upon the actual CCR computed from the costs and charges incurred in the period during which the discharge occurs. In that same final rule, we also established that, for discharges occurring on or after

August 8, 2003, at the time of any reconciliation, outlier payments may be adjusted to account for the time value of any underpayments or overpayments based upon a widely available index to be established in advance by the Secretary and will be applied from the midpoint of the cost reporting period to the date of reconciliation. (We note that, in that same final rule (68 FR 34513), we also established similar changes to the SSO policy under the LTCH PPS at § 412.529(c)(5)(ii).) These changes regarding the reconciliation of outlier payments under the LTCH PPS were made in conjunction with the changes regarding the determination of LTCHs' CCRs that we established under § 412.525(a)(4) in the June 9, 2003 IPPS high cost outlier final rule, as discussed in greater detail in section IV.D.3.b. of this preamble. (We note that the instructions for implementing these regulations under both the IPPS and the LTCH PPS are discussed in further detail in Program Memorandum Transmittal A–03–058. Additional information on the administration of the reconciliation process under the IPPS is provided in CMS Program Transmittal 707 (October 12, 2005; Change Request 3966). We note that irrespective of the proposed changes to the high cost outlier and SSO policies presented in this proposed rule, we are currently developing additional instructions on the administration of the existing reconciliation process under the LTCH PPS that would be similar to the IPPS reconciliation process.)

As discussed in section V.C.3.b. of this preamble, we are proposing, for discharges occurring on or after October 1, 2006, to codify into the LTCH PPS section of the regulations (subpart O of part 42 of the CFR) the provisions governing the determination of LTCHs' CCRs, including proposed modifications and editorial clarifications to our existing methodology for determining the annual LTCH CCR ceiling and applicable Statewide average CCRs under the LTCH PPS. (We are also proposing to make those same changes under the SSO policy at § 412.529 as discussed in section V.A.1. of this preamble).

In this proposed rule, under the broad authority of section 123 of the BBRA and section 307(b)(1) of BIPA, we are also proposing to revise § 412.525(a)(4), for discharges occurring on or after October 1, 2006, to codify in subpart O of part 42 of the CFR the provisions discussed above concerning the reconciliation of LTCH PPS outlier payments, including proposed editorial clarifications discussed in greater detail below in this section, that would more precisely describe the application of those policies. (We note that we are also proposing to make the same changes concerning the reconciliation of outlier payments under (and the SSO provisions at § 412.529(c)), as discussed below in section V.A.1.a. of this preamble.) We are proposing the additional revisions to § 412.525(a)(4) concerning the reconciliation of outlier payments, which are discussed in greater detail below in this section, because these proposed changes would be consistent with the proposed changes to the calculation of the LTCH CCR ceiling discussed above. Specifically, at § 412.525(a)(4)(iv)(D), similar to our current policy, we are proposing to specify that for discharges occurring on or after October 1, 2006, any reconciliation of outlier payments would be based on the CCR calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. In addition, at § 412.525(a)(4)(iv)(E), similar to our current policy, we are proposing to specify that for discharges occurring on or after October 1, 2006, at the time of any reconciliation, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Also consistent with our current policy, we are proposing that such an adjustment would be based upon a widely available index to be established in advance by the Secretary and would be applied from the midpoint of the cost reporting period to the date of reconciliation. We are proposing to make these additional revisions to § 412.525(a)(4) because we believe that such proposed changes would be more consistent with the LTCH PPS single payment rate (as discussed in greater detail previously), and because we believe it would be more appropriate and administratively simpler to include all of the regulatory provisions concerning the determination of LTCH PPS outlier payments applicable under the LTCH PPS regulations in subpart O of part 42 of the CFR.

e. Application of Outlier Policy to Short-Stay Outlier (SSO) Cases

As we discussed in the August 30, 2002 final rule (67 FR 56026), under some rare circumstances, a LTCH discharge could qualify as a SSO case (as defined under § 412.529 and discussed in section V.B.4. of this preamble) and also as a high-cost outlier case. In this scenario, a patient could be hospitalized for less than five-sixths of the geometric ALOS for the specific LTC–DRG, and yet incur extraordinarily high treatment costs. If the costs exceeded the outlier threshold (that is, the SSO payment plus the fixed-loss amount), the discharge would be eligible for payment as a high-cost outlier. Thus, for a SSO case in the 2007 LTCH PPS rate year, the high-cost outlier payment would be 80 percent of the difference between the estimated cost of the case and the proposed outlier threshold (the sum of the proposed fixed-loss amount of $18,489 and the amount paid under the SSO policy). (We note that in section V.A.1. of this preamble, we are also proposing changes to the SSO policy at § 412.529, which are consistent with the proposed revisions to § 412.525(a)(4) regarding our policies on the determination of LTCH CCRs and, the reconciliation of outlier payments.)

4. Other Payment Adjustments

As indicated earlier, we have broad authority under section 123(a)(1) of the BBRA as amended by section 307(b) of BIPA to determine appropriate adjustments under the LTCH PPS, including whether (and how) to provide for adjustments to reflect variations in the necessary costs of treatment among LTCHs. Thus, in the August 30, 2002 final rule (67 FR 56014 through 56027), we discussed our extensive data analysis and rationale for not implementing an adjustment for geographic reclassification, rural location, treating a disproportionate share of low-income patients (DSH), or indirect medical education (IME) costs. In that same final rule, we stated that we would collect data and reevaluate the appropriateness of these adjustments in the future once more LTCH data become available after the LTCH PPS is implemented.

Because the LTCH PPS has only been implemented for slightly over 3 years and there is a time lag in data availability, sufficient new data has not been generated that would enable us to conduct a comprehensive reevaluation of these payment adjustments. We now believe that after the completion of the 5-year transition, sufficient new data that will be generated while LTCHs are subject to the LTCH PPS may be available for a comprehensive reevaluation of payment adjustments such as geographic reclassification, rural location, DSH, and IME. Nonetheless, we are reviewing the limited data that are available and find no evidence to support additional proposed policy changes. Therefore, in this proposed rule, we are not proposing to make any adjustments for geographic reclassification, rural location, DSH, or

IME. However, we will continue to collect and interpret new data as they become available in the future to determine if these data support proposing any additional payment adjustments. Specifically, as we discuss in greater detail in section IV.D.6. of this preamble, we have revisited the possible one-time prospective adjustment to the LTCH prospective payment system rates at § 412.523(d)(3), and after further analysis and evaluation we now believe that it is appropriate to wait for the conclusion of the 5-year transition to 100 percent fully Federal payments under the LTCH PPS, to maximize the availability of data that are reflective of LTCH behavior in response to the implementation of the LTCH PPS to be used to conduct a comprehensive evaluation of the potential payment adjustment policies (such as rural location, DSH and IME) in conjunction with our evaluation of the possibility of making a one-time prospective adjustment to the LTCH prospective payment system rates provided for at § 412.523(d)(3).

5. Proposed Budget Neutrality Offset To Account for the Transition Methodology

Under § 412.533, we implemented a 5-year transition, during which a LTCH is paid an increasing percentage of the LTCH PPS Federal prospective payment and a decreasing percentage of its payments based on the reasonable cost-based payment methodology for each discharge. Furthermore, we allow a LTCH (other than those defined as ''new'' under § 412.23(e)(4) to elect to be paid based on 100 percent of the standard Federal rate in lieu of the blended methodology.

The standard Federal rate was determined as if all LTCHs will be paid based on 100 percent of the standard Federal rate. As stated earlier, we provide for a 5-year transition period that allows LTCHs to receive payments based partially on the reasonable cost-based methodology. In order to maintain budget neutrality for FY 2003 as required by section 123(a)(1) of the BBRA during the 5-year transition period, we reduce all LTCH Medicare payments (whether a LTCH elects payment based on 100 percent of the Federal rate or whether a LTCH is being paid under the transition blend methodology) to account for the cost of the applicable transition period methodology in a given LTCH PPS rate year.

Specifically, we reduce all LTCH Medicare payments during the 5-year transition by a factor that is equal to 1 minus the ratio of the estimated TEFRA reasonable cost-based payments that would be made if the LTCH PPS was not implemented, to the projected total Medicare program PPS payments (that is, payments made under the transition methodology and the option to elect payment based on 100 percent of the Federal rate).

In the RY 2006 LTCH PPS final rule (70 FR 24202), based on the best available data at that time, we projected that approximately 98 percent of LTCHs will be paid based on 100 percent of the standard Federal rate rather than receive payment under the transition blend methodology for the 2006 LTCH PPS rate year. Using the same methodology described in the August 30, 2002 final rule (67 FR 56034), this projection, which used updated data and inflation factors, was based on our estimate that either: (1) A LTCH has already elected payment based on 100 percent of the Federal rate prior to the start of the 2006 LTCH PPS rate year (July 1, 2005); or (2) a LTCH would receive higher payments based on 100 percent of the 2006 LTCH PPS rate year standard Federal rate compared to the payments it would receive under the transition blend methodology. Similarly, we projected that the remaining 2 percent of LTCHs will choose to be paid based on the applicable transition blend methodology (as set forth under § 412.533(a)) because they would receive higher payments than if they were paid based on 100 percent of the 2006 LTCH PPS rate year standard Federal rate.

Also in the RY 2006 LTCH PPS final rule (70 FR 24202), based on the best available data at that time and policy revisions described in that same rule, we projected that the full effect of the remaining 2 years of the transition period (including the election option) would result in a cost to the Medicare program of approximately $1.675 million. Specifically, for the RY 2006 LTCH PPS, we estimated that the cost of the transition would be approximately $1 million. Because this amount is only a small percentage of total LTCH PPS payments for the 2006 LTCH PPS rate year (estimated at over $3 billion), the formula that we use to establish the budget neutrality offset to account for the additional costs of the transition period resulted in a factor of zero percent. Therefore, in that same final rule, we established a 0.0 percent reduction (a budget neutrality offset of 1.000) to all LTCH payments in the 2006 LTCH PPS rate year to account for the $1 million estimated cost of the transition period methodology (including the option to elect payment based on 100 percent of the Federal rate). We also indicated that we would use a budget neutrality offset for each of the remaining years of the transition period to account for the estimated costs for the respective LTCH PPS rate years. In that same final rule, we estimated that there would be a 0.0 percent budget neutrality offset to LTCH PPS payments during the remaining years of the transition period since, we estimated at that time that the additional cost to the Medicare program resulting from the transition period methodology would be so small that the budget neutrality factor determined under our established methodology would round to zero.

In this proposed rule, based on the updated data using the same methodology established in the August 30, 2002 final rule (67 FR 56034), we are projecting that approximately 97 percent of LTCHs would be paid based on 100 percent of the proposed standard Federal rate rather than receive payment under the transition blend methodology during the 2007 LTCH PPS rate year. This projection, which used updated data, is based on our estimate that either: (1) A LTCH has already elected payment based on 100 percent of the Federal rate prior to the beginning of the 2007 LTCH PPS rate year (July 1, 2006); or (2) a LTCH would receive higher payments based on 100 percent of the proposed standard Federal rate compared to the payments they would receive under the transition blend methodology. Similarly, we project that the remaining 3 percent of LTCHs would choose to be paid based on the transition blend methodology at § 412.533 because those payments are estimated to be higher than if they were paid based on 100 percent of the proposed standard Federal rate. The applicable transition blend percentage is applicable for a LTCH's entire cost reporting period beginning on or after October 1 (unless the LTCH elects payment based on 100 percent of the Federal rate). We note that this projection is slightly lower than the projection that 98 percent of LTCHs would be paid based on 100 percent of the proposed standard Federal rate rather than receive payment under the transition blend methodology during the 2006 LTCH PPS rate year discussed in the RY 2006 LTCH PPS final rule (70 FR 24202). The reason for this slight decrease is due to how our established methodology (described in this section) determines which LTCHs would be projected to receive payments based on 100 percent of the Federal rate in a given rate year. Specifically, under our established methodology, if a LTCH has not already elected payment based on 100 percent of the Federal rate then we evaluate whether a LTCH would receive

higher payments based on 100 percent of the proposed standard Federal rate or under the applicable transition blend methodology based on the most recent available data. Based on the best available data at that time, we projected that a few LTCHs that had not already elected payment based on 100 percent of the Federal rate would make such an election for RY 2006 because we projected that their payments based on 100 percent of the Federal rate would exceed their payments under the applicable transition blend. Therefore, those LTCHs were counted in the number of LTCHS that would be paid based on 100 percent of the Federal rate in RY 2006. However, based on the most recent available data used for this proposed rule, those LTCHs have not elected to receive payments based on 100 percent of the Federal rate and are being paid under the applicable transition blend methodology. Under our methodology for determining the percentage of LTCHs paid based on 100 percent of the federal rate, based on the most recent available data, we are projecting that for the RY 2007 LTCH PPS rate year, the applicable transition blend methodology payments to those LTCHs would be greater than payment based 100 percent of the Federal rate, and therefore, those LTCHs would not be included in the number of LTCHS that we estimate would be paid based on 100 percent of the Federal rate in RY 2007. Based on the policies presented in this proposed rule, we are projecting a decrease in their estimated payments based on 100 percent of the Federal rate in RY 2007 payment as compared to their estimated payments based on 100 percent of the Federal rate in RY 2006 primarily as a result of the proposed changes to the SSO policy (see section V.A.1. of this preamble) and the proposed increase in the outlier fixed-loss amount (see section IV.D.3.c. of this preamble). Because we are projecting a decrease in payments based on 100 percent of the Federal rate for these LTCHs, the estimated RY 2007 payments based on the applicable transition blend methodology are now higher than their estimated RY 2007 payments based on 100 percent of the Federal rate, we do not project that these LTCH would elect payment based on 100 percent of the Federal rate for RY 2007. Thus, the slight decrease in the our projection in the number of LTCHs that would be paid based on 100 percent of the Federal rate for the 2007 LTCH PPS rate year is appropriate.

Based on the best available data and the proposed policies described in this proposed rule, we are projecting that in absence of a transition budget neutrality offset, the full effect of the final full year of the transition period (including the election option) as compared to payments as if all LTCHs would be paid based on 100 percent of the Federal rate would result in a cost to the Medicare program of approximately 2.8 million. (As discussed in the RY 2006 final rule (70 FR 24201), we are no longer projecting a small cost for the 2008 LTCH PPS rate year (July 1, 2007 through June 30, 2008) even though some LTCH's will have a cost reporting period for the 5th year of the transition period which will be concluding in the first 3 months of the 2008 LTCH PPS rate year because based on the most available data, we are projecting that the vast majority of LTCHs would have made the election to be paid based on 100 percent of the Federal rate rather than the transition blend which would result in a negligible cost to the Medicare program.)

Accordingly, using the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 56034), based on updated data and the policies and rates presented in this proposed rule, we are proposing a 0.1 percent reduction (a budget neutrality offset of 0.999) to all LTCHs' payments for discharges occurring on or after July 1, 2006 and through June 30, 2007, to account for the estimated cost of the transition period methodology (including the option to elect payment based on 100 percent of the Federal rate) of approximately $2.8 million for the 2007 LTCH PPS rate year. We note that this proposed offset for the 2007 LTCH PPS rate year is slightly larger than the 0.0 percent reduction (a budget neutrality offset of 1.000) established for the 2006 LTCH PPS rate year (70 FR 24202). This is because we are now projecting that a few less LTCHs would elect payment based on 100 percent of the Federal rate than we were projecting when we determined the transition period budget neutrality offset for the 2006 LTCH PPS rate year based on the most recent available data.

6. One-Time Prospective Adjustment to the Standard Federal Rate

As we discussed in the August 30, 2002 final rule (67 FR 56036), consistent with the statutory requirement for budget neutrality in section 123(a)(1) of the BBRA, we intended that estimated aggregate payments under the LTCH PPS for FY 2003 equal the estimated aggregate payments that would be made if the LTCH PPS were not implemented. Our methodology for estimating payments for purposes of the budget neutrality calculations uses the best available data at the time and necessarily reflects assumptions. As the LTCH PPS progresses, we are monitoring payment data and will evaluate the ultimate accuracy of the assumptions used in the budget neutrality calculations (for example, inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS) described in the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). To the extent these assumptions significantly differ from actual experience, the aggregate amount of actual payments may turn out to be significantly higher or lower than the estimates on which the budget neutrality calculations were based.

Section 123(a)(1) of the BBRA as amended by section 307(b) of BIPA provides broad authority to the Secretary in developing the LTCH PPS, including the authority for appropriate adjustments. Under this broad authority, as implemented in the existing regulations at § 412.523(d)(3), we have provided for the possibility of making a one-time prospective adjustment to the LTCH PPS rates by October 1, 2006, so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the LTCH PPS rates for future years. (As discussed in greater detail below, we are proposing to extend the deadline for making this adjustment to July 1, 2008 to this proposed rule.

In the RY 2006 LTCH PPS final (70 FR 24203), based on the best available data at that time, we estimated that total Medicare program payments for LTCH services over the next 5 LTCH PPS rate years would be $3.32 billion for the 2006 LTCH PPS rate year; $3.38 billion for the 2007 LTCH PPS rate year; $3.48 billion for the 2008 LTCH PPS rate year; $3.63 billion for the 2009 LTCH PPS rate year; and $3.79 billion for the 2010 LTCH PPS rate year.

In this proposed rule, consistent with the methodology established in the August 30, 2002 final rule (67 FR 56036), based on the most recent available data, we estimate that total Medicare program payments for LTCH services for the next 5 LTCH PPS rate years would be as shown in Table 9.

TABLE 9

LTCH PPS rate year	Estimated payments ($ in billions)
2007	$5.27
2008	5.44
2009	5.64
2010	5.88

TABLE 9—Continued

LTCH PPS rate year	Estimated payments ($ in billions)
2011	6.15

In accordance with the methodology established in the August 30, 2002 LTCH PPS final rule (67 FR 56037), these estimates are based on the most recent available date, including the projection that 97 percent of LTCHs would elect to be paid based on 100 percent of the 2007 LTCH PPS rate year proposed standard Federal rate rather than the applicable transition blend and an estimated increase in the number of discharges from LTCHs. (We note that the 5-year spending estimates shown in Table 9 are significantly higher than the 5-year spending estimates presented in the RY 2006 LTCH PPS final rule (70 FR 24203). This is primarily due to an adjustment by our Office of the Actuary (OACT) to account for the significant increase in the expected number of LTCH discharges based on the most recent complete available LTCH discharge data.) These estimates are also based on our estimate of LTCH PPS rate year payments to LTCHs using OACT's most recent estimate of the excluded hospital with capital (currently used under the LTCH PPS) market basket of 3.6 percent for the 2007 LTCH PPS rate year, 3.5 percent for the 2008 LTCH PPS rate year, 3.1 percent for the 2009 LTCH PPS rate year, 2.6 percent for the 2010 LTCH PPS rate year, and 3.0 percent for the 2011 LTCH PPS rate year. (We note that, although we are proposing a zero percent update to the LTCH PPS Federal rate for RY 2007 (as discussed in section IV.C.3. of this proposed rule) OACT develops its spending projections based on existing policy and therefore, changes that have not yet been implemented are not reflected in the spending projections shown in this section.) We also considered OACT's most recent projections of changes in Medicare beneficiary enrollment that there would be a change in Medicare fee-for-service beneficiary enrollment of −2.3 percent in the 2007 LTCH PPS rate year, −1.0 percent in the 2008 LTCH PPS rate year, 0.3 percent in the 2008 and 2009 LTCH PPS rate years and, 0.6 percent in the 2010 LTCH PPS rate year. (We note that, based on the most recent available data, OACT is projecting a slight decrease in Medicare fee-for-service Part A enrollment for the 2007 and 2008 LTCH PPS rate years, in part, because they are projecting an increase in Medicare managed care enrollment as a result of the implementation of several provisions of the MMA of 2003.)

As we discussed in the RY 2006 LTCH PPS final rule (70 FR 24204), because the LTCH PPS was only recently implemented, sufficient new data has not been generated that would enable us to conduct a comprehensive reevaluation of our budget neutrality calculations. Accordingly, we did not make a one-time adjustment under § 412.523(d)(3). At this time, we still do not have sufficient new data to enable us to conduct a comprehensive reevaluation of our budget neutrality calculations. Therefore, in this proposed rule, we are not proposing to make a one-time adjustment under § 412.523(d)(3) so that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS is not perpetuated in the PPS rates for future years. However, as discussed in greater detail below, we will continue to collect and interpret new data as the data become available in the future to determine if this adjustment should be proposed. Additionally, as discussed in greater detail below, we believe that it is appropriate to propose postponement of the requirement established in § 412.523(d)(3) due to the time lag in the availability of Medicare data upon which this adjustment would be based. Therefore, we propose to revise § 412.523(d)(3) by postponing the October 1, 2006 deadline to July 1, 2008.

In the August 30, 2002 final rule implementing the LTCH PPS (67 FR 55954), we set forth the implementing regulations, based upon the broad authority granted to the Secretary, under section 123 of the BBRA as amended by section 307(b) of the BIPA. Section 123(a)(1) of the BBRA, required that the system ''maintain budget neutrality'' for FY 2003, that is, that estimated aggregate payments under the LTCH prospective payment system would equal the estimated aggregate payments that would be made if the LTCH prospective payment system would not be implemented for FY 2003. The methodology for determining the LTCH PPS standard Federal rate for FY 2003 that would ''maintain budget neutrality'' is described in considerable detail in the August 30, 2002 final rule (67 FR 56027 through 56037). As we discussed in that same final rule, our methodology for estimating payments for the purposes of budget neutrality calculations used the best available data and necessarily reflects assumptions in estimating aggregate payments that would be made if the LTCH PPS was not implemented. We also stated our intentions to monitor LTCH PPS payment data to evaluate the ultimate accuracy of the assumptions used in the budget neutrality calculations (for example, inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent that those assumptions significantly differ from actual experience, the aggregate amount of actual payments during FY 2003 may turn out to be significantly higher or lower than the estimates upon which the budget neutrality calculations were based. (67 FR 56036) In that same final rule, the Secretary exercised his broad authority in establishing the LTCH PPS and provided for the possibility of a one-time prospective adjustment to the LTCH prospective payment system rates by October 1, 2006 at § 412.523(d)(3). The purpose of that provision was to prevent any significant difference between actual payments and estimated payments for the first year of the LTCH prospective payment system, when we established the budget neutral Federal rate, as required by the statute (discussed previously), from being perpetuated in the prospective payment system rates for future years.

When we implemented the LTCH PPS, we established at § 412.533 a 5-year transition to full payments based on the LTCH PPS standard Federal rate. In addition, during that 5-year period, existing LTCHs (those that had their first cost reporting period as an LTCH prior to October 1, 2002), could elect for either full payment under the adjusted Federal rate payment determined under § 412.523, or be phased-in to the full Federal rate payment over 5 years in annual increments of 20 percent, with the remainder of the payment amount being determined under the former cost-based reimbursement rules set forth in the TEFRA system, (under part 413 of the same subchapter). Thus, for LTCH cost reporting periods beginning on or after October 1, 2006, the fifth year of the transition, payments to all LTCHs will be based fully (100 percent) on the LTCH PPS standard Federal rate.

In addition to developing a LTCH PPS standard Federal rate that would ''maintain budget neutrality'' for FY 2003, under the LTCH PPS, Federal prospective payments are adjusted to account for various factors (as discussed below). As noted previously in this proposed rule, the Secretary was granted considerable discretion in the design of the payment system. Specifically, under section 307(b) of the BIPA, the Secretary shall ''examine and * * * may provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage adjustments,

geographic reclassification, outliers, updates, and a disproportionate share adjustment.'' Thus, the Secretary was also given tremendous discretionary authority to determine which adjustments to include in the LTCH PPS. In developing the LTCH PPS, to evaluate whether the accuracy of the payment system would be enhanced by the inclusion of particular payment adjustments, and hence the appropriateness of those payment adjustments for the LTCH PPS, we contracted with 3M Health Information Systems to assist us with the analyses. These analyses include, among other techniques, the use of regression models and payment simulations to determine whether there was a correlation between an LTCH's cost per case and the inclusion of particular payment adjustments. We examined payment variables applicable to the inpatient acute-care hospital and IRF prospective payment systems, including the local wage variation (wage index), disproportionate share patient percentage (DSH), indirect medical education (IME), variables that account for location in a rural or large urban area, and a cost of living adjustment (COLA) for Alaska and Hawaii (67 FR 56015 through 56027). We concluded, in that August 30, 2002 final rule, that based on the best available LTCH data and consistent with the broad legal authority afforded to the Secretary, the LTCH PPS would include payment adjustments featured in other prospective payment systems: payments for high cost outliers (§ 412.525(a)); an area wage adjustment which would be phased-in over 5-years (§ 412.525(c)); and a COLA (§ 412.525(b)). Additionally, we established several adjustments specific to the LTCH PPS, such as adjusted payments for short'stay outliers (§ 412.529), interrupted stays (§ 412.531), and on-site discharges and readmittances (§ 412.532).

In each final rule for the LTCH PPS subsequent to the implementation of the LTCH PPS for FY 2003, as new data from LTCHs generated under the LTCH PPS has become available, we have revisited our determinations regarding the inclusion of specific payment adjustments (68 FR 34140 through 34150, 69 FR 25684 through 25701, and 70 FR 24190 through 24198). Although no additional payment adjustments were added since the initial implementation of the LTCH PPS in FY 2003, we stated that we would collect data and reevaluate the appropriateness of these adjustments in the future when more LTCH PPS data becomes available after the implementation of the LTCH PPS. After revisiting this issue and conducting extensive data analysis, we now believe that the current deadline of October 1, 2006, for making the one time adjustment to eliminate any significant difference between the actual payments and estimated payments for the first year of the PPS is too short. After the conclusion of the 5-year transition period (that is, after RY 2007), we now believe that sufficient new data will be generated by the LTCH PPS for a comprehensive reevaluation of these payment adjustments, including geographic reclassification, rural location, DSH, and IME.

The final year of the 5-year transition to full payments for all LTCHs based on the adjusted Federal rate will begin for cost reporting periods beginning on or after October 1, 2006 (FY 2007) and end with cost reporting periods beginning before October 1, 2007 (FY 2008). After the conclusion of the 5-year transition period (October 1, 2007), we expect to have between 3 and 4 years (FYs 2003 through 2006) of LTCH data generated since the implementation of the LTCH PPS. We note that there is a lag time between the submission of claims data and cost report data, and the availability of that data in the MedPAR files and HCRIS, respectively. Based on a comprehensive analysis of that data, we may then propose to revise some LTCH PPS payment adjustments for future years for the LTCH PPS.

Consistent with our intent to wait for the conclusion of the 5-year transition to 100 percent fully Federal payments under the LTCH PPS, to maximize the availability of data used to conduct a comprehensive evaluation of the payment adjustment policies issued at the inception of the LTCH PPS for FY 2003, we believe that it is appropriate to propose postponement of the requirement established by existing § 412.523(d)(3), described previously, which allowed for the possibility of making a one-time prospective adjustment to the LTCH prospective payment system rates from the current date of October 1, 2006 to an adjustment that would be effective on or before July 1, 2008. Currently, due to the time lag in the availability of Medicare data, the best available full year of LTCH claims data are from FY 2004 and the most complete full year of LTCH cost report data are from FY 2003. We believe that postponing the deadline of the possible one-time prospective adjustment to the LTCH PPS rates provided for in § 412.523(d)(3) to July 1, 2008 would result in the availability of additional data generated under the LTCH PPS and therefore our decisions regarding a possible adjustment would be based on more complete and up-to-date data. This data would be reflective of LTCH behavior in response to the implementation of the LTCH PPS. In addition, after further analysis, we believe that after the end of the transition may be the appropriate time to implement this one-time prospective adjustment, which was written to ensure that the effect of any significant difference between actual payments and estimated payments for the first year of the LTCH PPS would not be perpetuated in the prospective payment rates for future years. We note that we are proposing a July 1, 2008 rather than an October 1, 2007 date in keeping with the established rate year cycle. Although the LTCH PPS Federal rate was initially established with an October 1 through September 30th rate cycle, currently the LTCH PPS Federal rate is updated on a July 1 through June 30 rate year cycle (68 FR 34125 through 34128).

The final year of the 5-year phase-in of the LTCH PPS will begin for cost reporting periods beginning on or after October 1, 2006, during which payments will be 100 percent of the adjusted Federal rate for all LTCHs. Since the inception of the LTCH PPS, we have noted that we fully intend to review our payment adjustments when more LTCH PPS data become available after the implementation of the LTCH PPS because at that point we would have a sufficient amount of data with which to evaluate the impact of existing policy and to make informed decisions for the future of the payment system. After further consideration explained previously, we believe that after the end of the 5-year transition period it would be the appropriate time for both our planned reevaluation of the LTCH PPS payment adjustments as well as the possible ''one-time adjustment of the payment rates'' at § 412.525(d)(3). Therefore, we are proposing to revise § 412.523(d)(3) to change the deadline for the establishment of the possible one-time prospective adjustment from October 1, 2006 to July 1, 2008 and to synchronize these interrelated data analyses for purposes of determining future proposed payment policies under the LTCH PPS.

In section IV.C.3. of this proposed rule, where we discuss the proposed zero percent update factor to the standard Federal rate for the 2007 LTCH PPS rate year, we describe two aspects of our data monitoring activities, both of which impact continuing annual policy updates and determinations for the LTCH PPS which are the basis of our annual rule-making activities and **Federal Register** publications.

For the on-going implementation of the payment system, which entails determining annual system updates for the LTCH PPS, we engage in data monitoring and analysis of patient and facility level data. The most recent claims and cost data are used for this rate-setting purpose. From the outset of the LTCH PPS, we established a monitoring component to the system directed by our Office of Research, Development, and Information (ORDI) with additional data analysis provided by 3M Health Information Systems. The purposes of this protocol, as described in section X. of this proposed rule was to evaluate the impact of the LTCH PPS on the LTCH universe and to provide on-going data analysis that would enable CMS to determine the effectiveness of various policies and to alert CMS to issues which could require further regulation. Frequently, reviews and analyses of the data utilized for the annual updates have suggested directions for future research, which have resulted in policy proposals. We have revised and formulated several significant policies since the outset of the LTCH PPS based on the data analyses, including the 3-day or fewer interruption of stay policy at § 412.531 (69 FR 25690 through 25700), the LTCH HwH and LTCH satellite payment adjustment at § 412.534 (69 FR 49191 through 49214), the proposed revisions to the SSO policy at § 412.529 in section V.A.1. of this proposed rule, and the proposed zero percent update to the standard Federal rate, as described in section IV.C.3. of this proposed rule.

In the previous discussion, we have noted that we intend to reevaluate the LTCH PPS at the end of the 5-year transition to full Federal payments, based upon a comprehensive analysis of data generated since the start of the payment system for cost reporting periods beginning during FY 2003, in order to determine whether further payment adjustments are warranted. We have also proposed to revise § 412.523(d)(3) to postpone the establishment of the possible one-time prospective adjustment from October 1, 2006 to July 1, 2008.

Evaluating the appropriateness of this adjustment will entail a thorough review of the actual Medicare costs incurred by LTCHs during the first year of the LTCH PPS, that is, for LTCH cost reporting periods beginning on or after October 1, 2002 during which we were statutorily required to maintain budget neutrality as specified in section 123 of the BBRA. When we established the FY 2003 standard Federal rate, in order to meet this requirement, we used the most recent LTCH cost data available at that time, and trended that data forward to estimate what Medicare would have paid to LTCHS under the TEFRA payment system if the PPS were not implemented (67 FR 56033). (The methodology for determining the LTCH PPS standard Federal rate for FY 2003 that would ''maintain budget neutrality'' is described in considerable detail in the August 30, 2002 final rule (67 FR 56027 through 56037).)

As we discussed in that same final rule, our methodology for estimating payments for the purposes of budget neutrality calculations, utilized the best available data and necessarily reflected assumptions in estimating aggregate payments that would have been made had the LTCH PPS not been implemented. We also stated our intentions to monitor LTCH PPS data to evaluate the ultimate accuracy of the assumptions used in the budget neutrality calculations (for example, inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). To the extent that those assumptions significantly differed from actual experience, the aggregate amount of actual payments during FY 2003 could result as significantly higher or lower than the estimates upon which the budget neutrality calculations were based (67 FR 56036).

At the outset of the LTCH PPS, we provided for the possibility of a one-time prospective adjustment at § 412.523(d)(3). Among other things, we wanted the opportunity to adjust the standard Federal payment rate once accurate data was available that reflected the actual cost-based payments that would have been made under the Medicare program during FY 2003 if the LTCH PPS had not been implemented, rather than perpetuate any error in the Federal rate in future years.

We are proposing to postpone the adjustment until July 1, 2008 because by that time, given the lag time typically involved in the entire cost report settlement procedure, we will be able to utilize the most accurate data reflecting the actual costs incurred by LTCHs for cost reporting periods beginning during FY 2003. It is important to note that there are many LTCHs with cost reporting periods from September 1 through August 30 which first became subject to the LTCH PPS on September 1, 2003. Given the lag time required for typical cost report settlement involving submission, desk review, and in some cases an audit, which can take approximately 2 additional years to complete (and we expect to audit a number of LTCH cost reports for the purpose of this analysis), we do not believe that the October 1, 2006 deadline established § 412.523(d)(3) is reasonable or realistic. In fact, we believe that for cost reports for providers on August 2004 fiscal year ending date, we would be in possession of the most reliable cost report data indicating the actual costs of the Medicare program of the LTCH PPS during the year in which we established the Federal payment rate by July 2007 and any proposed correction, if finalized could then be implemented on July 1, 2008.

Therefore, we believe that postponing the deadline for this possible one-time prospective adjustment until July 1, 2008 would allow us to have the best available data from the first year of the LTCH PPS upon which to base an adjustment such as this.

Specifically, we wish to emphasize the distinction between the sufficiency of the data utilized for the annual data analysis that resulted in our proposed zero percent update for RY 2007 and the proposed postponement of the possible one-time prospective adjustment to the standard Federal rate, at proposed § 412.523(d)(3). We believe that the proposed annual adjustment of zero percent is based on the best data from FY 2004, including case-mix data which is derived from the MedPAR files, and data analysis coordinated by ORDI, assisted by 3M Health Information Services. The case-mix data used to make this adjustment is current and accurate and is not dependent upon the procedures of the cost report settlement. However, the data review that we believe necessary for the comprehensive analysis of the accuracy of the Federal payment rate under § 412.523(d)(3), which would be applied prospectively (and therefore has the potential to affect all future LTCH PPS Federal rates), is dependent on Medicare data that will only be available by July, 2007. We believe that only through a thorough analysis of the most comprehensive and accurate data from the first year of the implementation of the LTCH PPS for FY 2003 (including settled and fully audited cost reports) will we be able to reliably determine whether the one-time prospective adjustment to the standard Federal rate, which if issued will have an impact on all future payments under the LTCH PPS, should be proposed.

V. Other Proposed Policy Changes for the 2007 LTCH PPS Rate Year

A. Proposed Adjustments for Special Cases

1. Adjustment for SSO Cases

a. Proposed Changes to the Method for Determining the Payment Amount for SSO Cases

In the August 30, 2002 rule for the LTCH PPS, under § 412.529, we established a special payment policy for SSO cases, that is LTCH PPS cases with a LOS of less than or equal to five-sixths of the geometric ALOS for each LTC–DRG. When we established the SSO policy, we explained that ''[a] short-stay outlier case may occur when a beneficiary receives less than the full course of treatment at the LTCH before being discharged. These patients may be discharged to another site of care or they may be discharged and not readmitted because they no longer require treatment. Furthermore, patients may expire early in their LTCH stay'' (67 FR 55995). Also in the August 30, 2002 final rule, we stated that when we first described the policy, in the March 27, 2002 proposed rule, ''* * * we based the proposed policy on the belief that many of these patients could have been treated more appropriately in an acute hospital subject to the acute care hospital inpatient prospective payment system'' (67 FR 55995). Therefore, under the LTCH PPS, we implemented a special payment adjustment for SSO cases. Under the existing SSO policy at § 412.529, for LTCH PPS discharges with a LOS of up to and including five-sixths the geometric ALOS for the LTC–DRG, in general, we adjust the per discharge payment under the LTCH PPS by the lesser of 120 percent of the estimated cost of the case, 120 percent of the LTC–DRG specific per diem amount multiplied by the LOS of that discharge, or the full LTC–DRG payment.

As noted previously, generally LTCHs are defined by statute as having an ALOS of greater than 25 days. We stated that we believe that the SSO payment adjustment results in more appropriate payments, since these cases most likely would not receive a full course of a LTCH-level of treatment in such a short period of time and a full LTC–DRG payment may not always be appropriate. Payment-to-cost ratios simulated for LTCHs, for the cases described above, indicated that if LTCHs received a full LTC–DRG payment for those cases, they were significantly ''overpaid'' for the resources they have actually expended.

In establishing the SSO policy we also believe that providing a reduced payment for SSO cases would discourage hospitals from admitting patients for whom they were unable to provide complete treatment in order to maximize payment. We also believed that the policy did not severely penalize providers that, in good faith, had admitted a patient and provided some services before realizing that the beneficiary could receive more appropriate treatment at another site of care. As we explained in the FY 2003 LTCH PPS final rule, establishing a SSO payment for these types of cases addressed the incentives inherent in a discharge-based prospective payment system for LTCHs for treating patients with a short LOS (67 FR 55995 through 56000).

When we established the SSO adjustment at the outset of the LTCH PPS, we noted in the August 30, 2002 final rule that the regression analyses and simulations based on prior years' LTCH claims data generated under the former reasonable cost-based (TEFRA) based system, upon which we based many of our policy determinations regarding the design of the LTCH PPS for FY 2003, indicated that nearly half of LTCH cases would be paid on an adjusted per discharge amount based on the SSO payment policy established at existing § 412.529 once the LTCH PPS was implemented. However, we did believe that ''* * * this data analysis does not necessarily predict the future behavior of LTCHs operating under a prospective payment system. The data used in the analysis are a product or reflection of the practice patterns of hospitals that operate under the mechanisms of the TEFRA payment system, which are different from the principles of a prospective payment system. However, these are the best data available upon which we can simulate LTCH behavior under the new LTCH prospective payment system. We believe that once the LTCH prospective payment system is implemented, the practice patterns of LTCHs will change. We anticipate that hospitals will alter their admission, treatment, and discharge patterns. Thus, we fully expect that an increasing majority of cases will be reimbursed on an unadjusted per discharge basis during the transition from reasonable cost-based reimbursement to prospective payments.'' (67 FR 55999)

As we noted in the August 30, 2003 final rule, ''* * * [B]ased on our experience in implementing other Medicare prospective payment systems, we fully expect that as new data are received, we may revisit policy decisions described in this final rule. Furthermore, our Office of Research, Development, and Information [ORDI] will be tracking the impact of the prospective payments on LTCHs, other hospitals that treat long-term care patients, and other post-acute care providers, which will enable us to determine whether additional policy changes are warranted'' (67 FR 55999).

A change in the SSO policy was published in the RY 2004 LTCH PPS final rule (68 FR 34148), following a thorough reexamination of the impact of the SSO policy on subclause (II) LTCHs, authorized by section 1886(d)(1)(B)(iv)(II) of the Act which we implemented at § 412.23(e)(2)(ii). At that time, we revised certain aspects of the SSO policy in order to meet the specific needs of this type of LTCH. This provision provided an exception to the general definition of an LTCH set forth in section 1886(d)(1)(B)(iv)(I) of the Act, implemented at § 412.23(e)(2)(i), specifying that to qualify as a LTCH, a hospital must have first been excluded as a LTCH in calendar year (CY) 1986, have an average inpatient LOS of greater than 20 days, and demonstrate that 80 percent or more of its annual Medicare inpatient discharges in the 12-month cost reporting period ending in FY 1997 have a principal diagnosis that reflects a finding of neoplastic disease (62 FR 46016 and 46026). In the RY 2004 final rule, we particularly noted that the Congress recognized the existence and importance of a distinct category of LTCHs that might not otherwise warrant exclusion from the acute care inpatient PPS under subclause (I) but which nonetheless fulfilled a unique and vital role in serving a particular subset of Medicare patients. Consistent with existing policies that differentiated subclause (II) LTCHs from other LTCHs, we determined that it was reasonable for us to consider whether or not a policy that was designed for LTCHs designated under subclause (I) could reasonably and equitably be applied to a subclause (II) LTCH without some measure of adjustment. Therefore, in the RY 2004 LTCH PPS final rule, we provided an additional adjustment to the SSO policy for subclause (II) LTCHs. Specifically, in the RY 2004 LTCH PPS final rule (68 FR 34147 through 34148), we made a temporary adjustment to the applicable percentages used in the SSO payment formula at § 412.529(c) (applied to the cost of the SSO or the per diem LTCH DRG payment) used to calculate Medicare payments under the SSO policy. Specifically, at existing § 412.529(c)(4) for LTCHs designated under section 1886(d)(1)(B)(iv)(II) of the Act and § 412.23(e)(2)(ii), we

established a temporary adjustment that will sunset upon their first cost reporting period beginning on or after October 1, 2006. Under existing policy, for SSOs from a subclause (I) LTCH, Medicare payment is the least of the following: 120 percent of the LTC–DRG per diem amount multiplied by the LOS of the discharge; 120 percent of the cost of the case; or the full LTC–DRG. Under this temporary § 412.529(c)(4) adjustment, we substitute the following percentages for the 120 percent figure used in the SSO payment formula at § 412.529(c) for subclause (I) hospitals. Therefore, for discharges from a subclause (II) LTCHs, occurring on or after July 1, 2003, for cost reporting periods beginning during the first year of the 5-year LTCH PPS transition period, the SSO percentage is 195 percent. For discharges occurring in the cost reporting periods beginning during the second year of the transition period, the applicable SSO percentage is 193 percent; for discharges occurring in cost reporting periods beginning during the third year of the transition period, the applicable percentage is 165 percent; for discharges occurring in the cost reporting period beginning during the fourth year of the transition, the percentage is 136 percent; and for discharges occurring in cost reporting periods beginning during the fifth year of the 5-year transition, (and for discharges occurring in all future cost reporting periods), the SSO percentage for ''subclause (II)'' LTCHs, would be 120 percent, that is, the same as it currently is for all other LTCHs under the LTCH PPS.

As we continue to monitor the SSO policy, an analysis of LTCH claims data from the FY 2004 MedPAR files (using version 23 of the GROUPER), reveals that approximately 37 percent of LTCH discharges continue to be paid under the provisions of the existing SSO policy at § 412.529. As noted previously, at the outset of the LTCH PPS, the data upon which we based our system indicated that 48.4 percent of patients admitted to LTCHs fell into the category of SSOs, a percentage that we believed to be inappropriately high, given that the category of LTCH was established to care for Medicare beneficiaries requiring long-term hospital-level care. We believe our existing policy accounts for the fact that an LTCH in good faith could admit a patient and provide some services before realizing that the beneficiary would receive more appropriate treatment at another site of care. But in establishing the SSO policy, which provided a reduced payment for cases with a LOS that is up to and including five-sixths of the geometric ALOS for the LTC–DRG, it was our intent to not encourage hospitals to admit patients for whom a long-term hospital stay was not medically necessary and therefore, for whom the LTCH would not be providing complete treatment. We were concerned that these inappropriate admissions could be made in order to maximize payment (67 FR 55995). As noted previously, when this policy was established, at the start of the LTCH PPS for cost reporting periods beginning on or after October 1, 2002, nearly one-half (48.4 percent) of all LTCH cases would have been paid as SSOs. However, we believed that the percentage of short-stay outliers would drop significantly from 48.4 percent once the LTCH PPS was implemented. We believe that the 37 percent of LTCH discharges (that is, more than one-third of all LTCH patients) that the FY 2004 MedPAR identified as SSO cases continues to be an inappropriate number of patients being treated in LTCHs who most likely do not require the full measure of resources available in a hospital that has been established to treat patients requiring long-stay hospital-level care. Generally, if these patients required the type of care associated with LTCHs, the patients would most likely be in the LTCH for the duration of the LOS associated with the particular LTC–DRG to which the case is assigned. Therefore, we are concerned that the existing SSO payment adjustment at § 412.529, which generally will pay a per discharge amount based upon the least of 120 percent of the specific LTC–DRG per diem amount (multiplied by the LOS); 120 percent of the estimated costs of the case; or the full LTC–DRG payment as specified in existing § 412.529(c)(1), may unintentionally provide a financial incentive for LTCHs to admit patients not requiring the level of care available in that setting.

In the August 30, 2002 final rule, when first we presented our rationale for establishing the SSO policy, we noted that since LTCHs are defined by statute as generally having an ALOS greater than 25 days, we had proposed payment adjustments to make appropriate payment for cases that may not necessarily require the type of services intended to be provided at a LTCH or may have been transferred from an acute hospital prematurely'' (67 FR 55999). We continue to have these concerns, and we believe that our data indicate that after more than 3 years of the LTCH PPS, a policy reexamination is both necessary and appropriate, when more than one-third of LTCH PPS patients are paid under the SSO provision. In order to address these concerns, we are proposing two specific changes to the existing SSO payment methodology under § 412.529. Under existing policy, in general, Medicare will pay for a SSO case at the least of the following: 120 percent of the estimated costs of the case, 120 percent of the per diem LTCH PPS payment amount for the specific LTC–DRG multiplied by the LOS of the discharge, or the full LTCH PPS payment for the LTC–DRG. We believe that the current payment adjustment for SSO cases appears to be providing a financial incentive to inappropriately admit short-stay patients to LTCHs as evidenced by the high percentage of SSO cases. Consistent with the Secretary's broad authority ''to provide for appropriate adjustments to the long-term hospital payment system * * * '' established under section 123 of the BBRA as amended by section 307(b)(1) of BIPA, we are proposing to reduce the current adjustment at existing § 412.529(c)(1)(ii) which is based on 120 percent of the costs of the case to 100 percent of the costs of the case for discharges occurring on or after July 1, 2006 at proposed § 412.529(c)(2)(ii). We believe that by reducing the Medicare payment to the LTCH for a specific SSO case so that it would be equal to but not exceed the estimated costs incurred for that case, we may be removing what we believe could be a financial incentive that the current policy has established to treat short stay cases in LTCHs. We are not proposing to change the payment option of 120 percent of the per diem for a specific LTC–DRG multiplied by the LOS for that case because of the specific calculations upon which we based this aspect of the SSO policy adjustment. As described in detail in the FY 2003 final rule LTCH PPS, when we first established the SSO policy, we found that five-sixths of the geometric ALOS would be the SSO threshold where the full LTC–DRG payment would be made at 120 percent. That is, by adjusting the per discharge payment by paying at 120 percent of the per diem DRG payment, once a stay reaches five-sixths of the geometric ALOS for the LTC–DRG, the full DRG payment will have been made. We continue to believe that this specific methodology, described above in this section, which results in a gradual increase in payment as the LOS increases without producing a payment ''cliff'' at any one point, provides a reasonable payment option under the SSO policy. (67 FR 55997, August 30, 2002)

We believe it is inappropriate that more than one-third of Medicare patients treated in the special category of hospitals that was established by the Congress, under section 1886(d)(1)(B)(iv) of the Act to address the treatment of patients requiring extended hospital-level care are actually short-stay patients, as defined in § 412.529(a), and do not receive such extended hospital-level care. Therefore, we are proposing reduce the current adjustment at existing § 412.529(c)(1)(ii) from 120 percent of the costs of the case to 100 percent of the costs of the case for discharges occurring on or after July 1, 2006, for LTCHs described in § 412.23(e)(2)(i) resulting in a LTCH PPS Medicare payment equivalent to but not exceeding the estimated costs of the case. We believe that the proposed revision to the SSO payment methodology further discourages inappropriate admissions of these patients to LTCHs because we would be removing the financial incentive to admit cases that do not typically belong in LTCHs but would be more appropriately treated in another setting (for example, an inpatient acute care hospital).

Further, since the vast majority of LTCH patients are admitted directly from IPPS acute care hospitals, a fact verified by our patient data files (National Claims History Files), a recent MedPAC Report (June 2003, p. 79), and by research done by the Urban Institute at the outset of the LTCH PPS and RTI, we believe that the admission of short-stay patients at LTCHs may indicate premature and even inappropriate discharges from the referring acute care hospitals. For example, if an acute care hospital patient required additional inpatient services, it would usually be most appropriate for the acute care hospital to continue to treat the patient rather than discharging and admitting the patient to an LTCH for a short-stay episode.

We believe that in order to remove what may be an inappropriate financial incentive for a LTCH to admit a short-stay case, as well as, to discourage LTCHs from behaving like acute care hospitals by having a significant number of cases with lengths of stay commensurate with acute care hospitals and also to discourage LTCHs from admitting patients that could be premature discharges from acute care hospitals, we are proposing in § 412.529(c)(2)(iv) to add a fourth payment method to the three alternatives under § 412.529(c) for SSO cases. Specifically, we are proposing to revise § 412.529 to provide that for discharges from LTCHs described in § 412.23(e)(2)(i) occurring on or after July 1, 2006, payment for a SSO case would be the least of the following: 120 percent of the per diem amount for a specific LTC–DRG multiplied by the LOS of the discharge; 100 percent of the estimated costs of the case (which we are proposing in this proposed rule as a change from the existing 120 percent of estimated costs); the full LTCH PPS payment for the LTC–DRG; or a LTCH PPS payment comparable to the payment that would otherwise be paid under the IPPS.

We believe that this proposed additional component to the SSO payment formula is particularly appropriate because it reflects our concern that generally, LTCHs that admit SSO patients with lengths of stay more typical of an acute care hospital may be, in fact, behaving like acute care hospitals. Therefore, we are proposing to include an alternative payment method under the LTCH PPS SSO adjustment that could result in an LTCH PPS payment to the LTCH for a SSO stay that would be comparable to what Medicare would pay to an acute care hospital for the same case. Furthermore, since over 80 percent of all LTCH patients (FY 2003 MedPAR) are admitted from acute care hospitals to an LTCH, of which many become a SSO, an acute care hospital's discharge of a patient who is still in need of acute-level care may indicate a premature and inappropriate discharge from the acute care hospital, an inappropriate admission to the LTCH, and result in a second, unnecessary Medicare payment to the LTCH. We originally established a similar payment adjustment under the LTCH PPS at § 412.534 for LTCH HwHs and LTCH satellites for which greater than 25 percent of its patients were admitted from a host hospital (69 FR 49191 through 49214). Under that policy, unless the patient reached high cost outlier status at the acute care hospital prior to discharge, Medicare payments to the LTCH HwH or satellite for those cases in excess of the threshold were based upon the lesser of a payment under the LTCH PPS or an LTCH PPS amount equivalent to what would otherwise have been paid under the IPPS. This payment adjustment reflected our belief that if patient-shifting between a host hospital and its co-located LTCH exceeded a specific threshold, the onsite LTCH was functioning like a de facto unit of the acute care hospital, a configuration not permitted by section 1886(d)(1)(B) of the Act, which authorizes rehabilitation and psychiatric units but not LTCH units. We reasoned that if the patient was in effect, being treated in a ''unit'' of the acute care hospital, it was reasonable to issue a payment methodology that took this into account. For LTCH HwH or satellite discharges in excess of the 25 percent (or appropriate percentage) threshold, therefore, as specified in § 412.534, Medicare will make a payment based upon the lesser of the LTCH PPS payment otherwise payable under subpart O and an amount under this subpart that is equivalent to an amount that would be paid under the IPPS.

We believe that adapting the underlying premise of the payment adjustment at § 412.534 to a new payment adjustment method under the SSO policy is particularly appropriate, since we are concerned (and our data seems to confirm) that LTCHs may be admitting patients that should otherwise be treated in acute care hospitals, as evidenced by lengths of stay more in keeping with an acute care hospital stay than the considerably longer stays characteristic of LTCHs. We believe this additional proposed payment method, under the LTCH PPS for SSO patients under which, following the procedure set forth under § 412.529, the LTCH could receive a Medicare payment comparable to that which would otherwise be paid under the IPPS, is an appropriate response to the fact that an LTCH treating such patients may, in fact, be functioning like an acute care hospital.

We are also very concerned that acute care hospitals may be shifting their patients to LTCHs, resulting in a high incidence of SSOs. This pattern may indicate a premature discharge from the acute care hospital (where less than a full course of treatment was delivered) and an unnecessary admission to the LTCH. Despite the fact that the payment adjustment at § 412.534, based on the 25 percent (or applicable percentage) threshold, focused on inappropriate patient movement between co-located providers (69 FR 49191 through 49214), we do not believe that co-location is a prerequisite to inappropriate patient-shifting between an acute care hospital and an LTCH. As we discuss in section V.B. of this proposed rule, with the explosive growth in the numbers of free-standing LTCHs since 2004, many of which receive patients from a single acute care hospital, we are monitoring patient shifting that is occurring with growing regularity. (This issue is discussed in depth in section X. of this proposed rule.)

We believe that it is essential to guard the Medicare Trust Fund against admission and discharge practices that could result in more than one payment

for what was essentially one episode of patient care and, as we noted above in this section, we are concerned that there may be a correlation between the fact that one-third of LTCH discharges are SSO cases and what, in some cases, may be inappropriate admissions of patients who are prematurely discharged from acute care hospitals. We would also note that from the outset of the LTCH PPS, in our FY 2003 final rule for the LTCH PPS, we stated that ''many of these [SSO] patients could have been treated more appropriately in an acute care hospital subject to the acute care hospital inpatient prospective payment system'' (67 FR 55995). Therefore, we are proposing a fourth alternative in the SSO payment formula at § 412.529 that is similar to the existing payment adjustment at § 412.534, discussed in section V.B. of this proposed rule.

In the discussion that follows, for the sake of clarity, we use phrases such as ''IPPS DRG relative weights,'' and the ''IPPS labor-related share,'' in describing features of the IPPS that we would use in calculating LTCH PPS payments under this proposed new alternative adjustment. We want to emphasize, however, that such a payment is not an IPPS payment but rather, a payment under the LTCH PPS that is generally derived from the IPPS payment methodology. Therefore, for Medicare payments for SSO cases under the LTCH PPS as specified in proposed § 412.529(c)(2)(iv), we are proposing that ''an amount under subpart O that is comparable to an amount that otherwise would be paid under the IPPS'' would be calculated based on the sum of the applicable operating and capital IPPS rates in effect at the time of the discharge from the LTCH as established in the applicable IPPS final rule published annually in the **Federal Register**. This is necessary since, under the IPPS, there are separate Medicare rates for operating (subpart D of part 412) and capital (subpart M of part 412) costs to acute care hospitals; while, under the LTCH PPS, there is a single payment for the operating and capital costs of the inpatient hospital services provided to LTCH Medicare patients. We are also proposing that ''an amount under subpart O that is comparable to an amount that otherwise would be paid under the IPPS'' would be calculated including the applicable differences in resource use (that is, IPPS DRG relative weights), differences in area wage levels (that is, wage index), a cost-of-living adjustment for hospitals located in Alaska and Hawaii, the treatment of a disproportionate share of low income patients (DSH), if applicable, and an adjustment for indirect medical education (IME), if applicable. (We would emphasize that under this proposed policy, Medicare payments, payable under subpart O, would be ''comparable'' to what would otherwise be paid under the IPPS, rather than ''equal'' to an IPPS payment because, as we explain, there are specific features of the IPPS that do not directly translate into the LTCH PPS, so would be no way to establish or evaluate whether the LTCH payments are ''equal'' to an amount that would be paid under the IPPS. In proposing to use the word ''comparable,'' to describe this payment alternative to the existing SSO policy, we intend to make clear that such payments would be calculated by applying IPPS principles to achieve a close approximation of payments that would be made under the IPPS, recognizing the fact that not all components of the IPPS can be carried out precisely in the LTCH PPS context.

Specifically, under this proposed policy, for payments under the LTCH PPS, we would calculate an amount payable under subpart O comparable to what would otherwise be paid under the IPPS for the costs of inpatient operating services which would be based on the standardized amount determined under § 412.64(c), adjusted by the applicable DRG weighting factors at § 412.60 as set forth at § 412.64(g). This amount would be further adjusted for different area wage levels using the applicable IPPS labor-related share based on the CBSA where the LTCH is physically located set forth at § 412.525(c) and the IPPS wage index for non-reclassified hospitals as shown in Tables 4A and 4B in the annual IPPS final rule. (In the RY 2006 LTCH PPS final rule (70 FR 24200), we discuss the inapplicability of geographic reclassification procedures for LTCHs.) For LTCHs located in Alaska and Hawaii, we propose that this amount would also be adjusted by the applicable proposed COLA factor used under the IPPS published annually in the IPPS final rule. (We note currently that the same COLA factors are used under both the IPPS and the LTCH PPS.)

We are additionally proposing that this proposed revised payment adjustment alternative (an amount comparable to what would otherwise be paid under the IPPS for the costs of inpatient operating services) would also include a DSH adjustment (see § 412.106), if applicable, for discharges governed by § 412.529.

Under this proposed revision to the LTCH PPS SSO payment adjustment at proposed § 412.529(c)(2)(iv), we are proposing that in the case of a LTCH that is a teaching hospital, we would determine the IME payment for the LTCH by imputing a limit on the number of full-time equivalent (FTE) residents that may be counted for IME (IME cap) based on the LTCH's direct GME cap (which would already have been established for an LTCH which had residency programs as set forth at § 413.79(c)(2)), thus calculating an IME payment for this LTCH that is in accord with the IPPS payment formula set forth at § 412.105. We are adapting this methodology from the payment adjustment established for LTCH HwHs and LTCH satellites under § 412.534 where the applicable payment alternative is described as an amount ''equivalent'' to what would otherwise be paid under the IPPS. The use of a proxy for the IME cap is necessary because it would not be appropriate to apply the IPPS IME rules literally in the context of this LTCH PPS payment adjustment. Under the IPPS, IME payment regulations at § 412.105, limits were established on the number of FTE residents a hospital is permitted to count for IME payments based on the hospital's 1996 cost report. This IME FTE resident cap under the IPPS would not translate appropriately to an LTCH since an LTCH would not have reported any FTE residents for IME on its 1996 cost report. Therefore, we believe the use of the LTCH's direct GME cap for the purpose of calculating the payment adjustment alternative under proposed § 412.529(c)(2)(iv) is reasonable since it is based on the best available data on residency programs at LTCHs (which could be computed from direct GME data for LTCHs that had residency programs). Using an imputed GME cap would enable us to factor an adjustment for residency programs into a Medicare payment under the LTCH PPS for those SSO cases where the least of the payment alternatives results in an amount under the LTCH PPS comparable to what would otherwise be paid under the IPPS. Both a DSH adjustment and an IME adjustment, as necessary, could be computed from data already collected on the LTCH's cost report.

Under this proposed LTCH PPS payment adjustment, an amount payable under subpart O comparable to what would otherwise be paid under the IPPS would also include payment for the costs of inpatient capital-related costs based on the capital Federal rate at § 412.308(c), which would be adjusted by the applicable IPPS DRG weighting factors at § 412.60 as set forth at § 412.312(b). This amount would be further adjusted by the applicable geographic adjustment factors set forth

at § 412.316, including wage index, (based on the CBSA where a LTCH is physically located and derived from the IPPS wage index for non-reclassified hospitals as shown in tables 4A and 4B of the annual IPPS final rule) large urban location, if applicable, and the IPPS COLA factor used under the IPPS for LTCHs located in Alaska and Hawaii. (The same COLA factors are used under both the IPPS and the LTCH PPS.).

For LTCH discharges governed by the proposed revision of the SSO policy under the LTCH PPS, an amount comparable to what would be paid under the IPPS for the inpatient capital-related costs would also include a DSH adjustment (§ 412.320), if applicable and an IME adjustment (§ 412.322), if applicable. (As with IPPS payment for operating costs, a DSH or an IME adjustment for the purposes of this proposed policy could be computed from data already collected on the LTCH's cost report, as necessary.)

Under this proposed policy, an amount payable under subpart O comparable to what would otherwise be paid under the IPPS would equal the sum of the amount comparable to what would otherwise be paid under the IPPS for the costs of inpatient operating services and the amount comparable to what would be paid under the IPPS for inpatient capital-related costs (as described previously). We note that we are proposing that ''a LTCH PPS payment amount comparable to what would be paid under the IPPS'' would not include additional payments for extraordinarily high cost cases under the IPPS outlier policy (§ 412.80(a)) since, under existing LTCH PPS policy, a SSO case that meets the criteria for a LTCH PPS high cost outlier payment at § 412.525(a)(1) (that is, if the estimated costs of the case exceed the adjusted LTC–DRG payment plus a fixed loss amount) would be receive an additional payment under the LTCH PPS high cost outlier policy at § 412.525(a) (67 FR 56026, August 30, 2002). For purposes of high cost outliers under the SSO policy, we use a fixed loss amount calculated under § 412.252(a) and not a fixed loss amount based on § 412.80(a). We propose to use the term ''comparable'' in the fourth payment alternative so that the public would realize that this payment alternative is not exactly the same as the one that is similarly worded in § 412.534(c)(2), (d)(1), and (e)(1), discussed in section V.B. of this proposed rule.

Therefore, as noted previously in this proposed rule, we are proposing to add an additional method to the existing payment alternatives (that is, the least of 120 percent of the per diem LTC–DRG multiplied by the number of inpatient days as specified in § 412.529(c)(2)(i), 120 percent of the costs of the case as specified in § 412.529(c)(2)(ii), or the full LTC–DRG payment as specified in § 412.529(c)(2)(iii)). Specifically, we are proposing in § 412.529(c)(2)(iv) that Medicare would pay an amount comparable to the amount that would have been paid under the IPPS for a particular case if that amount is lower than the existing 3 payment alternatives. Medicare would pay the LTCH 80 percent of the costs of the case that exceed the sum of the applicable option and the fixed loss amount determined under § 412.525(a). In addition, we are proposing a change to § 412.529(c)(2)(ii) that decreases the 120 percent of the costs to 100 percent of costs.

Under existing LTCH PPS SSO policy at § 412.529(c), the payment is ultimately based on the least of: 120 percent of the LTC–DRG specific per diem amount multiplied by the LOS of the discharge; 120 percent of the cost of the case; or the full LTC–DRG. A high cost outlier payment could be made for a SSO stay if the total costs of the case exceed the least of these three options, plus the appropriate fixed-loss amount under § 412.525. In this proposed rule, for reasons described previously, we have proposed to lower the 120 percent of costs to 100 percent, and we have also proposed a fourth alternative method for this formula: An LTCH PPS payment comparable to what would otherwise have been paid under the IPPS. We would emphasize that under this proposed policy we are not proposing to change the basic payment determinations in the existing SSO payment policy for high cost outliers. Therefore, as noted previously in this proposed rule, if the costs of the case exceeded the payment resulting from this formula plus the LTCH PPS fixed loss amount, Medicare payment to the LTCH for this case, would include high cost outlier payment set forth at § 412.525.

Accordingly, even with the proposed additional alternative to the SSO payment policy at proposed § 412.529(c)(2)(iv), high cost outlier payments for a SSO discharge would continue to be paid under the existing SSO policy established at the start of the LTCH PPS (for cost reporting periods beginning during FY 2003) where high cost outlier payments, based upon the use of the LTCH PPS fixed loss amount, were governed by § 412.525.

We note that the approach taken under § 412.534 for high cost outliers is different than the approach that has been taken for more than the last 3 years with short-stay outliers that are also high cost outliers (67 FR 56026, 68 FR 34145, 69 FR 25689, 70 FR 24197). Specifically, since the beginning of the LTCH PPS, a SSO that is also a high cost outlier has utilized the fixed loss amount calculated under § 412.525. Accordingly, we are not aware of any reason at this time to change this policy, regardless of the fact that we are now proposing to add a fourth alternative payment method under the SSO policy (that is, a payment under subpart O that is comparable to an amount otherwise payable under § 412.1(a)). Furthermore, we believe that it is beneficial from an administrative efficiency perspective to maintain our current policy for a SSO that also hits high cost outlier status.

We have provided that under the LTCH HwH and satellite payment adjustment at § 412.534, payment for discharges will be ''the lesser of the amount otherwise payable under this subpart [subpart O] or the amount that is otherwise payable under this subpart that is equivalent to the amount that would be otherwise payable under § 412.1(a) [the IPPS].'' We acknowledge that under this policy, if payment is based on the latter and the case is a high cost outlier, § 412.80 will govern the LTCH PPS payment. Therefore, if the estimated coast of the case exceeds the DRG payment plus the fixed loss amount under § 412.80(a), the LTCH would receive an additional payment based on the high cost outlier policy under the IPPS. If payment is based on an amount otherwise payable under Subpart O, and the case is a high cost outlier, § 412.525 will govern. If the estimated cost of the case exceeds the adjusted LTCH–DRG payment plus a fixed loss amount under § 412.525(a), the LTCH would receive an additional payment based on the LTCH PPS high cost outlier policy. We believe that proposing the additional alternative in § 412.529(c)(2)(iv) to the payment options under the SSO policy, which, if applicable, could result in a high cost outlier payment determined under § 412.525, is consistent with our existing SSO high cost outlier policy and the proposed policy would maintain that consistency. However, we are specifically asking for comments on whether we should use a fixed loss amount derived from the IPPS high cost outlier policy at § 412.80(a), where the least of the four options in the rate is comparable to the IPPS rate in the event that a SSO case also qualifies for a high cost outlier payment under the LTCH PPS.

We established special provisions for the SSO policy for subclause (II) LTCHs in the RY 2004 LTCH PPS final rule (68

FR 34147). We are proposing to exempt subclause (II) LTCHs from the proposed additional revisions to the SSO policy discussed previously until the 5th year of the phase-in for such an LTCH of the LTCH PPS (that is, for discharges occurring during cost reporting periods beginning on or after October 1, 2006). This proposed approach is consistent with our existing policy as it applies to subclause (II) LTCHs in that these LTCHs do not become subject to the specific SSO percentages established for subclause (I) LTCHs until cost reporting periods beginning on or after October 1, 2006. Therefore, since the percentages applied under the SSO policy for subclause II LTCHs do not go to 120 percent until the fifth year of the transition, the proposed reduction from 120 percent of the estimated costs of the case to 100 percent of the estimated costs would not apply to a subclause (II) LTCH until that time, nor would the proposed additional alternative, of an amount payable under Subpart O comparable to the amount that would otherwise be paid under the IPPS, apply to discharges from a subclause (II) LTCH until such an LTCH's cost reporting period beginning on or after October 1, 2006. Therefore, under our proposed policy, we are proposing that SSO discharges at a subclause (II) LTCH that had a cost reporting period beginning on January 1, for example, would be subject to all of the four payment alternatives (including the proposed reduction to 100 percent of costs and the proposed addition of option of ''a payment comparable to what would otherwise have been paid under the IPPS'') for discharges occurring on or after the start of its 5th year of the transition on January 1, 2007.

Our proposal to exempt subclause (II) LTCHs from the proposed revisions to the SSO policy at § 412.529(c)(2) until cost reporting periods beginning on or after October 1, 2006 is consistent with our understanding of Congressional intent in establishing this special category of LTCHs in section 4417(b) of the BBA, which states that 80 percent of the annual Medicare inpatient discharges, in such a subclause (II) LTCH, in the 12-month reporting period ending in Federal FY 1997 would have had principal diagnosis that reflects a finding of neoplastic disease. The Congress, in enacting subclause II, provided an exception to the general definition of LTCHs under subclause I. In the RY 2004 LTCH PPS final rule (68 FR 34148), we evaluated the SSO policy for subclause II LTCHs, and we noted that the unique Congressional mandate set forth in section 1886(d)(1)(B)(iv)(II) of the Act circumscribes such a LTCHs' admission policies to the extent that it is being identified as a LTCH in order to provide a particular type of service (for which the ALOS is greater than 20 days) to a particular population (at least 80 percent have a principal diagnosis of neoplastic disease). We stated that we believed that a LTCH in this category might not be able to readily address the type of patients and the costs it incurs for those patients as would LTCHs described under subclause I. We believed that it is necessary to adjust the short stay policy for subclause (II) LTCHs during the 5-year transition period, so that a LTCH of this type could continue to serve its community, as intended by the Congress (68 FR 34148).

We continue to believe that hospitals fitting this description fulfill a unique and vital service for certain Medicare beneficiaries. We further believe, as we discussed in significant detail in the RY 2004 final rule, that it was necessary to temporarily adjust the short stay policy for subclause (II) LTCHs during the 5-year transition period, so that an LTCH of this type could continue to serve its community as they adjust their behavior. We also stated in the FY 2004 final rule that we expected that during this 5-year period, the subclause (II) LTCHs will make every attempt to adopt the type of efficiency enhancing policies that generally result from the implementation of prospective payment systems in other health care settings (69 FR 34148). Therefore, we are proposing that hospitals that qualify as subclause (II) LTCHs would become subject to the new proposed payment options for SSO discharges, when a subclause (II) LTCH would also become fully subject to the general SSO policy at § 412.529, which would be for discharges occurring in the cost reporting period beginning on or after October 1, 2006.

b. Proposed Changes to the Determination of Cost-to-Charge Ratios (CCRs) and Reconciliation of SSO Cases

In the June 9, 2003 IPPS outlier final rule (68 FR 34507), we revised the short-stay policy at § 412.529 (and the high-cost outlier policy at § 412.525(a)) because, as we discussed above in this section, we believed that the SSO (and high cost outlier) policy are susceptible to the same payment vulnerabilities that became evident under the IPPS, and therefore, merited revision. Therefore, in the regulations under existing § 412.529(c)(5)(ii) and (iii), we established a policy for the determination of LTCH CCRs and the reconciliation of SSO payments, for discharges occurring on or after August 8, 2003 (§ 412.529(c)(5)(ii)) and October 1, 2003 (§ 412.529(c)(5)(iii)), respectively. (As noted above in this section, in that same final rule, we established the same changes to the high-cost outlier policy at existing § 412.525(a)(4)(ii) and (iii).)

As we discuss in section IV.D.3.b. of this preamble, we are proposing to revise the existing regulations at § 412.525(a)(4) to codify in subpart O of part 42 of the CFR the provisions governing the determination of LTCHs' CCRs, including proposed modifications and editorial clarifications to our existing methodology for determining the annual LTCH CCR ceiling and applicable Statewide average CCRs under the LTCH PPS, and the provisions governing the reconciliation of high cost outlier payments. We are proposing these changes, as we discuss in greater detail below in this section, because we believe that such proposed changes would be more consistent with the LTCH PPS single payment rate, and because we believe it would be more appropriate and administratively simpler to include the regulatory provisions that pertain only to LTCHs for the determination of LTCH PPS outlier payments applicable under the LTCH PPS regulations in subpart O of part 42 of the CFR (as opposed to subpart A). Since CCRs are also used in determining SSO payments under § 412.529, we are proposing, under the broad authority of section 123 of the BBRA and section 307(b)(1) of BIPA, to revise § 412.529(c) consistent with the proposed changes to § 412.525(a)(4) discussed in section IV.D.3. of this preamble.

Specifically, we are proposing that in § 412.529(c)(4)(iv)(C)(*2*) would specify, that for discharges occurring on or after October 1, 2006, if, among other things, a LTCH's CCR is in excess of the LTCH CCR ceiling (which would be calculated as 3 standard deviations above the corresponding national geometric mean CCR (established and published annually by CMS)), the FI may use a Statewide average CCR (also established annually by CMS). (We note that, similar to our current policy, we are also proposing under proposed § 412.529(c)(4)(iv)(C) that the FI may use a Statewide average CCR in two other circumstances, which are discussed in greater detail below in this section.) This proposed change is similar to our existing policy (established in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34494)) and the proposed change to the LTCH PPS high cost outlier policy discussed previously in this proposed rule. Under proposed § 412.529(c)(4)(iv)(C)(*2*), for discharges

occurring on or after October 1, 2006, we are proposing that we would determine the single ''total'' CCR ceiling (as we proposed under the high cost outlier policy at proposed § 412.525(a)(4)(iv)(C)(*2*), as explained in section IV.D.3.b. of this preamble) by first calculating the total (that is, operating and capital) CCR for each hospital and then determining the average total CCR for all hospitals. The total LTCH CCR ceiling would then be established at 3 standard deviations from that average total CCR rather than determining the LTCH CCR ceiling by adding together the separate IPPS operating CCR ceiling and IPPS capital CCR ceiling as we do under our current policy. (We note, as discussed in greater detail below in this section, in conjunction with this proposed change in the calculation of the LTCH CCR ceiling, we are also proposing a change in our methodology for calculating the applicable Statewide average CCRs under the LTCH PPS to be based on ''total'' hospital-specific CCRs.) Specifically, we are proposing under the SSO policy at § 412.529(c)(4)(iv)(C), to use the same IPPS CCR data that we currently use to annually determine the separate IPPS operating CCR and capital CCR ceilings (that we add together under our current policy to determine the annual CCR ceiling for LTCHs) to compute the single LTCH ''total'' CCR ceiling based on IPPS hospital-specific total (operating and capital) Medicare costs and charges, as explained above in this section. In addition, under this proposal, the total CCR ceiling would continue to be published annually in the IPPS proposed and final rules, and therefore, the public should continue to consult the annual IPPS proposed and final rules for changes to the applicable LTCH PPS Statewide average total CCRs that would be effective for discharges occurring on or after October 1, 2006 (since, under this proposal the current applicable combined Statewide average CCRs, established for discharges occurring on or after October 1, 2005 in the FY 2006 IPPS final rule, would remain in effect for discharges occurring on or before September 30, 2006.) The rationale for this proposed change to the SSO policy at proposed § 412.529(c)(4)(iv)(C) mirrors the rationale provided for the proposed changes to the high cost outlier policy at proposed § 412.525(a)(4)(iv)(C) discussed in section IV.D.3.b. of this preamble.

Also consistent with the proposed changes to § 412.525(a)(4)(iv), under the broad authority of section 123 of the BBRA and section 307(b)(1) of BIPA, we are also proposing at § 412.529(c)(4)(iv)(A) through (C), for discharges occurring on or after October 1, 2006, to codify in subpart O of part 42 of the CFR the remaining LTCH PPS SSO policy changes concerning the determination of LTCHs' CCRs that were established in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34506 through 34513), including proposed modifications and editorial clarifications to those existing policies established in that final rule in order to more precisely describe the application of those policies as they relate LTCHs. Specifically, similar to our current policy and consistent with the proposed changes to the high cost outlier policy at § 412.525(a)(4) discussed previously in this proposed rule, we are proposing in § 412.529(c)(4)(iv)(C) to specify that the FI may use a Statewide average CCR, which would be established annually by CMS, if it is unable to determine an accurate CCR for a LTCH in one of the following three circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (for this purpose, consistent with current policy, a new LTCH would be defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter); (2) LTCHs whose CCR is in excess of the LTCH CCR ceiling (that is, 3 standard deviations above the corresponding national geometric mean total CCR); and (3) other LTCHs for whom data with which to calculate a CCR is not available (for example, missing or faulty data). (As we noted in section IV.D.3.b. of this preamble and consistent with our current regulations, either CMS or the hospital may request the use of a different (higher or lower) CCR based on substantial evidence that such a CCR more accurately reflects the hospital's actual costs and charges. This applies to new (as defined above) as well. For instance, CMS may determine that the applicable Statewide average CCR should not be applied to hospitals that convert from acute-care IPPS hospitals to LTCHs (and receive a new LTCH provider number). Rather, the cost and charge data from the IPPS hospital's cost report (even if it is more or less than a 12-month cost reporting period) would be used to determine the LTCH's CCR.)

Also similar to our current practice and consistent with the proposed change to the high cost outlier policy discussed previously in this proposed rule, under § 412.525(c)(4)(iv)(C), for discharges occurring on or after October 1, 2006, we are proposing that we would annually establish Statewide average ''total'' CCRs for use under the LTCH PPS based on IPPS data by first calculating the total (that is, operating and capital) CCR for each hospital and then determining the average total CCR for all hospitals in each State rather than assigning the combined (operating and capital) Statewide average CCRs, as we do under our current policy. Specifically, in proposing to compute Statewide average total CCRs, we would use the same IPPS CCR data that we currently use to annually establish the separate IPPS operating Statewide average CCRs and capital Statewide CCRs (that we add together under our current policy to determine the applicable ''combined'' Statewide average CCR for LTCHs) to compute Statewide average total CCRs as explained above in this section. In addition, under this proposal, the Statewide average total CCRs would continue to be published annually in the IPPS proposed and final rules and therefore, the public should continue to consult the annual IPPS proposed and final rules for changes to the applicable LTCH PPS Statewide average total CCRs that would be effective for discharges occurring on or after October 1, 2006 (since, under this proposal, the current applicable combined Statewide average CCRs, established for discharges occurring on or after October 1, 2005 in the FY 2006 IPPS final rule, would remain in effect for discharges occurring on or before September 30, 2006).

Our rationale for this proposed change to the SSO policy at proposed § 412.529(c)(4)(iv)(C) mirrors the rationale provided for the proposed changes to the high cost outlier policy at proposed § 412.525(a)(4)(iv)(C) discussed in greater detail in section IV.D.3.b. of this preamble.

In addition, we are proposing under § 412.529(c)(4)(iv)(B), similar to our current policy and consistent with the proposed change to the high cost outlier policy discussed above, for discharges occurring on or after October 1, 2006, that the CCR applied at the time a claim is processed would be based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period. Furthermore, we are proposing under § 412.529(c)(4)(iv)(A) that CMS may specify an alternative to the CCR computed from the most recent settled cost report or the most recent tentative settled cost report, whichever is later, or a hospital may also request that its FI use a different (higher or lower) CCR based on substantial evidence presented by the hospital. As noted previously in this proposed rule, these proposed revisions to our policy

for determining a LTCH's CCR for discharges occurring on or after October 1, 2006 under proposed revised § 412.529(c)(4)(iv)(A) and (B) are similar to our existing policy established in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34506 through 34513) and consistent with the proposed changes to the high cost outlier policy previously discussed in this proposed rule.

Furthermore, similar to our current policy and consistent with the proposed change to the high cost outlier policy discussed previously in this proposed rule , under the broad authority under section 123 of the BBRA as amended by section 307(b) of BIPA, we are also proposing in under § 412.529(c)(4)(iv), for discharges occurring on or after October 1, 2006, to codify in the LTCH PPS regulations (subpart O of part 42 of the CFR) the outlier reconciliation provisions that were established in the June 9, 2003 IPPS high cost outlier final rule (68 FR 34506 through 34513) including proposed editorial clarifications to those provisions (which are the same as the proposed changes to the high cost outlier policy discussed above in section IV.D.3.d. of the preamble of this proposed rule). Specifically, under § 412.529(c)(4)(iv)(D), similar to our current policy and consistent with the proposed change to the high cost outlier policy, we are proposing to specify that, for discharges occurring on or after October 1, 2006, any reconciliation of outlier payments would be based on the CCR calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. In addition, at proposed § 412.529(c)(4)(iv)(E), similar to our current policy and consistent with the proposed change to the high cost outlier policy, we are proposing to specify that, for discharges occurring on or after October 1, 2006, at the time of any reconciliation, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. This adjustment would be based upon a widely available index that would be established in advance by the Secretary and would be applied from the midpoint of the cost reporting period to the date of reconciliation. Our rationale for these proposed changes to the SSO policy at proposed § 412.529(c)(4)(iv)(D) and (E) mirrors the rationale provided for the proposed changes to the high cost outlier policy at proposed § 412.525(a)(4)(iv)(D) and (E), discussed in greater detail in section IV.D.3.d. of this preamble.

2. The 3-Day or Less Interruption of Stay

In the RY 2005 LTCH PPS final rule, we revised the definition of an ''interruption of a stay'' at § 412.531(a) by establishing two distinct categories, ''[a] 3-day or less interruption of stay'' and ''[a] greater than 3-day interruption of stay'' at § 412.531(a)(2). The payment features of the ''greater than 3-day'' policy itself apply beginning with day 4 once the ''3-day or less'' policy no longer applies.

The 3-day or less interruption of stay policy is defined at § 412.531(a)(1) as ''a stay at a LTCH during which a Medicare inpatient is discharged from the LTCH to an acute care hospital, IRF, SNF, or the patient's home and readmitted to the same LTCH within 3 days of the discharge from the LTCH. The 3-day or less period begins with the date of discharge from the LTCH and ends not later than midnight of the third day.'' As discussed in detail in the RY 2005 LTCH PPS final rule (69 FR 25691 through 25700), there are several components to the payment for the 3-day or less interruption of stay.

First, subject to § 412.531(b)(1)(ii)(A)(*1*) and (b)(1)(ii)(A)(*2*), only one LTC–DRG payment will be made to the LTCH for the patient who is discharged from the LTCH to an acute care hospital, IRF, SNF, or patient's home and readmitted to the same LTCH within 3 days. Secondly, under § 412.531(b)(1)(ii)(A)(*2*), any off-site tests or medical treatment, either inpatient or outpatient, provided at an acute care hospital or an IRF, or care at a SNF and that are not otherwise excluded under § 412.509(a), must be provided by the LTCH ''under arrangements'' if the patient is readmitted to the LTCH within 3 days. We established a time-limited specific exception to the ''under arrangements'' requirement during the RY 2005 LTCH PPS, at § 412.531(b)(1)(ii)(A)(*1*), in the event that the treatment was grouped to a surgical DRG under the IPPS at an acute care hospital (69 FR 25696 through 25700).

We also stated that in addition to having sufficient data to decide upon continuing the exception, we will evaluate whether additional refinements to the overall 3-day or less interruption of stay policy were warranted (69 FR 25697). In the RY 2006 LTCH PPS final rule, we extended the surgical-DRG exception to the 3-day or less interruption of stay policy because, as we stated, ''[t]he 3-day interruption of stay policy was first implemented on July 1, 2004, and, therefore, we do not yet have sufficient data to accomplish the above evaluations * * *'' We continued, ''we will be analyzing claims data over the next year to determine whether the surgical DRG exception to the 'under arrangements' feature of the 3-day or less interrupted stay policy is actively accomplishing our goal of reducing unnecessary Medicare payments and to deter inappropriate Medicare payments while not compromising beneficiary access to medically necessary services. We believe that we will have sufficient data to evaluate continuation of the exception and also whether additional refinements to the overall 3-day or less interruption of stay policy are warranted'' (70 FR 24206).

We also specified that we were particularly interested in analyzing data from LTCHs to determine whether there was a significant increase in interruptions of 4 days since the establishment of the policy. To the extent interruption of stay had increased to at least 4 days (one day past the 3-day threshold that would prevent the 3-day or less policy from being triggered), we believed that this behavior could indicate inappropriate efforts to side-step the provisions of our 3-day or less interruption of stay policy.

As part of our on-going monitoring program (as discussed in Section X. of this proposed rule), ORDI analyzed claims from the MedPAR files for LTCH discharges from July 1, 2004 through June 30, 2005 and performed the data analysis necessary for evaluating the impact of the surgical DRG exception to the 3-day or less interruption of stay policy. As shown in Table 10, the data revealed the following for RY 2005 LTCH PPS.

TABLE 10

Total LTCH discharges	120,895
Total covered charges	$8,694,137,026.00
Average covered charge	$71,855.00
Total cases assigned an IPPS Surgical DRG	459

TABLE 10—Continued

Average covered charge for:	
Non-surgical DRGs	$18,103.00
Surgical DRGs	$22,429
Total covered charges for surgical stays were	$10,294,925

The 459 cases that were governed by the surgical DRG exception represented 0.003 percent of total LTCH discharges and the total covered charges for those surgical DRGs, $10,294,925, represented 0.1 percent of covered charges to LTCHs for RY 2005. Furthermore, the data revealed that the median value of the covered charges for the surgical DRGs at the acute care hospitals were $14,900. In addition, for FY 2004, 57 percent of the covered charges were below $21,720 and 90 percent were below $33,679.

These data do not convince us that a continuation of the surgical DRG exception to the 3 day or less interruption of stay policy is warranted. We believe that the numbers cited above support the following conclusions:

• The surgical cases that fell within this exception are present in only a small fraction of LTCH hospitalizations and that therefore, they were neither numerous nor would they be significantly costly for LTCHs to cover under arrangements;

• The surgical DRGs for which Medicare claims were submitted by the acute care hospital appear to support, in large part, our original hypothesis (that if a LTCH patient was discharged to an acute care hospital for only 1, 2, or 3 days, followed by a readmission to the LTCH, there could be reason to believe that the treatment delivered, even if it was grouped to a surgical DRG, was not a major procedure because of the relatively short LOS, and, therefore, should have been provided ''under arrangements.'') A reasonable and systematic examination of a subset of the above noted 459 surgical DRGs additionally revealed the following:

• Of 47 cases governed by the exception and for which Medicare made an additional surgical DRG payment to the acute care hospital, in over half of these cases, the entire stay in the LTCH was also grouped to a surgical LTC–DRG. In 10 of these cases, the IPPS DRG and the LTC–DRG were the same. This indicates that *at least* in these 10 cases, the LTCH claim included the procedure that was delivered at the acute care hospital (for which Medicare issued an additional payment to the IPPS) and is strongly suggestive of poor documentation in the medical record, poor coding, or gaming. Since LTCHs typically do not perform significant surgical procedures, three examples of additional irregularities are as follows:

—LTC–DRG 468, ''extensive OR procedures unrelated to principal diagnosis,'' with DRG 478, ''other vascular procedures w/cc'' at the acute care hospital;

—LTC–DRG 148, small and large bowel procedures w/cc at the LTCH and DRG 442 ''other OR procedures with injuries w/cc'' at the acute care hospital.

—LTC–DRG 76, other respiratory system OR procedures with CC at the LTCH and DRG 415, O.R. procedure for infectious and parasitic diseases at the acute care hospital.

• The specific surgical DRGs into which the acute care treatments were grouped appear to arise directly from the principle diagnoses at the LTCH, a concern that we originally stated in the January 30, 2004 proposed rule for the LTCH PPS when we described the ''under arrangements'' feature of the proposed 3-day or less interruption of stay policy (69 FR 4771).

Table 11 shows examples drawn from the above cited subset of claims for July 1, 2004 through June 30, 2005.

TABLE 11

LTC–DRG	DRGs
182 (Esophagitis gastroenteritis, and miscellaneous other digestive disorders >17 w/cc.	17 Other digestive system operating room procedures.
271 Skin ulcers	270 Other skin, subcutaneous tissue and breast procedures w/cc.
348 Prostatitis	336 Trans-urethral prostatectomy.
87 Pulmonary edema and respiratory failure	55 Miscellaneous ENT, mouth, or throat procedures.
418 Post-operative and post traumatic infections	415 Operating room procedure for infectious or parasitic diseases.
144 Other circulatory system diagnosis w/cc	120 Other circulatory system operating room procedures.

The basic premise of a PPS recognizes that Medicare pays hospitals an amount per discharge based on the average costs of delivering care for that diagnosis (which is assigned a DRG), and some cases require more hospital resources to be expended, where others, require less. Therefore, in some cases, Medicare payments will be lower than the hospital's costs but in other cases, the payments will exceed the costs. In the January 30, 2004 LTCH PPS proposed rule, we stated that surgical treatment that is directly related to the principle diagnosis at the LTCH and which only required 3 days or less of care at the acute care hospital, should be provided by the LTCH either directly or ''under arrangements'' since Medicare payment to the LTCH for this particular case was ''payment in full'' as specified in § 412.509(b) (69 FR 4771). It has been standard Medicare PPS policy for over two decades that the LTCH hospitalization, the surgical treatment arising from this hospitalization, and the post-operative stay at the LTCH are to be viewed as one episode of care and therefore, the LTC–DRG payment would be adequate compensation for the entire episode. (In fact, when LTCHs were paid under the reasonable-cost based TEFRA payment policy—subject to hospital-specific ceilings or 'target amounts'—prior to the FY 2003 implementation of the LTCH PPS, the ''under arrangements'' policy, enabled LTCHs to include the costs of these off-site treatments on Medicare claims, thereby resulting in higher TEFRA target amounts.) However, when we restated the ''under arrangements'' policy for the 3-day or less interruption of stay, and proposed its codification in the RY 2005 proposed rule for the LTCH PPS, in response to comments received on the January 30, 2004 proposed rule, we did agree to establish a 1-year exception to the ''under arrangements'' feature of the 3-day or less interruption of stay policy for cases that grouped to a surgical DRG

during an intervening acute care hospitalization. We subsequently extended this exception for an additional year in order to gather sufficient data with which to determine the value of retaining this exception to the general policy.

Therefore, based on the above data analysis and under the broad discretionary authority granted by section 123 of the BBRA as amended by section 307(b) of the BIPA for the Secretary for the development and implementation of the LTCH PPS, (including the ability to make appropriate adjustments), we are proposing not to renew the surgical-DRG exception to interrupted stay of 3 days or less policy for LTCH PPS RY 2007. Under § 412.531, with the proposed sunsetting of this exception for LTCH PPS RY 2007, treatment at an acute care hospital that was grouped to a surgical DRG would be considered part of the LTCH stay and paid for by the LTCH ''under arrangements.'' (see § 412.509(c)). Our analytic sample of LTCH cases that included a 3 day or less interruption of stay that was governed by the surgical DRG-exception, indicates that at least one-half of the LTCH claims themselves included surgical care, despite the patient's discharge to the acute care hospital for treatment that was grouped to a surgical DRG and for which a separate claim was submitted to Medicare by the acute care hospital. Since typically, LTCHs do not perform significant surgical procedures, upon analyzing the data, CMS coders have suggested that some of the LTCH claims may inappropriately be including the surgical procedure performed during the prior acute care stay, complications from which led to the LTCH admission. Alternatively, if LTCHs are presently coding for the surgical procedures that are being delivered in the acute care hospital during a 3-day or less interruption of stay, in many of these cases they should be paying for this treatment ''under arrangements.'' Furthermore, in the cases where both the same DRG is reported by both the LTCH and the acute care hospital treating the patient during the 3 day or less interruption, Medicare may be paying twice for the same treatment. In any event, the above scenarios are indicative of poor documentation in the medical record, poor coding, or gaming of the Medicare system.

Therefore, we are proposing to discontinue this policy because we do not believe that the surgical exception to the 3-day or less interruption of stay policy is ''* * * actively accomplishing our goal of reducing unnecessary Medicare payments and * * * deter[ing] unnecessary inappropriate Medicare payments while not compromising beneficiary access to medically necessary services'' (70 FR 24206).

However, there were cases among those that we reviewed, that may have been accurately coded, and that actually represented a LTCH patient whose LTCH treatment was interrupted by a surgery which entailed a 3-day or less inpatient stay at an acute care hospital for a problem unrelated to the on-going treatment at the LTCH. Once the proposed sunsetting of the surgical DRG exception goes into effect, an LTCH will be responsible for paying for surgical cases performed at an acute care hospital ''under arrangements'' but at that point, will also be able to include that surgical procedure on the claim that will be submitted to Medicare for the entire stay. Our coders tell us that the presence of a significant surgical procedure on the claim may impact the LTC–DRG to which a case is assigned by the GROUPER software used by the FI in determining the amount that Medicare will pay for that case. However, there may be situations where this does not occur and inclusion of the surgical procedure does not result in grouping the case to a higher-weighted LTC–DRG (and thus increase the Medicare payment). In these cases, we would emphasize, that, since, as noted previously, the ''under arrangements'' policy was a feature of the previous TEFRA payment policy, prior to the FY 2003 implementation of the LTCH PPS, and costs of off-site surgeries were typically included in LTCH claims, so that to the extent providers included those costs on their claims, that these costs were included in the establishment of the LTCH PPS base rate, which section 123(a)(1) of the BBRA required to be budget neutral for FY 2003, to what Medicare would pay had the PPS not been implemented.

We would further note that we do not believe that the numbers of cases nationwide that would fall within the surgical DRG exception would represent a significant financial burden for LTCHs to absorb over a cost-reporting period, given the nature of the LTCH PPS.

We also believe, that the LTCH PPS high cost outlier policy at § 412.525(a) will provide somewhat of a financial cushion for the LTCH in those very few cases where a LTCH patient whose hospitalization at the LTCH was interrupted for 3 days or less for a very costly surgical treatment at an acute care hospital, in the same way that it presently does if costs for a costly non-surgical inpatient or outpatient treatment during a 3 day or less interrupted stay at an acute care hospital, an IRF, or for care at a SNF, result in high cost outlier status for that case at the LTCH. Accordingly, we are not proposing to extend this exception because we believe that our analysis of the data from the MedPAR files from LTCH discharges occurring from July 1, 2004 through June 30, 2005 indicates that the exception does not appear to have an overall beneficial effect on the program nor would its absence have a strong negative impact on LTCHs.

Our further examination of the subset of the data indicates that the exception may be fostering confusion, perpetuating poor coding, and even encouraging gaming by creating a distinction within the well-established Medicare ''under arrangements'' policy between surgical and non-surgical procedures and treatments delivered during an episode of hospital-level care. Moreover, we have discovered many LTCHs are including the surgical procedures performed at the acute care hospital during the interruption, in their claims and therefore the LTCH hospitalizations are being grouped to surgical DRGs while claims for what appear to be the same surgeries are also being submitted by acute care hospitals. Use of the same surgical DRG in both the LTCH's claim for the case and the acute care hospital's claims for the surgery in some of these cases indicates that Medicare may be paying twice for the exact same operation, a situation directly contravened by sections 1862(a)(14) and 1861(w)(1) of the Act, § 411.15, § 412.509 and one that may involve fraud and abuse issues.

In the RY 2006 LTCH PPS final rule (70 FR 24206), we also expressed concerns about the whether our data would reveal an increase in the numbers of interruptions of 4 days indicating an effort by certain LTCHs to side-step the ''under arrangements'' provisions of our 3-day or less interruption of stay policy. Our data revealed that there were 1,076 4-day stays at acute care hospitals following a LTCH hospitalization during the 2005 rate year, of which 528 (just under half) returned for further treatment to the LTCH following the 4-day interruption. If the interruption in an LTCH patient's stay exceeds 3 days, under existing policy at § 412.531(b)(1)(ii)(B)and § 412.531(c), payment would be governed by the greater than 3-day or interruption of stay policy at § 412.531(b) and Medicare would generate a separate payment to an intervening provider where the patient received treatment or care, thus discharging the LTCH from responsibility to pay for the acute care services ''under arrangements.''

Furthermore, an interruption in a LTCH stay in excess of 3 days, where the patient returns home but still receives outpatient treatment prior to returning to the LTCH, would result not only in separate Medicare payments for the outpatient care but would also in an additional discharge payment to the LTCH since the greater than 3-day interruption of stay policy only applies to intervening acute care hospital, IRF, or SNF stays. We will be evaluating data from RY 2004 and RY 2005 on Medicare payments for services or care delivered during LTCH interruptions of stay of 4 days that would otherwise have been governed by the ''under arrangements'' feature of the 3-day or less interruption of stay policy at § 412.531(b)(1)(ii)(A)(2) to determine whether an additional day is being arbitrarily added to the interruption prior to readmittance to the LTCH for purposes of thwarting the goal of the policy. We believe it may be appropriate in the future to propose a revision to the 3-day interruption provision and to establish a 4-day threshold.

B. Special Payment Provisions for LTCH Hospitals Within Hospitals and LTCH Satellites

In the IPPS final rule for FY 2005, when we established the special payment provisions at § 412.534 for LTCHs that were HwHs or were satellites of LTCHs, we were seeking, in part, to address the on-going proliferation of LTCHs that were HwHs or satellites. (OSCAR files report that there were 105 LTCHs in 1993, of which 10 were HwHs. In October 2005, there are 373 LTCHs, many of which are HwHs.) We were particularly concerned with patient shifting between the host hospitals and the LTCH HwH or satellite for financial rather than for medical reasons (69 FR 49191) and with the resulting inappropriate increased cost to the Medicare system.

In that PPS final rule, we quoted the FY 1995 IPPS final rule where we first discussed the concern that LTCH HwHs were, in effect, operating as step-down units of acute care hospitals. We explained that this was inconsistent with the statutory framework and that such a configuration could lead to two Medicare bills being submitted and paid (one from the acute care hospital and the other from the LTCH) for what was essentially one episode of care. (69 FR 49191, 59 FR 45389) When we established the separateness and control criteria for LTCH HwHs at § 412.22(e) in the FY 1995 IPPS final rule, our main objective was to protect the integrity of the IPPS by ensuring that those costly, long-stay patients who could reasonably continue treatment in that setting would not be unnecessarily discharged to an onsite LTCH, a behavior that would skew and undermine the Medicare IPPS DRG system. We explained that the Federal standardized payment amount for the IPPS was based on the average cost of an acute care patient across all acute care hospitals. This assumes that, on average, both high-cost and low-cost patients are treated at a hospital. Although Medicare might pay a hospital less than was expended for a particular case, over a period of time, the hospital would also receive more than was expended for other cases. However, an acute care hospital that consistently discharges higher cost patients to a post-acute care setting for the purpose of lowering its costs undercuts the foundation of the IPPS DRG system, which is based on averages. In this circumstance, the hospital inappropriately would have incurred lower costs under the IPPS because the course of acute treatment was not completed and the hospital did not incur those additional costs for the remainder of the patient's stay at the IPPS acute care hospital. Once that patient is discharged from the IPPS acute care hospital to the LTCH, the patient, still under active treatment for an acute illness, will be admitted to a LTCH, thereby generating a second admission and Medicare payment that would not have taken place but for the fact of co-location (59 FR 45389).

As explained previously, there was and continues to be concern that the LTCH HwH/host configuration could result in patient admission, treatment, and discharge patterns that are guided more by attempts to maximize Medicare payments than by patient welfare. In order to establish clear division between a host hospital and an on-site LTCH where the linking of an IPPS hospital and a LTCH could lead to two Medicare payments for what was essentially one episode of patient care, we issued ''separateness and control'' regulations in that FY 1995 IPPS Final Rule at (former) § 412.23(e), for LTCHs that were seeking to co-locate with acute care hospitals as HwHs (59 FR 45390). In the ensuing decade, we revisited the issue of HwHs several times (for example, 60 FR 45836, 62 FR 46012, 67 FR 56010, 68 FR 45462), during which we clarified and amplified the separateness and control requirements. In the FY 1998 IPPS final rule, we extended the application of these rules beyond LTCHs to include other classes of facilities that might seek exclusion from the IPPS as HwHs, such as IRFs (although the vast majority of HwHs have continued to be LTCHs) (62 FR 46014). Additionally, although our original regulations for HwHs focused solely on the relationship between a LTCH HwH and an acute care host, and this is still, by far, the most common configuration, nothing in the regulations precludes other types of hospitals, for example, an IRFs from establishing HwHs (69 FR 49198).

In addition, in the FY 1998 final rule, we established a ''grandfathering'' provision for HwHs in existence prior to September 30, 1995 at § 412.22(f), and in the FY 2004 IPPS final rule, we clarified and codified the requirements for ''grandfathered'' HwHs (68 FR 45463). We believed at that time that these rules were sufficient solutions to our concerns about LTCH HwHs functioning as long-stay units of acute care hosts.

Therefore, prior to FY 2005, a HwH was required to meet the separateness and control criteria set forth at § 412.22(e). In order to be excluded from the IPPS, the HwH had to have a separate governing body, a separate chief medical officer, a separate medical staff, and a separate chief executive officer. Regarding the performance of basic hospital functions (former § 412.22(e)(5)), the hospital had to meet at least one of the following criteria: (1) The hospital performs the basic functions through the use of employees or under contracts or other agreements with entities other than the hospital occupying space in the same building or on the same campus, or a third entity that controls both hospitals; (2) for the same period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the cost of the services that the hospital obtained under contracts or other agreements with the hospital occupying space in the same building or on the same campus, or with a third entity that controls both hospitals, is no more than 15 percent of the hospital's total inpatient operating costs, as defined in § 412.2(c) (that is, inpatient operating costs include operating costs for routine services, such as costs of room, board, and routine nursing services; operating costs for ancillary services such as laboratory or radiology; special care unit operating costs; malpractice insurance costs related to serving inpatients; and preadmission services); or (3) for the same period of at least 6 months immediately preceding the first cost reporting period for which exclusion is sought, the hospital had an inpatient population of whom at least 75 percent were referred to the hospital from a source other than another hospital occupying space in the same

building or on the same campus or with a third entity that controls both hospitals.

It was our experience that the vast majority of HwHs elected to meet the second of the three criteria at § 412.22(e)(5), that is, the cost of the services that the hospital obtained from the co-located hospital or with a third entity that controls both hospitals could be no more than 15 percent of its total inpatient operating costs.

As detailed in the FY 2005 proposed rule and final rule for the IPPS (69 FR 28323 through 28327, 69 FR 49191 through 49214), with the noted explosive growth in the number of LTCHs, (and with LTCH HwHs, in particular) and concomitant costs to the Medicare program, we reevaluated the effectiveness of existing policies regarding HwHs insofar as whether they sufficiently protected the Medicare program from the problems that we envisioned in the FY 1995 IPPS final rule and subsequent rules. We also questioned the effectiveness of the ''separateness and control'' requirements alone because entities have used complex arrangements among corporate affiliates, and obtained services from those affiliates, thereby impairing or diluting the separateness of the corporate entity. While technically remaining within the parameters of the rule, these arrangements were intermingling corporate interests so that the corporate distinctness has been lost.

In accordance with notice and comment rule-making and following serious consideration of the public comments that we received on our proposed policy revisions for LTCH HwHs, regulatory changes were finalized for HwH separateness and control policies at § 412.22(e) and a new payment adjustment at § 412.534 was established for LTCH HwHs and satellites of LTCHs in our FY 2005 IPPS final rule (69 FR 49191 through 49214).

Specifically, for cost reporting periods beginning on or after October 1, 2004, for LTCHs we eliminated the 15 percent test under then existing § 412.22(e)(5)(ii), the performance of basic hospital functions test under former § 412.22(e)(5)(i) and the 75 percent of admissions from other than the host criteria at former § 412.22(e)(5)(iii) for LTCH HwHs. If a LTCH demonstrated compliance with the medical and administrative separateness, and control policies at § 412.22(e)(1)(i) through (e)(1)(iv) under our finalized policy, it satisfied the LTCH HwH requirements. We additionally established a payment adjustment for LTCH HwHs (and also for satellites of LTCHs) at § 412.534, which we believed addressed our on-going concerns regarding the relationship between LTCH discharges who were admitted from the host hospital. We included LTCH satellites in this payment adjustment because we believe that that the co-location of a host hospital and a LTCH satellite may result in the same incentives for inappropriate patient movement as exist for hosts and LTCH HwHs.

The payment adjustment at § 412.534, Special payment provisions for long-term care hospitals within hospitals and satellites of LTCHs, mandated that if a LTCH HwH or LTCH satellite's discharges that were admitted from its host hospital exceed 25 percent (or the applicable percentage) of its total Medicare discharges for the LTCH HwH or LTCH satellite's cost reporting period, an adjusted payment would be made. The adjustment would be the lesser of the otherwise payable amount under the LTCH PPS or the LTCH PPS amount that was equivalent to what Medicare would otherwise pay under the IPPS. In determining whether a hospital exceeded the 25 percent criterion, patients transferred from the host hospital that have already qualified for outlier payments at the host would not count as part of the host's 25 percent (or the applicable percentage) and therefore, the payment would not be subject to the adjustment. Those patients would be eligible for otherwise unadjusted payment under the LTCH PPS. Discharged Medicare patients that were admitted from the host before the LTCH HwH or LTCH satellite crosses the 25 percent threshold would be paid an otherwise unadjusted payment under the LTCH PPS.

We also finalized additional adjustments to the 25 percent policy for specific circumstances. For LTCH HwHs or LTCH satellites located in a rural area, instead of the 25 percent criterion, the payment adjustment would be imposed if the majority (that is, more than 50 percent) of the Medicare patients discharged from the LTCH HwH or LTCH satellite were admitted from the host. That is, for those LTCH HwH or satellite Medicare discharges in excess of the 50 percent threshold, the payment adjustment would be applied unless those cases had reached high cost outlier status at the host hospital prior to discharge, in which case, they would not be counted towards the 50 percent threshold. In addition, in determining the percentage of Medicare patients discharged from the LTCH HwH or LTCH satellite that were admitted from the rural host, any patients that had been Medicare outliers at the host and then discharged to the LTCH HwH or LTCH satellite would be considered as if they were admitted to the LTCH from a non-host hospital. For urban single or MSA dominant hospitals, we would allow the LTCH HwH or LTCH satellite to discharge Medicare patients that were admitted from the host up to the host's percentage of total Medicare discharges for like hospitals in the MSA. We would apply a floor of 25 percent and a ceiling of 50 percent to this variation. In addition, in determining the percentage of discharged Medicare patients that were admitted to the LTCH HwH or LTCH satellite from the urban single or MSA dominant host hospital, any patients that had been Medicare outliers at the host and then transferred to the LTCH HwH or LTCH satellite would be considered as if they were admitted to the LTCH from a non-host hospital.

We also provided a 4-year transition for existing LTCH HwHs or LTCH satellites for the purpose of providing a reasonable period during which the host and the LTCH HwH or LTCH satellite would be able to adapt to the requirements of the new policy. Also included in this transition policy were LTCHs-under-formation that satisfied the following two-prong requirement: (1) The hospital was paid under the provisions of subpart O of part 412 on October 1, 2005, and (2) whose qualifying period under § 412.23(e) began on or before October 1, 2004. For cost reporting periods beginning on or after October 1, 2004 through September 30, 2005, these hospitals were to be grandfathered, with the first year as a ''hold harmless'.

However, we required that even for grandfathered facilities, in the first cost reporting period, the hold harmless year, the percentage of Medicare discharges admitted from the host hospital to the LTCH HwH or LTCH satellite could not exceed the percentage of discharges admitted from the host hospital to the LTCH in its FY 2004 cost reporting period. Therefore, while we grandfathered existing LTCH HwHs and allowing for a 4-year transition, beginning on or after October 1, 2004 and before October 1, 2005 (FY 2005), those hospitals could not increase the percentage of discharges admitted from the host in excess of the percentage that they had admitted in FY 2004.

After the first grandfathered cost reporting period, these LTCH HwHs and LTCH satellites were required to meet a percentage transition over the 3 years beginning in FY 2006. For the second year (cost reporting periods beginning on or after October 1, 2005 but before October 1, 2006), the applicable percentage of discharges admitted from the host with no payment adjustment

would be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 75 percent. For the third year (cost reporting periods beginning on or after October 1, 2006 but before October 1, 2007), the applicable percentage of discharges admitted from the host with no payment adjustment would be the lesser of the percentage of their discharges admitted from their host for their FY 2004 cost reporting period or 50 percent, and finally 25 percent (or other applicable percentage) beginning with the third year (cost reporting periods beginning on or after October 1, 2008).

These finalized payment policies and the concerns that they address echo concerns first expressed in the FY 1995 final rule for the IPPS, when we began to regulate new entities that we named ''hospitals within hospitals.'' As noted elsewhere in this preamble, the reason that we proposed the changes in the criteria for LTCH HwH qualification at § 412.22(e) in the FY 2005 IPPS proposed rule (69 FR 28323 through 28327) was the nexus between these concerns and the recent explosive growth in the numbers of LTCH HwHs. Furthermore, as detailed in the FY 2005 IPPS final rule, (69 FR 49201), these regulations were grounded in a thorough review of the available data as well as exhaustive policy evaluations.

The present 25 percent policy is being implemented in a location-specific manner, which means that the computation of the percentage of LTCH HwH or LTCH satellite discharges admitted from a host is based solely on the admissions from the physically co-located host and not from other campuses or remote locations which may share a common Medicare Provider number with the host.

However as a result of our monitoring efforts to date (see section X. of the preamble to this proposed rule), we have become increasingly aware that the intent of our existing policy is being thwarted by creative patient-shifting in some communities where there is more than one LTCH HwH or LTCH satellite. We have come to understand, based upon specific inquiries from LTCHs and their attorneys or agents, and also from questions posed by our fiscal intermediaries (FIs), that some host hospitals within the same community are arranging to cross-refer to another's co-located LTCH (HwH or satellite). This behavior circumvents the intent of the payment adjustment which was to hinder the *de facto* establishment of a LTCH unit of a host hospital, which is precluded by law, and to discourage inappropriate patient-shifting between a host and a LTCH HwH or satellite. This practice undermines the basic premise of the IPPS DRG classification system and generates inappropriate Medicare payments. Another attempt to circumvent the present regulation at § 412.534 is a situation wherein a patient at a LTCH (that is co-located with a host as a HwH or satellite) admits a patient from the host, provides treatment, then transports the patient to another location of that LTCH (a free-standing hospital or another HwH or satellite not co-located with the host hospital) for special treatment after which the patient is discharged from that other location. Since the payment adjustment is being implemented in a location-specific basis, we believe that this ''transporting'' of the patient to another site is an attempt to side-step the location-specific feature of the existing payment adjustment. We have considerable concern about attempts to game Medicare by circumventing the intent of the 25 percent (or applicable percentage) patient threshold payment adjustment at § 412.534.

In addition, as a result of implementing the payment adjustment at § 412.534 for patients exceeding the 25 percent (or applicable percentage) threshold for LTCH HwHs and satellites of LTCHs, the most recent growth in the LTCH universe is occurring with the development of free-standing LTCHs. Many of these facilities receive patients from one referring hospital and as is the case with host/HwH or satellite configurations, we are concerned about these non-co-located LTCHs may, in fact, be functioning like a long-stay unit of those referring hospitals.

As we first stated in the FY 1995 IPPS final rule, ''we agree that the extent to which a facility accepts patients from outside sources can be an important indicator of its function as a separate facility, not merely a unit of another hospital. In general, a facility's functional separateness should be reflected in its ability to attract patients from sources other than the hospital that it serves. For example, if a facility receives all (or nearly all) of its admissions independently (that is, from outside sources), it can reasonably be assumed to be functioning separately from the host hospital (59 FR 45391).'' In establishing the concept of ''functional separateness'' in the above quote from the FY 1995 IPPS final rule, we were identifying a broader phenomenon than just the relationship between a host acute care hospital and a LTCH HwH or satellite of a LTCH. As noted below, this concern has been communicated to us from a variety of sources.

MedPAC's comments on the proposed payment adjustment for LTCH HwHs in the FY 2005 IPPS proposed rule focused directly on this issue and expressed concern that the 25 percent patient threshold policy would have a significant impact and could possibly lead to an inequitable situation for co-located LTCHs as compared to freestanding LTCHs. Among its concerns were the following: that freestanding LTCHs also have strong relationships with acute care hospitals, and that where on average LTCH HwHs receive 61 percent of their patients from their hosts, freestanding LTCHs receive 42 percent from their primary referring hospital; that a 25 percent rule that only applies to LTCH HwHs and not to freestanding LTCHs and may therefore be inequitable; and furthermore, this approach may be circumvented by an increase in the number of freestanding LTCHs instead of a LTCH HwH (69 FR 49211).

We received comments on the FY 2005 IPPS proposed rule (69 FR 28196) challenging a proposed policy to preclude common ownership of a host and a HwH (which we did not finalize). Two other commenters noted that the financial incentive to accept inappropriate patients from an acute care hospital can exist when the acute care hospital and the LTCH are commonly owned or when there is common governance, a situation that can exist even without co-location, that is, a freestanding LTCH, exempt from the requirements of § 412.22(e) could be owned and governed by the hospital from which it receives the majority of its referrals (69 FR 49202).

In discussion with a LTCH trade association, we were informed of a study that it commissioned from the Lewin Group that included a percentage breakdown of patients referred to free-standing (for example, non-co-located) LTCHs (and other post-acute providers) from ''single-source acute hospitals.'' According to the association, the data indicated ''* * * that it is common practice for LTCHs * * * to admit patients from a single-source acute care hospital'' and that 71.2 percent of free-standing LTCHs admit more than 25 percent of their patients from a single source acute-care hospital.

We are also anecdotally aware of the existence of frequent ''arrangements'' in many communities between Medicare acute and post-acute hospital-level providers that may not have any ties of ownership or governance relating to patient shifting that are based on mutual financial advantage rather than on significant medical benefits for a patient.

In our response to the MedPAC comment, we stated that ''[w]hile we also understand the reservations expressed in the comments, we want to emphasize that * * * we are establishing these revised payment policies in this final notice for LTCH HwHs or satellites and not freestanding LTCHs because of the considerable growth in the number of LTCH HwH and because, ever since we first became aware of the existence of LTCH HwHs in 1994, we have been mindful of the strong resemblance that they bore to LTCH units of acute care hospitals, a configuration precluded by statute (69 FR 49211).''

Notwithstanding this response and the finalized payment adjustment at § 412.534 which focused solely on LTCH HwHs and satellites of LTCHs, we took considerable note of these comments and the specific information that they included. Since the October 1, 2004 implementation of the payment adjustment for LTCH HwHs and satellites of LTCHs at § 412.534, through our LTCH PPS monitoring initiative (see Section X.), we have become aware that the growth in the LTCH universe is now occurring through the development of free-standing LTCHs. As of October 2005, there were 376 LTCHs in our OSCAR database, of which 201 are reported as freestanding (for example, not co-located with another Medicare hospital-level provider) and 175 of which are HwHs. But since October 1, 2004, of the 25 new LTCHs established, 22 are free-standing. We have been informed directly that at least one particular LTCH chain that formerly specialized in the establishment of HwHs and satellites is now concentrating on the development of free-standing LTCHs. Reviews of public documents posted at the corporate Web site and analysis of the expected consequences of the policy at other investor-oriented sites describe a focus on building free-standing LTCHs which we believe may imply a response to the payment adjustment for co-located LTCHs established under § 412.534.

We believe that this information indicates that the concerns that we expressed about the explosive growth in the number of LTCHs has shifted because of the implementation of the payment adjustment at § 412.534 from the development of co-located LTCHs as HwHs or satellites of LTCHs to the establishment of free-standing LTCHs.

We further conducted our own data analysis of sole-source (for example, one hospital referring to one LTCH) relationships between acute care hospitals and non-co-located LTCHs. The FY 2004 and FY 2005 MedPAR files indicate 63.7 percent of the 201 free-standing LTCHs have at least 25 percent of their Medicare discharges admitted from a sole acute care hospital; for 23.9 percent of the freestanding LTCHs, the percentage is 50 percent or more; and for 6.5 percent, 75 percent or more of their Medicare discharges are admitted from a sole acute care hospital.

We therefore believe that the danger of LTCHs functioning as ''units'' appears to be occurring not only in LTCH HwHs and LTCH satellites but also with free-standing LTCHs and that in many cases, these non-co-located LTCHs and their sole referral source may be functioning in ways that appear to have erased the line of ''functional separateness'' between these LTCHs and their referring acute care hospitals. We are concerned about these situations and in this context, we continue to believe that ''* * * the extent to which a facility accepts patients from outside sources can be an important indicator of its function as a separate facility, not merely a unit of another hospital (59 FR 45391).''

We believe that our analysis of the available data and our awareness of growth patterns and behavioral changes in the LTCH industry corroborate the concerns expressed in correspondence and comments, but particularly in MedPAC's comments on our proposed payment adjustment for co-located LTCHs in the FY 2004 IPPS final rule (69 FR 49211). In addition, the spiked increase in the number of free-standing LTCHs and their admission patterns appear to confirm MedPAC's concerns that the industry may be circumventing the intent of the payment adjustment policy at § 412.534 aimed at combating LTCHs functioning as ''units'' by creating free-standing LTCHs instead of LTCHs co-located as HwHs or satellites.

As we note previously in this proposed rule, we are keenly aware of the explosive growth in the number of free-standing LTCHs. Specifically, we are continuing to analyze patient claims data for acute care patients who are admitted to free-standing LTCHs for discharge and LOS information in order to evaluate whether Medicare is paying twice for what would essentially be one episode of care. We are considering appropriate adjustments to address this issue.

Furthermore, we want to emphasize that we are closely monitoring patient shifting activities between host hospitals and LTCH HwHs or LTCH satellites, paying particular attention to evidence of inappropriate cross-referrals. We believe that a pattern of this behavior by hospitals would indicate an attempt to side-step the requirements of § 412.534 and could warrant an investigation by HHS's Office of the Investigator General.

Under § 412.534 for LTCH cost reporting periods beginning on or after October 1, 2004, we published the existing payment adjustment detailed above, for LTCH HwHs and LTCH satellites that focused on the percentage of Medicare patients being shifted from host hospitals to co-located LTCHs. Under this provision, we specified that if greater than 25 percent (or the appropriate percentage) of a LTCH HwH's or LTCH satellite's discharges during any cost reporting year were admitted from a host hospital, a payment adjustment would be applied to those discharges that exceeded the applicable threshold percentage (unless those patients had reached high-cost outlier status at the host hospital as specified in § 412.534(c)). (For LTCHs that qualified under § 412.534(f), we established a 4-year transition to the full payment adjustment.) Specifically, this payment adjustment provides that Medicare will pay the lesser of the amount otherwise payable under the LTCH PPS or an LTCH PPS payment amount equivalent to what would be paid under the IPPS for discharges in excess of the threshold amount.

It has come to our attention that the phrase ''an amount equivalent to the amount that would otherwise be determined under the rules at subpart A, § 412.1(a)'', that is, the IPPS, in existing § 412.534(c)(2), (d)(1), and (e)(1) and our specific interpretation of its implementation may not be entirely apparent. Therefore, we are clarifying that, as explained below in this section, the use of the term ''equivalent'' does not necessarily mean precisely equal. We are also proposing to codify the formula that we currently use to give effect to this phrase in existing § 412.534, described in this proposed rule, for purposes of administrative clarity.

To clarify the meaning of the term ''equivalent,'' we want to emphasize that we chose that word rather than ''equal'' when referring to the amount payable under this subpart (the amount that is equivalent to the ''* * * amount that would be otherwise determined under the rules at subpart A, § 412.1(a)). The term ''equivalent'' was used in this regulation because, although it was and continues to be our intent to include a payment adjustment under the LTCH PPS that closely replicates what an IPPS payment would have been for the same episode of care, several features of the IPPS cannot be translated directly into the LTCH PPS. Therefore, we believed that the term ''equivalent'' would

support the ultimate goals of the policy adjustment, while also allowing for a reasonable and equitable implementation. For example, under the IPPS, payments for IME are limited based on the hospital's IME cap. The hospital's IME cap is determined based on the number of IME FTE residents counted by the hospital for purposes of IME on its 1996 cost report. In the case of a LTCH, since it necessarily would not have reported any FTE residents for IME on its 1996 cost report, it would not be appropriate to apply the IPPS IME rules literally in the context of this LTCH PPS payment adjustment.

We are clarifying that we chose to use the term ''equivalent'' in § 412.534(c)(2), (d)(1), and (e)(1) because we believe this language accurately reflects our intent to apply IPPS payment principles to develop a payment that approximates for LTCHs the payment for a particular case that would have been made under the IPPS. For example, in the case of a LTCH that is a teaching hospital, if a particular LTCH discharge is governed by the 25 percent payment policy adjustment set forth at § 412.534, we would determine the IME payment under the LTCH PPS by imputing an IME cap based on the LTCH's direct GME cap (which would have been determined for an LTCH that has residency programs as set forth at § 413.79(c)(2)) and using that imputed IME cap to calculate an IME payment for this LTCH. We believe this methodology is reasonable since it is based on the best available data on residency programs at LTCHs. Using an imputed IME cap could enable us to factor an adjustment for indirect costs of residency programs into a Medicare payment under the payment adjustment at § 412.534 for those cases in excess of the 25 percent (or applicable percentage) threshold where the Medicare payment would be based on an amount under the LTCH PPS equivalent to what would otherwise be paid under the IPPS.

As explained previously, we are proposing to codify the formula we use to give affect to the phrase ''an amount under subpart O that is equivalent to what otherwise would be paid under the IPPS.'' The existing regulations at § 412.534(c)(2), (d)(1), and (e)(1) establish the applicable payment adjustment for LTCH HwHs and satellites not subject to the transition established under § 412.534(f) for cost reporting periods beginning on or after October 1, 2004 and for cost reporting periods beginning on or after October 1, 2007 for those LTCH HwHs and LTCH satellites that will be transitioning to the full adjustment. Under those provisions, Medicare will pay for discharges from a LTCH HwH or LTCH satellite that were admitted from their host hospital in excess of the 25 percent (or applicable percentage) threshold based upon the lesser of the amount otherwise payable under [the LTCH PPS] or the amount payable under this subpart that is equivalent to the amount that would otherwise be payable under [the IPPS]. The paragraphs below detail the specific payment features of the IPPS that we use and are proposing to codify in regulation for administrative efficiency in order to allow Medicare to generate a fair and equitable ''equivalent'' IPPS payment under the LTCH PPS for those LTCH discharges governed by the payment adjustment at § 412.534.

In the discussion that follows, we use phrases such as ''IPPS DRG relative weights,'' the ''IPPS high cost outlier'' and the ''IPPS fixed loss amount'' in describing features of the IPPS that we use in calculating LTCH payments for LTCH HwHs and LTCH satellites. However, we want to emphasize that such a payment is not an IPPS payment but rather, a payment under the LTCH PPS that is generally derived from the IPPS payment methodology.

Specifically, under § 412.534, we are proposing to codify the formula that we use to give affect to the phrase, an amount payable under this subpart that is equivalent to what would be paid under the [IPPS]. This formula provides that an amount under subpart O that is equivalent to what would otherwise have been paid under the IPPS, would be calculated based on the sum of the applicable operating and capital IPPS rates in effect at the time of the discharge from the LTCH as established in the applicable IPPS final rule published annually in the **Federal Register** (since there is a single rate under the LTCH PPS to pay for the operating and capital costs of the inpatient hospitals services provided to LTCH Medicare patients) and applicable IPPS payment system adjustments for differences in resource use (that is, IPPS DRG relative weights); differences in area wage levels (that is, the IPPS wage index); cost-of-living adjustment, if applicable; the treatment of a disproportionate share of low income patients (DSH), if applicable; and indirect medical education (IME), if applicable. If the amount payable by Medicare for a specific discharge was the amount under subpart O that is equivalent to what would be otherwise payable under the IPPS and the case also qualified as an IPPS high cost outlier under this payment adjustment formula, payment would be based on the IPPS high cost outlier policy at § 412.80(a) because the resulting payment would then be more equivalent to what would have been payable under the IPPS. (Similarly, if under this payment adjustment, the lesser amount resulted in an ''otherwise payable amount under the LTCH PPS,'' and the stay qualified as a high-cost outlier, Medicare would generate a high cost outlier payment governed by the LTCH PPS high cost outlier policy at § 412.525(a).)

Under this formula, we are proposing to codify in regulations, an amount payable under this subpart that is equivalent to what would otherwise be paid under the IPPS for the costs of inpatient operating services would be based on the standardized amount determined under § 412.64(c), adjusted by the applicable IPPS DRG weighting factors as specified in § 412.64(g). This amount would be further adjusted for area wage levels using the applicable IPPS labor-related share based on the CBSA where the LTCH is physically located set forth at § 412.525(c) and the IPPS wage index for non-reclassified hospitals as shown in Tables 4A and 4B in the annual IPPS final rule. (In the RY 2005 LTCH PPS final rule (70 FR 24200) we discuss the inapplicability of geographic reclassification procedures for LTCHs.) For LTCHs located in Alaska and Hawaii, this amount would also be adjusted by the applicable COLA factors used under the IPPS. Furthermore, for LTCH discharges governed by this payment adjustment, an amount payable under subpart O that is equivalent to what would otherwise be paid under the IPPS for the costs of inpatient operating services would also include, where applicable, a DSH adjustment (§ 412.106) and where applicable, an IME adjustment (as discussed at § 413.79(c)(2)).

Additionally, to arrive at an LTCH PPS payment amount equivalent to what would otherwise be payable under the IPPS, a LTCH would also be paid under the LTCH PPS for the costs of inpatient capital-related costs, using the capital Federal rate determined under § 412.308(c), adjusted by the applicable IPPS DRG weighting factors at § 412.60. This amount would be further adjusted by the applicable geographic adjustment factors set forth at § 412.316, including local cost variation (based on the IPPS wage index for non-reclassified hospitals in Tables 4A and 4B of the annual IPPS final rule), large urban location and COLA, if applicable, based on the IPPS geographic classifications published annually in the IPPS final rule.

For discharges governed by this payment adjustment under the LTCH

PPS, an amount payable under subpart O that is equivalent to an amount that would otherwise be paid under the IPPS for the inpatient capital-related costs would also include a DSH adjustment (§ 412.320), if applicable and an equivalent IME adjustment, (§ 412.322) if applicable.

A LTCH PPS payment amount equivalent to what would be paid under the IPPS would be determined based on the sum of the amount equivalent to what would be paid under the IPPS inpatient operating services and the amount equivalent to what would be paid under the IPPS for inpatient capital-related costs. This is necessary since under the IPPS, there are separate Medicare rates for operating (subpart D of part 412) and capital (subpart M of part 412) costs to acute care hospitals while under the LTCH PPS, there is a single payment rate for the operating and capital costs of the inpatient hospitals services provided to LTCH Medicare patients.

We note that in section V.A.1. of this proposed rule, we have proposed an additional component to the SSO payment adjustment at proposed § 412.529(c)(2)(iv) that is based on an amount ''comparable'' to what would otherwise be paid under the IPPS rather than an amount ''equivalent'' under the existing payment adjustment at § 412.534. Although the proposed new payment adjustment option under the SSO policy was adapted from the existing LTCH HwH and LTCH satellite payment adjustment at § 412.534, it also preserves a distinction in the existing SSO policy established at the start of the LTCH PPS for FY 2003: The use of the LTCH PPS fixed loss amount should a SSO case also qualify for high cost outlier payments after the SSO payment amount is determined. In contrast, as noted previously, under the payment adjustment for LTCH HwHs and LTCH satellites at § 412.534, if the amount payable by Medicare for a specific discharge was the amount under subpart O that is *equivalent* to what would be otherwise payable under the IPPS and the case also qualified as a high cost outlier, the outlier payment for this case under the LTCH PPS would be based on the IPPS high cost outlier policy at § 412.80(a) because the resulting payment would then be more equivalent to what would have been payable under the IPPS. Similarly, if under this payment adjustment, the lesser amount resulted in an ''otherwise payable amount under the LTCH PPS,'' and the stay qualified as a high-cost outlier, Medicare would generate a high cost outlier payment governed by the LTCH PPS fixed loss amount calculated under § 412.525(a). If the estimated cost of the case exceeds the adjusted LTC–DRG plus a fixed loss amount under § 412.525(a), the LTCH would receive an additional payment based on the LTCH PPS high cost outlier policy.

Therefore, although there are significant similarities between the two payment adjustments, as detailed in section V.A.1 of this proposed rule, there is a distinction between them regarding the computation of any applicable high cost outlier payments. Under the LTCH HwH and satellite payment adjustment at § 412.534, payment for discharges governed by the policy, will be ''the lesser of the amount otherwise payable under this subpart [subpart O] or the amount that is otherwise payable under this subpart that is equivalent to the amount that would be otherwise payable under § 412.1(a) [the IPPS].'' From an implementation standpoint, Medicare would generate an applicable payment to the LTCH for this discharge (which could include a high cost outlier payment) but this payment would be subject to reconciliation at the end of the LTCH's cost reporting period when it would be determined whether or not the particular discharge was subject to the payment adjustment at § 412.534, that is, whether the discharge exceeded the 25 percent (or applicable percentage) threshold. If this is the case, and the calculation of the lesser of the amounts for a specific discharge resulted in Medicare paying an amount under the LTCH PPS that was equivalent to what would otherwise have been paid under the IPPS, and that payment included a high cost outlier payment, this LTCH PPS payment would be governed by the regulations at § 412.80(a), based on the IPPS high cost outlier policy. If the lesser of the two amounts is the otherwise payable amount under the LTCH PPS (which could be the case if the stay was a SSO, under § 412.529) the original LTCH PPS Medicare payment which included the high cost outlier payment under § 412.525 will be finalized by the FI.

In contrast, under the existing LTCH PPS SSO policy at § 412.529(c), high cost outlier payments could be made for a SSO stay, regardless of whether the payment is ultimately based on: 120 percent of the LTC–DRG specific per diem amount multiplied by the LOS of the discharge; 120 percent of the cost of the case; or the full LTC–DRG, if the total costs of the case exceed the least of these three options, plus the appropriate fixed-loss amount under § 412.525. In this proposed rule, for reasons described in section V.A.1, we have proposed to lower the 120 percent of costs to 100 percent, and we have also proposed the above noted additional alternative to this formula: An LTCH PPS payment comparable to what would otherwise have been paid under the IPPS. We have not proposed to change the existing SSO payment policy for high cost outliers, even though we are proposing this new alternative, and therefore, if the costs of the case exceeded the payment resulting from this formula by the fixed loss amount under the LTCH PPS, Medicare payment to the LTCH for this case, would include high cost outlier payment set forth at § 412.525.

Therefore, although there are significant similarities between the payment adjustment at existing § 412.534, under which Medicare pays an amount *equivalent* to what would otherwise have been paid under the IPPS (which we are proposing to clarify and codify at § 412.534(f)(1)), and the proposed additional payment alternative under the SSO adjustment at proposed § 412.529(c)(2)(iv), under which Medicare would pay an amount *comparable* to what would otherwise have been paid under the IPPS, we wish to emphasize the distinctions in applicable high cost outlier payments under these two payment adjustments.

Consequently, we are clarifying the term ''equivalent'' at § 412.534(c)(2), (d)(1), and (e)(1) in our payment adjustment and proposing to codify the formula we use to give affect to these existing regulations.

In § 412.534, we established special payment provisions for long-term care hospitals within hospitals and satellites of LTCHs. (69 FR 49206) At subparagraph (d), we set forth a further payment adjustment for LTCHs that were co-located as HwHs or as satellites of LTCHs with rural hospitals and we cited the definition of rural at § 412.62(f). This cite was incorrect since beginning in FY 2005, we adopted OMB's revised standards for defining MSAs (69 FR 49026) and therefore, the definition of rural that we intended to cite in § 412.534(d) was § 412.64(b)(1)(ii)(C). We are therefore proposing to correct § 412.534(d) to correctly cite the revised definition of rural at § 412.64(b)(1)(ii)(C).

VI. Computing the Proposed Adjusted Federal Prospective Payments for the 2007 LTCH PPS Rate Year

In accordance with § 412.525 and as discussed in section IV.C. of this proposed rule, the standard Federal rate is adjusted to account for differences in area wages by multiplying the labor-related share of the standard Federal rate by the appropriate LTCH PPS wage

index (as shown in Tables 1 and 2 of the Addendum to this proposed rule). The standard Federal rate is also adjusted to account for the higher costs of hospitals in Alaska and Hawaii by multiplying the nonlabor-related share of the standard Federal rate by the appropriate cost-of-living factor (shown in Table 7 in section IV.D.1.c. of this preamble). In the RY 2006 LTCH PPS final rule (70 FR 24180), we established a standard Federal rate of $38,086.04 for the 2006 LTCH PPS rate year. In this proposed rule, based on the best available data and the proposed policies described in this proposed rule, we are proposing that the standard Federal rate for the 2007 LTCH PPS rate year remain $38,086.04 as discussed in section IV.B. of this preamble. We illustrate the methodology used to adjust the proposed Federal prospective payments for the 2007 LTCH PPS rate year in the following examples:

Example: During the 2007 LTCH PPS rate year, a Medicare patient is in a LTCH located in Chicago, Illinois (CBSA 16974). This LTCH is in the fourth year of the wage index phase-in, thus, the proposed four-fifths wage index values are applicable. The proposed four-fifths wage index value for CBSA 16974 is 1.0632 (see Table 1 in the Addendum to this proposed rule). The Medicare patient is classified into LTC–DRG 9 (Spinal Disorders and Injuries), which has a relative weight of 0.9720 (see Table 3 of the Addendum to this proposed rule).

To calculate the LTCH's total proposed adjusted Federal prospective payment for this Medicare patient, we compute the proposed wage-adjusted Federal prospective payment amount by multiplying the proposed unadjusted standard Federal rate ($38,086.04) by the proposed labor-related share (75.923 percent) and the proposed wage index value (1.0632). This proposed wage-adjusted amount is then added to the nonlabor-related portion of the proposed unadjusted standard Federal rate (24.077 percent; adjusted for cost of living, if applicable) to determine the adjusted Federal rate, which is then multiplied by the LTC–DRG relative weight (0.9720) to calculate the total proposed adjusted Federal prospective payment for the 2007 LTCH PPS rate year ($38,795.95). Finally, as discussed in section IV.C.5. of this preamble, for the 2007 LTCH PPS rate year, we proposed a 0.0 percent reduction (a budget neutrality offset of 1.000) to the total proposed adjusted Federal prospective payment to account for the costs of the transition methodology.

The following illustrates the components of the calculations in the example in Table 12.

TABLE 12

Unadjusted Proposed Standard Federal Prospective Payment Rate	$38,086.04
Proposed Labor-Related Share	× 0.75923
Proposed Labor-Related Portion of the Federal Rate	= $28,916.06
Proposed 4/5ths Wage Index (CBSA 16974)	× 1.0632
Proposed Wage-Adjusted Labor Share of Federal Rate	= $30,743.55
Proposed Nonlabor-Related Portion of the Federal Rate ($38,086.04 × 0.24077)	+ $9,169.98
Proposed Adjusted Federal Rate Amount	= $39,913.53
LTC–DRG 9 Relative Weight	× 0.9720
Total Proposed Adjusted Federal Prospective Payment (Before the Budget Neutrality Offset)	= $38,795.95
Proposed Budget Neutrality Offset	× 0.999
Total Proposed Federal Prospective Payment (Including the Budget Neutrality Offset)	= $38,757.15

VII. Transition Period

To provide a stable fiscal base for LTCHs, under § 412.533, we implemented a 5-year transition period whereby a LTCH (except those defined as ''new'' under § 412.23(e)(4)) receives payment consisting of a portion based on reasonable cost-based reimbursement under the TEFRA system and a portion based on the Federal prospective payment rate (unless the LTCH elects payment based on 100 percent of the Federal rate). Under the average pricing system, payment is not based on the experience of an individual hospital. As discussed in the August 30, 2002 final rule (67 FR 56038), we believe that a 5-year phase-in provides LTCHs time to adjust their operations and capital financing to the LTCH PPS, which is based on prospectively determined Federal payment rates. Furthermore, we believe that the 5-year phase-in of the LTCH PPS also allows LTCH personnel to develop proficiency with the LTC–DRG coding system, which will result in improvement in the quality of the data used for generating our annual determination of relative weights and payment rates.

Under § 412.533, the 5-year transition period for all hospitals subject to the LTCH PPS begins with the hospital's first cost reporting period beginning on or after October 1, 2002 and extends through the hospital's last cost reporting period beginning before October 1, 2007. During the 5-year transition period, a LTCH's total payment under the LTCH PPS is based on two payment percentages—one based on reasonable cost-based (TEFRA) payments and the other based on the standard Federal prospective payment rate. The percentage of payment based on the LTCH PPS Federal rate increases by 20 percentage points each year, while the reasonable cost-based payment rate percentage decreases by 20 percentage points each year, for the next 4 fiscal years. For cost reporting periods beginning on or after October 1, 2006, Medicare payment to LTCHs will be determined entirely under the Federal rate. The blend percentages as set forth in § 412.533(a) are shown in Table 13.

TABLE 13

Cost reporting periods beginning on or after	Federal rate percentage	Reasonable cost principles rate percentage
October 1, 2002	20	80
October 1, 2003	40	60
October 1, 2004	60	40
October 1, 2005	80	20
October 1, 2006	100	0

For cost reporting periods that begin on or after October 1, 2005, and before October 1, 2006 (FY 2006), the total payment for an existing LTCH that has not elected payment under 100 percent of the Federal prospective payment rate

is 20 percent of the amount calculated under reasonable cost principles for that specific LTCH and 80 percent of the Federal prospective payment amount. For cost reporting periods that begin on or after October 1, 2006 (FY 2007), the total payment for a LTCH will be zero percent of the amount calculated under reasonable cost principles for that specific LTCH and 100 percent of the Federal prospective payment amount. As we noted in the June 6, 2003 final rule (68 FR 34155), the change in the effective date of the annual LTCH PPS rate update from October 1 to July 1 has no effect on the LTCH PPS transition period as set forth in § 412.533(a). That is, LTCHs paid under the transition blend under § 412.533(a) will receive those blend percentages for the entire 5-year transition period (unless they elect payments based on 100 percent of the Federal rate). Furthermore, LTCHs paid under the transition blend will receive the appropriate blend percentages of the Federal and reasonable cost-based rate for their entire cost reporting period as prescribed in § 412.533(a)(1) through (a)(5).

The reasonable cost-based rate percentage is a LTCH specific amount that is based on the amount that the LTCH would have been paid (under TEFRA) if the PPS were not implemented. Medicare FIs will continue to compute the LTCH reasonable cost-based payment amount according to § 412.22(b) of the regulations and sections 1886(d) and (g) of the Act.

In implementing the LTCH PPS, one of our goals is to transition hospitals to prospective payments based on 100 percent of the adjusted Federal prospective payment rate as soon as appropriate. Therefore, under § 412.533(c), we allow an LTCH (other than new LTCHs defined at § 412.23(e)(4)), which is subject to a blended rate, to elect payment based on 100 percent of the Federal rate at the start of any of its cost reporting periods during the 5-year transition period rather than incrementally shifting from reasonable cost-based payments to prospective payments. Once a LTCH elects to be paid based on 100 percent of the Federal rate, it will not be able to revert to the transition blend. For cost reporting periods that began on or after December 1, 2002 through September 30, 2006, a LTCH must notify its FI in writing of its election on or before the 30th day prior to the start of the LTCH's next cost reporting period regardless of any postmarks or anticipated delivery dates. For example, a LTCH with a cost reporting period that begins on May 1, 2006, must notify its FI in writing of an election on or before April 1, 2006.

Under § 412.533(c)(2)(i), the notification by the LTCH to make the election must be made in writing to the Medicare FI. Under § 412.533 (c)(2)(iii), the FI must receive the request on or before the specified date (that is, on or before the 30th day before the applicable cost reporting period begins for cost reporting periods beginning on or after December 1, 2002 through September 30, 2006), regardless of any postmarks or anticipated delivery dates.

Requests received, postmarked, or delivered by other means after the specified date in § 412.533(c)(2)(iii) will not be accepted. If the specified date falls on a day that the postal service or other delivery sources are not open for business, the LTCH will be responsible for allowing sufficient time for the delivery of the request before the deadline. If a LTCH's request is not received timely, payment will be based on the transition period blend percentages.

VIII. Payments to New LTCHs

Under § 412.23(e)(4), for purposes of Medicare payment under the LTCH PPS, we define a new LTCH as a provider of inpatient hospital services that meets the qualifying criteria for LTCHs, set forth in § 412.23(e)(1) and (e)(2), and under present or previous ownership (or both), has its first cost reporting period as a LTCH begins on or after October 1, 2002. We also specify in § 412.500 that the LTCH PPS is applicable to LTCHs for cost reporting periods beginning on or after October 1, 2002. As we discussed in the August 30, 2002 final rule (67 FR 56040), this definition of new LTCHs should not be confused with those LTCHs first paid under the TEFRA payment system for discharges occurring on or after October 1, 1997, described in section 1886(b)(7)(A) of the Act, as added by section 4416 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). As stated in § 413.40(f)(2)(ii), for cost reporting periods beginning on or after October 1, 1997, the payment amount for a ''new'' (post-FY 1998) LTCH is the lower of the hospital's net inpatient operating cost per case or 110 percent of the national median target amount payment limit for hospitals in the same class for cost reporting periods ending during FY 1996, updated to the applicable cost reporting period (see 62 FR 46019, August 29, 1997). Under the LTCH PPS, those ''new'' LTCHs that meet the definition of ''new'' under § 413.40(f)(2)(ii) and that have their first cost reporting period as a LTCH beginning prior to October 1, 2002, will be paid under the transition methodology described in § 412.533.

Under § 412.533(d), new LTCHs will not participate in the 5-year transition from reasonable cost-based reimbursement to prospective payment. As we discussed in the August 30, 2002 final rule (67 FR 56040), the transition period is intended to provide existing LTCHs time to adjust to payment under the new system. Since these new LTCHs with their first cost reporting periods as LTCHs beginning on or after October 1, 2002, would not have received payment under reasonable cost-based reimbursement for the delivery of LTCH services prior to the effective date of the LTCH PPS, we do not believe that those new LTCHs require a transition period in order to make adjustments to their operations and capital financing, as will LTCHs that have been paid under the reasonable cost-based methodology.

IX. Method of Payment

Under § 412.513, a Medicare LTCH patient is classified into a LTC-DRG based on the principal diagnosis, up to eight additional (secondary) diagnoses, and up to six procedures performed during the stay, as well as, age, sex, and discharge status of the patient. The LTC–DRG is used to determine the Federal prospective payment that the LTCH will receive for the Medicare-covered Part A services the LTCH furnished during the Medicare patient's stay. Under § 412.541(a), the payment is based on the submission of the discharge bill. The discharge bill also provides data to allow for reclassifying the stay from payment at the full LTC–DRG rate to payment for a case as a SSO (under § 412.529) or as an interrupted stay (under § 412.531), or to determine if the case will qualify for a high-cost outlier payment (under § 412.525(a)).

Accordingly, the ICD–9–CM codes and other information used to determine if an adjustment to the full LTC–DRG payment is necessary (for example, LOS or interrupted stay status) are recorded by the LTCH on the Medicare patient's discharge bill and submitted to the Medicare FI for processing. The payment represents payment in full, under § 412.521(b), for inpatient operating and capital-related costs, but not for the costs of an approved medical education program, bad debts, blood clotting factors, anesthesia services by hospital-employed nonphysician anesthetists or obtained under arrangement, or the costs of photocopying and mailing medical records requested by a Quality Improvement Organization (QIO), which are costs paid outside the LTCH PPS.

As under the previous reasonable cost-based payment system, under § 412.541(b), a LTCH may elect to be paid using the periodic interim payment (PIP) method described in § 413.64(h) and may be eligible to receive accelerated payments as described in § 413.64(g).

For those LTCHs that are paid during the 5-year transition based on the blended transition methodology in § 412.533(a) for cost reporting periods that began on or after October 1, 2002, and before October 1, 2006, the PIP amount is based on the transition blend. For those LTCHs that are paid based on 100 percent of the standard Federal rate, the PIP amount is based on the estimated prospective payment for the year rather than on the estimated reasonable cost-based reimbursement. We exclude high-cost outlier payments that are paid upon submission of a discharge bill from the PIP amounts. In addition, Part A costs that are not paid for under the LTCH PPS, including Medicare costs of an approved medical education program, bad debts, blood clotting factors, anesthesia services by hospital-employed nonphysician anesthetists or obtained under arrangement, and the costs of photocopying and mailing medical records requested by a QIO, are subject to the interim payment provisions (§ 412.541(c)).

Under § 412.541(d), LTCHs with unusually long lengths of stay that are not receiving payment under the PIP method may bill on an interim basis (60 days after an admission and at intervals of at least 60 days after the date of the first interim bill) and ''should include any high cost outlier payment determined as of the last day for which the services have been billed.''

X. Monitoring

In the August 30, 2002 final rule (67 FR 56014), we described an on-going monitoring component to the new LTCH PPS. Specifically, we discussed on-going analysis of the various policies that we believe would provide equitable payment for stays that reflect less than the full course of treatment and reduce the incentives for inappropriate admissions, transfers, or premature discharges of patients that are present in a discharge-based PPS. To this end, we have designed system features utilizing MedPAR data that will enable CMS and the FI to track beneficiary movement to and from a LTCH and to and from another Medicare provider. We also stated our intent to collect and interpret data on changes in average lengths of stay under the LTCH PPS for specific LTC–DRGs and the impact of these changes on the Medicare program. As a result of our data analysis, we have revisited a number of our original and even pre-LTCH PPS policies in order to address what we believe are behaviors by certain LTCHs that lead to inappropriate Medicare payments. In recent **Federal Register** publications, we have proposed and subsequently finalized revisions to the interruption of stay policy in the RY 2005 LTCH PPS final rule (69 FR 25690 through 25700), and we established a payment adjustment for LTCH HwHs and satellites in the FY 2005 IPPS final rule (69 FR 49191 through 49214).

On-going data analysis is also the basis for four of the policies that we are proposing in this notice. As noted in section V.A.2, we are proposing to ''sunset'' the surgical DRG exception to the 3 day or less interruption of stay policy at § 412.531(b)(1)(ii)(A)(*1*). As we discuss in detail in section V.A.1., we have determined that eliminating this exception will not result in significant hardship for LTCHs. In section V.A.2., we have also revisited the payment adjustment established for short-stay outliers (§ 412.529) as a consequence of recent data analysis and have proposed additional options under that policy. In addition to these three proposed policies, as a result of our analysis and on-going monitoring protocols, we are also proposing a zero percent update to the Federal payment rate for RY 2007, which is explained in detail in section IV.B.4. of this proposed rule.

As we discuss in section V.B.1., our monitoring of discharges between acute care hospitals and LTCHs reveals that a significant number of LTCHs that are ''free-standing'', that is, not colocated with other hospital-level providers (as defined in § 412.22(e) and § 412.22(h)), also admit their patients from one specific acute care hospital. When we established the payment adjustment for LTCH HwHs and satellites of LTCHs at § 412.534, we reiterated our concern that these on-site LTCHs could be functioning as units of their host (generally, an acute care hospital), a configuration that is not permitted in section 1886(d)(1)(B) of the Act. (The statute specifically allows only for IRF and IPF units in acute care hospitals but not for LTCH units.) Therefore, we note that in addition to monitoring compliance with the payment adjustment established under § 412.534 for LTCH HwHs and satellites of LTCHs, we will also be monitoring admissions of patients to freestanding LTCHs from referring acute hospitals. We believe that on-going data analysis of this patient movement may enable us to determine whether these ''free-standing'' LTCHs are functioning, in a similar way as some LTCH HwHs and LTCH satellites, as step-down units of their referring hospitals and are considering additional payment adjustments to address this issue.

As we discussed in the RY 2004 LTCH PPS final rule (68 FR 34157), the Medicare Payment Advisory Commission (MedPAC) endorsed our monitoring activity as a primary aspect of the design and on-going functioning of the LTCH PPS. Furthermore, the Commission pursued an independent research initiative that led to a section in the MedPAC Report entitled ''Defining long-term care hospitals'' published in the June, 2004 Report to Congress. This study included recommendations that we develop facility and patient criteria for LTCH admission and treatment and that we require a review by Quality Improvement Organizations (QIO) to evaluate whether LTCH admissions meet criteria for medical necessity once the recommended facility and patient criteria are established.

Therefore, in addition to pursuing our on-going monitoring program under the direction of ORDI, existing QIO monitoring and studies described in the RY 2006 LTCH PPS final rule (70 FR 24211), and our considerations of expanding the QIO role in the LTCH PPS, we awarded a contract to Research Triangle Institute, International (RTI) in September 2004 for a thorough examination of the feasibility of implementing MedPAC's recommendations in the June 2004 Report to Congress (which we detail in section XI. of this proposed rule). In the RY 2005 LTCH PPS final rule, we noted that this research contract, which was funded for FY 2005 was presently being executed and therefore, we anticipated that we would be able to include some preliminary findings in the RY 2007 LTCH PPS final rule. In this proposed rule, as noted previously, we have included a section that describes RTI's analyses for the purpose of providing an opportunity for public comment prior to the finalizing of RTI's final report.

XI. RTI Report on MedPAC June 2004 LTCH Recommendations

In the RY 2006 LTCH PPS final rule (70 FR 24209), we discussed Chapter 5 of MedPAC's June 2004 Report to Congress (RTC), ''Defining Long-Term Care Hospitals'' (LTCHs). In that Report, the Commission recommended that the Congress and the Secretary define LTCHs by facility and patient criteria to ensure that patients admitted to LTCH facilities are medically complex and have a good chance of improvement. In

addition, the Commission recommended expanding the statement of work for the Quality Improvement Organizations (QIOs) to enable them to monitor LTCH compliance with any newly-established hospital and patient criteria.

As detailed in that same final rule, in response to the recommendation in MedPAC's June 2004 Report, on September 27, 2004, we awarded a contract to Research Triangle Institute, International (RTI) for a thorough examination of the feasibility of implementing the Commission's recommendations based on the performance of a wide variety of analytic tasks using CMS data files, and information RTI would collect from physicians, providers, and LTCH trade associations. This contract, ''Long Term Care Hospital (LTCH) Payment System Refinement/Evaluation,'' will result in a report that will assist CMS in the development of criteria for assuring appropriate and cost-effective use of LTCHs in the Medicare program. With the recommendations of MedPAC's June 2004 Report to Congress as a point of departure, RTI began to evaluate the feasibility of developing patient and facility level characteristics for LTCHs in order to identify and distinguish the role of these hospitals as a Medicare provider.

In that same final rule, we also described RTI's project plan which will be completed in two phases. Phase I focuses on an analysis of LTCHs within the current Medicare system: their history as participating providers; their case mix; the criteria currently used by QIOs to determine the appropriateness of treatment in LTCHs; and the site of care for patients treated in areas that lack LTCHs. RTI is reviewing prior analyses of these issues by MedPAC and other contractors (such as the Urban Institute, 3M Health Information Systems, and The Lewin Group) and is also having additional discussions with MedPAC, other researchers, and the QIOs. Building on the work of Phase I, Phase II addresses the feasibility of MedPAC's proposed criteria based on a three-pronged approach: Medicare claims analysis to examine patient differences across settings; interviews with QIOs and providers to examine level of care definitions currently being used or tested; and finally site visits to interview providers with the objective of distinguishing LTCHs from other inpatient settings for payment purposes. During October through December 2005, RTI scheduled and conducted site visits to LTCHs throughout the country that are representative of the various types of LTCHs. A team of RTI researchers and CMS analysts, including a physician, participated in these visits.

A. Overview of the Issues

RTI's research is guided by a conceptual framework based upon several fundamental premises:

- The goal of the Medicare program is the cost-effective delivery of the highest quality of medical services to beneficiaries.
- LTCHs are the highest paid hospitals in the Medicare program. Despite the fact that their availability varies widely across the nation, they have increased in numbers exponentially over the last 10 years. The research is to determine whether this increase is due to growing patient demand or industry response to generous payment policies.
- In parts of the country that lack LTCHs, LTCH-type patients may receive hospital-level treatment at acute hospitals as outlier patients, at IRFs, or in some cases, IPFs with significantly lower payments per beneficiary discharge than at LTCHs. The research attempts to determine whether patient outcomes are equivalent across these sites.

In order to evaluate the feasibility of developing patient and facility-level criteria specific to LTCHs, it must be determined whether there are identifiable differences in the care delivered at LTCHs as compared with other hospital-level providers for the same type of Medicare patient and if so, what distinguishes the services delivered by LTCHs from services at other settings. One clear and easily measurable difference is Medicare payments for services since payments for LTCH-type patients may differ dramatically depending on site of care due to the different base payment rates for each provider category. Determining whether there is a correlation between the higher payments at LTCHs and improved patient outcomes for the same types of patients in different treatment settings is the central question RTI will answer. Since there is a wide variation in the range of post-acute care available throughout the country, if payments are equivalent per case and patient outcomes are generally equal in different areas of the country, the variations may be explained as a reflection of variations in regional practices. However, if outcomes differ substantially for certain types of patients, indicating that LTCH patients have better outcomes, the recent growth of the LTCH industry could result in the availability of a better level of care for Medicare beneficiaries nationwide. Alternatively, if payments differ between provider types but patient outcomes are equivalent, one could question whether higher cost LTCH services are needed for all types of cases currently treated, or more specifically, which types of patients benefit from the higher cost LTCH services. Building on MedPAC's earlier work (May 2004, June 2004), RTI researchers are examining differences in payments and outcomes for patients treated in these various settings.

B. Describing the LTCH Universe since FY 2003

RTI is examining changes in the availability of LTCHs over time. The number of LTCHs has more than tripled from 105 in 1993 to 363 as of March 2005. Although the two States with the largest number of LTCHs are Texas and Louisiana, substantial growth is also occurring in States with large numbers of elderly populations including Pennsylvania, Ohio, Michigan, Georgia, Indiana, and Oklahoma.

Using Geographic Information Services (GIS) software to spatially present the different types of inpatient post-acute services in acute care hospital referral regions (as defined by Dartmouth Atlas 2005), RTI is highlighting the regional variation in the availability of LTCHs and other substitute providers. The resulting maps indicate that while LTCHs are widely available in the northeast and southern States, in the western part of the nation they are localized in several small areas (for example, Nevada and Utah) and relatively few LTCHs exist on the west coast. IPFs and IRFs, in contrast, are more common in the west and north central parts of the U.S. where there are few, if any, LTCHs. Also, RTI is identifying significant changes in the LTCH universe in terms of their ownership. The draft report submitted to CMS notes the following facts:

- For-profit hospitals entered the market during the 1990s and grew continuously until 2005 when they accounted for 58 percent of all LTCHs.
- While the number of non-profit hospitals also grew rapidly, they continued to account for only one-third of all LTCHs through 2005.
- The number of government-owned hospitals declined dramatically from 25 percent to only 8 percent of the LTCHs in 2005.

There are generally three distinct types of LTCHs with the following basic characteristics and patients:

- The majority of LTCHs specialize in what they consider to be medically complex patients (including many respiratory and ventilator-dependent

patients), and some of these have ICU-type units;

- In some regions, LTCHs may focus on rehabilitation patients; and
- In other areas, LTCHs may be primarily treating patients who could otherwise be in IPFs.

LTCHs in these last two categories differ significantly from the first, because generally the patients are less medically complex.

C. Patient, Facility, and Alternative Treatment Site Analysis

RTI is analyzing claims from the 100 percent MedPAR files for CY 2003, including acute care, LTCH, IRF, IPF, and SNF records. Episodes are constructed to include 180 days of potential use beginning with admission to the index hospital and including payments and use of associated home health services. The fundamental goals of the analytic work are to identify differences between patient populations, utilization patterns, outcomes, Medicare program payments by site of care, and most significantly, to develop a profile of the LTCH admission in 2003. This profile is based on primary diagnoses and examines the use of other services prior and subsequent to the LTCH admission.

RTI is also analyzing the data for the acute care hospital patients with multiple comorbidities who have reached outlier status at the acute care hospital with data for LTCH patients with similar profiles. Data on acute care patients who have reached outlier status prior to admission to an LTCH are evaluated to determine if there are: (1) Clear factors that predicted LTCH use, (2) differences in hospital readmission rates between those who use LTCHs and those who do not; and (3) program cost differences between the two types of patients.

D. Specific Findings From Claims Analysis

The following is a summary of the specific issues that the RTI draft report will examine followed by a brief description of their draft findings from their review of 100 percent of CY 2003 MedPAR data.

1. LTCHs Population

Table 14 lists the 50 most common DRGs admitted to LTCHs in 2003 as a result of the draft report findings and their relative ranking in various settings. The top five types of admissions illustrate the heterogeneity of the population treated in these facilities and their relative importance as admissions to other facilities. While the relative ranking in each facility may differ, the absolute number of cases admitted to LTCHs may be similar to other settings (Table 15). For example, DRG 012: Nervous System Disorders are almost as likely to go to an IRF facility for a non-outlier stay as to be admitted to an LTCH according to the draft report findings. While this DRG is ranked 3rd among LTCH and 8th among IRF admissions, the number of cases admitted to LTCHs and non-outlier IRFs is fairly comparable (5,846 compared to 5,508, respectively). Further, nearly five times as many cases are admitted to IPFs (28,911).

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TABLE 14: Top 50 LTCH DRGs ranked across providers (based on RTI Draft Report)

DRG Code	DRG Name	LTCH Rank	Acute Outlier Rank	IRF Rank[1]	PSYCH Rank[2]
475	Respiratory System Diagnosis With Ventilator Support	1	3		
462	Rehabilitation	2		1	
012	Degenerative Nervous System Disorders	3		8	3
271	Skin Ulcers	4			
249	Aftercare, Musculoskeletal System & Connective Tissue	5		12	
087	Pulmonary Edema & Respiratory Failure	6			
088	Chronic Obstructive Pulmonary Disease	7	40	11	
466	Aftercare w/o History of Malignancy As Secondary Diagnosis	8			
089	Simple Pneumonia & Pleurisy Age >17 w CC	9	24		
079	Respiratory Infections & Inflammations Age >17 w CC	10	21		
127	Heart Failure & Shock	11	6	16	
416	Septicemia Age >17	12	5		
263	Skin Graft &/or Debrid for Skin Ulcer or Cellulitis w CC	13			
430	Psychoses	14			1
316	Renal Failure	15	22		
238	Osteomyelitis	16			
277	Cellulitis Age >17 w CC	17			
418	Postoperative & Post-Traumatic Infections	18			
130	Peripheral Vascular Disorders w CC	19		13	
320	Kidney & Urinary Tract Infections Age >17 w CC	20			
144	Other Circulatory System Diagnoses w CC	21	30		
463	Signs & Symptoms w CC	22		9	
076	Other Resp System O.R. Procedures w CC	23	18		
452	Complications of Treatment w CC	24			
188	Other Digestive System Diagnoses Age >17 w CC	25			
296	Nutritional & Misc Metabolic Disorders Age >17 w CC	26	36		
182	Esophagitis, Gastroent & Misc Digest Disorders Age >17 w CC	27	39		
468	Extensive O.R. Procedure Unrelated To Principal Diagnosis	28	9		
465	Aftercare w History of Malignancy As Secondary Diagnosis	29			
082	Respiratory Neoplasms	30			

DRG Code		DRG Name		LTCH Rank	Acute Outlier Rank	IRF Rank[1]	PSYCH Rank[2]
217		Wnd Debrid & Skn Grft except Hand, for Muscskelet & Conn Tiss Dis		31	33		
415		O.R. Procedure for Infectious & Parasitic Diseases		32	7		
243		Medical Back Problems		33		6	
294		Diabetes Age >35		34			
483		Tracheostomy except for Face, Mouth & Neck Diagnoses		35	1		
461		O.R. Proc w Diagnoses of Other Contact w Health Services		36		10	
034		Other Disorders of Nervous System w CC		37		18	
429		Organic Disturbances & Mental Retardation		38			2
014		Specific Cerebrovascular Disorders except TIA		39	23	5	
126		Acute & Subacute Endocarditis		40			
120		Other Circulatory System O.R. Procedures		41	26		
172		Digestive Malignancy w CC		42			
331		Other Kidney & Urinary Tract Diagnoses Age >17 w CC		43			
256		Other Musculoskeletal System & Connective Tissue Diagnoses		44			
132		Atherosclerosis w CC		45		14	
204		Disorders of Pancreas except Malignancy		46	47		
403		Lymphoma & Non-Acute Leukemia w CC		47	43		
020		Nervous System Infection except Viral Meningitis		47			
099		Respiratory Signs & Symptoms w CC		48			
242		Septic Arthritis		49			
101		Other Respiratory System Diagnoses w CC		50			
248		Tendonitis, Myositis & Bursitis		50			

RTI analyses of Medicare Administrative files, 2003.
[1]IRF Rank includes rankings for only the top 20 IRF DRGs.
[2]PSYCH Rank includes rankings for only the top 10 IPF DRGs.

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Table 15 shows the variation in these admission rates to different sites of care. While LTCHs treat a wide range of DRGs, the majority of these cases are also treated in alternative settings. For example, LTCHs treat only 16 percent of the total DRG 012 cases while the IPFs treated 71 percent of these cases. It is interesting to note, in general, that LTCHs treat a relatively small proportion of all types of cases compared to other settings.

2. Similarities Between the Acute Outlier and LTCH Samples

The most common admission to both the LTCHs and the subset of acute admissions with high-cost outlier payments are the respiratory patients. DRG 475 is the most common LTCH admission and the third most common in the acute outlier group, both admitting over 8,000 cases a year. Infection cases, such as DRG 416: Septicemia, are also quite common in the LTCH and acute outlier populations as are renal failure patients (DRG 316). These types of cases are frequently admitted as either a primary or secondary diagnosis in this population. While patients with skin conditions are common to both LTCHs and other hospitals, LTCHs appear to specialize in different subsets of the patients. LTCHs have a large number of DRG 271: Skin Ulcer patients (5,348 cases) while acute care hospitals are more likely to be treating DRG 217: Wound debridement cases. DRG 127: (Heart failure and shock) cases also are common across settings although the severity of illness may differ.

The population treated in LTCHs is diverse and frequently found in alternative settings. As indicated in Table 15, the top 50 DRGs for LTCHs constitute 86 percent of all LTCH discharges. These same DRGs account for 40 percent of acute outlier discharges, 93 percent of IRF outliers and 81 percent of IRF non-outliers (majority due to rehabilitation), 87 percent of psychiatric discharges (with 72 percent due to psychoses) and 56 percent of SNFs/swing beds discharges.

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TABLE 15: Top 50 LTCH DRGS, Discharges by Provider Type, 2003 (based on the RTI Draft Report)

Rank	DRG	DRG Description	LTCH		Acute Outliers		IRF Outliers		IRF Non-Outliers		Psych. Hospital/Units		SNFs/Swing Beds	
			Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N
1	475	Respiratory System Diagnosis With Ventilator Support	8.76	10,140	4.67	8,221	0.02	5	0.00	2	0.00	11	0.01	53
2	462	Rehabilitation	6.16	7,131	0.01	25	79.74	20,094	67.19	317,899	0.01	36	8.15	30,970
3	012	Degenerative Nervous System Disorders	5.05	5,846	0.20	360	0.75	188	1.16	5,508	6.09	28,911	4.98	18,936
4	271	Skin Ulcers	4.62	5,348	0.10	179	0.06	15	0.07	313	0.00	1	1.39	5,293
5	249	Aftercare, Musculoskeletal System & Connective Tissue	4.53	5,238	0.03	58	0.29	74	0.81	3,832	0.00	0	1.56	5,927
6	087	Pulmonary Edema & Respiratory Failure	4.20	4,863	0.37	659	0.27	69	0.16	749	0.00	11	1.53	5,823
7	088	Chronic Obstructive Pulmonary Disease	4.20	4,856	0.66	1,157	0.71	180	0.85	4,017	0.02	74	2.72	10,324
8	466	Aftercare w/o History of Malignancy As Secondary Diagnosis	3.81	4,413	0.01	12	0.02	4	0.35	1,657	0.00	5	1.35	5,136
9	089	Simple Pneumonia & Pleurisy Age >17 w CC	3.76	4,352	1.18	2,070	0.18	46	0.33	1,571	0.02	86	2.47	9,405
10	079	Respiratory Infections & Inflammations Age >17 w CC	3.55	4,113	1.35	2,374	0.11	27	0.07	335	0.00	20	0.71	2,715
11	127	Heart Failure & Shock	3.21	3,717	2.65	4,662	0.36	90	0.57	2,687	0.01	48	4.05	15,414
12	416	Septicemia Age >17	2.99	3,459	2.70	4,755	0.02	6	0.07	341	0.00	22	1.26	4,798
13	263	Skin Graft &/or Debrid for Skn Ulcer or Cellulitis w CC	2.59	2,996	0.52	911	0.02	6	0.00	17	0.00	3	0.02	76
14	430	Psychoses	2.14	2,479	0.09	163	0.00	0	0.01	29	72.26	343,219	2.27	8,627
15	316	Renal Failure	2.07	2,391	1.24	2,188	0.11	28	0.10	489	0.01	29	2.03	7,711
16	238	Osteomyelitis	1.62	1,874	0.09	158	0.06	16	0.08	358	0.00	4	0.45	1,729
17	277	Cellulitis Age >17 w CC	1.57	1,822	0.25	447	0.07	18	0.10	491	0.00	16	0.75	2,834
18	418	Postoperative & Post-Traumatic Infections	1.48	1,713	0.16	286	0.06	15	0.04	203	0.00	2	0.36	1,359
19	130	Peripheral Vascular Disorders w CC	1.25	1,451	0.29	505	0.36	90	0.70	3,314	0.00	11	1.23	4,684
20	320	Kidney & Urinary Tract Infections Age >17 w CC	1.20	1,388	0.40	701	0.05	12	0.08	383	0.02	116	1.19	4,534
21	144	Other Circulatory System Diagnoses w CC	1.16	1,338	0.79	1,389	0.09	22	0.21	989	0.01	25	0.76	2,892
22	463	Signs & Symptoms w CC	1.14	1,316	0.05	89	0.60	152	0.89	4,204	0.01	30	1.77	6,741
23	076	Other Resp System O.R. Procedures w CC	0.99	1,141	1.37	2,408	0.01	2	0.00	4	0.00	5	0.00	19
24	452	Complications of Treatment w CC	0.96	1,116	0.17	307	0.04	9	0.05	222	0.00	3	0.13	476
25	188	Other Digestive System Diagnoses Age >17 w CC	0.96	1,108	0.52	917	0.08	20	0.12	574	0.00	6	0.56	2,142
26	296	Nutritional & Misc Metabolic Disorders Age >17 w CC	0.88	1,019	0.68	1,199	0.07	17	0.10	459	0.02	100	0.84	3,196

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Rank	DRG	DRG Description	LTCH		Acute Outliers		IRF Outliers		IRF Non-Outliers		Psych. Hospital/Units		SNFs/Swing Beds	
			Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N	Percent of all Discharges	N
27	182	Esophagitis, Gastroent & Misc Digest Disorders Age >17 w CC	0.68	785	0.66	1,166	0.06	15	0.12	553	0.01	25	1.05	4,005
28	468	Extensive O.R. Procedure Unrelated To Principal Diagnosis	0.67	776	2.38	4,190	0.05	12	0.00	19	0.01	33	0.01	20
29	465	Aftercare w History of Malignancy As Secondary Diagnosis	0.66	760	0.00	1	0.00	1	0.03	128	0.00	0	0.09	330
30	082	Respiratory Neoplasms	0.64	736	0.39	680	0.02	6	0.10	462	0.00	10	0.37	1,415
31	217	Wnd Debrid & Skn Grft except Hand, for Muscskelet & Conn Tiss Dis	0.63	728	0.73	1,292	0.01	3	0.01	33	0.00	5	0.01	39
32	415	O.R. Procedure for Infectious & Parasitic Diseases	0.60	695	2.42	4,261	0.02	4	0.00	5	0.00	1	0.01	39
33	243	Medical Back Problems	0.58	672	0.16	283	0.58	147	2.20	10,398	0.00	21	1.73	6,584
34	483	Tracheostomy except for Face, Mouth & Neck Diagnoses	0.55	638	7.38	13,000	0.03	8	0.00	1	0.00	8	0.00	0
35	461	O.R. Proc w Diagnoses of Other Contact w Health Services	0.55	631	0.03	60	5.51	1,389	0.59	2,812	0.00	1	0.08	312
36	294	Diabetes Age >35	0.54	630	0.27	484	0.05	12	0.09	417	0.01	41	2.04	7,775
37	034	Other Disorders of Nervous System w CC	0.49	570	0.13	227	0.46	117	0.52	2,442	0.02	108	0.96	3,663
38	014	Specific Cerebrovascular Disorders except TIA	0.46	531	1.24	2,177	1.20	302	2.27	10,731	0.01	61	0.98	3,722
39	429	Organic Disturbances & Mental Retardation	0.46	528	0.05	83	0.01	3	0.03	129	8.78	41,720	3.14	11,946
40	126	Acute & Subacute Endocarditis	0.42	482	0.11	202	0.01	3	0.01	30	0.00	0	0.06	228
41	120	Other Circulatory System O.R. Procedures	0.41	474	0.95	1,676	0.02	5	0.00	13	0.00	2	0.01	55
42	172	Digestive Malignancy w CC	0.41	469	0.29	509	0.04	10	0.12	569	0.00	4	0.34	1,286
43	331	Other Kidney & Urinary Tract Diagnoses Age >17 w CC	0.40	458	0.31	546	0.01	2	0.04	171	0.00	13	0.31	1,191
44	256	Other Musculoskeletal System & Connective Tissue Diagnoses	0.39	451	0.02	36	0.07	17	0.19	879	0.00	4	0.69	2,611
45	132	Atherosclerosis w CC	0.37	425	0.08	140	0.33	83	0.70	3,333	0.00	16	0.99	3,759
46	204	Disorders of Pancreas except Malignancy	0.35	400	0.56	986	0.01	3	0.03	135	0.00	5	0.23	871
47	403	Lymphoma & Non-Acute Leukemia w CC	0.34	394	0.60	1,062	0.04	11	0.04	169	0.00	2	0.18	677
48	020	Nervous System Infection except Viral Meningitis	0.34	392	0.21	362	0.13	33	0.09	449	0.00	10	0.17	629
49	099	Respiratory Signs & Symptoms w CC	0.30	352	0.02	42	0.02	4	0.02	106	0.00	3	0.23	890
50	242	Septic Arthritis	0.29	334	0.01	20	0.04	11	0.03	123	0.00	1	0.11	428

RTI analyses of Medicare Administrative files, 2003.
SOURCE: BBAR037

3. Differences in DRG-Specific Diagnoses Across Treatment Settings

While certain DRGs may be common to multiple settings, the underlying diagnoses (ICD9–CM) may differ. Table 16 addresses whether facilities are specializing in certain subsets of patients within DRGs. As mentioned previously, the largest group of LTCH discharges are patients with respiratory system diagnosis with ventilator support (DRG 475) but within this DRG the majority of discharges from LTCHs come from ''other lung diseases'' (89.2 percent). Pulmonary collapse, some emphysema, acute edema of lung and acute respiratory failure fall under this category. Only 41 percent of acute outlier patients within DRG 475 were discharged with this ICD–9–CM code. Instead, the DRG 475 patients in the acute outlier setting had higher proportions admitted with pneumonia-related or chronic bronchitis diagnoses.

The underlying diagnoses in DRG 012: Degenerative nervous system disorders varied extensively across settings. More than 80 percent of the LTCH admissions had late effects of cerebrovascular disease, as did 74.5 percent of the IRF outliers; however, this dropped to 54.2 percent of the IRF non-outliers and 52.5 percent of those in SNF/swing beds. Psychiatric patients in this DRG were more likely to have cerebral degeneration (95.7 percent), which includes Alzheimer's disease. Parkinson's Disease is the third most common diagnoses in this group, accounting for 4.2 percent of the LTCH cases and over 26 percent of the non-outlier IRF cases.

The primary diagnoses for DRG 249: Aftercare of musculoskeletal system and connective tissue (DRG 249) also differed across settings. Four-fifths of patients in LTCHs and SNF/swing beds (82.4 percent, 78.6 percent, respectively) were there for ''other orthopedic aftercare,'' (which included, for example, the removal of fracture plate, pins, rods, screws) and the aftercare for healing traumatic or pathologic fractures. In contrast, in the acute outlier, IRF outlier, and IRF non-outlier populations these patients were more likely to be treated for a replacement and graft-related complications.

Among the 50 most frequent types of LTCH admissions, the most expensive case is DRG 076 (Other Respiratory System OR Procedures w/CC) which has an average Medicare episode payment of $120,806 (Table 17). While this case is ranked the 23rd most common type of LTCH admission, it is the most expensive type of episode due to its high acute and LTCH hospital payments. These cases have the second highest acute payments prior to LTCH admission ($60,612) and the second highest LTCH payment ($58,357). The combined acute and LTCH LOS is 81 days, of which two-thirds is LTCH days (55 days).

The most common LTCH case, DRG 475: Respiratory System Diagnosis with Ventilator Support is the second most expensive LTCH episode. Medicare payments for these cases are $118,635 on average and the average length stay from hospital admission to LTCH discharge is 70 days. These cases have the most expensive acute hospital stay and the fourth most expensive LTCH stay.

DRG 462: Rehabilitation is the second most common type of LTCH admission, although it accounts for only one-third as many admissions as go to IRFs with outlier payments. These cases are ranked 35th in terms of episode payments with almost half of the payments ($20,311) related to the LTCH admission. The average length stay in the LTCH is 27 days following 11 days in the acute hospital. This DRG is also the most common IRF admission and accounts for two-thirds of all IRF cases. In contrast to the LTCH, IRF payments range from $11,741 for the majority of cases to $23,104 for the small percent that receive IRF outlier adjustments. Little is known about the differences in severity across the different settings since Functional Independence Measures (FIM scores) are only collected in the IRF.

The majority of LTCH cases are admitted from an acute hospital (79.2 percent), and has higher LTCH payments than acute care hospital payments. This is particularly true among the 20 most expensive LTCH cases, the exceptions being DRG 76, DRG 475, DRG 87, DRG 99, and DRG 452 which have higher acute payments. The more common skin ailments, including DRG 263, DRG 217, and DRG 271, have LTCH payments two to three times greater than the preceding acute stay payment.

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TABLE 16: Top LTCH Primary Diagnoses Among Select DRGs by Provider Type, 2003 (based on the RTI Draft Report)

			LTCH %	Acute Outliers %	IRF Outliers %	IRF Non-Outliers %	Psych Hospital/Units %	SNF/ Swing Beds %
DRG475: Respiratory System Diagnosis With Ventilator Support								
			N=10140	N=8221	N=5	N=2	N=11	N=53
1	518	Other Lung Diseases*	89.16	41.31	100.00	100.00	72.73	67.92
2	482	Oth Bacterial Pneumonia*	2.22	11.87	0.00	0.00	0.00	3.77
3	486	Pneumonia, Organism Nos	1.99	15.48	0.00	0.00	0.00	7.55
4	491	Chronic Bronchitis*	1.70	6.45	0.00	0.00	0.00	3.77
5	507	Solid/Liq Pneumonitis*	1.60	11.29	0.00	0.00	18.18	3.77
6	496	Chr Airway Obstruct Nec	1.17	0.00	0.00	0.00	0.00	9.43
DRG462: Rehabilitation								
			N=7131	N=25	N=20094	N=317899	N=36	N=30979
1	V57	Rehabilitation Procedure*	100.00	100.00	100.00	100.00	100.00	99.99
2	V52	Fitting Of Prosthesis*	0.00	0.00	0.00	0.00	0.00	0.01
DRG012: Degenerative Nervous System Disorders								
			N=5846	N=360	N=188	N=5508	N=28911	N=18936
1	438	Late Eff Cerebrovasc Dis*	82.19	14.17	74.47	54.27	0.60	52.53
2	331	Cerebral Degeneration*	10.93	24.44	3.72	7.15	95.66	26.52
3	332	Parkinson's Disease*	4.16	10.00	13.30	26.16	2.84	13.81
4	342	Hemiplegia*	0.82	0.28	6.38	8.22	0.00	4.72
6	333	Extrapyramidal Dis Nec*	0.50	2.22	0.53	1.22	0.81	1.12
7	358	Myoneural Disorders*	0.48	42.50	0.00	1.16	0.00	0.47
8	335	Ant Horn Cell Disease*	0.31	3.89	1.60	1.34	0.00	0.40

			LTCH %	Acute Outliers %	IRF Outliers %	IRF Non-Outliers %	Psych Hospital/Units %	SNF/ Swing Beds %
DRG249: Aftercare, Musculoskeletal System & Connective Tissue								
			N=5238	N=58	N=74	N=3832	N=0	N=5297
1	V54	Oth Orthopedic Aftercare*	82.36	3.45	25.68	11.40	0.00	78.57
2	996	Replace & Graft Complic*	16.00	96.55	68.92	86.80	0.00	16.15
3	905	Late Eff Musculoskel Inj*	1.60	0.00	4.05	1.59	0.00	5.25
4	V52	Fitting Of Prosthesis*	0.04	0.00	1.35	0.21	0.00	0.00
5	V53	Adjustment Of Oth Device*	0.00	0.00	0.00	0.00	0.00	0.03
DRG296: Nutritional & Misc Metabolic Disorders Age >17 w CC								
			N=1019	N=1199	N=17	N=459	N=100	N=3196
1	263	Prot-Cal Malnutr Nec/Nos*	46.61	5.34	11.76	3.05	1.00	12.83
2	276	Fluid/Electrolyte Dis*	24.83	82.40	29.41	58.17	77.00	56.88
3	783	Nutrit/Metab/Devel Symp*	9.32	4.09	0.00	18.52	14.00	16.96
4	261	Nutritional Marasmus	8.24	1.58	0.00	1.09	0.00	0.59
5	275	Dis Mineral Metabolism*	2.94	3.00	0.00	5.23	2.00	2.03
6	262	Oth Severe Malnutrition	2.85	0.83	0.00	0.44	0.00	0.84
7	278	Obesity/Hyperaliment*	2.36	0.83	29.41	6.97	3.00	3.35
8	269	Oth Nutrition Deficiency*	1.28	0.00	5.88	0.44	0.00	0.78
9	260	Kwashiorkor	0.79	0.17	5.88	0.65	0.00	0.09
10	251	Oth Pancreatic Disorder*	0.39	1.08	5.88	2.83	0.00	4.97
11	266	B-Complex Deficiencies*	0.10	0.08	11.76	1.96	3.00	0.31

RTI analyses of Medicare Administrative files, 2003.

TABLE 17: Average Episode Payments and Length of Stay For Top 50 LTCH Admissions by Type of Hospitalization, 2003 (based on the RTI Draft Report)

LTCH Rank	DRG	DRG LABEL	Episode Payment	Prior Acute Payment	LTCH Payment	Other PAC Payments	Prior Acute LOS	LTCH LOS
3	12	Degenerative Nervous System Disorders	42,549	9,762	23,270	9,516	9	32
38	14	Specific Cerebrovascular Disorders except TIA	48,352	14,728	22,947	10,677	11	28
48	20	Nervous System Infection except Viral Meningitis	63,706	22,976	29,698	11,032	17	33
37	34	Other Disorders of Nervous System w CC	54,841	22,844	23,876	8,120	14	42
23	76	Other Resp System O.R. Procedures w CC	120,806	60,612	58,357	1,837	26	55
10	79	Respiratory Infections & Inflammations Age >17 w CC	49,480	16,190	24,650	8,639	14	29
30	82	Respiratory Neoplasms	30,205	13,689	16,909	0	13	23
6	87	Pulmonary Edema & Respiratory Failure	87,291	50,483	32,942	3,866	23	40
7	88	Chronic Obstructive Pulmonary Disease	38,975	9,498	20,920	8,558	10	25
9	89	Simple Pneumonia & Pleurisy Age >17 w CC	40,607	10,343	21,892	8,371	10	26
49	99	Respiratory Signs & Symptoms w CC	67,997	33,871	26,088	8,037	20	32
41	120	Other Circulatory System O.R. Procedures	60,084	14,706	36,685	8,694	13	43
40	126	Acute & Subacute Endocarditis	53,298	18,483	24,243	10,571	15	30
11	127	Heart Failure & Shock	40,564	11,488	20,767	8,309	12	25
19	130	Peripheral Vascular Disorders w CC	44,460	11,413	23,500	9,546	12	30
45	132	Atherosclerosis w CC	55,687	24,480	21,432	9,774	15	27
21	144	Other Circulatory System Diagnoses w CC	49,022	17,555	21,514	9,953	14	26
42	172	Digestive Malignancy w CC	37,456	16,515	19,089	1,852	16	25
27	182	Esophagitis, Gastroent & Misc Digest Disorders Age >17 w CC	41,396	9,789	22,587	9,020	13	28
25	188	Other Digestive System Diagnoses Age >17 w CC	56,087	19,886	26,507	9,693	18	29

LTCH Rank	DRG	DRG LABEL	Episode Payment	Prior Acute Payment	LTCH Payment	Other PAC Payments	Prior Acute LOS	LTCH LOS
46	204	Disorders of Pancreas except Malignancy	57,538	20,930	24,461	12,147	19	26
31	217	Wnd Debrid & Skn Grft except Hand,for Muscskelet & Conn Tiss Dis	60,879	14,126	37,949	8,804	13	46
16	238	Osteomyelitis	48,406	11,659	26,802	9,946	12	36
50	242	Septic Arthritis	45,547	11,068	24,964	9,514	12	32
33	243	Medical Back Problems	35,958	8,628	20,813	6,517	9	28
5	249	Aftercare, Musculoskeletal System & Connective Tissue	40,735	10,084	22,178	8,474	8	28
44	256	Other Musculoskeletal System & Connective Tissue Diagnoses	48,821	13,929	24,096	10,797	14	30
13	263	Skin Graft &/or Debrid for Skn Ulcer or Cellulitis w CC	57,663	12,035	39,725	5,904	12	50
4	271	Skin Ulcers	47,911	12,257	28,404	7,250	12	38
17	277	Cellulitis Age >17 w CC	39,912	8,075	22,050	9,788	9	28
36	294	Diabetes Age >35	41,474	9,019	23,395	9,060	10	33
26	296	Nutritional & Misc Metabolic Disorders Age >17 w CC	40,132	11,730	21,838	6,563	13	28
15	316	Renal Failure	53,639	18,062	24,578	10,999	16	29
20	320	Kidney & Urinary Tract Infections Age >17 w CC	38,522	7,606	22,035	8,882	9	28
43	331	Other Kidney & Urinary Tract Diagnoses Age >17 w CC	47,973	13,177	23,961	10,835	14	29
47	403	Lymphoma & Non-Acute Leukemia w CC	44,708	15,062	21,955	7,691	15	27
32	415	O.R. Procedure for Infectious & Parasitic Diseases	69,419	21,932	39,754	7,733	17	46
12	416	Septicemia Age >17	49,721	15,873	24,481	9,366	14	29
18	418	Postoperative & Post-Traumatic Infections	54,669	20,527	24,488	9,654	16	30
39	429	Organic Disturbances & Mental Retardation	31,124	7,235	18,210	5,679	8	44
14	430	Psychoses	26,347	5,058	19,514	1,775	7	35

LTCH Rank	DRG	DRG LABEL	Episode Payment	Prior Acute Payment	LTCH Payment	Other PAC Payments	Prior Acute LOS	LTCH LOS
24	452	Complications of Treatment w CC	59,745	26,090	25,553	8,102	20	31
35	461	O.R. Proc w Diagnoses of Other Contact w Health Services	67,114	21,370	35,722	10,022	17	44
2	462	Rehabilitation	41,838	13,060	20,311	8,466	11	27
22	463	Signs & Symptoms w CC	40,146	12,860	20,955	6,331	12	27
29	465	Aftercare w History of Malignancy As Secondary Diagnosis	53,551	24,024	20,700	8,827	16	25
8	466	Aftercare w/o History of Malignancy As Secondary Diagnosis	54,988	23,781	21,764	9,444	15	26
28	468	Extensive O.R. Procedure Unrelated To Principal Diagnosis	89,096	37,946	47,320	3,831	19	53
1	475	Respiratory System Diagnosis With Ventilator Support	118,635	71,947	44,239	2,449	27	43
34	483	Tracheostomy except for Face,Mouth & Neck Diagnoses	87,990	23,157	59,719	5,113	16	59

RTI analyses of Medicare Administrative files, 2003.
NOTE: Other PAC Payments include average Medicare payments for SNF, HH, IRF, and general acute readmissions.
SOURCE: LTCH sample, Gage124

BILLING CODE 4120-01-C

TABLE 18: Top 7 LTCH Hospital Discharges by DRG and Census Region, 2003 (based on the RTI Draft Report)

DRG		New England	Mid-Atlantic	E. North Central	W. North Central	South Atlantic	E. South Central	W. South Central	Western Mountain	Pacific
1.	475	428	800	2,676	605	1,595	664	1,980	590	802
2.	462	185	786	733	160	704	863	3,307	206	187
3.	012	869	334	455	600	411	248	2,568	164	197
4.	271	99	271	751	302	584	249	2,523	288	281
5.	249	917	316	415	71	490	190	2,450	168	221
6.	087	253	370	832	374	809	227	1,214	346	438
7.	088	850	229	524	175	434	164	2,043	195	242
Total Discharges		3,601	3,106	6,386	2,287	5,027	2,605	16,085	1,957	2,368

RTI analyses of Medicare Administrative files, 2003.

4. Variation of Payment and Use Patterns by Regional Location

Table 18 presents LTCH discharges by DRG and by census region to examine differences in the types of cases admitted to LTCHs across the regions. Use of these hospitals may vary because of the availability of alternative providers in certain parts of the country.

The West South Central region by far has the largest number of discharges from LTCHs. Excluding this region, the number of discharges was lowest in the Western Mountain region and highest in the East North Central region.

DRG 475 (respiratory with ventilator support) accounted for the highest number of discharges in most regions. These discharges were by far the most common among the 7 DRGs listed in the East North Central region and the South Atlantic. However, there were three regions where this DRG was not the most frequent type of discharge among those listed: New England, East South Central and West South Central. In the New England region, DRG 249 (Aftercare, Musculoskeletal System and Connective Tissues), DRG 012 (Degenerative Nervous System Disorders) and DRG 088 (COPD) were more common than DRG 475. In the East South Central and West South Central regions, DRG 462 (Rehabilitation) was the most common DRG.

5. Payment Variation Across Regions

Despite the fact that the LTCH PPS, like all prospective payment systems is designed to provide a uniform Medicare payment for each LTC–DRG, there are facility and patient level adjustments that may impact the payments for any specific case. Under the LTCH PPS, for example, there is an area wage adjustment (which is being phased-in over 5 years) which would impact payments regionally. There may also be variations among LTCHs and across regions in the admission of short stay outliers, the number of interrupted stay cases, and on-site discharges and readmittances, all of which could affect Medicare per discharge payments.

RTI examined Medicare payments and levels of use across different regions. Among the 20 most frequently admitted LTCH conditions, DRG 475 was the highest cost DRG across all regions. In the West South Central, with its high volume of LTCH admissions, the second most expensive type of case is the DRG 263: Skin Graft and Debridement for Skin Ulcer which ranked 13th in volume across all LTCH admissions.

Use levels also varied regionally. As with the payments, LOS for DRG 475 was highest in New England as compared to the shortest stays for these cases being in the West South Central region which had the highest number of these admissions. In general, New England lengths of stay were longer than in other parts of the nation for respiratory and infection cases as well as nervous system disorders. Skin ulcers, pulmonary edema, respiratory infections, skin graft and debridements, psychoses, and renal failure cases also tended to stay longer in the northeast.

6. Identifying LTCH Patients Relative to Other PAC Patients

While the proportion of post acute patients entering LTCHs is relatively small compared to other post acute settings (only 1.8 percent in 2002), the number of beneficiaries discharged from IPPS hospitals in 2002 into LTCHs more than doubled between 1996 and 2002. Thirty-six percent of the LTCH admissions were subsequently admitted to a SNF, IRF, or readmitted to an acute care hospital.

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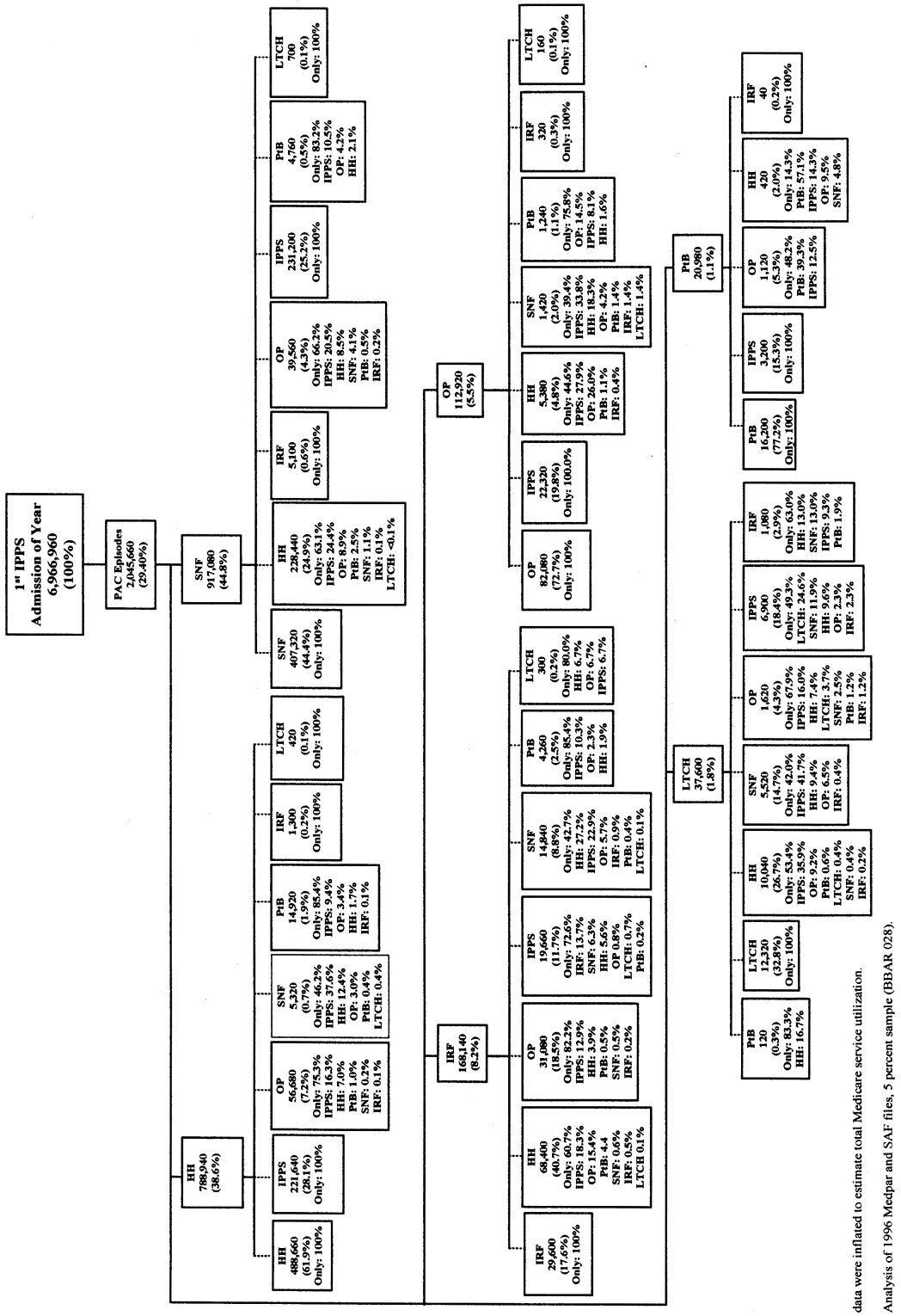
FIGURE 1: Post acute care transitions for IPPS hospital discharges, 2002



NOTE: Sample data were inflated to estimate total Medicare service utilization.

SOURCE: RTI Analysis of 1996 Medpar and SAF files, 5 percent sample (BBAR 028).

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LTCH users tend to have a higher number of comorbidities relative to other types of post acute episodes. RTI also evaluated medical complexity by using Hierarchical Coexisting Condition (HCC) scores which are based on a patient's Medicare expenditures from the year preceding the index IPPS admission. ''LTCH only'' users had the highest average HCC score of any episode type.

7. Average Medicare Payments

Several studies have shown that LTCH stays are more costly to the Medicare program on average than stays within other post acute settings (MedPAC 2003).

a. LTCH and Acute Outlier Episodes of Care

RTI compared the resources, payments, and outcomes of LTCH patients with one of 50 common LTCH DRGs to those admitted to an acute care hospital and for whom the acute care hospital received an outlier payment ('Acute Outlier') (Table 19). These two samples are separate, yet somewhat overlapping. The LTCH sample provides a profile of all LTCH admissions and it includes the 80 percent of admissions who had a prior hospital stay, of which 12.4 percent had an outlier adjustment as well as the remaining 20 percent who may have been admitted from home, a SNF, IRF, or physician's office. The acute outlier sample includes all acute care cases that received an outlier payment for one of the top 50 LTCH DRGs. This sample contains both cases that did and did not use LTCHs and provides an overview of high cost, longer stay patients in the acute hospital who could have potentially been admitted to an LTCH. Episodes are defined as 180 day periods beginning with an index stay at either the LTCH or the acute setting.

Using 2003 claims, the two sets of episodes were created based on the index, or qualifying, acute care hospital stay. An episode is defined as all Medicare services provided in an acute hospital, LTCH, IRF, SNF, IPF, or home health agency within 180 days of the index admission. Within the 100 percent of 2003 MedPAR files, 102,749 LTCH episodes were identified.

The acute outlier episode sample has 54,023 cases that had a qualifying admission at an acute hospital with an outlier payment and an LTCH-like DRG. Only about 11 percent of these cases were discharged to an LTCH despite the sample being based on the top 50 DRGs commonly treated in an LTCH.

Demographic Characteristics. The two samples differed in terms of their demographic characteristics. Compared to acute outlier episodes, LTCH admissions were older (73.1 years vs. 71.4 years), more likely to be female (55 percent vs. 50 percent) and living in a State with a higher concentration of LTCHs (57 percent vs. 23 percent). Acute outlier episodes had a higher proportion of deaths compared to LTCH cases (61 percent vs. 42 percent).

Severity of Illness. Several measures of severity of illness were included and they are useful for understanding differences in the types of resources used in these two types of hospitals. The results show that both Acute Outlier (AO) and LTCH episodes had comparably high numbers of comorbid diagnosis on the index claim (8.8 vs. 8.1, respectively). The Charlson Comorbidity Index, a widely used severity and mortality measure in health services research, scores were also comparable but relatively low (1.6 vs. 1.5, respectively). However, there were substantially more procedures performed during the index AO stay (4.6 vs. 1.7 procedures). Both types of admissions had intensive care unit (ICU) stays and coronary care unit (CCU) stays, although these were longer in the acute outlier episodes compared to LTCH cases (21 days vs. 1 day, on average across all cases). Almost 22 percent of the acute outlier sample with ICU/CCU days had surgery during the outlier stay. These differences reflect differences in the types of procedures completed in an acute hospital compared to an LTCH.

Regarding the most common conditions (that is, DRG) in both settings, LTCH episodes were more likely to have a DRG for respiratory conditions (DRG 079, 087, 088, 089), and ''Degenerative Nervous System Disorders.'' AO populations were more likely than LTCH admissions to be treated for ''Heart Failure & Shock.''. The following LTCH DRGs also accounted for a larger share of the LTCH sample than the acute outlier group: Aftercare, Musculoskeletal System & Connective Tissue; Aftercare w/o History of Malignancy As Secondary Diagnosis; Skin Ulcers; and a DRG for Rehabilitation. Interestingly, despite DRG 475 being the most common LTCH admission, they represent a higher share of the acute outlier episodes than the LTCH admissions (14 percent vs. 9 percent among LTCH episodes).

Acute hospital readmission rates (Table 20) were somewhat higher in LTCH episodes (40 percent) than acute outlier episodes (36 percent). Of those readmitted from an LTCH episode, 2.3 percent received outlier adjustments for the subsequent acute stay. Subsequent service use also differed between the two populations. The LTCH sample was more likely to use home health care (33.2 percent v. 24.3 percent). However, they were less likely to use an IRF or SNF (5 percent vs. 7 percent and 26 percent vs. 31 percent, respectively).

Almost 80 percent of the LTCH admissions were admitted from an acute hospitalization within 5 days prior to the index LTCH admission. Among these episodes, 63 percent had surgery during this prior hospitalization and 12 percent of the acute stays included an outlier payment, with an average hospital payment of $24,790 per stay. Among these outlier episodes, almost all cases had surgery (99 percent) and required intensive or coronary care (93 percent) with lengthy stays in the acute hospital prior to the LTCH admission.

TABLE 19: Episode Characteristics (based on the RTI Draft Report)

Characteristics	Acute outlier episodes	LTCH Episodes
Sample Size	54,023	102,749
Demographics		
Age (years)	71.4	73.1
Female (%)	50.1	55.4
White race (%)	77.6	75.4
Died during year (%)	60.6	41.5
% living in high LTCH States *	22.9	57.2
Severity		
Diagnosis count at index admission	8.8	8.1
Procedure count at index admission	4.6	1.7
Average number of days in ICU and CCU	21.2	1.1
Surgery/ICU/CCU	21.9	-
Charlson Comorbidity Index	1.6	1.5
Selected DRGs or conditions at index admission as % of admissions		
Respiratory (DRG=079,087,088,089)	10.8	15.6
Ventilator (DRG=475)	14.4	8.9
CHF (DRG=127)	8.1	3.2
Nervous (DRG=012)	0.6	5.3
Aftercare, musculoskeletal and connective tissue (DRG=249)	0.0	4.6
Aftercare, no history of malignancy (DRG=466)	0.0	3.8
Skin Ulcer (DRG=271)	0.0	4.4
Rehabilitation (DRG=462)	0.0	6.4

RTI analyses of Medicare Administrative files, 2003.

* High LTCH States include Indiana, Louisiana, Massachusetts, Michigan, Pennsylvania, Ohio, and Texas.

TABLE 20: Episode Utilization (based on the RTI Draft Report)

	Acute Outlier	LTCH
Total number of cases	54,023	102,749
Post-index admission to...		
Acute hospitals (Readmissions)	36.2%	40.0%
with acute outlier payment	-	2.3
LTCH	10.5	9.7
Home health agency	24.3	33.2
IRF	7.4	4.6
IPF	0.6	1.5
SNF	30.9	26.2
Prior acute hospitalization...	-	79.2
Percent of episodes with surgery at prior acute admission	-	62.7
Percent with an acute outlier payment...	-	12.4
Of acute outliers...		
Average outlier payment	-	$24,790.49
Percent with surgery	-	99.2%
Average number of procedures	-	5.4
Percent with ICU/CCU stay	-	93.1%
Average number of ICU days	-	19.5
Average number of CCU days	-	4.0

RTI analyses of Medicare Administrative files, 2003.

b. Acute Outlier Episodes Compared to LTCH Episodes

RTI has noted the differences between the LTCH population and the subset of acute admissions with a DRG commonly found in the LTCH admissions and for whom an outlier payment is made. The acute outlier sample is further broken out by whether the case resulted in an LTCH admission. Table 21 shows that only 10.5 percent of the acute outlier cases with these DRGs were discharged to an LTCH. As expected, the average episode payments for LTCH users were 87 percent greater than payments for outlier episodes that did not include LTCH admissions. About half the difference is due to the LTCH payment but the other half is largely due to substantially higher payments for the acute outlier stay ($80,380 for those discharged to an LTCH compared to $54,390 for outlier cases who did not use LTCHs). The average LTCH payment in the outlier sample is also higher than the average LTCH admission payment ($34,990 compared to $26,786).

The average hospitalization in the acute care hospital for an outlier stay is significantly longer than the average stay preceding an LTCH admission (25 to 28 days versus 14.5 days). While 79.2 percent of all LTCH admissions have an acute care stay in the 5 days preceding LTCH admission, only 12 percent of them are outlier cases. The majority of LTCH admissions are not acute outliers. Also, once in the LTCH, about 40 percent of all cases are discharged with a SSO adjustment. Despite this, the average length stay in the all LTCHs is 32.8 days.

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TABLE 21: Comparison of Utilization and Expenditures Between Acute Outlier and LTCH Episodes (based on the RTI Draft Report)

Analysis of Use	Acute Outlier episode				LTCH episodes	
	No LTCH Admission		LTCH Admission			
	Average Pmt/Use	% of total AO episodes	Average Pmt/Use	% of total AO episodes	Average Pmt/Use	% of total LTCH episodes
Number of episodes	48348	----	5675	—	102,749	—
Total episode payments per user	69557	100%	$130532	100.0%	$55,314	100.0%
LTCH payments	----	---	34990	10.5	26,786	100.0
Acute hospital payments	54390	100%	80380	100.0	22,100	79.2%
IRF payments	19353	7%	17237	9%	16,261	4.6%
IPF	8587	1%	5951	0%	9,565	1.5%
SNF payments	10352	31%	11694	29%	11,352	26.2%
Home health payments	3591	24%	3888	24%	4,115	33.3%
Readmit acute hospitalization payments	21664	35%	21231	44%	14,512	40.0%
Total episode LOS (days) per user						
LTCH	------	-----	38	10.5%	32.8	100.0%
Acute	25.6		28.2		14.5	79.2%
IRF	19.7	7%	20.4	9%	19.6	4.6%
Psych	17.3	01%	12.5	0%	19.3	1.5%
SNF	77.7	31%	69.5	29%	88.5	26.2%
Home Health	55	24%	57	24%	64.2	33.3%
Readmit acute hospitalization	18.4	35%	16.8	44%	14.2	40.0%
Ancillary service use, among users only						
Index intensive care day count	22.3	72%	28.0	85%	14.0	8.0%
Index coronary care day count	15.7	27%	17.1	27%	20.1	0.1%
% with surgical procedure codes at index	90%		11%		—	59.8%
Index inhalation therapy charge amount	26935	91%	40209	96%	12,825	70.9%
Index lab charge amount	26730	99%	34935	100%	3984	95.7%

Analysis of Use	Acute Outlier episode				LTCH episodes	
	No LTCH Admission		LTCH Admission			
	Average Pmt/Use	% of total AO episodes	Average Pmt/Use	% of total AO episodes	Average Pmt/Use	% of total LTCH episodes
Index MRI charge amount	4157	15%	4272	16%	2,827	2.7%
Index OT charge amount	1232	41%	1133	52%	2,116	79.1%
Index operating room charge	10013	71%	14785	88%	4,009	17.3%
Index PT charge amount	2175	77%	1996	84%	2,564	86.7%
Index radiology charge	10341	99%	13223	100%	1,663	76.2%
Index med/surg supply charge	20671	98%	29029	100%	5,925	92.1%

RTI analyses of Medicare Administrative files, 2003.

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The subsequent use of IRFs and SNFs is slightly lower in the LTCH universe than in the acute outlier sample. However, within the acute outliers, those who were first discharged to LTCHs were less likely to use IRFs and SNFs, although their payments were generally higher when they did use these services.

Determining and Evaluating Levels of Care

A key issue in defining the distinct role of LTCHs in the Medicare provider continuum is the need to objectively define the service intensity level an LTCH should provide relative to other providers in the continuum. As part of this effort, RTI is examining the definitions currently used by the Medicare program, LTCH providers, potential substitute providers, and insurers regarding the relative role of acute hospitals, LTCHs, IRFs, and SNFs. Included are reviews of the Medicare conditions of participation governing each of these providers, the QIOs and insurance industry's guidelines for determining appropriate levels of care, and the post acute industry's definitions of their own and others levels of care as developed for Congressional testimony or internal discussions. In addition, RTI has conducted site visits to speak with the physicians and discharge planning staff at LTCHs regarding the types of cases they typically do or do not admit.

First, because of the rising interest in better defining post acute care in all settings, several groups developed definitions of intensity for the post acute continuum either for Congressional testimony or as internal working documents of provider associations or in managed care organizations. These definitions were made available to RTI and compared across industries to understand the role each expects LTCHs and the alternative providers to serve in treating Medicare beneficiaries. These comparisons can be summarized in terms of the frequency of physician visits and nursing hours, as shown in Table 22. The LTCHs and IRFs also tend to differ by the primary diagnosis, with the LTCHs focusing on medical intensity and IRFs focusing on rehabilitation intensity.

TABLE 22.—CLINICAL INTENSITY ASSOCIATED WITH DIFFERENT LEVELS OF CARE

[Based on the RTI Draft Report]

	LTCH	IRF	SNF
Physician visits	Daily 2–3/week	2–3/week Close med Supervision	General supervision at least every 14–30 days.
Consulting physician	2–3/week	Frequent	As needed.
Nursing hours	6–12 hr/day	6.5 Rehab RN	2.5–4 hours/day.

RTI analyses of Medicare Administrative files, 2003.
Source: RTI analysis of PAC comparisons developed by the PAC industries.

Second, RTI reviewed the Medicare certification and conditions of participation regulations for LTCHs and potential substitute providers. These certification regulations define: What constitutes a type of provider; their certification requirements; and the coverage criteria associated with each. Many of the requirements are common across the IPPS, IRF, IPF, and LTCHs. Each is providing inpatient acute care. In addition, the IRFs and IPFs have staffing requirements that include team-related management of their patients, professional specializations that reflect the respective services, and special provisions governing their units and satellite facilities. LTCHs lack most of these requirements. Instead, they must meet the same requirements as IPPS acute hospitals and then demonstrate that they meet the LOS requirement, that is, they treat Medicare patients for an average of greater than 25 days on an annual basis. They have additional requirements governing their ability to open HwHs. However, they lack many of the staffing and treatment requirements that Medicare requires for IRFs and IPFs to qualify as specialized inpatient hospitals.

Third, RTI reviewed insurance and industry-based definitions of the level of care distinctions that are commonly applied to different Medicare providers. These standards are generally used by the Medicare QIOs and private insurance review entities to make coverage decisions. QIOs have statutory authority under section 1154(a) of the Act to: Review the necessity and reasonability of services delivered under Medicare; whether these services meet professionally recognized standards of health care; and whether these services, consistent with the provision of appropriate medical care, could be ''effectively provided more economically * * * in an inpatient health care facility of a different type.''

Although QIOs are not required to utilize uniform criteria nationwide for these determinations, most of them rely on Interqual as a baseline screening tool with physician-level decision-making for cases that appear to fall outside the acceptable level of care guidelines. QIOs were interviewed regarding the specific strengths and weaknesses of the screening criteria they presently use and their applicability for CMS purposes.

Phone interviews with QIOs in Connecticut, Louisiana Maryland/DC, Massachusetts, Michigan, Nevada/Utah, New York, Pennsylvania and Texas (nine QIOs that represent 11 States/districts) were conducted. In general, States were selected that had a high number or growing number of LTCHs and also those that had possible substitute providers, such as IRFs, IPFs or SNFs. RTI also selected States that had high numbers of LTCHs and at least one other type of provider to examine how the QIOs view similar cases and make determinations regarding appropriate use of LTCHs compared to potential substitutions.

In general, most of the QIOs and many of the hospital chains used a variation of the Interqual definitions of level of care to determine appropriateness of admissions. These criteria measure a potential patient's severity of illness based on combinations of conditions and intensity of service based on expected resources needed to treat the patient if admitted. In addition, hospitals may use other criteria to determine if a patient is appropriate for treatment at their facility. Parts of the LTCH industry have proposed guidelines for their hospitals to use in determining appropriate admissions. These criteria are less specific than those used by the QIOs although all are used as guidelines with the final determinations made by physicians.

Fourth, patient assessment tools, screening criteria, and intensity measures were collected from LTCHs through their associations and corporate entities. These tools are used by LTCHs to determine appropriateness of admissions, intensity of patients served,

and outcomes expected from the treatment. They provide information on items commonly used by LTCHs to track patient conditions, treatment needs, and determine staffing levels. In addition to information on patient demographics, insurance, and medical history, the forms contain items on patient acuity, including measures of their blood gas, glucose levels, oxygen saturation levels, respiratory rates, and functional levels, as well as, treatment needs (such as tube feeding, central lines, and IV medications, GI suctioning, dialysis (hemodialysis or peritoneal), ventilator weaning, pain management, wound measures, or telemetry monitoring.) These measures cover the range of special services provided by LTCHs and can be useful for measuring patient acuity differences. While they provide objective measures of patient intensity, much work remains to be done in setting the levels for determining whether a patient belongs in an LTCH or an alternative site of care. Proposed levels were already developed by Interqual and other private sector entities, as well as, parts of the industry. More discussion is needed to set specific levels of care determinations that include the range of specialists treating these patients. RTI is reviewing these proposed criteria along with existing criteria and patient assessment models used by QIOs, LTCHs, and incorporating input from clinicians with the objective of developing recommendations to CMS regarding a patient assessment instrument for LTCHs.

Site Visits

RTI researchers, accompanied by CMS analysts (including a physician with clinical experience in LTCHs) visited LTCHs around the country. Sites were selected based on a breakdown of hospital referral regions (as defined by Dartmouth Atlas 2005) to select areas that vary in the availability of LTCHs, IRFs, IPFs, and SNFs across the U.S. and with the input and cooperation of LTCH industry groups.

Facilities were selected to provide an overview of the range of populations typically treated in LTCHs and varying in geographic distribution, facility age, and medical specializations. Hospitals were selected to include free standing, HwHs, and satellites as well as LTCHs representing several different types of facilities such as: Older non-profit LTCHs specializing in specific types of cases; newer for-profit chains, co-located LTCHs that are part of a medical system; and other providers that treat LTCH-type patients.

These site visits are essential in providing an in-depth examination of LTCHs' populations and services relative to other types of facilities and under different models of care. Personnel at LTCHs were asked to contrast their level of care with that provided in other treatment settings, including acute care hospitals, IRFs, and SNFs.

Interview materials were developed to ensure that the same questions were asked regarding the difference in intensity or level of care for patients treated in an LTCH versus other inpatient hospital-level settings or SNFs. The following groups were interviewed from host hospitals: Discharge planners, medical directors, admissions directors, nursing/quality assurance directors, therapy directors, and in some cases, the finance directors. The focus was on the types of patients admitted, differences in expectations regarding outcomes and, relative payment to cost differences across differently certified beds.

Although we expect the final RTI report on this project to have a substantial impact on future Medicare policy for LTCHs, we still believe that even with the development of defined patient and perhaps facility-level criteria, that the retention of many of the specific payment adjustment features of the LTCH PPS presently in place may still be both necessary and appropriate for purposes of protecting the integrity of the Medicare Trust Fund. We expect that the RTI's final report will be submitted to us in late Spring 2006.

XII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

Section 412.525 Adjustments to the Federal Prospective Payment Provision for Short-Stay Outliers

Section 412.525(a)(4)(iv)(A) states that CMS may specify an alternative to the cost-to-charge ratio otherwise applicable under paragraph (a)(4)(iv)(B) of this section. In addition, a hospital may also request that its FI use a different (higher or lower) CCR based on substantial evidence provided by the hospital.

The burden associated with this requirement is the time and effort necessary for a hospital to gather, process, and submit the necessary documentation to its FI to substantiate its request for the use of a different CCR by their FI. For example, necessary documentation, as stipulated by CMS and the FI, may include but not be limited to financial records documenting the hospital's cost and charges.

The estimated burden for this requirement is 8 hours per hospital. Therefore, we estimate that it would require 80 annual hours (8 hours × 10 facilities), to comply with this requirement.

Section 412.529 Special Payment Provision for Short-Stay Outliers

Section 412.529(c)(4)(iv)(A) states that CMS may specify an alternative to the CCR otherwise applicable under paragraph (c)(4)(iv)(B) of this section. In addition, a hospital may also request that its FI use a different (higher or lower) CCR based on substantial evidence provided by the hospital.

The burden associated with this requirement is the time and effort necessary for a hospital to gather, process, and submit the necessary documentation to its FI to substantiate its request for the use of a different CCR by their FI. For example, necessary documentation, as stipulated by CMS and the FI, may include but not be limited to financial records documenting the hospital's cost and charges.

The estimated burden for this requirement is 8 hours per hospital. Therefore, we estimate that it would require 80 annual hours (8 hours × 10 facilities), to comply with this requirement.

We will be submitting a copy of this proposed rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Attn: William N. Parham, III, [CMS–1485–P], Room C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, [CMS–1485–P], *carolyn_lovett@omb.eop.gov.* Fax (202) 395–6974.

XIII. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this proposed rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4), and Executive Order 13132.

1. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely assigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any one year). We are using the proposed rates, factors and policies presented in this proposed rule, including updated proposed wage index values, and the best available claims data to estimate proposed payments for the 2007 LTCH PPS rate year. Based on the best available data for 259 LTCHs, we estimate that the proposed change to the SSO policy (as discussed in section V.A.1. of this preamble) for the 2007 LTCH PPS rate year, in conjunction with the proposed changes to the area wage adjustment (discussed in section IV.D.1. of the preamble of this proposed rule) the proposed increase in the outlier fixed-loss amount (discussed in section IV.D.3.c. of this preamble) and the proposed slight increase in the budget neutrality offset to account for the transition methodology (as discussed in section IV.D.5. of this preamble), would result in a decrease in estimated payments from the 2006 LTCH PPS rate year of approximately $362 million for the 259 LTCHs. (An estimate of Medicare program payments for LTCH services for the next 5 years is shown in section XIII.B.5. of this proposed rule.) Because the combined distributional effects and costs to the Medicare program are greater than $100 million, this proposed rule is considered a major economic rule, as defined in this section.

2. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $26 million or less in any 1 year. For purposes of the RFA, all hospitals (and most other providers and suppliers) are considered small entities according to the Small Business Administration's latest size standards (for further information, see the Small Business Administration's regulation at 65 FR 69432, November 17, 2000). Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary LTCHs. Therefore, we assume that all LTCHs are considered small entities for the purpose of the analysis that follows. Medicare fiscal intermediaries are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

Currently, our database of 259 LTCHs includes the data for 61 non-profit (voluntary ownership control) LTCHs and 189 proprietary LTCHs. The remaining 9 LTCHs are Government-owned and operated (see Table 23). The impact of the proposed changes for the 2007 LTCH PPS rate year is discussed below in section XIII.B.4.c. of this proposed rule. The provisions of this proposed rule are estimated to result in approximately an 11 percent decrease in estimated payments per discharge in the 2007 LTCH PPS rate year on average to LTCHs (as shown in Table 23). As discussed in greater detail below in this section (and as shown in Table 23), the majority of the approximately 11 percent decrease in estimated payments in the 2007 LTCH PPS rate year as compared to the 2006 LTCH PPS rate year is due to the proposed change in the payment formula for SSO cases (discussed in section V.A.1.a. of the preamble of this proposed rule). We do not believe that this proposed change would result in an adverse impact on affected LTCHs for the reasons discussed below in this section. We believe that, if implemented, the proposed changes to the SSO policy would accomplish our stated goal of removing the incentive for LTCHs to admit patients for whom a long-term hospital stay is not necessary and therefore, for whom the LTCH would not be providing complete treatment.

As we discuss in greater detail in section V.A.1.a. of the preamble of this proposed rule, currently about 37 percent of all LTCH cases are short-stay outliers, most of which were admitted to the LTCH directly from an acute-care hospital. Thus, many short-stay cases may be still in need of acute-level care at the time of admission to the LTCH, which may indicate a premature and inappropriate discharge from the acute care hospital. As we also discussed in the preamble above, we believe that the proposed changes to the SSO policy would result in a more appropriate payment for short-stay cases treated at LTCHs. We believe that by removing the financial incentive for LTCHs to admit such a larger percentage of short-stay cases by paying appropriately for these cases, LTCHs would change their admission patterns for these patients. Specifically, we believe that if the proposed changes to the SSO are implemented, most LTCHs would substantially reduce the number of short-stay cases that they admit (and most of those patients would continue to receive treatment at the acute-care hospital from which they are typically discharged from immediately prior to their LTCH (short-stay) admission).

The estimated 11.1 percent decrease in LTCH PPS payments for RY 2007 was determined based on the current LTCH admission pattern of SSO cases (that is, currently about 37 percent of all LTCH cases). Thus, we believe that the estimated 11.1 percent decrease in LTCH payments per discharge for RY 2007 would only occur if LTCHs were to continue to admit the same number of SSO patients. Since the majority of the approximately 11 percent decrease in estimated payments is due to the proposed change in the SSO policy and since we anticipate that LTCHs would no longer admit such a large percentage of SSO patients if such proposed changes are implemented, we believe that the actual decrease in LTCHs' payments for RY 2007 would be considerably less than 11 percent. (Although we expect LTCHs to admit fewer cases under this proposed change,

we believe that most LTCHs, which are HwHs, would not experience an increase in cost per discharge as a result of unoccupied beds. Rather, we expect that LTCHs would make a commensurate reduction in available beds. LTCHs would lease fewer beds, and therefore, the LTCHs' cost per discharge would not increase dramatically.)

Furthermore, our Medicare margins analysis of the most recent LTCH cost report data, show that LTCH PPS payments for FY 2003 were 8.8 percent higher than LTCHs' Medicare costs, and preliminary cost report data for FY 2004 reveal an even higher Medicare margin of 11.7 percent (as discussed in greater detail in section IV.C.3. of the preamble to this proposed rule). Since LTCH PPS payments appear to be more than adequate to cover the costs of the efficient delivery of care to patients at LTCHs, based on this margins analysis, we believe that even with an estimated decrease in LTCHs' payments per discharge for the 2007 LTCH PPS rate year, which may result from, among other things, the continued treatment of some short-stay cases and the estimated slight decrease in payments due to the proposed changes to the area wage adjustment (see Table 23 below in this section) LTCH PPS payments in RY 2007 would still be sufficient to compensate LTCHs for the costs of the efficient delivery of LTCH services to LTCH patients. Thus, we do not expect that the provisions of this proposed rule would result in an adverse financial impact on affected LTCHs nor would there be an effect on beneficiaries' access to care.

For the reasons discussed above, we do not expect an estimated decrease of 11.1 percent to the LTCH PPS Medicare payment rates to have a significant adverse effect on the ability of most LTCHs to provide cost efficient services to Medicare patients. In addition, LTCHs provide some services to (and generate revenue from) patients other than Medicare beneficiaries. The revenue to LTCHs from treating those patients is not affected by this proposed rule. Accordingly, we certify that this proposed rule would not have a significant impact on a substantial number of small entities, in accordance with RFA.

3. Impact on Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a proposed or final rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As shown in Table 23, we are estimating an 11.3 percent decrease in payment per discharge for the 2007 LTCH PPS rate year as compared to the 2006 LTCH PPS rate year based on the data of the 9 rural hospitals in our database of 259 LTCHs for which complete data were available.

As discussed above in this section, the majority of the approximately 11 percent decrease in estimated payments in the 2007 LTCH PPS rate year as compared to the 2006 LTCH PPS rate year for rural LTCHs is due to the proposed change in the payment formula for SSO cases (discussed in section V.A.1.a of the preamble of this proposed rule). We do not believe that this proposed change would result in an adverse impact on rural LTCHs because, under this proposed change, we believe that LTCHs (including rural LTCHs) would significantly reduce the number of short-stay cases that they admit since such a policy would remove the financial incentive for LTCHs to treat short-stay cases by paying appropriately for them (as we discussed in greater detail above in section XIII.A.2. of this proposed rule). Furthermore, we believe that if the proposed changes to the SSO policy are implemented, although most LTCHs (including rural LTCHs) would admit fewer short-stay cases, most of those patients would continue to receive treatment at the acute-care hospital from which they are typically discharged from immediately prior to their LTCH (short-stay) admission, and most LTCHs (which are HwHs) would not experience an increase in cost per discharge as a result of unoccupied beds.

The estimated 11.3 percent decrease in LTCH PPS payments for RY 2007 for rural LTCHs was determined based on the current LTCH admission pattern of SSO cases (that is, currently about 37 percent of all LTCH cases). Thus, we believe that the estimated 11.3 percent decrease in LTCH payments per discharge for RY 2007 for rural LTCHs would only occur if rural LTCHs were to continue to admit the same percentage of SSO patients. Since the majority of the approximately 11 percent decrease in estimated payments for rural LTCHs is due to the proposed change in the SSO policy and since we anticipate that LTCHs (including rural LTCHs) would no longer admit such a large percentage of SSO patients if such proposed changes are implemented, we believe that the actual decrease in rural LTCHs' payments for RY 2007 would be considerably less than 11 percent. Therefore, we believe that the estimated 11.3 percent decrease in payments per discharge for the 2007 LTCH PPS rate year for rural LTCHs would only occur if LTCHs maintain the same level of SSO patients.

Moreover, as also discussed in greater detail above in section XIII.A.2. of this proposed rule, based on our Medicare margins analysis for LTCHs which shows payments in excess of costs for FYs 2003 and 2004, we believe that even with an estimated decrease in LTCHs' payments per discharge for the 2007 LTCH PPS rate year, LTCH PPS payments to rural LTCHs would still be sufficient to compensate LTCHs for the costs of the efficient delivery of LTCH services to LTCH patients. (For additional information on the impact of the proposed changes on rural LTCHs presented in this proposed rule, refer to the discussion of the impact analysis in section XIII.B.4 of this proposed rule.)

For the reasons discussed in this section, we do not expect that the provisions of this proposed rule would result in an adverse financial impact on rural LTCHs nor would there be an effect on beneficiaries' access to care. Therefore, we do not expect an estimated decrease of 11.3 percent to the LTCH PPS Medicare payment rates for rural LTCHs to have a significant adverse effect on the ability of most LTCHs to provide cost efficient services to Medicare patients. Accordingly, we substantiate that the rates and policies set forth in this proposed rule would not have an adverse impact on rural hospitals based on the data of the 9 rural hospitals in our database of 259 LTCHs for which data were available.

4. Unfunded Mandates

Section 202 of the UMRA requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $120 million or more. This proposed rule would not mandate any requirements for State, local, or tribal governments, nor would it result in expenditures by the private sector of $110 million or more in any one year.

5. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

We have examined this proposed rule under the criteria set forth in Executive

Order 13132 and have determined that this proposed rule would not have any significant impact on the rights, roles, and responsibilities of State, local, or tribal governments or preempt State law, based on the 9 State and local LTCHs in our database of 259 LTCHs for which data were available.

B. Anticipated Effects of Proposed Payment Rate Changes

We discuss the impact of the proposed changes to the payment rates, factors, and policies presented in this proposed rule in terms of their fiscal impact on the Medicare budget and on LTCHs.

1. Budgetary Impact

Section 123(a)(1) of BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' Therefore, in calculating the FY 2003 standard Federal rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that aggregate payments under the LTCH PPS are estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented. However, as discussed in greater detail in the August 30, 2002 final rule (67 FR 56033 through 56036), the FY 2003 LTCH PPS standard Federal rate ($34,956.15) was calculated based on all LTCHs being paid 100 percent of the standard Federal rate in FY 2003. As discussed in section IV.D.5. of this proposed rule, we would apply a proposed budget neutrality offset to payments to account for the monetary effect of the 5-year transition period and the policy to permit LTCHs to elect to be paid based on 100 percent of the proposed standard Federal rate rather than a blend of proposed Federal prospective payments and reasonable cost-based payments during the transition. The amount of the proposed offset is equal to 1 minus the ratio of the estimated payments based on 100 percent of the LTCH PPS Federal rate to the projected total Medicare program payments that would be made under the transition methodology and the option to elect payment based on 100 percent of the Federal prospective payment rate.

2. Impact on Providers

The basic methodology for determining a LTCH PPS payment is set forth in § 412.515 through § 412.525. In addition to the basic LTC–DRG payment (standard Federal rate x LTC–DRG relative weight), we make adjustments for differences in area wage levels, cost-of-living adjustment for Alaska and Hawaii, and short-stay outliers. Furthermore, LTCHs may also receive high-cost outlier payments for those cases that qualify based on the threshold established each rate year. Section 412.533 provides for a 5-year transition to payments based on 100 percent of the Federal prospective payment rate. During the 5-year transition period, payments to LTCHs are based on an increasing percentage of the LTCH PPS Federal rate and a decreasing percentage of payment based on reasonable cost-based methodology. Section 412.533(c) provides for a one-time opportunity for LTCHs to elect payments based on 100 percent of the LTCH PPS Federal rate.

In order to understand the impact of the proposed changes to the LTCH PPS discussed in this proposed rule on different categories of LTCHs for the 2007 LTCH PPS rate year, it is necessary to estimate payments per discharge under the LTCH PPS rates, factors and policies established for the RY 2006 LTCH PPS final rule and to estimate proposed payments per discharge that would be made under the proposed LTCH PPS rates, factors and policies for the 2007 LTCH PPS rate year (as discussed in the preamble of this proposed rule). We also evaluated the percent change in payments per discharge of estimated 2006 LTCH PPS rate year payments to estimated proposed 2007 LTCH PPS rate year payments for each category of LTCHs.

Hospital groups were based on characteristics provided in the Online Survey Certification and Reporting (System) (OSCAR) data, FYs 2001 through 2003 cost report data, and Provider Specific File data. Hospitals with incomplete characteristics were grouped into the ''unknown'' category. Hospital groups include:

- Location: Large Urban/Other Urban/ Rural
- Participation date
- Ownership control
- Census region
- Bed size

To estimate the impacts among the various categories of providers during the LTCH PPS transition period, it is necessary that reasonable cost-based methodology payments and prospective payments contain similar inputs. More specifically, in the impact analysis showing the impact reflecting the applicable transition blend percentages of prospective payments and reasonable cost-based methodology payments and the option to elect payment based on 100 percent of the proposed Federal rate (see Table 24), we estimated payments only for those providers for whom we are able to calculate payments based on reasonable cost-based methodology. For example, if we did not have at least 2 years of historical cost data for a LTCH, we were unable to determine an update to the LTCH's target amount to estimate payment under reasonable cost-based methodology.

Using LTCH cases from the FY 2004 MedPAR file and cost data from FYs 1999 through 2003 to estimate payments under the current reasonable cost-based principles, we have obtained both case-mix and cost data for 259 LTCHs. Thus, for the impact analyses reflecting the applicable transition blend percentages of proposed prospective payments and reasonable cost-based methodology payments and the option to elect payment based on 100 percent of the Federal rate (see Table 23), we used data from 259 LTCHs. While currently there are more than 375 LTCHs, the most recent growth is predominantly in for-profit LTCHs that provide respiratory and ventilator-dependent patient care. We believe that the discharges from the FY 2004 MedPAR data for the 259 LTCHs in our database provide sufficient representation in the LTC–DRGs containing discharges for patients who received respiratory and ventilator-dependent care based on the relatively large number of LTCH cases in LTC–DRGs for these diagnoses. However, using cases from the FY 2004 MedPAR file we had case-mix data for 337 LTCHs. Cost data to determine current payments under reasonable cost-based methodology payments are not needed to simulate payments based on 100 percent of the proposed Federal rate. Therefore, for the impact analyses reflecting fully phased-in prospective payments (see Table 24), we used data from 337 LTCHs.

These impacts reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs for the 2006 LTCH PPS rate year (July 1, 2005 through June 30, 2006) compared to the 2007 LTCH PPS rate year (July 1, 2006 through June 30, 2007). Prospective payments for the 2006 LTCH rate year were based on the standard Federal rate of $38,086.04, the outlier fixed-loss amount of $10,501, and the hospitals' estimated case-mix based on FY 2004 LTCH claims data. Estimated proposed prospective payments for the 2007 LTCH PPS rate year would be based on the proposed standard Federal rate of $38,086.04 (based on the proposed zero percent update discussed in section IV.C.3. of this proposed rule), the proposed outlier fixed-loss amount of $18,489, and the same FY 2004 LTCH claims data.

3. Calculation of Prospective Payments

To estimate payments under the LTCH PPS, we simulated payments on a case-by-case basis by applying the

proposed payment policy for short-stay outliers (as described in section V.A.1. of this proposed rule), the proposed adjustments for area wage differences (as described in section IV.D.1. of this proposed rule), and for the cost-of-living for Alaska and Hawaii (as described in section IV.D.2. of this proposed rule). Additional payments would also be made for high-cost outlier cases (as described in section IV.D.3. of this proposed rule). As noted in section IV.D.4. of this proposed rule, we are not proposing to make adjustments for rural location, geographic reclassification, indirect medical education costs, or a disproportionate share of low-income patients because sufficient new data have not been generated that would enable us to conduct a comprehensive reevaluation of these payment adjustments. We adjusted for area wage differences for estimated 2006 LTCH PPS rate year payments by computing a weighted average of a LTCH's applicable wage index during the period from July 1, 2005 through June 30, 2006 because some providers may experience a change in the wage index phase-in percentage during that period. For cost reporting periods beginning on or after October 1, 2004 and before September 30, 2005 (FY 2005), the labor portion of the Federal rate was adjusted by three-fifths of the applicable LTCH PPS wage index. For cost reporting periods beginning on or after October 1, 2005 and before September 30, 2006 (FY 2006), the labor portion of the Federal rate is adjusted by four-fifths of the applicable LTCH PPS wage index. Therefore, during RY 2006, a provider with a cost reporting period that began October 1, 2005 would have 3 months of payments under the three-fifths wage index value and 9 months of payment under the four-fifths wage index value. For this provider, we computed a blended wage index of 25 percent (3 months/12 months) of the three-fifths wage index value and 75 percent (9 months/12 months) of the four-fifths wage index value. The applicable LTCH PPS wage index values for the 2006 LTCH PPS rate year are shown in Tables 1 and 2 of the Addendum to the RY 2006 LTCH PPS final rule (70 FR 24224 through 24247). We adjusted for area wage differences for estimated 2006 LTCH PPS rate year payments using the current LTCH PPS labor-related share of 72.885 percent (70 FR 241852).

Similarly, we adjusted for area wage differences for estimated proposed 2007 LTCH PPS rate year payments by computing a weighted average of a LTCH's applicable wage index during the period from July 1, 2006 through June 30, 2007 because some providers may experience a change in the wage index phase-in percentage during that period. For cost reporting periods that began on or after October 1, 2005 and on or before September 30, 2006 (FY 2006), the labor portion of the Federal rate is adjusted by four-fifths of the applicable LTCH PPS wage index. For cost reporting periods beginning on or after October 1, 2006, the labor portion of the Federal rate is adjusted by the full (five-fifths) applicable LTCH PPS wage index. The applicable proposed LTCH PPS wage index values for the 2007 LTCH PPS rate year are shown in Tables 1 and 2 of the Addendum to this proposed rule. We adjusted for area wage differences for estimated proposed 2007 LTCH PPS rate year payments using the proposed LTCH PPS labor-related share of 75.923 percent (see section IV.D.1.c. of this proposed rule).

For those providers projected to receive payment under the transition blend methodology, we also calculated payments using the applicable transition blend percentages. During the 2006 LTCH PPS rate year, based on the transition blend percentages set forth in § 412.533(a), some providers may experience a change in the transition blend percentage during the period from July 1, 2005 through June 30, 2006. For example, during the period from July 1, 2005 through June 30, 2006, a provider with a cost reporting period beginning on October 1, 2004 (which is paid under the 40/60 transition blend (40 percent of payments based on reasonable cost-based methodology and 60 percent of payments under the LTCH PPS)) had 3 months (July 1, 2005 through September 30, 2005) under the 40/60 blend and 9 months (October 1, 2005 through June 30, 2006) of payment under the 20/80-transition blend (20 percent of payments based on reasonable cost-based methodology and 80 percent of payments under the LTCH PPS). The 20/80 transition blend will continue until the provider's cost reporting period beginning on October 1, 2006 (FY 2007).

Similarly, during the 2007 LTCH PPS rate year, based on the transition blend percentages set forth in § 412.533(a), some of the providers that would be paid under the transition blend methodology may experience a change in the transition blend percentage during the period from July 1, 2006 through June 30, 2007. For example, during the period from July 1, 2006 through June 30, 2007, a provider with a cost reporting period beginning on October 1, 2005 (which is paid under the 20/80 transition blend) would have 3 months (July 1, 2006 through September 30, 2006) under the 20/80 blend and 9 months (October 1, 2006 through June 30, 2007) of payment based on 100 percent of Federal rate payments under the LTCH PPS (and zero percent based on reasonable cost-based methodology). The provider will continue to receive payments based on 100 percent of the LTCH PPS Federal rate for its cost reporting period beginning on October 1, 2006 (FY 2007).

In estimating blended transition payments, we estimated payments based on the reasonable cost-based methodology, in accordance with the requirements at section 1886(b) of the Act. For those providers who have not already made the election (as determined from PSF data) to be paid based on 100 percent of the Federal rate, we compared the estimated blended transition payment to the LTCH's estimated payment if it would elect payment based on 100 percent of the Federal rate. If we estimated that the LTCH would be paid more based on 100 percent of the Federal rate, we assumed that it would elect to bypass the transition methodology and would receive payments based on 100 percent of prospective payment.

We applied the applicable budget neutrality offset to payments to account for the effect of the 5-year transition methodology and election of payment based on 100 percent of the Federal rate on Medicare program payments (established in the August 30, 2002 final rule (67 FR 56034)). In estimating 2006 LTCH PPS rate year payments, we applied the 0.0 percent (a budget neutrality factor of 1.0) budget neutrality offset to payments to account for the effect of the 5-year transition methodology and election of payment based on 100 percent of the Federal rate on Medicare program payments (see the RY 2006 LTCH PPS final rule (70 FR 24202)) to each LTCH's estimated payments under the LTCH PPS for the 2006 LTCH PPS rate year. Similarly, in estimating proposed 2007 LTCH PPS rate year payments, we applied the proposed 0.1 percent (a budget neutrality factor of 0.999) budget neutrality offset to payments to account for the effect of the 5-year transition methodology and election of payment based on 100 percent of the Federal rate on Medicare program payments (see section IV.D.5. of this proposed rule) to each LTCH's estimated payments under the LTCH PPS for the 2007 LTCH PPS rate year. The impact, based on our projection using the best available data for 259 LTCHs that approximately 3 percent of LTCHs would be paid based on the transition blend methodology and 97 percent of LTCHs would elect

payment based on 100 percent of the Federal rate is shown in Table 23.

In Table 24, we also show the impact if all LTCHs would be paid 100 percent of the Federal rate; that is, as if there were a mandatory immediate transition to fully Federal prospective payments under the LTCH PPS for the 2006 LTCH PPS rate year and the 2007 LTCH PPS rate year. In the impact analysis shown in Table 24, the respective budget neutrality adjustments to account for the 5-year transition methodology on LTCHs' Medicare program payments for the 2006 and 2007 LTCH PPS rate years (0.0 percent and the proposed 0.1 percent, respectively) were not applied to LTCHs' estimated payments under the LTCH PPS.

Tables 23 and 24 illustrate the estimated aggregate impact of the payment system among various classifications of LTCHs.

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of long-term care cases.
- The fourth column shows the estimated payment per discharge for the 2006 LTCH PPS rate year.
- The fifth column shows the estimated proposed payment per discharge for the 2007 LTCH PPS rate year.
- The sixth column shows the estimated percent decrease in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for proposed changes to the area wage adjustment at § 412.525(c) (as discussed in section IV.D.1. of the preamble of this proposed rule).
- The seventh column shows the estimated percent change in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for proposed changes to the SSO policy at § 412.529 (as discussed in section V.A.1.a. of the preamble of this proposed rule).
- The eighth column shows the percent decrease in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for all proposed changes (as discussed in the preamble of this proposed rule.)

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TABLE 23: Projected Impact Reflecting Applicable Transition Blend Percentages of Prospective Payments and Reasonable Cost-Based (TEFRA) Payments and Option to Elect Payment Based on 100 Percent of the Federal Rate[1]

(Estimated 2006 LTCH PPS Rate Year Payments Compared to Estimated Proposed 2007 LTCH PPS Rate Year Payments)

LTCH Classification	Number of LTCHs	Number of LTCH Cases	Average RY 2006 LTCH PPS Payment Per Case[2]	Average Proposed RY 2007 LTCH PPS Payment Per Case[3]	Percent Change in Payments Per Discharge from RY 2006 to RY 2007 for Proposed Area Wage Adjustment Changes[4]	Percent Decrease in Proposed Payments Per Discharge from RY 2006 to RY 2007 for Proposed Changes to the SSO Policy[5]	Percent Decrease in Proposed Payments Per Discharge from RY 2006 to RY 2007 for All Proposed Changes[6]
ALL PROVIDERS	259	101,628	$32,133	$28,574	-0.5	11.4	11.1
BY LOCATION:							
RURAL	9	2,337	$26,576	$23,577	-3.0	8.7	11.3
URBAN	250	99,291	$32,264	$28,692	-0.4	11.4	11.1
LARGE	107	34,592	$30,104	$26,257	0.1	11.1	10.2
OTHER	143	64,699	$33,419	$29,994	-1.5	12.0	11.8
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	15	7,816	$26,414	$23,247	0.4	13.3	12.0
OCT. 1983 - SEPT. 1993	45	22,126	$34,415	$30,889	0.1	11.2	10.2
OCT. 1993 - SEPT. 2002	199	71,686	$32,052	$28,441	-0.8	11.3	11.3
BY OWNERSHIP CONTROL:							
VOLUNTARY	61	23,016	$30,721	$26,658	-0.6	13.5	13.2
PROPRIETARY	189	76,363	$32,741	$29,339	-0.4	10.7	10.4
GOVERNMENT	9	2,249	$25,953	$22,239	-1.9	13.1	14.3

BY CENSUS REGION:							
NEW ENGLAND	13	9,370	$26,545	$23,177	0.8	14.4	12.7
MIDDLE ATLANTIC	18	6,080	$32,583	$29,138	-0.8	10.5	10.6
SOUTH ATLANTIC	24	9,063	$35,918	$31,970	-0.6	11.2	11.0
EAST NORTH CENTRAL	50	15,165	$35,307	$31,577	-0.5	10.8	10.6
EAST SOUTH CENTRAL	15	4,718	$33,288	$29,271	-1.4	11.5	12.1
WEST NORTH CENTRAL	17	4,755	$36,017	$31,884	-1.0	11.3	11.5
WEST SOUTH CENTRAL	89	40,288	$29,252	$25,754	-1.1	11.5	12.0
MOUNTAIN	20	5,670	$33,277	$29,608	0.4	12.3	11.0
PACIFIC	13	6,519	$40,243	$37,711	2.0	9.2	6.3
BY BED SIZE:							
BEDS: 0-24	22	3,658	$32,365	$27,996	-1.6	12.7	13.5
BEDS: 25-49	127	34,341	$31,862	$28,097	-1.1	11.5	11.8
BEDS: 50-74	37	13,560	$34,462	$30,630	-0.4	11.5	11.1
BEDS: 75-124	37	16,861	$33,267	$29,853	0.0	11.1	10.3
BEDS: 125-199	24	21,106	$30,353	$27,022	-0.4	11.3	11.0
BEDS: 200 +	12	12,102	$31,748	$28,727	0.7	11.0	9.5

[1] These calculations take into account that some providers may experience a change in the LTCH PPS blend percentage changes during the 2006 and 2007 LTCH PPS rate years. For example, during the period of July 1, 2006 through June 30, 2007, a provider with a cost reporting period beginning October 1, 2005 would have 3 months (July 1, 2006 through September 30, 2006) of payments under the 20/80 blend (4/5ths wage index) and 9 months (October 1, 2006 through June 30, 2007) of payment under the full (5/5ths) wage index).

[2] Estimated average payment per case for the 12-month period of July 1, 2005 through June 30, 2006.

[3] Estimated average payment per case for the 12-month period of July 1, 2006 through June 30, 2007.

[4] Percent change in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for the proposed changes to the area wage adjustment policy at §412.525(c) (as discussed in section IV.D.1. of the preamble of this proposed rule).

[5] Percent decrease in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for the proposed changes to the short-stay outlier policy at §412.529 (as discussed in section V.A.1.a. of the preamble of this proposed rule).

[6] Percent decrease in estimated payments per discharge from the 2006 LTCH PPS rate year (as established in the RY 2006 LTCH PPS final rule (70 FR 24168 through 24261)) to those proposed for the 2007 LTCH PPS rate year (as discussed in the preamble of this proposed rule).

Table 24: Projected Impact Reflecting the Fully Phased-In LTCH PPS Prospective Payments[1]

(Estimated 2006 LTCH PPS Rate Year Payments Compared to Estimated Proposed 2007 LTCH PPS Rate Year Payments)

LTCH Classification	Number of LTCHs	Number of LTCH Cases	Average RY 2006 LTCH PPS Payment Per Case[2]	Average Proposed RY 2007 LTCH PPS Payment Per Case[3]	Percent Change in Payments Per Discharge from RY 2006 to RY 2007 for Proposed Area Wage Adjustment Changes[4]	Percent Decrease in Proposed Payments Per Discharge from RY 2006 to RY 2007 for Proposed Changes to the SSO Policy[5]	Percent Decrease in Proposed Payments Per Discharge from RY 2006 to RY 2007 for All Proposed Changes[6]
ALL PROVIDERS	337	118,525	$31,939	$28,340	-0.6	11.6	11.3
BY LOCATION:							
RURAL	19	3,761	$26,612	$23,357	-3.0	10.0	12.2
URBAN	318	114,764	$32,113	$28,504	-0.5	11.6	11.2
LARGE	173	72,680	$33,116	$29,673	0.0	11.3	10.4
OTHER	145	42,084	$30,382	$26,485	-1.5	12.2	12.8
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	16	7,848	$26,374	$23,245	0.4	13.2	11.9
OCT. 1983 - SEPT. 1993	45	22,126	$34,391	$30,830	0.1	11.4	10.4
OCT. 1993 - SEPT. 2002	208	74,435	$31,962	$28,364	-0.8	11.3	11.3
AFTER OCT. 2002	68	14,116	$31,064	$27,150	-1.0	12.4	12.6
BY OWNERSHIP CONTROL:							
VOLUNTARY	69	25,396	$30,715	$26,604	-0.6	13.8	13.4
PROPRIETARY	221	85,879	$32,640	$29,208	-0.5	10.9	10.5
GOVERNMENT	9	2,249	$25,905	$22,235	-1.9	13.1	14.2
UNKNOWN	38	5,001	$28,830	$25,010	-1.4	12.7	13.2
BY CENSUS REGION:							

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NEW ENGLAND	14	9,402	$26,511	$23,178	0.8	14.3	12.6
MIDDLE ATLANTIC	23	7,035	$31,983	$28,642	-0.9	10.4	10.4
SOUTH ATLANTIC	41	12,150	$35,668	$31,603	-0.7	11.7	11.4
EAST NORTH CENTRAL	61	17,353	$34,923	$31,107	-0.6	11.2	10.9
EAST SOUTH CENTRAL	22	5,861	$33,334	$29,184	-1.6	11.9	12.4
WEST NORTH CENTRAL	17	4,755	$36,017	$31,650	-1.0	12.0	12.1
WEST SOUTH CENTRAL	122	49,392	$29,191	$25,702	-1.1	11.6	12.0
MOUNTAIN	22	6,032	$33,228	$29,589	0.4	12.2	11.0
PACIFIC	15	6,545	$40,182	$37,637	2.0	9.3	6.3
BY BED SIZE:							
BEDS: 0-24	35	5,997	$30,310	$26,328	-1.8	-12.2	-13.1
BEDS: 25-49	172	42,034	$32,112	$28,262	-1.1	-11.7	-12.0
BEDS: 50-74	42	14,789	$33,862	$30,040	-0.5	-11.8	-11.3
BEDS: 75-124	43	20,430	$32,907	$29,496	0.0	-11.2	-10.4
BEDS: 125-199	25	22,243	$30,329	$26,918	-0.4	-11.7	-11.2
BEDS: 200 +	13	12,134	$31,708	$28,724	0.7	-11.0	-9.4
UNKNOWN	7	898	$23,983	$21,237	-2.2	-9.8	-11.5

[1] These calculations take into account that some providers may experience a change in the LTCH PPS blend percentage changes during the 2006 and 2007 LTCH PPS rate years. For example, during the period of July 1, 2006 through June 30, 2007, a provider with a cost reporting period beginning October 1, 2005 would have 3 months (July 1, 2006 through September 30, 2006) of payments under the 20/80 blend (4/5ths wage index) and 9 months (October 1, 2006 through June 30, 2007) of payment under the full (5/5ths) wage index.

[2] Estimated average payment per case for the 12-month period of July 1, 2005 through June 30, 2006.

[3] Estimated average payment per case for the 12-month period of July 1, 2006 through June 30, 2007.

[4] Percent change in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for the proposed changes to the area wage adjustment policy at §412.525(c) (as discussed in section IV.D.1. of the preamble of this proposed rule).

[5] Percent decrease in estimated payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year for the proposed changes to the short-stay outlier policy at §412.529 (as discussed in section V.A.1.a. of the preamble of this proposed rule).

[6] Percent decrease in estimated payments per discharge from the 2006 LTCH PPS rate year (as established in the RY 2006 LTCH PPS final rule (70 FR 24168 through 24261)) to those proposed for the 2007 LTCH PPS rate year (as discussed in the preamble of this proposed rule).

4. Results

Based on the most recent available data (as described previously for 259 LTCHs), we have prepared the following summary of the impact (as shown above in Table 23) of the LTCH PPS set forth in this proposed rule. The impact analysis in Table 23 shows that estimated payments per discharge are expected to decrease approximately 11 percent on average for all LTCHs from the 2006 LTCH PPS rate year as compared to the 2007 LTCH PPS rate year as a result of the proposed changes presented in this proposed rule. As noted previously, the estimated percent decrease in payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year is largely attributable to the proposed change in the payment formula for SSO cases (discussed in section V.A.1.a. of this proposed rule). Specifically, under the proposed changes to the SSO policy for RY 2007, approximately 96 percent of LTCH SSO cases (which is approximately 36 percent of all LTCH cases) would receive a lower payment than under the current SSO policy. We believe this proposed policy is appropriate given that many of these short-stay cases most likely do not belong in a LTCH, which in general are intended to treat patients with an ALOS of greater than 25 days. As we discussed in greater detail in section IV.D.3.c. of the preamble of this proposed rule), given the regulatory requirement at § 412.525(a) that estimated outlier payments equal to 8 percent of estimated total LTCH PPS payments, this estimated decrease in LTCH PPS payments for RY 2007 resulting from the proposed changes to the SSO policy would require a proposed increase in the high-cost outlier fixed-loss amount in order to maintain that estimated outlier payments at 8 percent of the reduced estimated total LTCH PPS payments (resulting from the proposed changes to the SSO policy). The proposed increase in the outlier fixed-loss amount and the proposed slight increase in the budget neutrality offset to account for the transition methodology (discussed in section IV.D.5. of this proposed rule) are also factors contributing to the proposed decrease in payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year. For example, many LTCHs are expected to receive a decrease in high-cost outlier payments. A result of the proposed increase to the fixed-loss amount from the 2006 LTCH PPS rate year ($10,501) to the 2007 LTCH PPS rate year ($18,489), fewer cases would qualify as outlier cases (that is, the estimated cost of the case exceeds the outlier threshold). Since, many LTCHs would receive fewer outlier payments, total estimated payments per discharge would discharge (as discussed in section IV.D.3. of this proposed rule).

a. Location

Based on the most recent available data, the majority of LTCHs are in urban areas. Approximately 3.5 percent of the LTCHs are identified as being located in a rural area, and approximately 2.3 percent of all LTCH cases are treated in these rural hospitals. Impact analysis in Table 23 shows that the percent decrease in estimated payments per discharge for the 2006 LTCH PPS rate year compared to the 2007 LTCH PPS rate year for rural LTCHs would be −11.3 percent, and would be −11.1 percent for urban LTCHs (see Table 23). While rural LTCHS are expected to experience a lower decrease in payments due to the proposed changes in the SSO policy because they treat a smaller percentage of SSO cases, they are projected to experience a higher decrease in payments per discharge as a result of the proposed changes to the area wage adjustment (discussed in section IV.D.1. of the preamble of this proposed rule). Specifically, rural LTCHs are expected to experience a higher decrease in payments per discharge as a result of the proposed changes to the area wage adjustment because the wage index for all rural LTCHs is less than 1.0, and therefore, they would experience a decrease in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment.

Large urban LTCHs are projected to experience a 12.8 percent decrease in payments per discharge from the 2006 LTCH PPS rate year compared to the 2007 LTCH PPS rate year, while other urban LTCHs are projected to experience a 11.8 percent decrease in payments per discharge from the 2006 LTCH PPS rate year compared to the 2007 LTCH PPS rate year (see Table 23). Other urban LTCHs are projected to experience a higher than average decrease in payments per discharge primarily because of the proposed changes to the area wage adjustment (discussed in section IV.D.1. of the preamble of this proposed rule). Specifically, the majority of other urban LTCHs (over 80 percent) are located in urban areas that have a proposed wage index value of less than 1.0, and therefore, would experience a higher than average decrease in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment. In addition, other urban LTCHs have a slightly higher percentage of SSO cases and therefore are projected to experience a slightly higher than average decrease in payments per discharge as a result of the proposed changes to the SSO policy (as discussed in greater detail above in this section).

b. Participation Date

LTCHs are grouped by participation date into three categories: (1) Before October 1983; (2) between October 1983 and September 1993; and (3) between October 1993 and September 2002. At this time, we do not have sufficient cost report data for any of the LTCHs that began participating in the Medicare program after October 2002 (the implementation of the LTCH PPS), and, therefore, they are not included in the impact analysis shown in Table 23.

Based on the most recent available data, the majority, approximately 71 percent, of the LTCH cases are in hospitals that began participating between October 1993 and September 2002, and are projected to experience an 11.3 percent decrease in payments per discharge from the 2006 LTCH PPS rate year compared to the 2007 LTCH PPS rate year. Approximately 22 percent of the cases are in LTCHs that began participating in Medicare between October 1983 and September 1993, and those LTCHs are projected to experience a 10.2 percent decrease in payments per discharge from the 2006 LTCH PPS rate year compared to the 2007 LTCH PPS rate year (see Table 23). We are projecting that LTCHs that began participating in Medicare between October 1983 and September 1993 would experience a lower than average decrease in payments for RY 2007 primarily because we are projecting that these LTCH would experience a slight increase (0.1 percent) in payments per discharge due to the proposed changes to the area wage adjustment. Specifically, many of the LTCHs that began participating in Medicare between October 1983 and September 1993 are located in areas where the proposed RY 2007 wage index value would be greater than the RY 2006 wage index value. In addition, several of these LTCH are located in areas that have a proposed wage index value of greater than 1.0, and therefore, would experience a slight increase in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment.

LTCHs that began participating before October 1983 are projected to experience a 12.0 percent decrease in payments per discharge from the 2006 LTCH PPS rate year compared to the 2007 LTCH PPS rate year (see Table 23).

We are projecting that LTCHs that began participating in Medicare before October 1983 would experience a higher than average decrease in payments for RY 2007 as compared to RY 2006 primarily because many of these LTCHs have a higher than average percentage of SSO cases, and therefore, we are projecting that they would experience a higher than average decrease in payments per discharge due to the proposed changes to the SSO policy.

c. Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary; proprietary; and government.

Based on the most recent available data, approximately 3.5 percent of LTCHs are government owned and operated. We expect that for these government-owned and operated LTCHs, 2007 LTCH PPS rate year payments per discharge would decrease 14.3 percent in comparison to the 2006 LTCH PPS rate year (see Table 23). We are projecting that government-run LTCHs would experience a higher than average decrease in payment in RY 2007 as compared to RY 2006 primarily due to the proposed changes to the SSO policy, since many of these LTCHs have a higher than average percentage of SSO cases. Also contributing to the projected higher than average decrease in payments in RY 2007 as compared to RY 2006 for government-run LTCHs is the effect of the proposed changes to the area wage adjustment. Specifically, all but 1 of the 9 government-run LTCHs in our database are located in areas where the proposed wage index value for RY 2007 is less than 1.0, and therefore, would experience a higher than average decrease in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment.

Similarly, we project that 2006 LTCH PPS rate year payments per discharge for voluntary LTCHs would decrease 13.2 percent in comparison to the 2006 LTCH PPS rate year (see Table 23). We are projecting that voluntary LTCHs would experience a higher than average decrease in payments in RY 2007 as compared to RY 2006 primarily due to the proposed changes to the SSO policy, since approximately two-thirds (40 LTCHs) of the voluntary LTCHs have a higher than average percentage of SSO cases.

The majority (approximately 73 percent) of LTCHs are proprietary. We project that 2007 LTCH PPS rate year payments per discharge for these proprietary LTCHs would decrease 10.4 percent in comparison to the 2006 LTCH PPS rate year (see Table 23). We are projecting that proprietary LTCHs would experience a lower than average decrease in payments in RY 2007 as compared to RY 2006 primarily due to our estimate that these LTCHs would experience a lower than average decrease in payments due to the proposed changes to the SSO policy, since many proprietary LTCHs have a lower than average percentage of SSO cases.

d. Census Region

Payments per discharge for the 2007 LTCH PPS rate year are estimated to decrease for LTCHs located in all regions in comparison to the 2006 LTCH PPS rate year. As explained in greater detail above in this section, the estimated percent decrease in payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year is largely attributable to the proposed change in the payment formula for SSO cases, the proposed changes in the area wage adjustment, the proposed increase in outlier fixed-loss amount, and the proposed slight decrease in the transition period budget neutrality offset.

Of the 9 census regions, we project that the estimated decrease in proposed 2007 LTCH PPS rate year payments per discharge in comparison to the 2006 LTCH PPS rate year would have the largest impact on LTCHs in the New England region (12.7 percent; see Table 23). LTCHs located in New England are expected to experience an increase (0.8 percent) in payments due to the proposed changes in the area wage adjustment, since all New England LTCHs are located in areas where the proposed wage index value for RY 2007 is greater than 1.0, and therefore, would experience an increase in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment. However, even with this projected increase in payments from the proposed changes in the area wage adjustment, because the vast majority of New England LTCH treat a higher than average percentage of SSO cases, we are projecting that these LTCHs would experience a higher than average decrease in payments in RY 2007 as a result of the proposed changes to the SSO policy.

We project that proposed 2007 LTCH PPS rate year payments per discharge would decrease the least for LTCHs in the Pacific region in comparison to the 2006 LTCH PPS rate year (6.3 percent; see Table 23). We estimate that for LTCHs located in the Pacific region, the projected decrease in payments per discharge for the 2007 LTCH PPS rate year compared to the 2006 LTCH PPS rate year is less than the decreases projected for other regions, because all LTCHs in this region are located in areas where the proposed RY 2007 wage index value is greater than the RY 2006 wage index value. Furthermore, all of the LTCHs located in the Pacific region are located in areas where the proposed wage index value for RY 2007 is greater than 1.0, and therefore, would experience an increase in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment. In addition, many of the Pacific LTCHs treat a lower than average percentage of SSO cases, and therefore, we are projecting that these LTCHs would experience a lower than average decrease in average payments as a result of the proposed changes to the SSO policy.

e. Bed Size

LTCHs were grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and 200+ beds.

We are projecting a decrease in 2007 LTCH PPS rate year payments per discharge in comparison to the 2006 LTCH PPS rate year for all bed size categories. Most LTCHs are in bed size categories where 2007 LTCH PPS rate year payments per discharge are projected to decrease by at least 10 percent in comparison to the 2006 LTCH PPS rate year. As discussed in greater detail above in this section, the estimated percent decrease in payments per discharge from the 2006 LTCH PPS rate year to the 2007 LTCH PPS rate year is largely attributable to the proposed change in the payment formula for SSO cases, the proposed changes in the area wage adjustment, the proposed increase in outlier fixed-loss amount, and the proposed slight increase in the transition period budget neutrality offset.

We project that LTCHs with greater than 200 beds would have the smallest decrease in estimated 2007 LTCH PPS rate year payments per discharge in comparison to the 2006 LTCH PPS rate year (9.5 percent), followed by LTCHs with 75–124 beds (10.3 percent). This lower than average decrease in projected payments per discharge for LTCHs with

greater than 200 beds and for LTCHs with 75–124 beds is largely due to the proposed changes to the area wage adjustment. Specifically, for LTCHs with 75–124 beds, the majority of these LTCHs are located in areas where the proposed change in the wage index value from RY 2006 to RY 2007 would be very small, and therefore we are projecting that the proposed changes to the area wage adjustment would have a negligible impact on these LTCHs' RY 2007 payments (0.0 percent) rather than decreasing their RY 2007 payments (as we estimate would be the impact of such proposed changes for ''All Providers'' as shown in Table 23). For LTCHs with greater than 200 beds, the majority of these LTCHs are located in areas where the proposed RY 2007 wage index value is greater than the RY 2006 wage index value. In addition, the majority of LTCHs with greater than 200 beds are located in areas where the proposed RY 2007 wage index value is greater than 1.0, and therefore, would experience an increase in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment.

Payments per discharge for the 2007 LTCH PPS rate year for LTCHs with 0–24 beds are projected to decrease the most in comparison to the 2006 LTCH PPS rate year (13.5 percent; see Table 23), followed by LTCHs with 25–49 beds (11.8 percent; see Table 23). This higher than average decrease in projected payments per discharge for LTCHs with less than 49 beds (that is, LTCHs in the 0–24 bed size category and LTCHs in the 25–49 bed size category) is largely due to the proposed changes to the area wage adjustment. Specifically, the majority of LTCHs with 49 beds or less are located in areas where the proposed RY 2007 wage index value is less than the RY 2006 wage index value. In addition, the majority of LTCHs with 49 beds or less are located in areas where the proposed RY 2007 wage index is less than 1.0, and therefore, would experience a higher than average decrease in payments per discharge as a result of the proposed increase in the labor-related share and the progression of the 5-year phase-in of the wage index adjustment. Furthermore, many of LTCHs with 0–24 beds have a higher than average percent of SSO cases, and therefore, would experience a higher than average decrease in payments per discharge as a result of the proposed changes to the SSO policy.

5. Effect on the Medicare Program

Based on actuarial projections, we estimate that Medicare spending (total estimated Medicare program payments) for LTCH services over the next 5 years would be as shown in Table 25:

TABLE 25

LTCH PPS rate year	Estimated payments ($ in billions)
2007	$5.27
2008	5.44
2009	5.64
2010	5.88
2011	6.15

These estimates are based on the most recent and complete LTCH data available, including the projection that 97 percent of LTCHs would elect to be paid based on 100 percent of the 2007 LTCH PPS rate year proposed standard Federal rate rather than the applicable transition blend, and an estimated increase in the number of discharges from LTCHs. (We note that the 5-year spending estimates shown in above Table 25 are significantly higher than the 5-year spending estimates presented in the 2006 LTCH PPS final rule (70 FR 24203). This is primarily due to an adjustment by our Office of the Actuary (OACT) to account for the significant increase in the expected number of LTCH discharges based on the most recent complete available LTCH discharge data.) These estimates are also based on the current estimate of the increase in the excluded hospital with capital market basket (currently used under the LTCH PPS) of 3.6 percent for the 2007 LTCH PPS rate year, 3.5 percent for the 2008 LTCH PPS rate year, 3.1 for the 2009 LTCH PPS rate year, 2.6 percent for the 2010 LTCH PPS rate year and 3.0 percent for the 2011 LTCH PPS rate year. (We note that, although we are proposing a zero percent update to the LTCH PPS Federal rate for RY 2007 (as discussed in section IV.C.3. of this proposed rule), OACT develops its spending projections based on existing policy and therefore, changes that have not yet been implemented are not reflected in the spending projections shown in Table 25.) We estimate that there would be a change in Medicare fee-for service beneficiary enrollment of −2.3 percent in the 2007 LTCH PPS rate year, −1.0 percent in the 2008 LTCH PPS rate year, 0.3 percent in 2009 and 2010 LTCH PPS rate years, and 0.6 percent in the 2011 LTCH PPS rate year, and an estimated increase in the total number of LTCHs. (We note that, based on the most recent available data, OACT is projecting a decrease in Medicare fee-for-service Part A enrollment, in part, because they are projecting an increase in Medicare managed care enrollment as a result of the implementation of several provisions of the MMA.)

Consistent with the statutory requirement for budget neutrality, as we discussed in the August 30, 2002 final rule that implemented the LTCH PPS, in developing the LTCH PPS, we intended for estimated aggregate payments under the LTCH PPS in FY 2003 would equal the estimated aggregate payments that would have been made if the LTCH PPS were not implemented. Our methodology for estimating payments for purposes of the budget neutrality calculations uses the best available data and necessarily reflects assumptions. As we collect data from LTCHs, we will monitor payments and evaluate the ultimate accuracy of the assumptions used to calculate the budget neutrality calculations (that is, inflation factors, intensity of services provided, or behavioral response to the implementation of the LTCH PPS). As discussed in section IV.D.6. of this proposed rule, we still do not have sufficient new cost report and claims data generated under the LTCH PPS to enable us to conduct a comprehensive reevaluation of our FY 2003 budget neutrality calculation at this time.

Section 123 of BBRA and section 307 of BIPA provide the Secretary with extremely broad authority in developing the LTCH PPS, including the authority for appropriate adjustments. In accordance with this broad authority, we may discuss in a future proposed rule a possible one-time prospective adjustment to the LTCH PPS rates under § 412.523(d)(3) to maintain budget neutrality so that the effect of the difference between actual payments and estimated payments for the first year of LTCH PPS is not perpetuated in the PPS rates for future years. As discussed in section IV.D.6. of this proposed rule, due to the lag time in the availability of Medicare data upon which this adjustment would be based, we believe that it is appropriate to propose a postponement of the requirement established in § 412.523(d)(3) from the existing October 1, 2006 deadline to July 1, 2008.

6. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries under the LTCH PPS, but we expect that

paying prospectively for LTCH services would enhance the efficiency of the Medicare program.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf),* in Table 26, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule. Table 26 provides our best estimate of the proposed decrease in Medicare payments under the LTCH PPS as a result of the proposed changes presented in this proposed rule based on the data for 259 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

TABLE 26.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2006 LTCH PPS RATE YEAR TO THE 2007

[LTCH PPS rate year (in millions)]

Category	Transfers
Annualized Monetized Transfers.	Negative transfer—Estimated decrease in expenditures: $362.
From Whom To Whom?	Federal Government To LTCH Medicare Providers.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 42 CFR chapter IV as set forth below:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

1. The authority citation for part 412 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart O—Prospective Payment System for Long-Term Care Hospitals

2. Section 412.523 is amended by—

A. Revising paragraph (c)(3)(ii).

B. Adding new paragraph (c)(3)(iii).

C. Revising paragraph (d)(3).

The revisions and addition read as follows:

§ 412.523 Methodology for calculating the Federal prospective payment rates.

* * * * *

(c) * * *

(3) * * *

(ii) *For long-term care hospital prospective payment system rate years beginning on or after July 1, 2003 and ending on or before June 30, 2006.* The standard Federal rate for long-term care hospital prospective payment system rate years beginning on or after July 1, 2003 and ending on or before June 30, 2006 is the standard Federal rate for the previous long-term care hospital prospective payment system rate year, updated by the increase factor described in paragraph (a)(2) of this section, and adjusted, as appropriate, as described in paragraph (d) of this section. For the rate year from July 1, 2003 through June 30, 2004, the updated and adjusted standard Federal rate is offset by a budget neutrality factor to account for updating the FY 2003 standard Federal rate on July 1 rather than October 1.

(iii) *For long-term care hospital prospective payment system rate year July 1, 2006 through June 30, 2007.* The standard Federal rate for long-term care hospital prospective payment system rate year July 1, 2006 through June 30, 2007 is the standard Federal rate for the previous long-term care hospital prospective payment system rate year, updated by an update factor of zero percent. The standard Federal rate is adjusted, as appropriate, as described in paragraph (d) of this section.

* * * * *

(d) * * *

(3) *One-time prospective adjustment.* The Secretary reviews payments under this prospective payment system and may make a one-time prospective adjustment to the long-term care hospital prospective payment system rates on or before July 1, 2008, so that the effect of any significant difference between actual payments and estimated payments for the first year of the long-term care hospital prospective payment system is not perpetuated in the prospective payment rates for future years.

* * * * *

3. Section 412.525 is amended by—

A. Revising paragraph (a)(3).

B. Revising paragraph (a)(4)(ii).

C. Revising paragraph (a)(4)(iii).

D. Adding new paragraph (a)(4)(iv).

The revisions and addition read as follows:

§ 412.525 Adjustments to the Federal prospective payment.

(a) * * *

(3) The additional payment equals 80 percent of the difference between the estimated cost of the patient care (determined by multiplying the hospital-specific cost-to-charge ratio by the Medicare allowable covered charge) and the sum of the adjusted LTCH PPS Federal prospective payment and the fixed-loss amount.

(4) * * *

(ii) For discharges occurring on or after August 8, 2003 and before October 1, 2006, high-cost outlier payments are subject to the provisions of § 412.84(i)(1), (i)(3), and (i)(4) and (m) for adjustments of cost-to-charge ratios.

(iii) For discharges occurring on or after October 1, 2003 and before October 1, 2006, high-cost outlier payments are subject to the provisions of § 412.84(i)(2) for adjustments to cost-to-charge ratios.

(iv) For discharges occurring on or after October 1, 2006, high cost stay outlier payments are subject to the following provisions:

(A) CMS may specify an alternative to the cost-to-charge ratio otherwise applicable under paragraph (a)(4)(iv)(B) of this section. A hospital may also request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. A request must be approved by the CMS Regional Office.

(B) The cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(C) The fiscal intermediary may use a Statewide average cost-to-charge ratio, which CMS establishes annually, if it is unable to determine an accurate cost-to-charge ratio for a hospital in one of the following circumstances:

(*1*) New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(*2*) Hospitals whose cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean cost to charge ratio. CMS establishes and publishes this mean annually.

(*3*) Other hospitals for whom data with which to calculate a cost-to-charge ratio is not available.

(D) Any reconciliation of outlier payments is based on the cost-to-charge

ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled.

(E) At the time of any reconciliation under paragraph (a)(4)(iv)(D) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment is based upon a widely available index to be established in advance by the Secretary, and is applied from the midpoint of the cost reporting period to the date of reconciliation.

* * * * *

4. Section 412.529 is amended by—

A. Revising paragraph (c).

B. Adding new paragraph (d).

The revision and addition read as follows:

§ 412.529 Special payment provision for short-stay outliers.

* * * * *

(c) *Method for determining the payment amount.* (1) For discharges from long-term care hospitals described under § 412.23(e)(2)(i), occurring before July 1, 2006, the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is the least of the following amounts:

(i) 120 percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section multiplied by the length of stay of the discharge;

(ii) 120 percent of the cost of the case determined under paragraph (d)(2) of this section; or

(iii) The Federal prospective payment for the LTC–DRG.

(2) For discharges occurring on or after July 1, 2006, from long-term care hospitals described under § 412.23(e)(2)(i), and for discharges occurring in cost reporting periods beginning on or after October 1, 2006, from the long-term care hospitals described under § 412.23(e)(2)(ii), the LTCH prospective payment system adjusted payment amount for a short-stay outlier case is the least of the following amounts:

(i) 120 percent of the LTC–DRG specific per diem amount determined under paragraph (d)(1) of this section multiplied by the length of stay of the discharge;

(ii) 100 percent of the cost of the case determined under paragraph (d)(2) of this section;

(iii) The Federal prospective payment for the LTC–DRG; or

(iv) An amount payable under subpart O that is comparable to an amount that is otherwise paid under the hospital inpatient prospective payment system determined under paragraph (d)(3) of this section.

(3) The adjusted payment amount for discharges from long-term care hospitals described under § 412.23(e)(2)(ii) that occur on or after October 1, 2002, through June 30, 2003, is determined under paragraph (c)(1) of this section. Effective for discharges occurring on or after July 1, 2003, subject to provisions of paragraph (c)(3)(v) of this section, for long-term care hospitals described under § 412.23(e)(2)(ii), the adjusted payment amount for a short-stay outlier is determined under the formulas set forth in paragraphs (c)(3)(i) through (iv) of this section.

(i) For the first year of the transition period, as specified at § 412.533(a)(1), under the formula set forth in paragraph (c)(1) of this section, the percentages specified for the LTC–DRG specific per diem amount and the cost of the case under paragraphs (c)(1)(i) and (c)(1)(ii) of this section are substituted with 195 percent.

(ii) For the second year of the transition period, as specified at § 412.533(a)(2), under the formula set forth in paragraph (c)(1) of this section, the percentages specified for the LTC–DRG specific per diem amount and the cost of the case under paragraphs (c)(1)(i) and (c)(1)(ii) of this section are substituted with 193 percent.

(iii) For the third year of the transition period, as specified at § 412.533(a)(3), under the formula set forth in paragraph (c)(1) of this section, the percentages specified for the LTC–DRG specific per diem amount and the cost of the case under paragraphs (c)(1)(i) and (c)(1)(ii) of this section are substituted with 165 percent.

(iv) For the fourth year of the transition period, as specified at § 412.533(a)(4), under the formula set forth in paragraph (c)(1) of this section, the percentages specified for the LTC–DRG specific per diem amount and cost of the case under paragraphs (c)(1)(i) and (c)(1)(ii) of this section are substituted with 136 percent.

(v) For discharges occurring in cost reporting periods beginning on or after October 1, 2006 (beginning with the fifth year of the transition period), as specified at § 412.533(a)(5)), short-stay outlier payments to long-term care hospitals described under § 412.23(e)(2)(ii) are made in accordance with the formula set forth in paragraph (c)(2) of this section.

(4) *Short-stay outlier payments.* (i) For discharges occurring on or after October 1, 2002 and before August 8, 2003, no reconciliations are made to short-stay outlier payments upon cost report settlement to account for differences between cost-to-charge ratio and the actual cost-to-charge ratio of the case.

(ii) For discharges occurring on or after August 8, 2003 and before October 1, 2006, short-stay outlier payments are subject to the provisions of § 412.84(i)(1), (i)(3), and (i)(4) and (m) for adjustments of cost-to-charge ratios.

(iii) For discharges occurring on or after October 1, 2003 and before October 1, 2006, short-stay outlier payments are subject to the provisions of § 412.84(i)(2) for adjustments to cost-to-charge ratios.

(iv) For discharges occurring on or after October 1, 2006, short-stay outlier payments are subject to the following provisions:

(A) CMS may specify an alternative to the cost-to-charge ratio otherwise applicable under paragraph (c)(4)(iv)(B) of this section. A hospital may also request that its fiscal intermediary use a different (higher or lower) cost-to-charge ratio based on substantial evidence presented by the hospital. This request must be approved by the CMS Regional Office.

(B) The cost-to-charge ratio applied at the time a claim is processed is based on either the most recent settled cost report or the most recent tentative settled cost report, whichever is from the latest cost reporting period.

(C) The fiscal intermediary may use a Statewide average cost-to-charge ratio, which CMS establishes annually, if it is unable to determine an accurate cost-to-charge ratio for a hospital in one of the following circumstances:

(*1*) New hospitals that have not yet submitted their first Medicare cost report. (For this purpose, a new hospital is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18 of this chapter.)

(*2*) Hospitals whose cost-to-charge ratio is in excess of 3 standard deviations above the corresponding national geometric mean. CMS establishes and publishes this mean annually.

(*3*) Other hospitals for whom data with which to calculate a cost-to-charge ratio is not available.

(D) Any reconciliation of outlier payments is based on the cost-to-charge ratio calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled.

(E) At the time of any reconciliation under paragraph (c)(4)(iv)(C)(*4*) of this section, outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Any adjustment is based upon a widely

available index to be established in advance by the Secretary, and is applied from the midpoint of the cost reporting period to the date of reconciliation.

(d) *Calculation of costs.* (1) CMS calculates a per diem amount for short-stay outliers for each LTC–DRG by dividing the product of the standard Federal payment rate and the LTC–DRG weight by the geometric mean length of stay of the specific LTC–DRG.

(2) To determine the cost of a case, CMS uses the hospital-specific cost-to-charge ratio and the Medicare allowable charges for the case.

(3) CMS calculates, under Subpart O, an amount comparable to what would otherwise be paid under the hospital Inpatient prospective payment system based on the sum of the applicable operating inpatient prospective payment system standardized amount and capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge.

(i) *Operating inpatient prospective payment system standardized amount.* The operating inpatient prospective payment system standardized amount—

(A) Is adjusted for the applicable inpatient prospective payment system DRG weighting factors.

(B) Is adjusted for different area wage levels based on the geographic classifications set forth at § 412.64(b)(1)(ii)(A) through (C) and the applicable inpatient prospective payment system labor-related share, using the applicable inpatient prospective payment system wage index value for non-reclassified inpatient prospective payment system hospitals. For LTCHs located in Alaska and Hawaii, this amount is also adjusted by the applicable inpatient prospective payment system cost of living adjustment factors.

(C) Includes, where applicable, adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(ii) *Capital inpatient prospective payment system Federal rate.* The capital inpatient prospective payment system Federal rate—

(A) Is adjusted for the applicable inpatient prospective payment system DRG weighting factors.

(B) Is adjusted for the applicable geographic adjustment factors, including local cost variation based on the geographic classifications set forth at § 412.64(b)(1)(ii)(A) through (C) and the applicable full inpatient prospective payment system wage index value for non-reclassified inpatient prospective payment system hospitals and, applicable large urban location cost of living adjustment factors for LTCHs in Alaska and Hawaii, if applicable.

(C) Includes, where applicable, adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

5. Section 412.531 is amended by—

A. Revising paragraph (b)(1)(i)(C).

B. Redesignating paragraph (b)(1)(ii)(A)(*2*) as (b)(1)(ii)(A)(*3*).

C. Adding new paragraph (b)(1)(ii)(A)(*2*).

The revisions and additions read as follows:

§ 412.531 Special payment provisions when an interruption of a stay occurs in a long-term care hospital.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(C) Surgical DRG exception to the 3-day or less interruption of stay policy.

(*1*) The number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the beneficiary receives a procedure grouped to a surgical DRG under the inpatient prospective payment system in an acute care hospital during the 2005 and 2006 LTCH prospective payment system rate years are not included in determining the length of stay of the patient at the long-term care hospital.

(*2*) For discharges occurring on or after July 1 2006, the number of days that a beneficiary spends away from a long-term care hospital during a 3-day or less interruption of stay under paragraph (a)(1) of this section during which the beneficiary receives a procedure grouped to a surgical DRG under the inpatient prospective payment system in an acute care hospital are included in determining the length of stay of the patient at the long-term care hospital.

* * * * *

(ii) * * *

(A) * * *

(*2*) For discharges occurring on or after July 1, 2006, for a 3-day or less interruption of stay under paragraph (a)(1) of this section in which a long-term care hospital discharges a patient to an acute care hospital and the patient's treatment during the interruption is grouped into a surgical DRG under the acute care inpatient hospital prospective payment system, the services must be provided under arrangements in accordance with § 412.509(c). CMS does not make a separate payment to the acute care hospital for the surgical treatment. The LTC–DRG payment made to the long-term care hospital is considered payment in full as specified in § 412.521(b).

* * * * *

6. Section 412.534 is amended by—

A. Revising paragraph (c)(1).

B. Revising paragraph (c)(2).

C. Revising paragraph (d)(1).

D. Revising paragraph (e)(1).

E. Redesignating paragraph (f) as paragraph (g).

F. Adding new paragraph (f).

The revisions and addition read as follows:

§ 412.534 Special payment provisions for long-term care hospitals within hospitals and satellites of long-term care hospitals.

* * * * *

(c) * * *

(1) Except as provided in paragraph (g) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or its satellite facility has a discharged Medicare inpatient population of whom no more than 25 percent were admitted to the hospital or its satellite facility from the co-located hospital, payments are made under the rules at § 412.500 through § 412.541 in this subpart with no adjustment under this section.

(2) Except as provided in paragraph (d), (e), or (g) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than 25 percent were admitted to the hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 25 percent threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent, as set forth in paragraph (f) of this section, to the amount that would be determined under the rules at Subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at § 412.500 through § 412.541 with no adjustment under this section.

* * * * *

(d) * * *

(1) Subject to paragraph (g) of this section, in the case of a long-term care hospital or satellite facility that is located in a rural area as defined in

§ 412.64(b)(1)(ii)(C) and is co-located with another hospital for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than 50 percent were admitted to the long-term care hospital or satellite facility from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital or satellite facility to exceed the 50 percent threshold for discharged patients who were admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount payable under this subpart that is equivalent, as set forth in paragraph (f) of this section, to the amount that were otherwise payable under subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart at § 412.500 through § 412.541 with no adjustment under this section.

* * * * *

(e) * * *

(1) Subject to paragraph (g) of this section, In the case of a long-term care hospital or satellite facility that is co-located with the only other hospital in the MSA or with a MSA dominant hospital as defined in paragraph (e)(4) of this section, for any cost reporting period beginning on or after October 1, 2004 in which the long-term care hospital or satellite facility has a discharged Medicare inpatient population of whom more than the percentage calculated under paragraph (e)(2) of this section were admitted to the hospital from the co-located hospital, payments for the patients who are admitted from the co-located hospital and who cause the long-term care hospital to exceed the applicable threshold for discharged patients who have been admitted from the co-located hospital are the lesser of the amount otherwise payable under this subpart or the amount under this subpart that is equivalent, as set forth in paragraph (f) of this section, to the amount that otherwise would be determined under Subpart A, § 412.1(a). Payments for the remainder of the long-term care hospital's or satellite facility's patients are made under the rules in this subpart with no adjustment under this section.

* * * * *

(f) *Calculation of rates.* (1) *Calculation of LTCH prospective payment system amount.* CMS calculates an amount payable under subpart O equivalent to an amount that would otherwise be paid under the hospital inpatient prospective payment system based on the sum of the applicable operating inpatient prospective payment system standardized amount and capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge.

(2) *Operating inpatient prospective payment system standardized amount.* The operating inpatient prospective payment system standardized amount—

(i) Is adjusted for the applicable inpatient prospective payment system DRG weighting factors;

(ii) Is adjusted for different area wage levels based on the geographic classifications set forth at § 412.64(b)(1)(ii)(A) through (C) and the applicable inpatient prospective payment system labor-related share, using the applicable inpatient prospective payment system wage index value for non-reclassified inpatient prospective payment system hospitals. For LTCHs located in Alaska and Hawaii, this amount is also adjusted by the applicable inpatient prospective payment system cost of living adjustment factors;

(iii) Includes, where applicable, adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(3) *Capital inpatient prospective payment system Federal rate.* The capital inpatient prospective payment system Federal rate —

(i) Is adjusted for the applicable inpatient prospective payment system DRG weighting factors;

(ii) Is adjusted by the applicable geographic adjustment factors, including local cost variation based on the applicable geographic classifications set forth at § 412.64(b)(1)(ii)(A) through (C) and the applicable full inpatient prospective payment system wage index value for non-reclassified inpatient prospective payment system hospitals, applicable large urban location and cost of living adjustment factors for LTCHs for Alaska and Hawaii, if applicable;

(iii) Includes, where applicable, capital inpatient prospective payment system adjustments for indirect medical education costs and the costs of serving a disproportionate share of low-income patients.

(4) *High cost outlier.* An additional payment for high cost outlier cases is based on the fixed loss amount paid under the inpatient prospective payment system if the estimated operating and capital costs exceed the applicable inpatient prospective payment system outlier threshold.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: December 8, 2005.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: January 19, 2006.

Michael O. Leavitt,

Secretary.

Editorial Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix A—Description of a Preliminary Model of an Update Framework under the LTCH PPS

Section 307(b) of BIPA requires that the Secretary shall examine and may provide for appropriate adjustments to the LTCH PPS, including updates. Updates are necessary to appropriately account for changes in the prices of goods and services used by a provider in furnishing care to patients. A market basket has historically been used under the Medicare program in setting update factors for services furnished by providers. When we established the LTCH PPS for FY 2003 in the August 30, 2002 final rule (67 FR 56030), we established under § 412.523(c)(3)(ii) that for FYs after FY 2003, the LTCH PPS Federal rate was to be the previous year's Federal rate updated by the most recent estimate of the LTCH PPS market basket. When we moved the date of the annual update of the LTCH PPS from October 1 to July 1, beginning with the RY 2004 LTCH PPS final rule (68 FR 34138), we revised § 412.523(c)(3)(ii) to specify that for LTCH PPS rate years beginning on or after July 1, 2003, the annual update to the standard Federal rate for the LTCH prospective payment system will be equal to the previous rate year's Federal rate updated by the most recent estimate of the LTCH PPS market basket. (Currently, the LTCH PPS market basket is the FY 1997-based excluded hospital with capital market basket index (68 FR 34134 through 34137); however, we are proposing to adopt the FY 2002-based RPL market basket, as discussed in section IV.B. of this proposed rule.) As we discuss in section IV.C.3. of this proposed rule, based on our analysis of the best available LTCH case-mix and margins data, we are proposing to revise § 412.523(c) to specify that for the 2007 LTCH PPS rate year, the standard Federal rate from the previous year would be updated by a factor of zero percent. However, in the future we may propose to develop an update framework to update payments to LTCHs that would account for other appropriate factors that affect the efficient delivery of services and care provided to Medicare patients. The update framework would be proposed in accordance with the notice and comment rulemaking process. While we are not implementing a specific update framework for the LTCH prospective payment system at this time in this proposed rule, we are providing a conceptual basis for developing such an update framework.

A. Need for an Update Framework

Under the LTCH prospective payment system, Medicare payments to LTCHs are based on a predetermined national payment amount per discharge. Under section 123 of the BBRA and section 307(b) of the BIPA, the Secretary has broad discretionary authority to make appropriate adjustments to the LTCH payment system, including updates to the payment rates. Our goal is to develop a method for analyzing and comparing expected trends in the underlying cost per discharge to use in establishing these updates. However, as stated earlier, until an appropriate update framework is developed, future updates may be based on the increase in the applicable LTCH PPS market basket.

The market basket for the LTCH PPS, developed by OACT, represents only one component in the measure of growth in LTCHs' costs per discharge. It captures only the pure price change of inputs (labor, materials, and capital) used by the hospital to produce a constant quantity and quality of care. However, other factors also contribute to the change in costs per discharge, including changes in case-mix, intensity, and productivity.

Previously, under the acute care hospital IPPS for operating costs (the operating IPPS), we utilized an update framework to account for these other factors and to make annual recommendations to the Congress concerning the magnitude of the update. We continue to use a similar framework under the acute care hospital IPPS for capital costs (the capital IPPS) to determine the annual update to the capital PPS Federal rate. We also use a similar framework under the SNF PPS. Based on our experience in developing other update frameworks, we are currently examining these factors and exploring ways that they could be measured and incorporated into an update framework for the LTCH PPS. We are also examining additional conceptual and data issues that must be considered when the framework is constructed and applied.

In the August 30, 2002 final rule (67 FR 56087), we pointed out that it is important to develop successively more refined models of an update framework based on our evaluation of public comments and recommendations submitted to us on this issue. We would then further study the potential adjustments using the best available data. To actively pursue the development of an analytical framework that would support the continued appropriateness and relevance of the payment rates for services provided to beneficiaries in LTCHs, in this proposed rule, we are soliciting comments concerning the use and feasibility of the conceptual approach outlined in section B of this Appendix. Specifically, we are requesting comments concerning which factors are appropriate and should be accounted for in the framework, and suggestions concerning potential data sources and analysis to support the model. As with the existing methodology used under both the capital IPPS and SNF PPS, the features of a LTCH-specific update framework would need to be based on sound policy and methodology. Although we received no comments on the conceptual basis for a LTCH PPS update framework presented in the August 30, 2002 final rule, we continue to be interested in comments concerning the potential development of an update framework for the LTCH prospective payment system. Therefore, in this proposed rule we are again presenting a conceptual basis for the framework along with an illustrative LTCH PPS framework for RY 2007 (shown in section E of this Appendix).

B. Factors Inherent in LTCH Payments Per Discharge

In order to understand the factors that determine LTCH costs per discharge, it is first necessary to understand the factors that determine LTCH payments per discharge. Payments per discharge under the LTCH PPS are based on the cost and an implicit normal profit margin to the LTCH in providing an efficient level of care. We have developed a methodology to identify a mutually exclusive and exhaustive set of factors included in LTCH payments per discharge. The discussion here details a set of equations to identify these factors.

In its simplest form, the average payment per discharge to a LTCH can be separated into a cost term and a profit term as shown in Equation 1.

$$\text{EQUATION 1:}\quad \frac{\text{Payments}}{\text{Discharge}} = \frac{\text{Costs}}{\text{Discharge}} + \frac{\text{Profits}}{\text{Discharge}}$$

This equation can be made multiplicative by converting profit per discharge into a profit rate as shown in Equation 2.

$$\text{EQUATION 2:}\quad \frac{\text{Payments}}{\text{Discharge}} = \frac{\text{Costs}}{\text{Discharge}} * \frac{\text{Payments}}{\text{Costs}}$$

An output price term can be introduced into the equation by multiplying and dividing through by input prices and productivity. As shown in Equation 3, the term inside the brackets represents the output price, since an output price reflects the input price and profit margin adjusted for productivity.

$$\text{EQUATION 3:}\quad \frac{\text{Payments}}{\text{Discharge}} = \frac{\text{Costs}}{\text{Discharge}} * \left(\frac{\text{Payments}}{\text{Costs}} * \frac{\text{Input Prices}}{\text{Productivity}} \right) * \frac{\text{Productivity}}{\text{Input Prices}}$$

The cost per discharge term can be further separated by accounting for real case-mix. Under the LTCH PPS, LTC–DRGs are used to classify patients. Based on accurate DRG classification data, average real case-mix per discharge can be incorporated, as shown in Equation 4.

$$\text{EQUATION 4:}$$

$$\frac{\text{Payments}}{\text{Discharge}} = \frac{\text{Costs} / \text{Discharge}}{\text{Real Case Mix/Discharge}} * \frac{\text{Real Case Mix}}{\text{Discharge}} * \left(\frac{\text{Payments}}{\text{Costs}} * \frac{\text{Input Prices}}{\text{Productivity}} \right) * \frac{\text{Productivity}}{\text{Input Prices}}$$

The term ''real'' is imperative here because only true case-mix should be measured, not case-mix caused by improper coding behavior. We believe payment should be based on changes in ''real'' case mix (that is, the treatment of more resource intensive and costly patients) rather than case mix caused by improper coding behavior or changes in coding practice (that is, ''apparent'' case mix change) because ''apparent'' case mix increase does not result in an increase in a hospital's cost of treating those patients. By rearranging the terms in Equation 4, a set of mutually exclusive and exhaustive factors such as those shown in Equation 5 can be identified.

EQUATION 5:

$$\frac{\text{Payments}}{\text{Discharge}} = \left(\frac{\frac{\text{Costs}}{\text{Discharge}}}{\text{Input Prices} * \frac{\text{Real Case Mix}}{\text{Discharge}}} * \text{Productivity} \right) * \frac{\text{Real Case Mix}}{\text{Discharge}} * \frac{1}{\text{Productivity}} * \text{Input Prices} * \frac{\text{Payments}}{\text{Costs}}$$

The term in brackets can be analyzed in two steps. First, excluding the productivity term results in case-mix adjusted real cost per discharge, which is input intensity per discharge. Second, multiplying input intensity by productivity results in case-mix adjusted real payment per discharge, or output intensity per discharge. The rationale behind this step is explained in detail in section C.

The result of this exercise is that LTCH payment per discharge can be determined from the following factors as shown in Equation 6.

EQUATION 6:

$$\text{Payment Per Discharge} = \frac{\left(\begin{matrix} \text{Case-Mix-Constant} \\ \text{Real Output Intensity} \\ \text{Per Discharge} \end{matrix} \right) * \left(\begin{matrix} \text{Real Case Mix} \\ \text{per Discharge} \end{matrix} \right) * (\text{Input Prices}) * (\text{Profit Margins})}{\text{Productivity}}$$

Thus, it holds that the change in LTCH payment per discharge is a function of the change in these factors as shown in Equation 6. In order to determine an annual update that most accurately reflects the underlying cost to the LTCH of efficiently providing care, the four factors related to cost must be accounted for when an update framework is developed. A brief discussion of each factor, including specific conceptual and data issues, is provided in section C.

C. Defining Each Factor Inherent in LTCH Costs Per Discharge

Each cost factor from Equation 6 in section B is discussed here in detail. Because this is a basic conceptual discussion, it is likely that more detailed issues may be relevant that are not explored here.

1. Input Prices

Input prices are the pure prices of inputs used by the LTCH in providing services. When we refer to inputs, we are referring to costs, which have both a price and a quantity component. The price is an input price, and the quantity component reflects real inputs or real costs. Similarly, when we refer to outputs, we are referring to payments, which also have both a price and a quantity component. The price component is the transaction output price, and the quantity component is the real output or real payment. The real inputs include labor, capital, and other materials, such as drugs. By definition, an input price reflects prices that LTCHs encounter in purchasing these inputs, whereas an output price reflects the prices that buyers encounter in purchasing LTCH services. We currently measure input prices using the excluded hospital with capital market basket; however, as discussed section IV.B. of this proposed rule, we are proposing to adopt the RPL market basket, which is based on the operating and capital costs of IRFs, IPFs and LTCHs. While not specific to LTCHs, we believe this index would adequately reflect the input prices faced by LTCHs.

2. Productivity

Productivity measures the efficiency of the LTCH in producing outputs. It is the amount of real outputs, or real payments that can be produced from a given amount of real inputs or real costs. For LTCHs, these inputs are in the form of both labor and capital; thus, they represent multifactor productivity, as not just labor productivity is reflected. Equation 7 shows how multifactor productivity can be measured in terms of available data, such as payments, costs, and input prices:

$$\text{EQUATION 7: Productivity} = \frac{\text{Real Payments}}{\text{Real Costs}} = \frac{(\text{Payments/Output Price})}{(\text{Costs/Input Price})} = \frac{\text{Payments}}{\text{Costs}} * \frac{\text{Input Price}}{\text{Output Price}}$$

Rearranging the terms, this multifactor productivity equation (Equation 7) was used as the basis for incorporating an output price term in Equation 3. This equation is the basis for understanding the relationship between input prices, output prices, profit margins, and productivity.

Equation 6 shows that productivity is divided through the equation, offsetting other factors. The theory behind this offset is that if an efficient LTCH in a competitive market can produce more output with the same amount of inputs, the full increase in input costs does not have to be passed on by the provider to maintain a normal profit margin.

3. Real Case Mix Per Discharge

Real case mix per discharge is the average overall mix of care provided by the LTCH, as measured using the LTC–DRG classification

system. Over time, a measure of real case mix will change as care is given in more or less complex LTC–DRGs. Changes in the level of care within a LTC–DRG classification group would not be reflected in a case-mix measure based on LTC–DRGs, but instead should be captured in the intensity factor of Equation 6. The important distinction here is the difference between real and nominal case-mix. Under the LTCH prospective payment system, LTCHs will submit claims using the LTC–DRG classification system. The case-mix reflected by the claims is considered ''nominal''. However, the reported classification can reflect the true level of care provided or improper coding behavior. An example of improper coding behavior would be the upcoding, or case-mix ''creep,'' that took place when the acute care hospital IPPS was implemented. (For further details, see ProPAC's March 1, 1994 Report and Recommendations to Congress (pp. 73–74).) Any change in case-mix that is not associated with the actual level of care or a true change in the level of care provided must be excluded in order to determine real case-mix.

4. Case-Mix Constant Real Output Intensity Per Discharge

Intensity is the true underlying nature of the product or service and can take the form of output or input intensity, or both. In the case of LTCHs, output intensity per discharge is associated with real payment per discharge, while input intensity per discharge is associated with real cost per discharge. For example, input intensity would be associated with a nurse's hours when providing treatment, whereas output intensity would be associated with the type and number of treatments a nurse provides. The underlying nature of LTCH services is determined by factors such as technological capabilities, increased utilization of inputs (such as labor or drugs), site of care, and practice patterns. Because these factors can be difficult to measure, intensity per discharge is usually calculated as a residual after the other factors from Equation 6 were accounted for.

Accounting for output intensity associated with an efficient LTCH can be more accurately analyzed using a LTCH's costs rather than its payments. This analysis would also provide an alternative to developing or using a transaction output price index. Equation 8 shows how to use the definition of an output price as defined earlier to convert the equation for output intensity per discharge to reflect costs instead of payments, as used in Equation 6.

EQUATION 8: Case-Mix-Constant Real Output Intensity per Discharge

$$= \frac{[\text{Payments} / \text{Discharge}]}{\text{Output Prices} * \text{Real Case Mix/Discharge}}$$

$$= \frac{[\text{Payments/Discharge}]}{\left(\frac{\text{Payments}}{\text{Costs}} * \frac{\text{Input Prices}}{\text{Productivity}}\right) * \text{Real Case Mix/Discharge}}$$

$$= \frac{[\text{Payments/Discharge}] * \text{Costs}}{\text{Payments} * \frac{\text{Input Prices}}{\text{Productivity}} * \text{Real Case Mix/Discharge}}$$

$$= \frac{\text{Payments} * [\text{Costs/Discharge}]}{\text{Payments} * \frac{\text{Input Prices}}{\text{Productivity}} * \text{Real Case Mix/Discharge}}$$

$$= \frac{[\text{Costs/Discharge}]}{\frac{\text{Input Prices}}{\text{Productivity}} * \text{Real Case Mix/Discharge}}$$

$$= \frac{[\text{Costs/Discharge}]}{\text{Input Prices} * \text{Real Case Mix/Discharge}} * \text{Productivity}$$

The last equation in Equation 8 is identical to the term in brackets in Equation 5, case-mix constant real input intensity per discharge multiplied by productivity. Thus, output intensity per discharge can be defined in such a way that cost data from the LTCH are utilized. This equation can be broken down even further to account for different types of input intensity per discharge. We discuss this matter more fully in section D.

D. Applying the Factors That Affect LTCH Costs Per Discharge in an Update Framework

As discussed earlier, payments per discharge under the LTCH PPS have been updated annually since the LTCH PPS was implemented for cost-reporting periods beginning on or after October 1, 2002. Under this proposed rule, the standard Federal rate from the previous year would be updated by a factor of zero percent based on our analysis of LTCH margins and case-mix using the best available data. The development of an update framework with a sound conceptual basis provides the capability to understand the underlying trends in LTCH costs per discharge for an efficient provider.

Previously we identified factors inherent in LTCH costs per discharge. Changes in these factors determine the change in LTCH costs per discharge and fitting these factors into an appropriate framework would allow us to accurately reflect changes in the underlying costs for efficient LTCHs. The following explanation accounts for each of these factors from Equation 6 under the LTCH PPS:

- Change in case-mix constant real output intensity per discharge would be accounted for in the update framework, reflecting the factors that affect not only case-mix constant real input intensity per discharge, but also productivity, which is determined separately. Factors that can cause changes in case-mix constant real input intensity per discharge include, but are not limited to, changes in site of service, changes in within-LTC–DRG case-mix, changes in practice patterns, changes in the use of inputs, and changes in technology available.
- Changes in nominal case-mix are automatically included in the payment to the LTCH. Therefore, the update framework should include an adjustment to convert changes in nominal case-mix per discharge to changes in real case-mix per discharge, if they are different.
- Change in multifactor productivity would be accounted for in the update framework. The availability of historical data

on input prices, payments, and costs are useful in the analysis of this factor.

• Changes in input prices for labor, material, and capital would be accounted for in the update framework using an input price index, or market basket. To assist in updating payments for LTCH services, OACT currently has developed an input price index; this is currently the excluded hospital with capital market basket, and we are proposing to use the RPL market basket as discussed in section IV.B. of the preamble of this proposed rule.

• In an update framework, a forecast error adjustment would be included to reflect that the updates are set prospectively and a forecast error for a given year should not be perpetuated in payments for future years. In the case of the acute care hospital IPPS, this prospective adjustment is made on a 2-year lag and only if the error exceeds a defined threshold (0.25 percentage points).

E. Illustrative LTCH Prospective Payment System Update Framework for the 2007 LTCH PPS Rate Year

Table 27 shows an illustrative update framework for the LTCH PPS for RY 2007. Some of the factors in the LTCH framework are computed using Medicare cost report data, while others are determined based on policy considerations. This is consistent with the factors in the capital IPPS and SNF PPS update frameworks. This design for a LTCH update framework is for illustrative purposes only, as much more work needs to be done to determine the appropriate level of detail for each factor.

MedPAC supported this for updating payments and applied a similar framework when it proposed updates to hospital payments in its annual Report to Congress (MedPAC, 2000). The appropriateness of this framework for updating hospital payments was also discussed in the article, ''Are PPS Payments Adequate? Issues for Updating and Assessing Rates'' (*Health Care Financing Review*, Winter 1992). We believe a similar framework would be useful for analyzing updates to LTCH payments.

If we applied this update framework to determine the LTCH PPS standard Federal rate for RY 2007, the update factor for RY 2007 would be −0.5 percent. This estimate is based on the best available data at this time. The estimated update factor is based on a projected 3.6 percent increase in the proposed RPL market basket, a 0.0 adjustment for intensity, a −0.9 percent adjustment for productivity, a −4.0 percent adjustment for case-mix, and a forecast error correction of 0.8 percent. The following is a description of the policy adjustments that have been applied under the illustrative LTCH PPS update framework for RY 2007.

The case-mix index is the measure of the average DRG weight for cases paid under the LTCH PPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons:

• The average resource use of Medicare patients changes (''real'' case-mix change);

• Changes in hospital coding of patient records result in higher weight DRG assignments (''apparent'' case-mix index).

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients as opposed to changes in coding behavior that result in assignment of cases to higher weighted DRGs but do not reflect higher resource requirements.

As discussed in section IV.C.3. of the preamble of this proposed rule, for RY 2007, we are estimating a 6.75 percent nominal increase in the case-mix index. We estimate that the real case-mix increase would equal 2.75 percent in RY 2007. The net adjustment for change in case-mix is the difference between the projected increase in real case-mix and the projected nominal increase in real case-mix. Therefore, the estimated adjustment for case-mix change would be −4.0 percentage points (2.75 percent minus 6.75 percent).

The framework also contains an adjustment for forecast error. The market basket forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increases in prices and the forecast used in calculating the update factors. There is a 2-year lag between the forecast and the measurement of the forecast error. A forecast error of 0.8 percentage points was calculated for the RY 2005 update. That is, current historical data indicate that the forecasted RY 2005 market basket (3.1 percent) understated the actual realized price increases (3.9 percent) by 0.8 percentage points. Therefore, a 0.8 percent adjustment would be appropriate to account for the forecast error under the illustrative LTCH PPS update framework for RY 2007.

Under this framework, we also make an adjustment for productivity, an efficiency measure. Productivity measures the ability of hospitals to reduce the quantity of inputs required to produce a unit of service while maintaining quality. MedPAC has recommended a productivity target based on the Bureau of Labor Statistics' estimate of the 10-year moving national average rate of productivity growth. The productivity target currently equals 0.9 percent. This target is lower than the productivity estimate calculated using the latest available LTCH cost report data. Therefore, under the illustrative LTCH PPS update framework for RY 2007, we would recommend a 0.9 percent adjustment for productivity.

We also make an adjustment for changes in intensity. The intensity factor reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in these types of factors, such as the use of quality-enhancing services, for changes in within-DRG severity, and for expected modification of practice patterns to remove non-cost effective services. Based on the latest available LTCH data, we calculated a negative intensity factor. As we have done in the past under the IPPS, when we have found that case-mix consistent intensity is declining, we believe that it would be appropriate to apply a zero intensity adjustment under the illustrative LTCH PPS update framework for RY 2007 (August 1, 2000, 65 FR 47119).

Table 27 illustrates what a possible LTCH PPS update framework would be if we proposed to determine the annual update to the LTCH PPS Federal rate based on a framework model such as this for RY 2007. This conceptual model of a LTCH PPS update framework is for illustrative purposes only. As we discuss in greater detail in section IV.C.3. of the preamble of this proposed rule, we are proposing a 0 percent update to the LTCH PPS standard Federal rate for RY 2007.

TABLE 27.—ILLUSTRATIVE LTCH PPS UPDATE FRAMEWORK FOR RY 2007

Factors	Percent change
Price (+):	
Proposed RPL Market Basket	3.6
Forecast Error	0.8
Productivity (−)	0.9
Output Intensity (+)	0.0
Input Intensity Productivity	0.9
Case-mix Creep Adjustment (+)	−4.0
Nominal Case-Mix	−6.75
Real Case-Mix	2.75
Other factors (+)	0.0
Total	−0.5

F. Additional Conceptual and Data Issues

Additional conceptual issues specific to the LTCH PPS include the relevance of a site-of-service substitution adjustment, the necessity of an adjustment for LTC–DRG reclassification, the handling of one-time factors, and consistency with other types of hospital updates since LTCHs are similar in structure to these other types of hospitals.

Under the acute care hospital IPPS, a site-of-service substitution factor (captured as part of intensity) was necessary because of the incentive to shift care from inpatient hospital to other settings such as hospital outpatient departments, SNFs, or HHAs. For the LTCH PPS, it is not clear without additional research whether there is an incentive to shift care either into or out of the LTCH because of the changes in behavior created by the different Medicare payment systems.

A reclassification and recalibration adjustment under the acute care hospital IPPS is necessary to account for changes in the case-mix or the types of patients treated by hospitals resulting from the annual reclassification and recalibration of the DRGs. This adjustment for case-mix is applied to the current FY update, but reflects the effect of revisions in the FY that is 2 years before that fiscal year. Whether a LTC–DRG reclassification adjustment would be necessary in the update framework would depend on the data availability and the likelihood of revisions to LTC–DRG classifications on a periodic basis.

There is also a question about how to handle one-time factors (an example of these could be the increased costs of converting computer systems to Year 2000 compliance). An update framework might be an appropriate mechanism to account for these items, but because of uncertainty surrounding their impact on costs, determining an appropriate adjustment amount may be difficult.

LTCHs are heterogeneous and are designated as a separate payment category only because their patients have longer average lengths of stay. This raises the question of whether certain factors in an update framework for LTCHs should be consistent with the factors in an update framework for other types of hospitals since they face similar cost pressures. Additional research in this area would need to be conducted to determine the reasonableness of having consistent updates.

The purpose of this conceptual discussion is not to determine how the identified factors of the update framework would be measured. We recognize that there are significant measurement issues in accurately determining the factors that would account for growth in costs per discharge for efficiently providing care. This is driven, in part, by the shift from a cost-based payment system with an upper payment limit to a PPS. Significant research and data collection would be necessary to accurately measure these factors over the historical period. One example of this would be to measure the distinction between real and nominal case-mix change. However, many of these same concerns were also encountered and successfully addressed in the hospital IPPS update framework.

The discussion here provides the conceptual basis for developing an update framework for the LTCH PPS that reflects changes in the underlying costs of efficiently providing services. It is important to note that the framework would not handle distribution issues such as geographic wage variations. Due to some variations in technical methodologies for measuring the factors of an update framework, and because of some of the data concerns mentioned earlier, implementing an update framework for the LTCH PPS would involve making significant policy decisions on issues similar to those made for the hospital IPPS update framework. We invite comments on the type of data sources to use, what other factors (if any) we should consider in an update framework, and any additional comments concerning the issues discussed in this proposed rule regarding the update framework.

The following addendum will not appear in the Code of Federal Regulations.

Addendum

This addendum contains the tables referred to throughout the preamble to this proposed rule. The tables presented below are as follows:

Table 1: Proposed Long-Term Care Hospital Wage Index for Urban Areas for Discharges Occurring from July 1, 2006 through June 30, 2007.

Table 2: Proposed Long-Term Care Hospital Wage Index for Rural Areas for Discharges Occurring from July 1, 2006 through June 30, 2007.

Table 3: FY 2006 LTC-DRG Relative Weights and Geometric Mean Length of Stay for Discharges Occurring from October 1, 2005 through September 30, 2006. (Note: This is the same information provided in Table 11 of the FY 2006 IPPS final rule (August 12, 2005; 70 FR 47681 through 47690), which has been reprinted here for convenience.)

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
10180	Abilene, TX.			
	Callahan County, TX.			
	Jones County, TX.			
	Taylor County, TX	0.8738	0.8317	0.7896
10380	Aguadilla-Isabela-San Sebastián, PR.			
	Aguada Municipio, PR.			
	Aguadilla Municipio, PR.			
	A±asco Municipio, PR.			
	Isabela Municipio, PR.			
	Lares Municipio, PR.			
	Moca Municipio, PR.			
	Rinón Municipio, PR.			
	San Sebastián Municipio, PR	0.6843	0.5790	0.4738
10420	Akron, OH.			
	Portage County, OH.			
	Summit County, OH	0.9389	0.9186	0.8982
10500	Albany, GA.			
	Baker County, GA.			
	Dougherty County, GA.			
	Lee County, GA.			
	Terrell County, GA.			
	Worth County, GA	0.9177	0.8902	0.8628
10580	Albany-Schenectady-Troy, NY.			
	Albany County, NY.			
	Rensselaer County, NY.			
	Saratoga County, NY.			
	Schenectady County, NY.			
	Schoharie County, NY	0.9153	0.8871	0.8589
10740	Albuquerque, NM.			
	Bernalillo County, NM.			
	Sandoval County, NM.			
	Torrance County, NM.			
	Valencia County, NM	0.9810	0.9747	0.9684
10780	Alexandria, LA.			
	Grant Parish, LA.			
	Rapides Parish, LA	0.8820	0.8426	0.8033
10900	Allentown-Bethlehem-Easton, PA-NJ.			
	Warren County, NJ.			
	Carbon County, PA.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Lehigh County, PA.			
	Northampton County, PA	0.9891	0.9854	0.9818
11020	Altoona, PA.			
	Blair County, PA	0.9366	0.9155	0.8944
11100	Amarillo, TX.			
	Armstrong County, TX.			
	Carson County, TX.			
	Potter County, TX.			
	Randall County, TX	0.9494	0.9325	0.9156
11180	Ames, IA.			
	Story County, IA	0.9722	0.9629	0.9536
11260	Anchorage, AK.			
	Anchorage Municipality, AK.			
	Matanuska-Susitna Borough, AK	1.1137	1.1516	1.1895
11300	Anderson, IN.			
	Madison County, IN	0.9152	0.8869	0.8586
11340	Anderson, SC.			
	Anderson County, SC	0.9398	0.9198	0.8997
11460	Ann Arbor, MI.			
	Washtenaw County, MI	1.0515	1.0687	1.0859
11500	Anniston-Oxford, AL.			
	Calhoun County, AL	0.8609	0.8146	0.7682
11540	Appleton, WI.			
	Calumet County, WI.			
	Outagamie County, WI	0.9573	0.9430	0.9288
11700	Asheville, NC.			
	Buncombe County, NC.			
	Haywood County, NC.			
	Henderson County, NC.			
	Madison County, NC	0.9571	0.9428	0.9285
12020	Athens-Clarke County, GA.			
	Clarke County, GA.			
	Madison County, GA.			
	Oconee County, GA.			
	Oglethorpe County, GA	0.9913	0.9884	0.9855
12060	Atlanta-Sandy Springs-Marietta, GA.			
	Barrow County, GA.			
	Bartow County, GA.			
	Butts County, GA.			
	Carroll County, GA.			
	Cherokee County, GA.			
	Clayton County, GA.			
	Cobb County, GA.			
	Coweta County, GA.			
	Dawson County, GA.			
	DeKalb County, GA.			
	Douglas County, GA.			
	Fayette County, GA.			
	Forsyth County, GA.			
	Fulton County, GA.			
	Gwinnett County, GA.			
	Haralson County, GA.			
	Heard County, GA.			
	Henry County, GA.			
	Jasper County, GA.			
	Lamar County, GA.			
	Meriwether County, GA.			
	Newton County, GA.			
	Paulding County, GA.			
	Pickens County, GA.			
	Pike County, GA.			
	Rockdale County, GA.			
	Spalding County, GA.			
	Walton County, GA	0.9876	0.9834	0.9793
12100	Atlantic City, NJ.			
	Atlantic County, NJ	1.0969	1.1292	1.1615
12220	Auburn-Opelika, AL.			
	Lee County, AL	0.8860	0.8480	0.8100
12260	Augusta-Richmond County, GA-SC.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Burke County, GA.			
	Columbia County, GA.			
	McDuffie County, GA.			
	Richmond County, GA.			
	Aiken County, SC.			
	Edgefield County, SC	0.9849	0.9798	0.9748
12420	Austin-Round Rock, TX.			
	Bastrop County, TX.			
	Caldwell County, TX.			
	Hays County, TX.			
	Travis County, TX.			
	Williamson County, TX	0.9662	0.9550	0.9437
12540	Bakersfield, CA.			
	Kern County, CA	1.0282	1.0376	1.0470
12580	Baltimore-Towson, MD.			
	Anne Arundel County, MD.			
	Baltimore County, MD.			
	Carroll County, MD.			
	Harford County, MD.			
	Howard County, MD.			
	Queen Anne's County, MD.			
	Baltimore City, MD	0.9938	0.9918	0.9897
12620	Bangor, ME.			
	Penobscot County, ME	0.9996	0.9994	0.9993
12700	Barnstable Town, MA.			
	Barnstable County, MA	1.1560	1.2080	1.2600
12940	Baton Rouge, LA.			
	Ascension Parish, LA.			
	East Baton Rouge Parish, LA.			
	East Feliciana Parish, LA.			
	Iberville Parish, LA.			
	Livingston Parish, LA.			
	Pointe Coupee Parish, LA.			
	St. Helena Parish, LA.			
	West Baton Rouge Parish, LA.			
	West Feliciana Parish, LA	0.9156	0.8874	0.8593
12980	Battle Creek, MI.			
	Calhoun County, MI	0.9705	0.9606	0.9508
13020	Bay City, MI.			
	Bay County, MI	0.9606	0.9474	0.9343
13140	Beaumont-Port Arthur, TX.			
	Hardin County, TX.			
	Jefferson County, TX.			
	Orange County, TX	0.9047	0.8730	0.8412
13380	Bellingham, WA.			
	Whatcom County, WA	1.1039	1.1385	1.1731
13460	Bend, OR.			
	Deschutes County, OR	1.0472	1.0629	1.0786
13644	Bethesda-Gaithersburg-Frederick, MD.			
	Frederick County, MD.			
	Montgomery County, MD	1.0890	1.1186	1.1483
13740	Billings, MT.			
	Carbon County, MT.			
	Yellowstone County, MT	0.9300	0.9067	0.8834
13780	Binghamton, NY.			
	Broome County, NY.			
	Tioga County, NY	0.9137	0.8850	0.8562
13820	Birmingham-Hoover, AL.			
	Bibb County, AL.			
	Blount County, AL.			
	Chilton County, AL.			
	Jefferson County, AL.			
	St. Clair County, AL.			
	Shelby County, AL.			
	Walker County, AL	0.9375	0.9167	0.8959
13900	Bismarck, ND.			
	Burleigh County, ND.			
	Morton County, ND	0.8544	0.8059	0.7574
13980	Blacksburg-Christiansburg-Radford, VA.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Giles County, VA.			
	Montgomery County, VA.			
	Pulaski County, VA.			
	Radford City, VA	0.8772	0.8363	0.7954
14020	Bloomington, IN.			
	Greene County, IN.			
	Monroe County, IN.			
	Owen County, IN	0.9068	0.8758	0.8447
14060	Bloomington-Normal, IL.			
	McLean County, IL	0.9445	0.9260	0.9075
14260	Boise City-Nampa, ID.			
	Ada County, ID.			
	Boise County, ID.			
	Canyon County, ID.			
	Gem County, ID.			
	Owyhee County, ID	0.9431	0.9242	0.9052
14484	Boston-Quincy, MA.			
	Norfolk County, MA.			
	Plymouth County, MA.			
	Suffolk County, MA	1.0935	1.1246	1.1558
14500	Boulder, CO.			
	Boulder County, CO	0.9840	0.9787	0.9734
14540	Bowling Green, KY.			
	Edmonson County, KY.			
	Warren County, KY	0.8927	0.8569	0.8211
14740	Bremerton-Silverdale, WA.			
	Kitsap County, WA	1.0405	1.0540	1.0675
14860	Bridgeport-Stamford-Norwalk, CT.			
	Fairfield County, CT	1.1555	1.2074	1.2592
15180	Brownsville-Harlingen, TX.			
	Cameron County, TX	0.9882	0.9843	0.9804
15260	Brunswick, GA.			
	Brantley County, GA.			
	Glynn County, GA.			
	McIntosh County, GA	0.9587	0.9449	0.9311
15380	Buffalo-Niagara Falls, NY.			
	Erie County, NY.			
	Niagara County, NY	0.9707	0.9609	0.9511
15500	Burlington, NC.			
	Alamance County, NC	0.9343	0.9124	0.8905
15540	Burlington-South Burlington, VT.			
	Chittenden County, VT.			
	Franklin County, VT.			
	Grand Isle County, VT	0.9646	0.9528	0.9410
15764	Cambridge-Newton-Framingham, MA.			
	Middlesex County, MA	1.0703	1.0938	1.1172
15804	Camden, NJ.			
	Burlington County, NJ.			
	Camden County, NJ.			
	Gloucester County, NJ	1.0310	1.0414	1.0517
15940	Canton-Massillon, OH.			
	Carroll County, OH.			
	Stark County, OH	0.9361	0.9148	0.8935
15980	Cape Coral-Fort Myers, FL.			
	Lee County, FL	0.9614	0.9485	0.9356
16180	Carson City, NV.			
	Carson City, NV	1.0140	1.0187	1.0234
16220	Casper, WY.			
	Natrona County, WY	0.9416	0.9221	0.9026
16300	Cedar Rapids, IA.			
	Benton County, IA.			
	Jones County, IA.			
	Linn County, IA	0.9295	0.9060	0.8825
16580	Champaign-Urbana, IL.			
	Champaign County, IL.			
	Ford County, IL.			
	Piatt County, IL	0.9756	0.9675	0.9594
16620	Charleston, WV.			
	Boone County, WV.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Clay County, WV.			
	Kanawha County, WV.			
	Lincoln County, WV.			
	Putnam County, WV	0.9067	0.8756	0.8445
16700	Charleston-North Charleston, SC.			
	Berkeley County, SC.			
	Charleston County, SC.			
	Dorchester County, SC	0.9547	0.9396	0.9245
16740	Charlotte-Gastonia-Concord, NC-SC.			
	Anson County, NC.			
	Cabarrus County, NC.			
	Gaston County, NC.			
	Mecklenburg County, NC.			
	Union County, NC.			
	York County, SC	0.9850	0.9800	0.9750
16820	Charlottesville, VA.			
	Albemarle County, VA.			
	Fluvanna County, VA.			
	Greene County, VA.			
	Nelson County, VA.			
	Charlottesville City, VA	1.0112	1.0150	1.0187
16860	Chattanooga, TN-GA.			
	Catoosa County, GA.			
	Dade County, GA.			
	Walker County, GA.			
	Hamilton County, TN.			
	Marion County, TN.			
	Sequatchie County, TN	0.9453	0.9270	0.9088
16940	Cheyenne, WY.			
	Laramie County, WY	0.9265	0.9020	0.8775
16974	Chicago-Naperville-Joliet, IL.			
	Cook County, IL.			
	DeKalb County, IL.			
	DuPage County, IL.			
	Grundy County, IL.			
	Kane County, IL.			
	Kendall County, IL.			
	McHenry County, IL.			
	Will County, IL	1.0474	1.0632	1.0790
17020	Chico, CA.			
	Butte County, CA	1.0307	1.0409	1.0511
17140	Cincinnati-Middletown, OH-KY-IN.			
	Dearborn County, IN.			
	Franklin County, IN.			
	Ohio County, IN.			
	Boone County, KY.			
	Bracken County, KY.			
	Campbell County, KY.			
	Gallatin County, KY.			
	Grant County, KY.			
	Kenton County, KY.			
	Pendleton County, KY.			
	Brown County, OH.			
	Butler County, OH.			
	Clermont County, OH.			
	Hamilton County, OH.			
	Warren County, OH	0.9769	0.9692	0.9615
17300	Clarksville, TN-KY.			
	Christian County, KY.			
	Trigg County, KY.			
	Montgomery County, TN.			
	Stewart County, TN	0.8970	0.8627	0.8284
17420	Cleveland, TN.			
	Bradley County, TN.			
	Polk County, TN	0.8883	0.8511	0.8139
17460	Cleveland-Elyria-Mentor, OH.			
	Cuyahoga County, OH.			
	Geauga County, OH.			
	Lake County, OH.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Lorain County, OH.			
	Medina County, OH	0.9528	0.9370	0.9213
17660	Coeur d'Alene, ID.			
	Kootenai County, ID	0.9788	0.9718	0.9647
17780	College Station-Bryan, TX.			
	Brazos County, TX.			
	Burleson County, TX.			
	Robertson County, TX	0.9340	0.9120	0.8900
17820	Colorado Springs, CO.			
	El Paso County, CO.			
	Teller County, CO	0.9681	0.9574	0.9468
17860	Columbia, MO.			
	Boone County, MO.			
	Howard County, MO	0.9007	0.8676	0.8345
17900	Columbia, SC.			
	Calhoun County, SC.			
	Fairfield County, SC.			
	Kershaw County, SC.			
	Lexington County, SC.			
	Richland County, SC.			
	Saluda County, SC	0.9434	0.9246	0.9057
17980	Columbus, GA-AL.			
	Russell County, AL.			
	Chattahoochee County, GA.			
	Harris County, GA.			
	Marion County, GA.			
	Muscogee County, GA	0.9136	0.8848	0.8560
18020	Columbus, IN.			
	Bartholomew County, IN	0.9753	0.9670	0.9588
18140	Columbus, OH.			
	Delaware County, OH.			
	Fairfield County, OH.			
	Franklin County, OH.			
	Licking County, OH.			
	Madison County, OH.			
	Morrow County, OH.			
	Pickaway County, OH.			
	Union County, OH	0.9916	0.9888	0.9860
18580	Corpus Christi, TX.			
	Aransas County, TX.			
	Nueces County, TX.			
	San Patricio County, TX	0.9130	0.8840	0.8550
18700	Corvallis, OR.			
	Benton County, OR	1.0437	1.0583	1.0729
19060	Cumberland, MD-WV.			
	Allegany County, MD.			
	Mineral County, WV	0.9590	0.9454	0.9317
19124	Dallas-Plano-Irving, TX.			
	Collin County, TX.			
	Dallas County, TX.			
	Delta County, TX.			
	Denton County, TX.			
	Ellis County, TX.			
	Hunt County, TX.			
	Kaufman County, TX.			
	Rockwall County, TX	1.0137	1.0182	1.0228
19140	Dalton, GA.			
	Murray County, GA.			
	Whitfield County, GA	0.9447	0.9263	0.9079
19180	Danville, IL.			
	Vermilion County, IL	0.9417	0.9222	0.9028
19260	Danville, VA.			
	Pittsylvania County, VA.			
	Danville City, VA	0.9093	0.8791	0.8489
19340	Davenport-Moline-Rock Island, IA-IL.			
	Henry County, IL.			
	Mercer County, IL.			
	Rock Island County, IL.			
	Scott County, IA	0.9234	0.8979	0.8724

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
19380	Dayton, OH.			
	Greene County, OH.			
	Miami County, OH.			
	Montgomery County, OH.			
	Preble County, OH	0.9438	0.9251	0.9064
19460	Decatur, AL.			
	Lawrence County, AL.			
	Morgan County, AL	0.9081	0.8775	0.8469
19500	Decatur, IL.			
	Macon County, IL	0.8840	0.8454	0.8067
19660	Deltona-Daytona Beach-Ormond Beach, FL.			
	Volusia County, FL	0.9579	0.9439	0.9299
19740	Denver-Aurora, CO.			
	Adams County, CO.			
	Arapahoe County, CO.			
	Broomfield County, CO.			
	Clear Creek County, CO.			
	Denver County, CO.			
	Douglas County, CO.			
	Elbert County, CO.			
	Gilpin County, CO.			
	Jefferson County, CO.			
	Park County, CO	1.0434	1.0578	1.0723
19780	Des Moines-West Des Moines, IA.			
	Dallas County, IA.			
	Guthrie County, IA.			
	Madison County, IA.			
	Polk County, IA.			
	Warren County, IA	0.9801	0.9735	0.9669
19804	Detroit-Livonia-Dearborn, MI.			
	Wayne County, MI	1.0254	1.0339	1.0424
20020	Dothan, AL.			
	Geneva County, AL.			
	Henry County, AL.			
	Houston County, AL	0.8633	0.8177	0.7721
20100	Dover, DE.			
	Kent County, DE	0.9866	0.9821	0.9776
20220	Dubuque, IA.			
	Dubuque County, IA	0.9414	0.9219	0.9024
20260	Duluth, MN-WI.			
	Carlton County, MN.			
	St. Louis County, MN.			
	Douglas County, WI	1.0128	1.0170	1.0213
20500	Durham, NC.			
	Chatham County, NC.			
	Durham County, NC.			
	Orange County, NC.			
	Person County, NC	1.0146	1.0195	1.0244
20740	Eau Claire, WI.			
	Chippewa County, WI.			
	Eau Claire County, WI	0.9521	0.9361	0.9201
20764	Edison, NJ.			
	Middlesex County, NJ.			
	Monmouth County, NJ.			
	Ocean County, NJ.			
	Somerset County, NJ	1.0749	1.0999	1.1249
20940	El Centro, CA.			
	Imperial County, CA	0.9344	0.9125	0.8906
21060	Elizabethtown, KY.			
	Hardin County, KY.			
	Larue County, KY	0.9281	0.9042	0.8802
21140	Elkhart-Goshen, IN.			
	Elkhart County, IN	0.9776	0.9702	0.9627
21300	Elmira, NY.			
	Chemung County, NY	0.8950	0.8600	0.8250
21340	El Paso, TX.			
	El Paso County, TX	0.9386	0.9182	0.8977
21500	Erie, PA.			
	Erie County, PA	0.9242	0.8990	0.8737

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
21604	Essex County, MA.			
	Essex County, MA	1.0323	1.0430	1.0538
21660	Eugene-Springfield, OR.			
	Lane County, OR	1.0491	1.0654	1.0818
21780	Evansville, IN-KY.			
	Gibson County, IN.			
	Posey County, IN.			
	Vanderburgh County, IN.			
	Warrick County, IN.			
	Henderson County, KY.			
	Webster County, KY	0.9228	0.8970	0.8713
21820	Fairbanks, AK.			
	Fairbanks North Star Borough, AK	1.0845	1.1126	1.1408
21940	Fajardo, PR.			
	Ceiba Municipio, PR.			
	Fajardo Municipio, PR.			
	Luquillo Municipio, PR	0.6492	0.5322	0.4153
22020	Fargo, ND-MN.			
	Cass County, ND.			
	Clay County, MN	0.9092	0.8789	0.8486
22140	Farmington, NM.			
	San Juan County, NM	0.9105	0.8807	0.8509
22180	Fayetteville, NC.			
	Cumberland County, NC.			
	Hoke County, NC	0.9650	0.9533	0.9416
22220	Fayetteville-Springdale-Rogers, AR-MO.			
	Benton County, AR.			
	Madison County, AR.			
	Washington County, AR.			
	McDonald County, MO	0.9197	0.8929	0.8661
22380	Flagstaff, AZ.			
	Coconino County, AZ	1.1255	1.1674	1.2092
22420	Flint, MI.			
	Genesee County, MI	1.0393	1.0524	1.0655
22500	Florence, SC.			
	Darlington County, SC.			
	Florence County, SC	0.9368	0.9158	0.8947
22520	Florence-Muscle Shoals, AL.			
	Colbert County, AL.			
	Lauderdale County, AL	0.8963	0.8618	0.8272
22540	Fond du Lac, WI.			
	Fond du Lac County, WI	0.9784	0.9712	0.9640
22660	Fort Collins-Loveland, CO.			
	Larimer County, CO	1.0073	1.0098	1.0122
22744	Fort Lauderdale-Pompano Beach-Deerfield Beach, FL.			
	Broward County, FL	1.0259	1.0346	1.0432
22900	Fort Smith, AR-OK.			
	Crawford County, AR.			
	Franklin County, AR.			
	Sebastian County, AR.			
	Le Flore County, OK.			
	Sequoyah County, OK	0.8938	0.8584	0.8230
23020	Fort Walton Beach-Crestview-Destin, FL.			
	Okaloosa County, FL	0.9323	0.9098	0.8872
23060	Fort Wayne, IN.			
	Allen County, IN.			
	Wells County, IN.			
	Whitley County, IN	0.9876	0.9834	0.9793
23104	Fort Worth-Arlington, TX.			
	Johnson County, TX.			
	Parker County, TX.			
	Tarrant County, TX.			
	Wise County, TX	0.9692	0.9589	0.9486
23420	Fresno, CA.			
	Fresno County, CA	1.0323	1.0430	1.0538
23460	Gadsden, AL.			
	Etowah County, AL	0.8763	0.8350	0.7938
23540	Gainesville, FL.			
	Alachua County, FL.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Gilchrist County, FL	0.9633	0.9510	0.9388
23580	Gainesville, GA.			
	Hall County, GA	0.9324	0.9099	0.8874
23844	Gary, IN.			
	Jasper County, IN.			
	Lake County, IN.			
	Newton County, IN.			
	Porter County, IN	0.9637	0.9516	0.9395
24020	Glens Falls, NY.			
	Warren County, NY.			
	Washington County, NY	0.9135	0.8847	0.8559
24140	Goldsboro, NC.			
	Wayne County, NC	0.9265	0.9020	0.8775
24220	Grand Forks, ND-MN.			
	Polk County, MN.			
	Grand Forks County, ND	0.8741	0.8321	0.7901
24300	Grand Junction, CO.			
	Mesa County, CO	0.9730	0.9640	0.9550
24340	Grand Rapids-Wyoming, MI.			
	Barry County, MI.			
	Ionia County, MI.			
	Kent County, MI.			
	Newaygo County, MI	0.9634	0.9512	0.9390
24500	Great Falls, MT.			
	Cascade County, MT	0.9431	0.9242	0.9052
24540	Greeley, CO.			
	Weld County, CO	0.9742	0.9656	0.9570
24580	Green Bay, WI.			
	Brown County, WI.			
	Kewaunee County, WI.			
	Oconto County, WI	0.9690	0.9586	0.9483
24660	Greensboro-High Point, NC.			
	Guilford County, NC.			
	Randolph County, NC.			
	Rockingham County, NC	0.9462	0.9283	0.9104
24780	Greenville, NC.			
	Greene County, NC.			
	Pitt County, NC	0.9655	0.9540	0.9425
24860	Greenville, SC.			
	Greenville County, SC.			
	Laurens County, SC.			
	Pickens County, SC	1.0016	1.0022	1.0027
25020	Guayama, PR.			
	Arroyo Municipio, PR.			
	Guayama Municipio, PR.			
	Patillas Municipio, PR	0.5909	0.4545	0.3181
25060	Gulfport-Biloxi, MS.			
	Hancock County, MS.			
	Harrison County, MS.			
	Stone County, MS	0.9357	0.9143	0.8929
25180	Hagerstown-Martinsburg, MD-WV.			
	Washington County, MD.			
	Berkeley County, WV.			
	Morgan County, WV	0.9693	0.9591	0.9489
25260	Hanford-Corcoran, CA.			
	Kings County, CA	1.0022	1.0029	1.0036
25420	Harrisburg-Carlisle, PA.			
	Cumberland County, PA.			
	Dauphin County, PA.			
	Perry County, PA	0.9588	0.9450	0.9313
25500	Harrisonburg, VA.			
	Rockingham County, VA.			
	Harrisonburg City, VA	0.9453	0.9270	0.9088
25540	Hartford-West Hartford-East Hartford, CT.			
	Hartford County, CT.			
	Litchfield County, CT.			
	Middlesex County, CT.			
	Tolland County, CT	1.0644	1.0858	1.1073
25620	Hattiesburg, MS.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Forrest County, MS.			
	Lamar County, MS.			
	Perry County, MS	0.8561	0.8081	0.7601
25860	Hickory-Lenoir-Morganton, NC.			
	Alexander County, NC.			
	Burke County, NC.			
	Caldwell County, NC.			
	Catawba County, NC	0.9353	0.9137	0.8921
25980	Hinesville-Fort Stewart, GA.			
	Liberty County, GA.			
	Long County, GA	0.8597	0.8130	0.7662
26100	Holland-Grand Haven, MI.			
	Ottawa County, MI	0.9433	0.9244	0.9055
26180	Honolulu, HI.			
	Honolulu County, HI	1.0728	1.0971	1.1214
26300	Hot Springs, AR.			
	Garland County, AR	0.9403	0.9204	0.9005
26380	Houma-Bayou Cane-Thibodaux, LA.			
	Lafourche Parish, LA.			
	Terrebonne Parish, LA	0.8736	0.8315	0.7894
26420	Houston-Sugar Land-Baytown, TX.			
	Austin County, TX.			
	Brazoria County, TX.			
	Chambers County, TX.			
	Fort Bend County, TX.			
	Galveston County, TX.			
	Harris County, TX.			
	Liberty County, TX.			
	Montgomery County, TX.			
	San Jacinto County, TX.			
	Waller County, TX	0.9998	0.9997	0.9996
26580	Huntington-Ashland, WV-KY-OH.			
	Boyd County, KY.			
	Greenup County, KY.			
	Lawrence County, OH.			
	Cabell County, WV.			
	Wayne County, WV	0.9686	0.9582	0.9477
26620	Huntsville, AL.			
	Limestone County, AL.			
	Madison County, AL	0.9488	0.9317	0.9146
26820	Idaho Falls, ID.			
	Bonneville County, ID.			
	Jefferson County, ID	0.9652	0.9536	0.9420
26900	Indianapolis-Carmel, IN.			
	Boone County, IN.			
	Brown County, IN.			
	Hamilton County, IN.			
	Hancock County, IN.			
	Hendricks County, IN.			
	Johnson County, IN.			
	Marion County, IN.			
	Morgan County, IN.			
	Putnam County, IN.			
	Shelby County, IN	0.9952	0.9936	0.9920
26980	Iowa City, IA.			
	Johnson County, IA.			
	Washington County, IA	0.9848	0.9798	0.9747
27060	Ithaca, NY.			
	Tompkins County, NY	0.9876	0.9834	0.9793
27100	Jackson, MI.			
	Jackson County, MI	0.9582	0.9443	0.9304
27140	Jackson, MS.			
	Copiah County, MS.			
	Hinds County, MS.			
	Madison County, MS.			
	Rankin County, MS.			
	Simpson County, MS	0.8987	0.8649	0.8311
27180	Jackson, TN.			
	Chester County, TN.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Madison County, TN	0.9378	0.9171	0.8964
27260	Jacksonville, FL.			
	Baker County, FL.			
	Clay County, FL.			
	Duval County, FL.			
	Nassau County, FL.			
	St. Johns County, FL	0.9574	0.9432	0.9290
27340	Jacksonville, NC.			
	Onslow County, NC	0.8942	0.8589	0.8236
27500	Janesville, WI.			
	Rock County, WI	0.9723	0.9630	0.9538
27620	Jefferson City, MO.			
	Callaway County, MO.			
	Cole County, MO.			
	Moniteau County, MO.			
	Osage County, MO	0.9032	0.8710	0.8387
27740	Johnson City, TN.			
	Carter County, TN.			
	Unicoi County, TN.			
	Washington County, TN	0.8762	0.8350	0.7937
27780	Johnstown, PA.			
	Cambria County, PA	0.9012	0.8683	0.8354
27860	Jonesboro, AR.			
	Craighead County, AR.			
	Poinsett County, AR	0.8747	0.8329	0.7911
27900	Joplin, MO.			
	Jasper County, MO.			
	Newton County, MO	0.9149	0.8866	0.8582
28020	Kalamazoo-Portage, MI.			
	Kalamazoo County, MI.			
	Van Buren County, MI	1.0229	1.0305	1.0381
28100	Kankakee-Bradley, IL.			
	Kankakee County, IL	1.0433	1.0577	1.0721
28140	Kansas City, MO-KS.			
	Franklin County, KS.			
	Johnson County, KS.			
	Leavenworth County, KS.			
	Linn County, KS.			
	Miami County, KS.			
	Wyandotte County, KS.			
	Bates County, MO.			
	Caldwell County, MO.			
	Cass County, MO.			
	Clay County, MO.			
	Clinton County, MO.			
	Jackson County, MO.			
	Lafayette County, MO.			
	Platte County, MO.			
	Ray County, MO	0.9686	0.9581	0.9476
28420	Kennewick-Richland-Pasco, WA.			
	Benton County, WA.			
	Franklin County, WA	1.0371	1.0495	1.0619
28660	Killeen-Temple-Fort Hood, TX.			
	Bell County, TX.			
	Coryell County, TX.			
	Lampasas County, TX	0.9116	0.8821	0.8526
28700	Kingsport-Bristol-Bristol, TN-VA.			
	Hawkins County, TN.			
	Sullivan County, TN.			
	Bristol City, VA.			
	Scott County, VA.			
	Washington County, VA	0.8832	0.8443	0.8054
28740	Kingston, NY.			
	Ulster County, NY	0.9553	0.9404	0.9255
28940	Knoxville, TN.			
	Anderson County, TN.			
	Blount County, TN.			
	Knox County, TN.			
	Loudon County, TN.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Union County, TN	0.9065	0.8753	0.8441
29020	Kokomo, IN.			
	Howard County, IN.			
	Tipton County, IN	0.9705	0.9606	0.9508
29100	La Crosse, WI-MN.			
	Houston County, MN.			
	La Crosse County, WI	0.9738	0.9651	0.9564
29140	Lafayette, IN.			
	Benton County, IN.			
	Carroll County, IN.			
	Tippecanoe County, IN	0.9242	0.8989	0.8736
29180	Lafayette, LA.			
	Lafayette Parish, LA.			
	St. Martin Parish, LA	0.9057	0.8742	0.8428
29340	Lake Charles, LA.			
	Calcasieu Parish, LA.			
	Cameron Parish, LA	0.8700	0.8266	0.7833
29404	Lake County-Kenosha County, IL-WI.			
	Lake County, IL.			
	Kenosha County, WI	1.0257	1.0343	1.0429
29460	Lakeland, FL.			
	Polk County, FL	0.9347	0.9130	0.8912
29540	Lancaster, PA.			
	Lancaster County, PA	0.9816	0.9755	0.9694
29620	Lansing-East Lansing, MI.			
	Clinton County, MI.			
	Eaton County, MI.			
	Ingham County, MI	0.9876	0.9835	0.9794
29700	Laredo, TX.			
	Webb County, TX	0.8841	0.8454	0.8068
29740	Las Cruces, NM.			
	Dona Ana County, NM	0.9080	0.8774	0.8467
29820	Las Vegas-Paradise, NV.			
	Clark County, NV	1.0862	1.1150	1.1437
29940	Lawrence, KS.			
	Douglas County, KS	0.9122	0.8830	0.8537
30020	Lawton, OK.			
	Comanche County, OK	0.8723	0.8298	0.7872
30140	Lebanon, PA.			
	Lebanon County, PA	0.9075	0.8767	0.8459
30300	Lewiston, ID-WA.			
	Nez Perce County, ID.			
	Asotin County, WA	0.9932	0.9909	0.9886
30340	Lewiston-Auburn, ME.			
	Androscoggin County, ME	0.9599	0.9465	0.9331
30460	Lexington-Fayette, KY.			
	Bourbon County, KY.			
	Clark County, KY.			
	Fayette County, KY.			
	Jessamine County, KY.			
	Scott County, KY.			
	Woodford County, KY	0.9445	0.9260	0.9075
30620	Lima, OH.			
	Allen County, OH	0.9535	0.9380	0.9225
30700	Lincoln, NE.			
	Lancaster County, NE.			
	Seward County, NE	1.0128	1.0171	1.0214
30780	Little Rock-North Little Rock, AR.			
	Faulkner County, AR.			
	Grant County, AR.			
	Lonoke County, AR.			
	Perry County, AR.			
	Pulaski County, AR.			
	Saline County, AR	0.9248	0.8998	0.8747
30860	Logan, UT-ID.			
	Franklin County, ID.			
	Cache County, UT	0.9498	0.9331	0.9164
30980	Longview, TX.			
	Gregg County, TX.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Rusk County, TX.			
	Upshur County, TX	0.9238	0.8984	0.8730
31020	Longview, WA.			
	Cowlitz County, WA	0.9747	0.9663	0.9579
31084	Los Angeles-Long Beach-Glendale, CA.			
	Los Angeles County, CA	1.1070	1.1426	1.1783
31140	Louisville-Jefferson County, KY-IN.			
	Clark County, IN.			
	Floyd County, IN.			
	Harrison County, IN.			
	Washington County, IN.			
	Bullitt County, KY.			
	Henry County, KY.			
	Jefferson County, KY.			
	Meade County, KY.			
	Nelson County, KY.			
	Oldham County, KY.			
	Shelby County, KY.			
	Spencer County, KY.			
	Trimble County, KY	0.9551	0.9401	0.9251
31180	Lubbock, TX.			
	Crosby County, TX.			
	Lubbock County, TX	0.9270	0.9026	0.8783
31340	Lynchburg, VA.			
	Amherst County, VA.			
	Appomattox County, VA.			
	Bedford County, VA.			
	Campbell County, VA.			
	Bedford City, VA.			
	Lynchburg City, VA	0.9215	0.8953	0.8691
31420	Macon, GA.			
	Bibb County, GA.			
	Crawford County, GA.			
	Jones County, GA.			
	Monroe County, GA.			
	Twiggs County, GA	0.9666	0.9554	0.9443
31460	Madera, CA.			
	Madera County, CA	0.9228	0.8970	0.8713
31540	Madison, WI.			
	Columbia County, WI.			
	Dane County, WI.			
	Iowa County, WI	1.0395	1.0527	1.0659
31700	Manchester-Nashua, NH.			
	Hillsborough County, NH.			
	Merrimack County, NH	1.0212	1.0283	1.0354
31900	Mansfield, OH.			
	Richland County, OH	0.9935	0.9913	0.9891
32420	Mayagüez, PR.			
	Hormigueros Municipio, PR.			
	Mayagüez Municipio, PR	0.6412	0.5216	0.4020
32580	McAllen-Edinburg-Mission, TX.			
	Hidalgo County, TX	0.9360	0.9147	0.8934
32780	Medford, OR.			
	Jackson County, OR	1.0135	1.0180	1.0225
32820	Memphis, TN-MS-AR.			
	Crittenden County, AR.			
	DeSoto County, MS.			
	Marshall County, MS.			
	Tate County, MS.			
	Tunica County, MS.			
	Fayette County, TN.			
	Shelby County, TN.			
	Tipton County, TN	0.9638	0.9518	0.9397
32900	Merced, CA.			
	Merced County, CA	1.0665	1.0887	1.1109
33124	Miami-Miami Beach-Kendall, FL.			
	Miami-Dade County, FL	0.9850	0.9800	0.9750
33140	Michigan City-La Porte, IN.			
	LaPorte County, IN	0.9639	0.9519	0.9399

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
33260	Midland, TX.			
	Midland County, TX	0.9708	0.9611	0.9514
33340	Milwaukee-Waukesha-West Allis, WI.			
	Milwaukee County, WI.			
	Ozaukee County, WI.			
	Washington County, WI.			
	Waukesha County, WI	1.0088	1.0117	1.0146
33460	Minneapolis-St. Paul-Bloomington, MN-WI.			
	Anoka County, MN.			
	Carver County, MN.			
	Chisago County, MN.			
	Dakota County, MN.			
	Hennepin County, MN.			
	Isanti County, MN.			
	Ramsey County, MN.			
	Scott County, MN.			
	Sherburne County, MN.			
	Washington County, MN.			
	Wright County, MN.			
	Pierce County, WI.			
	St. Croix County, WI	1.0645	1.0860	1.1075
33540	Missoula, MT.			
	Missoula County, MT	0.9684	0.9578	0.9473
33660	Mobile, AL.			
	Mobile County, AL	0.8735	0.8313	0.7891
33700	Modesto, CA.			
	Stanislaus County, CA	1.1131	1.1508	1.1885
33740	Monroe, LA.			
	Ouachita Parish, LA.			
	Union Parish, LA	0.8819	0.8425	0.8031
33780	Monroe, MI.			
	Monroe County, MI	0.9681	0.9574	0.9468
33860	Montgomery, AL.			
	Autauga County, AL.			
	Elmore County, AL.			
	Lowndes County, AL.			
	Montgomery County, AL	0.9171	0.8894	0.8618
34060	Morgantown, WV.			
	Monongalia County, WV.			
	Preston County, WV	0.9052	0.8736	0.8420
34100	Morristown, TN.			
	Grainger County, TN.			
	Hamblen County, TN.			
	Jefferson County, TN	0.8777	0.8369	0.7961
34580	Mount Vernon-Anacortes, WA.			
	Skagit County, WA	1.0272	1.0363	1.0454
34620	Muncie, IN.			
	Delaware County, IN	0.9358	0.9144	0.8930
34740	Muskegon-Norton Shores, MI.			
	Muskegon County, MI	0.9798	0.9731	0.9664
34820	Myrtle Beach-Conway-North Myrtle Beach, SC.			
	Horry County, SC	0.9360	0.9147	0.8934
34900	Napa, CA.			
	Napa County, CA	1.1586	1.2114	1.2643
34940	Naples-Marco Island, FL.			
	Collier County, FL	1.0083	1.0111	1.0139
34980	Nashville-Davidson—Murfreesboro, TN.			
	Cannon County, TN.			
	Cheatham County, TN.			
	Davidson County, TN.			
	Dickson County, TN.			
	Hickman County, TN.			
	Macon County, TN.			
	Robertson County, TN.			
	Rutherford County, TN.			
	Smith County, TN.			
	Sumner County, TN.			
	Trousdale County, TN.			
	Williamson County, TN.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Wilson County, TN	0.9874	0.9832	0.9790
35004	Nassau-Suffolk, NY.			
	Nassau County, NY.			
	Suffolk County, NY	1.1631	1.2175	1.2719
35084	Newark-Union, NJ-PA.			
	Essex County, NJ.			
	Hunterdon County, NJ.			
	Morris County, NJ.			
	Sussex County, NJ.			
	Union County, NJ.			
	Pike County, PA	1.1130	1.1506	1.1883
35300	New Haven-Milford, CT.			
	New Haven County, CT	1.1132	1.1510	1.1887
35380	New Orleans-Metairie-Kenner, LA.			
	Jefferson Parish, LA.			
	Orleans Parish, LA.			
	Plaquemines Parish, LA.			
	St. Bernard Parish, LA.			
	St. Charles Parish, LA.			
	St. John the Baptist Parish, LA.			
	St. Tammany Parish, LA	0.9397	0.9196	0.8995
35644	New York-White Plains-Wayne, NY-NJ.			
	Bergen County, NJ.			
	Hudson County, NJ.			
	Passaic County, NJ.			
	Bronx County, NY.			
	Kings County, NY.			
	New York County, NY.			
	Putnam County, NY.			
	Queens County, NY.			
	Richmond County, NY.			
	Rockland County, NY.			
	Westchester County, NY	1.1913	1.2550	1.3188
35660	Niles-Benton Harbor, MI.			
	Berrien County, MI	0.9327	0.9103	0.8879
35980	Norwich-New London, CT.			
	New London County, CT	1.0807	1.1076	1.1345
36084	Oakland-Fremont-Hayward, CA.			
	Alameda County, CA.			
	Contra Costa County, CA	1.3208	1.4277	1.5346
36100	Ocala, FL.			
	Marion County, FL	0.9355	0.9140	0.8925
36140	Ocean City, NJ.			
	Cape May County, NJ	1.0607	1.0809	1.1011
36220	Odessa, TX.			
	Ector County, TX	0.9930	0.9907	0.9884
36260	Ogden-Clearfield, UT.			
	Davis County, UT.			
	Morgan County, UT.			
	Weber County, UT	0.9417	0.9223	0.9029
36420	Oklahoma City, OK.			
	Canadian County, OK.			
	Cleveland County, OK.			
	Grady County, OK.			
	Lincoln County, OK.			
	Logan County, OK.			
	McClain County, OK.			
	Oklahoma County, OK	0.9419	0.9225	0.9031
36500	Olympia, WA.			
	Thurston County, WA	1.0556	1.0742	1.0927
36540	Omaha-Council Bluffs, NE-IA.			
	Harrison County, IA.			
	Mills County, IA.			
	Pottawattamie County, IA.			
	Cass County, NE.			
	Douglas County, NE.			
	Sarpy County, NE.			
	Saunders County, NE.			
	Washington County, NE	0.9736	0.9648	0.9560

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
36740	Orlando-Kissimmee, FL.			
	Lake County, FL.			
	Orange County, FL.			
	Osceola County, FL.			
	Seminole County, FL	0.9678	0.9571	0.9464
36780	Oshkosh-Neenah, WI.			
	Winnebago County, WI	0.9510	0.9346	0.9183
36980	Owensboro, KY.			
	Daviess County, KY.			
	Hancock County, KY.			
	McLean County, KY	0.9268	0.9024	0.8780
37100	Oxnard-Thousand Oaks-Ventura, CA.			
	Ventura County, CA	1.0973	1.1298	1.1622
37340	Palm Bay-Melbourne-Titusville, FL.			
	Brevard County, FL	0.9903	0.9871	0.9839
37460	Panama City-Lynn Haven, FL.			
	Bay County, FL	0.8803	0.8404	0.8005
37620	Parkersburg-Marietta-Vienna, WV-OH.			
	Washington County, OH.			
	Pleasants County, WV.			
	Wirt County, WV.			
	Wood County, WV	0.8962	0.8616	0.8270
37700	Pascagoula, MS.			
	George County, MS.			
	Jackson County, MS	0.8894	0.8525	0.8156
37860	Pensacola-Ferry Pass-Brent, FL.			
	Escambia County, FL.			
	Santa Rosa County, FL	0.8858	0.8477	0.8096
37900	Peoria, IL.			
	Marshall County, IL.			
	Peoria County, IL.			
	Stark County, IL.			
	Tazewell County, IL.			
	Woodford County, IL	0.9322	0.9096	0.8870
37964	Philadelphia, PA.			
	Bucks County, PA.			
	Chester County, PA.			
	Delaware County, PA.			
	Montgomery County, PA.			
	Philadelphia County, PA	1.0623	1.0830	1.1038
38060	Phoenix-Mesa-Scottsdale, AZ.			
	Maricopa County, AZ.			
	Pinal County, AZ	1.0076	1.0102	1.0127
38220	Pine Bluff, AR.			
	Cleveland County, AR.			
	Jefferson County, AR.			
	Lincoln County, AR	0.9208	0.8944	0.8680
38300	Pittsburgh, PA.			
	Allegheny County, PA.			
	Armstrong County, PA.			
	Beaver County, PA.			
	Butler County, PA.			
	Fayette County, PA.			
	Washington County, PA.			
	Westmoreland County, PA	0.9307	0.9076	0.8845
38340	Pittsfield, MA.			
	Berkshire County, MA	1.0109	1.0145	1.0181
38540	Pocatello, ID.			
	Bannock County, ID.			
	Power County, ID	0.9611	0.9481	0.9351
38660	Ponce, PR.			
	Juana Díaz Municipio, PR.			
	Ponce Municipio, PR.			
	Villalba Municipio, PR	0.6963	0.5951	0.4939
38860	Portland-South Portland-Biddeford, ME.			
	Cumberland County, ME.			
	Sagadahoc County, ME.			
	York County, ME	1.0229	1.0306	1.0382
38900	Portland-Vancouver-Beaverton, OR-WA.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Clackamas County, OR.			
	Columbia County, OR.			
	Multnomah County, OR.			
	Washington County, OR.			
	Yamhill County, OR.			
	Clark County, WA.			
	Skamania County, WA	1.0760	1.1013	1.1266
38940	Port St. Lucie-Fort Pierce, FL.			
	Martin County, FL.			
	St. Lucie County, FL	1.0074	1.0098	1.0123
39100	Poughkeepsie-Newburgh-Middletown, NY.			
	Dutchess County, NY.			
	Orange County, NY	1.0535	1.0713	1.0891
39140	Prescott, AZ.			
	Yavapai County, AZ	0.9921	0.9895	0.9869
39300	Providence-New Bedford-Fall River, RI-MA.			
	Bristol County, MA.			
	Bristol County, RI.			
	Kent County, RI.			
	Newport County, RI.			
	Providence County, RI.			
	Washington County, RI	1.0580	1.0773	1.0966
39340	Provo-Orem, UT.			
	Juab County, UT.			
	Utah County, UT	0.9700	0.9600	0.9500
39380	Pueblo, CO.			
	Pueblo County, CO	0.9174	0.8898	0.8623
39460	Punta Gorda, FL.			
	Charlotte County, FL	0.9553	0.9404	0.9255
39540	Racine, WI.			
	Racine County, WI	0.9398	0.9198	0.8997
39580	Raleigh-Cary, NC.			
	Franklin County, NC.			
	Johnston County, NC.			
	Wake County, NC	0.9815	0.9753	0.9691
39660	Rapid City, SD.			
	Meade County, SD.			
	Pennington County, SD	0.9392	0.9190	0.8987
39740	Reading, PA.			
	Berks County, PA	0.9812	0.9749	0.9686
39820	Redding, CA.			
	Shasta County, CA	1.1322	1.1762	1.2203
39900	Reno-Sparks, NV.			
	Storey County, NV.			
	Washoe County, NV	1.0589	1.0786	1.0982
40060	Richmond, VA.			
	Amelia County, VA.			
	Caroline County, VA.			
	Charles City County, VA.			
	Chesterfield County, VA.			
	Cumberland County, VA.			
	Dinwiddie County, VA.			
	Goochland County, VA.			
	Hanover County, VA.			
	Henrico County, VA.			
	King and Queen County, VA.			
	King William County, VA.			
	Louisa County, VA.			
	New Kent County, VA.			
	Powhatan County, VA.			
	Prince George County, VA.			
	Sussex County, VA.			
	Colonial Heights City, VA.			
	Hopewell City, VA.			
	Petersburg City, VA.			
	Richmond City, VA	0.9597	0.9462	0.9328
40140	Riverside-San Bernardino-Ontario, CA.			
	Riverside County, CA.			
	San Bernardino County, CA	1.0616	1.0822	1.1027

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
40220	Roanoke, VA.			
	Botetourt County, VA.			
	Craig County, VA.			
	Franklin County, VA.			
	Roanoke County, VA.			
	Roanoke City, VA.			
	Salem City, VA	0.9024	0.8699	0.8374
40340	Rochester, MN.			
	Dodge County, MN.			
	Olmsted County, MN.			
	Wabasha County, MN	1.0679	1.0905	1.1131
40380	Rochester, NY.			
	Livingston County, NY.			
	Monroe County, NY.			
	Ontario County, NY.			
	Orleans County, NY.			
	Wayne County, NY	0.9473	0.9297	0.9121
40420	Rockford, IL.			
	Boone County, IL.			
	Winnebago County, IL	0.9990	0.9987	0.9984
40484	Rockingham County-Strafford County, NH.			
	Rockingham County, NH.			
	Strafford County, NH	1.0224	1.0299	1.0374
40580	Rocky Mount, NC.			
	Edgecombe County, NC.			
	Nash County, NC	0.9349	0.9132	0.8915
40660	Rome, GA.			
	Floyd County, GA	0.9648	0.9531	0.9414
40900	Sacramento—Arden-Arcade—Roseville, CA.			
	El Dorado County, CA.			
	Placer County, CA.			
	Sacramento County, CA.			
	Yolo County, CA	1.1781	1.2375	1.2969
40980	Saginaw-Saginaw Township North, MI.			
	Saginaw County, MI	0.9453	0.9270	0.9088
41060	St. Cloud, MN.			
	Benton County, MN.			
	Stearns County, MN	0.9979	0.9972	0.9965
41100	St. George, UT.			
	Washington County, UT	0.9635	0.9514	0.9392
41140	St. Joseph, MO-KS.			
	Doniphan County, KS.			
	Andrew County, MO.			
	Buchanan County, MO.			
	DeKalb County, MO	0.9711	0.9615	0.9519
41180	St. Louis, MO-IL.			
	Bond County, IL.			
	Calhoun County, IL.			
	Clinton County, IL.			
	Jersey County, IL.			
	Macoupin County, IL.			
	Madison County, IL.			
	Monroe County, IL.			
	St. Clair County, IL.			
	Crawford County, MO.			
	Franklin County, MO.			
	Jefferson County, MO.			
	Lincoln County, MO.			
	St. Charles County, MO.			
	St. Louis County, MO.			
	Warren County, MO.			
	Washington County, MO.			
	St. Louis City, MO	0.9372	0.9163	0.8954
41420	Salem, OR.			
	Marion County, OR.			
	Polk County, OR	1.0265	1.0354	1.0442
41500	Salinas, CA.			
	Monterey County, CA	1.2477	1.3302	1.4128
41540	Salisbury, MD.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Somerset County, MD.			
	Wicomico County, MD	0.9438	0.9251	0.9064
41620	Salt Lake City, UT.			
	Salt Lake County, UT.			
	Summit County, UT.			
	Tooele County, UT	0.9653	0.9537	0.9421
41660	San Angelo, TX.			
	Irion County, TX.			
	Tom Green County, TX	0.8963	0.8617	0.8271
41700	San Antonio, TX.			
	Atascosa County, TX.			
	Bandera County, TX.			
	Bexar County, TX.			
	Comal County, TX.			
	Guadalupe County, TX.			
	Kendall County, TX.			
	Medina County, TX.			
	Wilson County, TX	0.9388	0.9184	0.8980
41740	San Diego-Carlsbad-San Marcos, CA.			
	San Diego County, CA	1.0848	1.1130	1.1413
41780	Sandusky, OH.			
	Erie County, OH	0.9411	0.9215	0.9019
41884	San Francisco-San Mateo-Redwood City, CA.			
	Marin County, CA.			
	San Francisco County, CA.			
	San Mateo County, CA	1.2996	1.3995	1.4994
41900	San Germán-Cabo Rojo, PR.			
	Cabo Rojo Municipio, PR.			
	Lajas Municipio, PR.			
	Sabana Grande Municipio, PR.			
	San Germán Municipio, PR	0.6790	0.5720	0.4650
41940	San Jose-Sunnyvale-Santa Clara, CA.			
	San Benito County, CA.			
	Santa Clara County, CA	1.3059	1.4079	1.5099
41980	San Juan-Caguas-Guaynabo, PR.			
	Aguas Buenas Municipio, PR.			
	Aibonito Municipio, PR.			
	Arecibo Municipio, PR.			
	Barceloneta Municipio, PR.			
	Barranquitas Municipio, PR.			
	Bayamón Municipio, PR.			
	Caguas Municipio, PR.			
	Camuy Municipio, PR.			
	Canóvanas Municipio, PR.			
	Carolina Municipio, PR.			
	Cataño Municipio, PR.			
	Cayey Municipio, PR.			
	Ciales Municipio, PR.			
	Cidra Municipio, PR.			
	Comerío Municipio, PR.			
	Corozal Municipio, PR.			
	Dorado Municipio, PR.			
	Florida Municipio, PR.			
	Guaynabo Municipio, PR.			
	Gurabo Municipio, PR.			
	Hatillo Municipio, PR.			
	Humacao Municipio, PR.			
	Juncos Municipio, PR.			
	Las Piedras Municipio, PR.			
	Loíza Municipio, PR.			
	Manatí Municipio, PR.			
	Maunabo Municipio, PR.			
	Morovis Municipio, PR.			
	Naguabo Municipio, PR.			
	Naranjito Municipio, PR.			
	Orocovis Municipio, PR.			
	Quebradillas Municipio, PR.			
	Río Grande Municipio, PR.			
	San Juan Municipio, PR.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	San Lorenzo Municipio, PR.			
	Toa Alta Municipio, PR.			
	Toa Baja Municipio, PR.			
	Trujillo Alto Municipio, PR.			
	Vega Alta Municipio, PR.			
	Vega Baja Municipio, PR.			
	Yabucoa Municipio, PR	0.6773	0.5697	0.4621
42020	San Luis Obispo-Paso Robles, CA.			
	San Luis Obispo County, CA	1.0809	1.1079	1.1349
42044	Santa Ana-Anaheim-Irvine, CA.			
	Orange County, CA	1.0935	1.1247	1.1559
42060	Santa Barbara-Santa Maria, CA.			
	Santa Barbara County, CA	1.1016	1.1355	1.1694
42100	Santa Cruz-Watsonville, CA.			
	Santa Cruz County, CA	1.3100	1.4133	1.5166
42140	Santa Fe, NM.			
	Santa Fe County, NM	1.0552	1.0736	1.0920
42220	Santa Rosa-Petaluma, CA.			
	Sonoma County, CA	1.2096	1.2794	1.3493
42260	Sarasota-Bradenton-Venice, FL.			
	Manatee County, FL.			
	Sarasota County, FL	0.9783	0.9711	0.9639
42340	Savannah, GA.			
	Bryan County, GA.			
	Chatham County, GA.			
	Effingham County, GA	0.9677	0.9569	0.9461
42540	Scranton—Wilkes-Barre, PA.			
	Lackawanna County, PA.			
	Luzerne County, PA.			
	Wyoming County, PA	0.9124	0.8832	0.8540
42644	Seattle-Bellevue-Everett, WA.			
	King County, WA.			
	Snohomish County, WA	1.0946	1.1262	1.1577
42680	Sebastian-Vero Beach, FL.			
	Indian River County, FL	0.9660	0.9547	0.9434
43100	Sheboygan, WI.			
	Sheboygan County, WI	0.9347	0.9129	0.8911
43300	Sherman-Denison, TX.			
	Grayson County, TX	0.9704	0.9606	0.9507
43340	Shreveport-Bossier City, LA.			
	Bossier Parish, LA.			
	Caddo Parish, LA.			
	De Soto Parish, LA	0.9256	0.9008	0.8760
43580	Sioux City, IA-NE-SD.			
	Woodbury County, IA.			
	Dakota County, NE.			
	Dixon County, NE.			
	Union County, SD	0.9629	0.9505	0.9381
43620	Sioux Falls, SD.			
	Lincoln County, SD.			
	McCook County, SD.			
	Minnehaha County, SD.			
	Turner County, SD	0.9781	0.9708	0.9635
43780	South Bend-Mishawaka, IN-MI.			
	St. Joseph County, IN.			
	Cass County, MI	0.9873	0.9830	0.9788
43900	Spartanburg, SC.			
	Spartanburg County, SC	0.9503	0.9338	0.9172
44060	Spokane, WA.			
	Spokane County, WA	1.0543	1.0724	1.0905
44100	Springfield, IL.			
	Menard County, IL.			
	Sangamon County, IL	0.9275	0.9034	0.8792
44140	Springfield, MA.			
	Franklin County, MA.			
	Hampden County, MA.			
	Hampshire County, MA	1.0149	1.0198	1.0248
44180	Springfield, MO.			
	Christian County, MO.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Dallas County, MO.			
	Greene County, MO.			
	Polk County, MO.			
	Webster County, MO	0.8942	0.8590	0.8237
44220	Springfield, OH.			
	Clark County, OH	0.9038	0.8717	0.8396
44300	State College, PA.			
	Centre County, PA	0.9014	0.8685	0.8356
44700	Stockton, CA.			
	San Joaquin County, CA	1.0784	1.1046	1.1307
44940	Sumter, SC.			
	Sumter County, SC	0.9026	0.8702	0.8377
45060	Syracuse, NY.			
	Madison County, NY.			
	Onondaga County, NY.			
	Oswego County, NY	0.9744	0.9659	0.9574
45104	Tacoma, WA.			
	Pierce County, WA	1.0445	1.0594	1.0742
45220	Tallahassee, FL.			
	Gadsden County, FL.			
	Jefferson County, FL.			
	Leon County, FL.			
	Wakulla County, FL	0.9213	0.8950	0.8688
45300	Tampa-St. Petersburg-Clearwater, FL.			
	Hernando County, FL.			
	Hillsborough County, FL.			
	Pasco County, FL.			
	Pinellas County, FL	0.9540	0.9386	0.9233
45460	Terre Haute, IN.			
	Clay County, IN.			
	Sullivan County, IN.			
	Vermillion County, IN.			
	Vigo County, IN	0.8982	0.8643	0.8304
45500	Texarkana, TX-Texarkana, AR.			
	Miller County, AR.			
	Bowie County, TX	0.8970	0.8626	0.8283
45780	Toledo, OH.			
	Fulton County, OH.			
	Lucas County, OH.			
	Ottawa County, OH.			
	Wood County, OH	0.9744	0.9659	0.9574
45820	Topeka, KS.			
	Jackson County, KS.			
	Jefferson County, KS.			
	Osage County, KS.			
	Shawnee County, KS.			
	Wabaunsee County, KS	0.9352	0.9136	0.8920
45940	Trenton-Ewing, NJ.			
	Mercer County, NJ	1.0500	1.0667	1.0834
46060	Tucson, AZ.			
	Pima County, AZ	0.9404	0.9206	0.9007
46140	Tulsa, OK.			
	Creek County, OK.			
	Okmulgee County, OK.			
	Osage County, OK.			
	Pawnee County, OK.			
	Rogers County, OK.			
	Tulsa County, OK.			
	Wagoner County, OK	0.9126	0.8834	0.8543
46220	Tuscaloosa, AL.			
	Greene County, AL.			
	Hale County, AL.			
	Tuscaloosa County, AL	0.9187	0.8916	0.8645
46340	Tyler, TX.			
	Smith County, TX	0.9501	0.9334	0.9168
46540	Utica-Rome, NY.			
	Herkimer County, NY.			
	Oneida County, NY	0.9015	0.8686	0.8358
46660	Valdosta, GA.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Brooks County, GA.			
	Echols County, GA.			
	Lanier County, GA.			
	Lowndes County, GA	0.9320	0.9093	0.8866
46700	Vallejo-Fairfield, CA.			
	Solano County, CA	1.2962	1.3949	1.4936
47020	Victoria, TX.			
	Calhoun County, TX.			
	Goliad County, TX.			
	Victoria County, TX	0.8896	0.8528	0.8160
47220	Vineland-Millville-Bridgeton, NJ.			
	Cumberland County, NJ	0.9896	0.9862	0.9827
47260	Virginia Beach-Norfolk-Newport News, VA-NC.			
	Currituck County, NC.			
	Gloucester County, VA.			
	Isle of Wight County, VA.			
	James City County, VA.			
	Mathews County, VA.			
	Surry County, VA.			
	York County, VA.			
	Chesapeake City, VA.			
	Hampton City, VA.			
	Newport News City, VA.			
	Norfolk City, VA.			
	Poquoson City, VA.			
	Portsmouth City, VA.			
	Suffolk City, VA.			
	Virginia Beach City, VA.			
	Williamsburg City, VA	0.9279	0.9039	0.8799
47300	Visalia-Porterville, CA.			
	Tulare County, CA	1.0074	1.0098	1.0123
47380	Waco, TX.			
	McLennan County, TX	0.9111	0.8814	0.8518
47580	Warner Robins, GA.			
	Houston County, GA	0.9187	0.8916	0.8645
47644	Warren-Troy-Farmington Hills, MI.			
	Lapeer County, MI.			
	Livingston County, MI.			
	Macomb County, MI.			
	Oakland County, MI.			
	St. Clair County, MI	0.9923	0.9897	0.9871
47894	Washington-Arlington-Alexandria, DC-VA-MD-WV.			
	District of Columbia, DC.			
	Calvert County, MD.			
	Charles County, MD.			
	Prince George's County, MD.			
	Arlington County, VA.			
	Clarke County, VA.			
	Fairfax County, VA.			
	Fauquier County, VA.			
	Loudoun County, VA.			
	Prince William County, VA.			
	Spotsylvania County, VA.			
	Stafford County, VA.			
	Warren County, VA.			
	Alexandria City, VA.			
	Fairfax City, VA.			
	Falls Church City, VA.			
	Fredericksburg City, VA.			
	Manassas City, VA.			
	Manassas Park City, VA.			
	Jefferson County, WV	1.0556	1.0741	1.0926
47940	Waterloo-Cedar Falls, IA.			
	Black Hawk County, IA.			
	Bremer County, IA.			
	Grundy County, IA	0.9134	0.8846	0.8557
48140	Wausau, WI.			
	Marathon County, WI	0.9754	0.9672	0.9590
48260	Weirton-Steubenville, WV-OH.			

TABLE 1.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR URBAN AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]—Continued

CBSA Code	Urban Area (Constituent Counties)	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
	Jefferson County, OH.			
	Brooke County, WV.			
	Hancock County, WV	0.8691	0.8255	0.7819
48300	Wenatchee, WA.			
	Chelan County, WA.			
	Douglas County, WA	1.0042	1.0056	1.0070
48424	West Palm Beach-Boca Raton-Boynton Beach, FL.			
	Palm Beach County, FL	1.0040	1.0054	1.0067
48540	Wheeling, WV-OH.			
	Belmont County, OH.			
	Marshall County, WV.			
	Ohio County, WV	0.8297	0.7729	0.7161
48620	Wichita, KS.			
	Butler County, KS.			
	Harvey County, KS.			
	Sedgwick County, KS.			
	Sumner County, KS	0.9492	0.9322	0.9153
48660	Wichita Falls, TX.			
	Archer County, TX.			
	Clay County, TX.			
	Wichita County, TX	0.8971	0.8628	0.8285
48700	Williamsport, PA.			
	Lycoming County, PA	0.9018	0.8691	0.8364
48864	Wilmington, DE-MD-NJ.			
	New Castle County, DE.			
	Cecil County, MD.			
	Salem County, NJ	1.0283	1.0377	1.0471
48900	Wilmington, NC.			
	Brunswick County, NC.			
	New Hanover County, NC.			
	Pender County, NC	0.9749	0.9666	0.9582
49020	Winchester, VA-WV.			
	Frederick County, VA.			
	Winchester City, VA.			
	Hampshire County, WV	1.0128	1.0171	1.0214
49180	Winston-Salem, NC.			
	Davie County, NC.			
	Forsyth County, NC.			
	Stokes County, NC.			
	Yadkin County, NC	0.9366	0.9155	0.8944
49340	Worcester, MA.			
	Worcester County, MA	1.0617	1.0822	1.1028
49420	Yakima, WA.			
	Yakima County, WA	1.0093	1.0124	1.0155
49500	Yauco, PR.			
	Guánica Municipio, PR.			
	Guayanilla Municipio, PR.			
	Peñuelas Municipio, PR.			
	Yauco Municipio, PR	0.6645	0.5526	0.4408
49620	York-Hanover, PA.			
	York County, PA	0.9608	0.9478	0.9347
49660	Youngstown-Warren-Boardman, OH-PA.			
	Mahoning County, OH.			
	Trumbull County, OH.			
	Mercer County, PA	0.9162	0.8882	0.8603
49700	Yuba City, CA.			
	Sutter County, CA.			
	Yuba County, CA	1.0553	1.0737	1.0921
49740	Yuma, AZ.			
	Yuma County, AZ	0.9476	0.9301	0.9126

[1] As discussed in section IV.D.1.d. of the preamble of this proposed rule, because there will no longer be any LTCHs in their cost reporting periods that began during FYs 2003 or 2004 (the first and second years of the 5-year wage index phase-in, respectively), we are no longer showing the 1/5 and 2/5 wage index value. For further details on the 5-year phase-in of the wage index, see section IV.D.1. of this proposed rule.

[2] Three-fifths of the proposed full wage index value, applicable for a LTCH's cost reporting period beginning on or after October 1, 2004 through September 30, 2005 (Federal FY 2005). That is, for a LTCH's cost reporting period that begins during Federal FY 2005 and located in Chicago, Illinois (CBSA 16974), the proposed 3/5 wage index value is computed as ((3*1.0790) + 2))/5 = 1.0474. For further details on the 5-year phase-in of the wage index, see section IV.D.1. of this proposed rule.

[3] Four-fifths of the proposed full wage index value, applicable for a LTCH's cost reporting period beginning on or after October 1, 2005 through September 30, 2006 (Federal FY 2006). That is, for a LTCH's cost reporting period that begins during Federal FY 2006 and located in Chicago, Illinois (CBSA 16974), the proposed 4/5 wage index value is computed as ((4*1.0790) + 1))/5 = 1.0632. For further details on the 5-year phase-in of the wage index, see section IV.D.1. of this proposed rule.

[4] The proposed wage index values are calculated using the same wage data used to compute the wage index used by acute care hospitals under the IPPS for Federal FY 2006 (that is, fiscal year 2002 audited acute care hospital inpatient wage data without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act).

TABLE 2.—PROPOSED LONG-TERM CARE HOSPITAL WAGE INDEX FOR RURAL AREAS FOR DISCHARGES OCCURRING FROM JULY 1, 2006 THROUGH JUNE 30, 2007 [1]

CBSA Code	Nonurban Area	3/5 Wage Index [2]	4/5 Wage Index [3]	Full Wage Index [4]
01	Alabama	0.8468	0.7957	0.7446
02	Alaska	1.1186	1.1582	1.1977
03	Arizona	0.9261	0.9014	0.8768
04	Arkansas	0.8480	0.7973	0.7466
05	California	1.0632	1.0843	1.1054
06	Colorado	0.9628	0.9504	0.9380
07	Connecticut	1.1038	1.1384	1.1730
08	Delaware	0.9747	0.9663	0.9579
10	Florida	0.9141	0.8854	0.8568
11	Georgia	0.8597	0.8130	0.7662
12	Hawaii	1.0331	1.0441	1.0551
13	Idaho	0.8822	0.8430	0.8037
14	Illinois	0.8963	0.8617	0.8271
15	Indiana	0.9174	0.8899	0.8624
16	Iowa	0.9105	0.8807	0.8509
17	Kansas	0.8821	0.8428	0.8035
18	Kentucky	0.8660	0.8213	0.7766
19	Louisiana	0.8447	0.7929	0.7411
20	Maine	0.9306	0.9074	0.8843
21	Maryland	0.9612	0.9482	0.9353
22	Massachusetts [5]	.....	.....	.....
23	Michigan	0.9337	0.9116	0.8895
24	Minnesota	0.9479	0.9306	0.9132
25	Mississippi	0.8604	0.8139	0.7674
26	Missouri	0.8740	0.8320	0.7900
27	Montana	0.9257	0.9010	0.8762
28	Nebraska	0.9194	0.8926	0.8657
29	Nevada	0.9439	0.9252	0.9065
30	New Hampshire	1.0490	1.0654	1.0817
31	New Jersey [5]	.....	.....	.....
32	New Mexico	0.9181	0.8908	0.8635
33	New York	0.8892	0.8523	0.8154
34	North Carolina	0.9124	0.8832	0.8540
35	North Dakota	0.8357	0.7809	0.7261
36	Ohio	0.9296	0.9061	0.8826
37	Oklahoma	0.8549	0.8065	0.7581
38	Oregon	0.9896	0.9861	0.9826
39	Pennsylvania	0.8975	0.8633	0.8291
40	Puerto Rico [5]	.....	.....	.....
41	Rhode Island [5]	.....	.....	.....
42	South Carolina	0.9183	0.8910	0.8638
43	South Dakota	0.9136	0.8848	0.8560
44	Tennessee	0.8737	0.8316	0.7895
45	Texas	0.8802	0.8402	0.8003
46	Utah	0.8871	0.8494	0.8118
47	Vermont	0.9898	0.9864	0.9830
49	Virginia	0.8808	0.8410	0.8013
50	Washington	1.0306	1.0408	1.0510
51	West Virginia	0.8630	0.8174	0.7717
52	Wisconsin	0.9705	0.9607	0.9509
53	Wyoming	0.9554	0.9406	0.9257

[1] As discussed in section IV.D.1.d. of the preamble of this proposed rule, because there are no longer any LTCHs in their cost reporting periods that began during FYs 2003 and 2004 (the first and second years of the 5-year wage index phase-in, respectively), we are no longer showing the 1/5 and 2/5 wage index value. For further details on the 5-year phase-in of the wage index, see section IV.D.1. of this proposed rule.

[2] The proposed wage index values are calculated using the same wage data used to compute the wage index used by acute care hospitals under the IPPS for Federal FY 2006 (that is, fiscal year 2002 audited acute care hospital inpatient wage data without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act).

[3] Three-fifths of the proposed full wage index value, applicable for a LTCH's cost reporting period beginning on or after October 1, 2004 through September 30, 2005 (Federal FY 2005). That is, for a LTCH's cost reporting period that begins during Federal FY 2005 and located in rural Illinois, the proposed 3/5 wage index value is computed as ((3*0.8271) + 2))/5 = 0.8963. For further details on the 5-year phase-in of the wage index, see section IV.D.1. of this proposed rule.

[4] Four-fifths of the proposed full wage index value, applicable for a LTCH's cost reporting period beginning on or after October 1, 2005 through September 30, 2006 (Federal FY 2006). That is, for a LTCH's cost reporting period that begins during Federal FY 2006 and located in rural Illinois, the proposed 4/5 wage index value is computed as ((3*0.9271) + 2))/5 = 0.8617. For further details on the 5-year phase-in of the wage index, see section IV.D.1. of this proposed rule.

[5] All counties within the State are classified as urban.

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
1	[5] CRANIOTOMY AGE >17 W CC	1.7034	38.5
2	[7] CRANIOTOMY AGE > 17 W/O CC	1.7034	38.5
3	[7] CRANIOTOMY AGE 0–17	1.7034	38.5
6	[7] CARPAL TUNNEL RELEASE	0.4499	19.0
7	PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W CC	1.3984	37.7
8	[3] PERIPH & CRANIAL NERVE & OTHER NERV SYST PROC W/O CC	0.7637	24.8
9	SPINAL DISORDERS & INJURIES	0.9720	33.7
10	NERVOUS SYSTEM NEOPLASMS W CC	0.7554	24.5
11	[2] NERVOUS SYSTEM NEOPLASMS W/O CC	0.5837	21.3
12	DEGENERATIVE NERVOUS SYSTEM DISORDERS	0.6851	25.5
13	MULTIPLE SCLEROSIS & CEREBELLAR ATAXIA	0.6531	23.1
14	INTERCRANIAL HEMORRHAGE OR STROKE WITH INFARCT	0.7783	26.0
15	NONSPECIFIC CVA & PRECEREBRAL OCCULUSION WITHOUT INFARCT	0.7314	26.8
16	NONSPECIFIC CEREBROVASCULAR DISORDERS W CC	0.7471	23.5
17	[1] NONSPECIFIC CEREBROVASCULAR DISORDERS W/O CC	0.4499	19.0
18	CRANIAL & PERIPHERAL NERVE DISORDERS W CC	0.7197	23.6
19	CRANIAL & PERIPHERAL NERVE DISORDERS W/O CC	0.4773	21.2
20	NERVOUS SYSTEM INFECTION EXCEPT VIRAL MENINGITIS	1.0277	27.2
21	[3] VIRAL MENINGITIS	0.7637	24.8
22	[4] HYPERTENSIVE ENCEPHALOPATHY	1.1820	29.6
23	NONTRAUMATIC STUPOR & COMA	0.8054	25.4
24	SEIZURE & HEADACHE AGE >17 W CC	0.6251	22.6
25	[1] SEIZURE & HEADACHE AGE >17 W/O CC	0.4499	19.0
26	[7] SEIZURE & HEADACHE AGE 0–17	0.4499	19.0
27	TRAUMATIC STUPOR & COMA, COMA >1 HR	0.9444	27.1
28	TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W CC	0.8890	30.2
29	[2] TRAUMATIC STUPOR & COMA, COMA <1 HR AGE >17 W/O CC	0.5837	21.3
30	[7] TRAUMATIC STUPOR & COMA, COMA <1 HR AGE 0–17	0.5837	21.3
31	[3] CONCUSSION AGE >17 W CC	0.7637	24.8
32	[7] CONCUSSION AGE >17 W/O CC	0.4499	19.0
33	[7] CONCUSSION AGE 0–17	0.4499	19.0
34	OTHER DISORDERS OF NERVOUS SYSTEM W CC	0.8004	25.3
35	OTHER DISORDERS OF NERVOUS SYSTEM W/O CC	0.5698	24.2
36	[7] RETINAL PROCEDURES	1.1820	29.6
37	[7] ORBITAL PROCEDURES	1.1820	29.6
38	[7] PRIMARY IRIS PROCEDURES	1.1820	29.6
39	[7] LENS PROCEDURES WITH OR WITHOUT VITRECTOMY	1.1820	29.6
40	[4] EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE >17	1.1820	29.6
41	[7] EXTRAOCULAR PROCEDURES EXCEPT ORBIT AGE 0–17	1.1820	29.6
42	[7] INTRAOCULAR PROCEDURES EXCEPT RETINA, IRIS & LENS	1.1820	29.6
43	[7] HYPHEMA	1.1820	29.6
44	[2] ACUTE MAJOR EYE INFECTIONS	0.5837	21.3
45	[7] NEUROLOGICAL EYE DISORDERS	1.1820	29.6
46	[2] OTHER DISORDERS OF THE EYE AGE >17 W CC	0.5837	21.3
47	[7] OTHER DISORDERS OF THE EYE AGE >17 W/O CC	1.1820	29.6
48	[7] OTHER DISORDERS OF THE EYE AGE 0–17	1.1820	29.6
49	[7] MAJOR HEAD & NECK PROCEDURES	1.1820	29.6
50	S7 IALOADENECTOMY	1.1820	29.6
51	[7] SALIVARY GLAND PROCEDURES EXCEPT SIALOADENECTOMY	1.1820	29.6
52	[7] CLEFT LIP & PALATE REPAIR	1.1820	29.6
53	[7] SINUS & MASTOID PROCEDURES AGE >17	1.1820	29.6
54	[7] SINUS & MASTOID PROCEDURES AGE 0–17	1.1820	29.6
55	[7] MISCELLANEOUS EAR, NOSE, MOUTH & THROAT PROCEDURES	1.1820	29.6
56	[7] RHINOPLASTY	1.1820	29.6
57	[7] T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	0.4499	19.0
58	[7] T&A PROC, EXCEPT TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	0.4499	19.0
59	[7] TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE >17	0.4499	19.0
60	[7] TONSILLECTOMY &/OR ADENOIDECTOMY ONLY, AGE 0–17	0.4499	19.0
61	[3] MYRINGOTOMY W TUBE INSERTION AGE >17	0.7637	24.8
62	[7] MYRINGOTOMY W TUBE INSERTION AGE 0–17	0.4499	19.0
63	[4] OTHER EAR, NOSE, MOUTH & THROAT O.R. PROCEDURES	1.1820	29.6
64	EAR, NOSE, MOUTH & THROAT MALIGNANCY	1.1480	26.2

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
65	[1] DYSEQUILIBRIUM	0.4499	19.0
66	[7] EPISTAXIS	0.4499	19.0
67	[3] EPIGLOTTITIS	0.7637	24.8
68	OTITIS MEDIA & URI AGE >17 W CC	0.5111	18.0
69	[1] OTITIS MEDIA & URI AGE >17 W/O CC	0.4499	19.0
70	[7] OTITIS MEDIA & URI AGE 0–17	0.4499	19.0
71	[7] LARYNGOTRACHEITIS	0.5837	21.3
72	[7] NASAL TRAUMA & DEFORMITY	0.7637	24.8
73	OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE >17	0.7535	21.9
74	[7] OTHER EAR, NOSE, MOUTH & THROAT DIAGNOSES AGE 0–17	0.4499	19.0
75	[5] MAJOR CHEST PROCEDURES	1.7034	38.5
76	OTHER RESP SYSTEM O.R. PROCEDURES W CC	2.5523	43.9
77	[5] OTHER RESP SYSTEM O.R. PROCEDURES W/O CC	1.7034	38.5
78	PULMONARY EMBOLISM	0.6900	21.9
79	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W CC	0.8280	22.9
80	RESPIRATORY INFECTIONS & INFLAMMATIONS AGE >17 W/O CC	0.5986	21.7
81	[7] RESPIRATORY INFECTIONS & INFLAMMATIONS AGE 0–17	0.4499	19.0
82	RESPIRATORY NEOPLASMS	0.7174	20.1
83	[2] MAJOR CHEST TRAUMA W CC	0.5837	21.3
84	[7] MAJOR CHEST TRAUMA W/O CC	0.5837	21.3
85	PLEURAL EFFUSION W CC	0.7264	21.2
86	[1] PLEURAL EFFUSION W/O CC	0.4499	19.0
87	PULMONARY EDEMA & RESPIRATORY FAILURE	1.0816	25.4
88	CHRONIC OBSTRUCTIVE PULMONARY DISEASE	0.6585	19.6
89	SIMPLE PNEUMONIA & PLEURISY AGE >17 W CC	0.6987	20.8
90	SIMPLE PNEUMONIA & PLEURISY AGE >17 W/O CC	0.4970	17.8
91	[7] SIMPLE PNEUMONIA & PLEURISY AGE 0–17	0.4499	19.0
92	INTERSTITIAL LUNG DISEASE W CC	0.6704	20.2
93	[2] INTERSTITIAL LUNG DISEASE W/O CC	0.5837	21.3
94	PNEUMOTHORAX W CC	0.5880	17.0
95	[1] PNEUMOTHORAX W/O CC	0.4499	19.0
96	BRONCHITIS & ASTHMA AGE >17 W CC	0.6417	19.4
97	[2] BRONCHITIS & ASTHMA AGE >17 W/O CC	0.5837	21.3
98	[7] BRONCHITIS & ASTHMA AGE 0–17	0.5837	21.3
99	RESPIRATORY SIGNS & SYMPTOMS W CC	0.9219	23.2
100	[3] RESPIRATORY SIGNS & SYMPTOMS W/O CC	0.7637	24.8
101	OTHER RESPIRATORY SYSTEM DIAGNOSES W CC	0.8147	21.1
102	[1] OTHER RESPIRATORY SYSTEM DIAGNOSES W/O CC	0.4499	19.0
103	[6] HEART TRANSPLANT OR IMPLANT OF HEART ASSIST SYSTEM	0.0000	0.0
104	[7] CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W CARDIAC CATH	0.7637	24.8
105	[7] CARDIAC VALVE & OTHER MAJOR CARDIOTHORACIC PROC W/O CARDIAC CATH	0.7637	24.8
106	[7] CORONARY BYPASS W PTCA	0.7637	24.8
108	[7] OTHER CARDIOTHORACIC PROCEDURES	0.7637	24.8
110	[3] MAJOR CARDIOVASCULAR PROCEDURES W CC	0.7637	24.8
111	[7] MAJOR CARDIOVASCULAR PROCEDURES W/O CC	0.7637	24.8
113	AMPUTATION FOR CIRC SYSTEM DISORDERS EXCEPT UPPER LIMB & TOE	1.4887	39.3
114	UPPER LIMB & TOE AMPUTATION FOR CIRC SYSTEM DISORDERS	1.2389	33.2
117	[4] CARDIAC PACEMAKER REVISION EXCEPT DEVICE REPLACEMENT	1.1820	29.6
118	[4] CARDIAC PACEMAKER DEVICE REPLACEMENT	1.1820	29.6
119	[3] VEIN LIGATION & STRIPPING	0.7637	24.8
120	OTHER CIRCULATORY SYSTEM O.R. PROCEDURES	1.0979	31.7
121	CIRCULATORY DISORDERS W AMI & MAJOR COMP, DISCHARGED ALIVE	0.8429	23.2
122	[2] CIRCULATORY DISORDERS W AMI W/O MAJOR COMP, DISCHARGED ALIVE	0.5837	21.3
123	CIRCULATORY DISORDERS W AMI, EXPIRED	1.1811	20.4
124	[4] CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH & COMPLEX DIAG	1.1820	29.6
125	[3] CIRCULATORY DISORDERS EXCEPT AMI, W CARD CATH W/O COMPLEX DIAG	0.7637	24.8
126	ACUTE & SUBACUTE ENDOCARDITIS	0.8386	25.3
127	HEART FAILURE & SHOCK	0.6857	21.2
128	[2] DEEP VEIN THROMBOPHLEBITIS	0.5837	21.3
129	[7] CARDIAC ARREST, UNEXPLAINED	0.7637	24.8
130	PERIPHERAL VASCULAR DISORDERS W CC	0.6741	23.2
131	PERIPHERAL VASCULAR DISORDERS W/O CC	0.4675	20.4
132	ATHEROSCLEROSIS W CC	0.6565	21.8
133	[1] ATHEROSCLEROSIS W/O CC	0.4499	19.0
134	HYPERTENSION	0.6354	24.8
135	CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W CC	0.7211	23.7
136	[2] CARDIAC CONGENITAL & VALVULAR DISORDERS AGE >17 W/O CC	0.5837	21.3
137	[7] CARDIAC CONGENITAL & VALVULAR DISORDERS AGE 0–17	0.5837	21.3

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
138	CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W CC	0.6201	20.5
139	[2] CARDIAC ARRHYTHMIA & CONDUCTION DISORDERS W/O CC	0.5837	21.3
140	[1] ANGINA PECTORIS	0.4499	19.0
141	[8] SYNCOPE & COLLAPSE W CC	0.4271	18.3
142	[8] SYNCOPE & COLLAPSE W/O CC	0.4271	18.3
143	[1] CHEST PAIN	0.4499	19.0
144	OTHER CIRCULATORY SYSTEM DIAGNOSES W CC	0.7413	21.7
145	OTHER CIRCULATORY SYSTEM DIAGNOSES W/O CC	0.4568	18.2
146	[7] RECTAL RESECTION W CC	1.7034	38.5
147	[7] RECTAL RESECTION W/O CC	1.7034	38.5
148	MAJOR SMALL & LARGE BOWEL PROCEDURES W CC	1.8616	40.9
149	[7] MAJOR SMALL & LARGE BOWEL PROCEDURES W/O CC	0.7637	24.8
150	[4] PERITONEAL ADHESIOLYSIS W CC	1.1820	29.6
151	[2] PERITONEAL ADHESIOLYSIS W/O CC	0.5837	21.3
152	[3] MINOR SMALL & LARGE BOWEL PROCEDURES W CC	0.7637	24.8
153	[7] MINOR SMALL & LARGE BOWEL PROCEDURES W/O CC	0.7637	24.8
154	[5] STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W CC	1.7034	38.5
155	[7] STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE >17 W/O CC	1.7034	38.5
156	[7] STOMACH, ESOPHAGEAL & DUODENAL PROCEDURES AGE 0–17	1.7034	38.5
157	[4] ANAL & STOMAL PROCEDURES W CC	1.1820	29.6
158	[7] ANAL & STOMAL PROCEDURES W/O CC	1.1820	29.6
159	[7] HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W CC	0.7637	24.8
160	[7] HERNIA PROCEDURES EXCEPT INGUINAL & FEMORAL AGE >17 W/O CC	0.7637	24.8
161	[5] INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W CC	1.7034	38.5
162	[7] INGUINAL & FEMORAL HERNIA PROCEDURES AGE >17 W/O CC	0.7637	24.8
163	[7] HERNIA PROCEDURES AGE 0–17	0.7637	24.8
164	[1] APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W CC	1.7034	38.5
165	[7] APPENDECTOMY W COMPLICATED PRINCIPAL DIAG W/O CC	1.7034	38.5
166	[7] APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W CC	1.7034	38.5
167	[7] APPENDECTOMY W/O COMPLICATED PRINCIPAL DIAG W/O CC	1.7034	38.5
168	[4] MOUTH PROCEDURES W CC	1.1820	29.6
169	[7] MOUTH PROCEDURES W/O CC	0.7637	24.8
170	OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W CC	1.6271	35.9
171	[1] OTHER DIGESTIVE SYSTEM O.R. PROCEDURES W/O CC	0.4499	19.0
172	DIGESTIVE MALIGNANCY W CC	0.8553	21.8
173	[2] DIGESTIVE MALIGNANCY W/O CC	0.5837	21.3
174	G.I. HEMORRHAGE W CC	0.7119	22.2
175	[1] G.I. HEMORRHAGE W/O CC	0.4499	19.0
176	COMPLICATED PEPTIC ULCER	0.8426	21.5
177	[3] UNCOMPLICATED PEPTIC ULCER W CC	0.7637	24.8
178	[3] UNCOMPLICATED PEPTIC ULCER W/O CC	0.7637	24.8
179	INFLAMMATORY BOWEL DISEASE	0.9675	24.0
180	G.I. OBSTRUCTION W CC	0.9375	23.5
181	[3] G.I. OBSTRUCTION W/O CC	0.7637	24.8
182	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE >17 W CC	0.7745	22.6
183	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE >17 W/O CC	0.3870	16.8
184	[7] ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS AGE 0–17	0.4499	19.0
185	[3] DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE >17	0.7637	24.8
186	[7] DENTAL & ORAL DIS EXCEPT EXTRACTIONS & RESTORATIONS, AGE 0–17	0.7637	24.8
187	[7] DENTAL EXTRACTIONS & RESTORATIONS	0.7637	24.8
188	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE >17 W CC	0.9952	24.0
189	OTHER DIGESTIVE SYSTEM DIAGNOSES AGE >17 W/O CC	0.4707	18.2
190	[7] OTHER DIGESTIVE SYSTEM DIAGNOSES AGE 0–17	0.4499	19.0
191	[4] PANCREAS, LIVER & SHUNT PROCEDURES W CC	1.1820	29.6
192	[7] PANCREAS, LIVER & SHUNT PROCEDURES W/O CC	1.1820	29.6
193	[3] BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W CC	0.7637	24.8
194	[7] BILIARY TRACT PROC EXCEPT ONLY CHOLECYST W OR W/O C.D.E. W/O CC	0.7637	24.8
195	[3] CHOLECYSTECTOMY W C.D.E. W CC	0.7637	24.8
196	[7] CHOLECYSTECTOMY W C.D.E. W/O CC	0.7637	24.8
197	[3] CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W CC	0.7637	24.8
198	[7] CHOLECYSTECTOMY EXCEPT BY LAPAROSCOPE W/O C.D.E. W/O CC	0.7637	24.8
199	[7] HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR MALIGNANCY	1.7034	38.5
200	[5] HEPATOBILIARY DIAGNOSTIC PROCEDURE FOR NON-MALIGNANCY	1.7034	38.5
201	OTHER HEPATOBILIARY OR PANCREAS O.R. PROCEDURES	2.0371	36.1
202	CIRRHOSIS & ALCOHOLIC HEPATITIS	0.6610	20.6
203	MALIGNANCY OF HEPATOBILIARY SYSTEM OR PANCREAS	0.7896	19.5
204	DISORDERS OF PANCREAS EXCEPT MALIGNANCY	0.9441	22.7
205	DISORDERS OF LIVER EXCEPT MALIG, CIRR, ALC HEPA W CC	0.6642	20.5

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
206	[2] DISORDERS OF LIVER EXCEPT MALIG, CIRR, ALC HEPA W/O CC	0.5837	21.3
207	DISORDERS OF THE BILIARY TRACT W CC	0.7570	21.5
208	[2] DISORDERS OF THE BILIARY TRACT W/O CC	0.5837	21.3
210	[5] HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W CC	1.7034	38.5
211	[4] HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE >17 W/O CC	1.1820	29.6
212	[7] HIP & FEMUR PROCEDURES EXCEPT MAJOR JOINT AGE 0–17	1.7034	38.5
213	AMPUTATION FOR MUSCULOSKELETAL SYSTEM & CONN TISSUE DISORDERS	1.1948	34.0
216	[4] BIOPSIES OF MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE	1.1820	29.6
217	WND DEBRID & SKN GRFT EXCEPT HAND, FOR MUSCSKELET & CONN TISS DIS	1.2927	38.0
218	[5] LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W CC	1.7034	38.5
219	[1] LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE >17 W/O CC	0.4499	19.0
220	[7] LOWER EXTREM & HUMER PROC EXCEPT HIP, FOOT, FEMUR AGE 0–17	1.7034	38.5
223	[3] MAJOR SHOULDER/ELBOW PROC, OR OTHER UPPER EXTREMITY PROC W CC	0.7637	24.8
224	[7] SHOULDER, ELBOW OR FOREARM PROC, EXC MAJOR JOINT PROC, W/O CC	0.7637	24.8
225	FOOT PROCEDURES	0.9869	28.4
226	SOFT TISSUE PROCEDURES W CC	0.9443	29.5
227	[3] SOFT TISSUE PROCEDURES W/O CC	0.7637	24.8
228	[4] MAJOR THUMB OR JOINT PROC, OR OTH HAND OR WRIST PROC W CC	1.1820	29.6
229	[7] HAND OR WRIST PROC, EXCEPT MAJOR JOINT PROC, W/O CC	0.4499	19.0
230	[5] LOCAL EXCISION & REMOVAL OF INT FIX DEVICES OF HIP & FEMUR	1.7034	38.5
232	[7] ARTHROSCOPY	0.4499	19.0
233	OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W CC	1.3522	34.6
234	[7] OTHER MUSCULOSKELET SYS & CONN TISS O.R. PROC W/O CC	0.4499	19.0
235	[3] FRACTURES OF FEMUR	0.7637	24.8
236	FRACTURES OF HIP & PELVIS	0.6531	25.2
237	[1] SPRAINS, STRAINS, & DISLOCATIONS OF HIP, PELVIS & THIGH	0.4499	19.0
238	OSTEOMYELITIS	0.8278	28.3
239	PATHOLOGICAL FRACTURES & MUSCULOSKELETAL & CONN TISS MALIGNANCY	0.6935	23.6
240	CONNECTIVE TISSUE DISORDERS W CC	0.7310	24.8
241	[1] CONNECTIVE TISSUE DISORDERS W/O CC	0.4499	19.0
242	SEPTIC ARTHRITIS	0.7864	26.5
243	MEDICAL BACK PROBLEMS	0.6061	23.4
244	BONE DISEASES & SPECIFIC ARTHROPATHIES W CC	0.5259	22.2
245	BONE DISEASES & SPECIFIC ARTHROPATHIES W/O CC	0.4635	20.4
246	[1] NON-SPECIFIC ARTHROPATHIES	0.4499	19.0
247	SIGNS & SYMPTOMS OF MUSCULOSKELETAL SYSTEM & CONN TISSUE	0.5548	21.9
248	TENDONITIS, MYOSITIS & BURSITIS	0.6574	22.6
249	AFTERCARE, MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE	0.6577	24.7
250	[2] FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W CC	0.5837	21.3
251	[1] FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE >17 W/O CC	0.4499	19.0
252	[7] FX, SPRN, STRN & DISL OF FOREARM, HAND, FOOT AGE 0–17	0.7637	24.8
253	FX, SPRN, STRN & DISL OF UPARM, LOWLEG EX FOOT AGE >17 W CC	0.6802	26.3
254	[2] FX, SPRN, STRN & DISL OF UPARM, LOWLEG EX FOOT AGE >17 W/O CC	0.5837	21.3
255	[7] FX, SPRN, STRN & DISL OF UPARM, LOWLEG EX FOOT AGE 0–17	0.7637	24.8
256	OTHER MUSCULOSKELETAL SYSTEM & CONNECTIVE TISSUE DIAGNOSES	0.7924	25.3
257	[7] TOTAL MASTECTOMY FOR MALIGNANCY W CC	0.7637	24.8
258	[7] TOTAL MASTECTOMY FOR MALIGNANCY W/O CC	0.7637	24.8
259	[2] SUBTOTAL MASTECTOMY FOR MALIGNANCY W CC	0.5837	21.3
260	[7] SUBTOTAL MASTECTOMY FOR MALIGNANCY W/O CC	0.7637	24.8
261	[7] BREAST PROC FOR NON-MALIGNANCY EXCEPT BIOPSY & LOCAL EXCISION	0.7637	24.8
262	[1] BREAST BIOPSY & LOCAL EXCISION FOR NON-MALIGNANCY	0.4499	19.0
263	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W CC	1.3222	39.5
264	SKIN GRAFT &/OR DEBRID FOR SKN ULCER OR CELLULITIS W/O CC	0.9584	32.0
265	SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W CC	1.0398	33.1
266	[3] SKIN GRAFT &/OR DEBRID EXCEPT FOR SKIN ULCER OR CELLULITIS W/O CC	0.7637	24.8
267	[7] PERIANAL & PILONIDAL PROCEDURES	0.7637	24.8
268	[5] SKIN, SUBCUTANEOUS TISSUE & BREAST PLASTIC PROCEDURES	1.7034	38.5
269	OTHER SKIN, SUBCUT TISS & BREAST PROC W CC	1.3037	36.1
270	[3] OTHER SKIN, SUBCUT TISS & BREAST PROC W/O CC	0.7637	24.8
271	SKIN ULCERS	0.8720	27.7
272	MAJOR SKIN DISORDERS W CC	0.7420	22.6
273	[1] MAJOR SKIN DISORDERS W/O CC	0.4499	19.0
274	[3] MALIGNANT BREAST DISORDERS W CC	0.7637	24.8
275	[7] MALIGNANT BREAST DISORDERS W/O CC	0.7637	24.8
276	[2] NON-MALIGANT BREAST DISORDERS	0.5837	21.3
277	CELLULITIS AGE >17 W CC	0.6264	21.0
278	CELLULITIS AGE >17 W/O CC	0.4420	17.8
279	[7] CELLULITIS AGE 0–17	0.4499	19.0

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
280	TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W CC	0.6698	24.3
281	[1] TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE >17 W/O CC	0.4499	19.0
282	[7] TRAUMA TO THE SKIN, SUBCUT TISS & BREAST AGE 0–17	0.4499	19.0
283	MINOR SKIN DISORDERS W CC	0.6935	23.9
284	[1] MINOR SKIN DISORDERS W/O CC	0.4499	19.0
285	AMPUTAT OF LOWER LIMB FOR ENDOCRINE, NUTRIT, & METABOL DISORDERS	1.3501	35.6
286	[7] ADRENAL & PITUITARY PROCEDURES	1.7034	38.5
287	SKIN GRAFTS & WOUND DEBRID FOR ENDOC, NUTRIT & METAB DISORDERS	1.1387	33.9
288	[4] O.R. PROCEDURES FOR OBESITY	1.1820	29.6
289	[7] PARATHYROID PROCEDURES	1.1820	29.6
290	[5] THYROID PROCEDURES	1.7034	38.5
291	[7] THYROGLOSSAL PROCEDURES	1.1820	29.6
292	OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W CC	1.3409	31.7
293	[2] OTHER ENDOCRINE, NUTRIT & METAB O.R. PROC W/O CC	0.5837	21.3
294	DIABETES AGE >35	0.7293	25.0
295	[3] DIABETES AGE 0–35	0.7637	24.8
296	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W CC	0.7212	23.1
297	NUTRITIONAL & MISC METABOLIC DISORDERS AGE >17 W/O CC	0.5227	18.4
298	[7] NUTRITIONAL & MISC METABOLIC DISORDERS AGE 0–17	0.5837	21.3
299	[4] INBORN ERRORS OF METABOLISM	1.1820	29.6
300	ENDOCRINE DISORDERS W CC	0.6376	21.2
301	[1] ENDOCRINE DISORDERS W/O CC	0.4499	19.0
302	[6] KIDNEY TRANSPLANT	0.0000	0.0
303	[4] KIDNEY, URETER & MAJOR BLADDER PROCEDURES FOR NEOPLASM	1.1820	29.6
304	[5] KIDNEY, URETER & MAJOR BLADDER PROC FOR NON-NEOPL W CC	1.7034	38.5
305	[1] KIDNEY, URETER & MAJOR BLADDER PROC FOR NON-NEOPL W/O CC	0.4499	19.0
306	[2] PROSTATECTOMY W CC	0.5837	21.3
307	[7] PROSTATECTOMY W/O CC	0.5837	21.3
308	[3] MINOR BLADDER PROCEDURES W CC	0.7637	24.8
309	[7] MINOR BLADDER PROCEDURES W/O CC	0.7637	24.8
310	[4] TRANSURETHRAL PROCEDURES W CC	1.1820	29.6
311	[7] TRANSURETHRAL PROCEDURES W/O CC	1.1820	29.6
312	[1] URETHRAL PROCEDURES, AGE >17 W CC	0.4499	19.0
313	[7] URETHRAL PROCEDURES, AGE >17 W/O CC	0.4499	19.0
314	[7] URETHRAL PROCEDURES, AGE 0–17	0.4499	19.0
315	OTHER KIDNEY & URINARY TRACT O.R. PROCEDURES	1.4055	31.6
316	RENAL FAILURE	0.8219	22.7
317	ADMIT FOR RENAL DIALYSIS	0.9852	25.2
318	KIDNEY & URINARY TRACT NEOPLASMS W CC	0.7586	20.2
319	[1] KIDNEY & URINARY TRACT NEOPLASMS W/O CC	0.4499	19.0
320	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W CC	0.6179	22.2
321	KIDNEY & URINARY TRACT INFECTIONS AGE >17 W/O CC	0.4792	19.0
322	[7] KIDNEY & URINARY TRACT INFECTIONS AGE 0–17	0.4499	19.0
323	[4] URINARY STONES W CC, &/OR ESW LITHOTRIPSY	1.1820	29.6
324	[7] URINARY STONES W/O CC	0.4499	19.0
325	[2] KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W CC	0.5837	21.3
326	[7] KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE >17 W/O CC	0.4499	19.0
327	[7] KIDNEY & URINARY TRACT SIGNS & SYMPTOMS AGE 0–17	0.4499	19.0
328	[1] URETHRAL STRICTURE AGE >17 W CC	0.4499	19.0
329	[7] URETHRAL STRICTURE AGE >17 W/O CC	0.4499	19.0
330	[7] URETHRAL STRICTURE AGE 0–17	0.4499	19.0
331	OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W CC	0.8010	23.1
332	[2] OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE >17 W/O CC	0.5837	21.3
333	[7] OTHER KIDNEY & URINARY TRACT DIAGNOSES AGE 0–17	0.5837	21.3
334	[2] MAJOR MALE PELVIC PROCEDURES W CC	0.5837	21.3
335	[7] MAJOR MALE PELVIC PROCEDURES W/O CC	1.7034	38.5
336	[2] TRANSURETHRAL PROSTATECTOMY W CC	0.5837	21.3
337	[7] TRANSURETHRAL PROSTATECTOMY W/O CC	0.5837	21.3
338	[7] TESTES PROCEDURES, FOR MALIGNANCY	0.5837	21.3
339	[4] TESTES PROCEDURES, NON-MALIGNANCY AGE >17	1.1820	29.6
340	[7] TESTES PROCEDURES, NON-MALIGNANCY AGE 0–17	1.1820	29.6
341	[4] PENIS PROCEDURES	1.1820	29.6
342	[7] CIRCUMCISION AGE >17	1.1820	29.6
343	[7] CIRCUMCISION AGE 0–17	1.1820	29.6
344	[1] OTHER MALE REPRODUCTIVE SYSTEM O.R. PROCEDURES FOR MALIGNANCY	0.4499	19.0
345	[5] OTHER MALE REPRODUCTIVE SYSTEM O.R. PROC EXCEPT FOR MALIGNANCY	1.7034	38.5
346	MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W CC	0.6060	20.6
347	[2] MALIGNANCY, MALE REPRODUCTIVE SYSTEM, W/O CC	0.5837	21.3

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
348	[2] BENIGN PROSTATIC HYPERTROPHY W CC	0.5837	21.3
349	[7] BENIGN PROSTATIC HYPERTROPHY W/O CC	1.1820	29.6
350	INFLAMMATION OF THE MALE REPRODUCTIVE SYSTEM	0.6798	21.9
351	[7] STERILIZATION, MALE	1.1820	29.6
352	OTHER MALE REPRODUCTIVE SYSTEM DIAGNOSES	0.6375	23.4
353	[7] PELVIC EVISCERATION, RADICAL HYSTERECTOMY & RADICAL VULVECTOMY	1.1820	29.6
354	[7] UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W CC	1.1820	29.6
355	[7] UTERINE,ADNEXA PROC FOR NON-OVARIAN/ADNEXAL MALIG W/O CC	1.1820	29.6
356	[7] FEMALE REPRODUCTIVE SYSTEM RECONSTRUCTIVE PROCEDURES	1.1820	29.6
357	[7] UTERINE & ADNEXA PROC FOR OVARIAN OR ADNEXAL MALIGNANCY	1.1820	29.6
358	[7] UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W CC	1.1820	29.6
359	[7] UTERINE & ADNEXA PROC FOR NON-MALIGNANCY W/O CC	1.1820	29.6
360	[4] VAGINA, CERVIX & VULVA PROCEDURES	1.1820	29.6
361	[7] LAPAROSCOPY & INCISIONAL TUBAL INTERRUPTION	0.7637	24.8
362	[7] ENDOSCOPIC TUBAL INTERRUPTION	0.7637	24.8
363	[7] D&C, CONIZATION & RADIO-IMPLANT, FOR MALIGNANCY	0.7637	24.8
364	[5] D&C, CONIZATION EXCEPT FOR MALIGNANCY	1.7034	38.5
365	[5] OTHER FEMALE REPRODUCTIVE SYSTEM O.R. PROCEDURES	1.7034	38.5
366	MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W CC	0.7072	20.3
367	[7] MALIGNANCY, FEMALE REPRODUCTIVE SYSTEM W/O CC	0.7637	24.8
368	INFECTIONS, FEMALE REPRODUCTIVE SYSTEM	0.6416	20.7
369	[3] MENSTRUAL & OTHER FEMALE REPRODUCTIVE SYSTEM DISORDERS	0.7637	24.8
370	[7] CESAREAN SECTION W CC	0.7637	24.8
371	[7] CESAREAN SECTION W/O CC	0.5837	21.3
372	[7] VAGINAL DELIVERY W COMPLICATING DIAGNOSES	0.7637	24.8
373	[7] VAGINAL DELIVERY W/O COMPLICATING DIAGNOSES	0.7637	24.8
374	[7] VAGINAL DELIVERY W STERILIZATION &/OR D&C	0.7637	24.8
375	[7] VAGINAL DELIVERY W O.R. PROC EXCEPT STERIL &/OR D&C	0.7637	24.8
376	[7] POSTPARTUM & POST ABORTION DIAGNOSES W/O O.R. PROCEDURE	0.7637	24.8
377	[7] POSTPARTUM & POST ABORTION DIAGNOSES W O.R. PROCEDURE	0.7637	24.8
378	[7] ECTOPIC PREGNANCY	0.7637	24.8
379	[7] THREATENED ABORTION	0.7637	24.8
380	[7] ABORTION W/O D&C	0.7637	24.8
381	[7] ABORTION W D&C, ASPIRATION CURETTAGE OR HYSTEROTOMY	0.7637	24.8
382	[7] FALSE LABOR	0.7637	24.8
383	[7] OTHER ANTEPARTUM DIAGNOSES W MEDICAL COMPLICATIONS	0.7637	24.8
384	[7] OTHER ANTEPARTUM DIAGNOSES W/O MEDICAL COMPLICATIONS	0.7637	24.8
385	[7] NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	0.7637	24.8
386	[7] EXTREME IMMATURITY	1.1820	29.6
387	[7] PREMATURITY W MAJOR PROBLEMS	1.1820	29.6
388	[7] PREMATURITY W/O MAJOR PROBLEMS	0.7637	24.8
389	[7] FULL TERM NEONATE W MAJOR PROBLEMS	1.1820	29.6
390	[7] NEONATE W OTHER SIGNIFICANT PROBLEMS	1.1820	29.6
391	[7] NORMAL NEWBORN	0.7637	24.8
392	[7] SPLENECTOMY AGE >17	0.7637	24.8
393	[7] SPLENECTOMY AGE 0–17	0.7637	24.8
394	[5] OTHER O.R. PROCEDURES OF THE BLOOD AND BLOOD FORMING ORGANS	1.7034	38.5
395	RED BLOOD CELL DISORDERS AGE >17	0.6581	22.0
396	[7] RED BLOOD CELL DISORDERS AGE 0–17	0.5837	21.3
397	COAGULATION DISORDERS	0.8675	22.9
398	RETICULOENDOTHELIAL & IMMUNITY DISORDERS W CC	0.8240	23.7
399	[2] RETICULOENDOTHELIAL & IMMUNITY DISORDERS W/O CC	0.5837	21.3
401	[5] LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W CC	1.7034	38.5
402	[7] LYMPHOMA & NON-ACUTE LEUKEMIA W OTHER O.R. PROC W/O CC	0.5837	21.3
403	LYMPHOMA & NON-ACUTE LEUKEMIA W CC	0.8757	21.3
404	[2] LYMPHOMA & NON-ACUTE LEUKEMIA W/O CC	0.5837	21.3
405	[7] ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE 0–17	0.5837	21.3
406	[4] MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R. PROC W CC	1.1820	29.6
407	[7] MYELOPROLIF DISORD OR POORLY DIFF NEOPL W MAJ O.R. PROC W/O CC	1.1820	29.6
408	[4] MYELOPROLIF DISORD OR POORLY DIFF NEOPL W OTHER O.R. PROC	1.1820	29.6
409	RADIOTHERAPY	0.8642	23.5
410	CHEMOTHERAPY W/O ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS	1.1684	26.4
411	[7] HISTORY OF MALIGNANCY W/O ENDOSCOPY	0.7637	24.8
412	[7] HISTORY OF MALIGNANCY W ENDOSCOPY	0.7637	24.8
413	OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W CC	0.8920	20.5
414	[7] OTHER MYELOPROLIF DIS OR POORLY DIFF NEOPL DIAG W/O CC	0.5837	21.3
415	O.R. PROCEDURE FOR INFECTIOUS & PARASITIC DISEASES	1.4251	35.6
416	SEPTICEMIA AGE >17	0.8241	23.5

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
417	[7] SEPTICEMIA AGE 0–17	0.7637	24.8
418	POSTOPERATIVE & POST-TRAUMATIC INFECTIONS	0.8252	24.7
419	[4] FEVER OF UNKNOWN ORIGIN AGE >17 W CC	1.1820	29.6
420	[7] FEVER OF UNKNOWN ORIGIN AGE >17 W/O CC	1.1820	29.6
421	VIRAL ILLNESS AGE >17	0.9441	27.3
422	[7] VIRAL ILLNESS & FEVER OF UNKNOWN ORIGIN AGE 0–17	0.4499	19.0
423	OTHER INFECTIOUS & PARASITIC DISEASES DIAGNOSES	0.9505	21.8
424	[3] O.R. PROCEDURE W PRINCIPAL DIAGNOSES OF MENTAL ILLNESS	0.7637	24.8
425	[2] ACUTE ADJUSTMENT REACTION & PSYCHOLOGICAL DYSFUNCTION	0.5837	21.3
426	DEPRESSIVE NEUROSES	0.4113	20.7
427	NEUROSES EXCEPT DEPRESSIVE	0.4653	23.8
428	[1] DISORDERS OF PERSONALITY & IMPULSE CONTROL	0.4499	19.0
429	ORGANIC DISTURBANCES & MENTAL RETARDATION	0.5813	26.8
430	PSYCHOSES	0.4330	24.2
431	[1] CHILDHOOD MENTAL DISORDERS	0.4499	19.0
432	[2] OTHER MENTAL DISORDER DIAGNOSES	0.5837	21.3
433	[2] ALCOHOL/DRUG ABUSE OR DEPENDENCE, LEFT AMA	0.5837	21.3
439	SKIN GRAFTS FOR INJURIES	1.3677	35.6
440	WOUND DEBRIDEMENTS FOR INJURIES	1.3442	36.1
441	[1] HAND PROCEDURES FOR INJURIES	0.4499	19.0
442	OTHER O.R. PROCEDURES FOR INJURIES W CC	1.3937	33.4
443	[3] OTHER O.R. PROCEDURES FOR INJURIES W/O CC	0.7637	24.8
444	TRAUMATIC INJURY AGE >17 W CC	0.7584	26.3
445	[1] TRAUMATIC INJURY AGE >17 W/O CC	0.4499	19.0
446	[7] TRAUMATIC INJURY AGE 0–17	0.4499	19.0
447	[2] ALLERGIC REACTIONS AGE >17	0.5837	21.3
448	[7] ALLERGIC REACTIONS AGE 0–17	0.5837	21.3
449	[3] POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W CC	0.7637	24.8
450	[7] POISONING & TOXIC EFFECTS OF DRUGS AGE >17 W/O CC	0.7637	24.8
451	[7] POISONING & TOXIC EFFECTS OF DRUGS AGE 0–17	0.7637	24.8
452	COMPLICATIONS OF TREATMENT W CC	0.9265	25.3
453	COMPLICATIONS OF TREATMENT W/O CC	0.5871	23.8
454	[3] OTHER INJURY, POISONING & TOXIC EFFECT DIAG W CC	0.7637	24.8
455	[7] OTHER INJURY, POISONING & TOXIC EFFECT DIAG W/O CC	0.7637	24.8
461	O.R. PROC W DIAGNOSES OF OTHER CONTACT W HEALTH SERVICES	1.2245	34.0
462	REHABILITATION	0.5787	22.4
463	SIGNS & SYMPTOMS W CC	0.6258	23.8
464	SIGNS & SYMPTOMS W/O CC	0.5554	24.1
465	AFTERCARE W HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS	0.6958	21.9
466	AFTERCARE W/O HISTORY OF MALIGNANCY AS SECONDARY DIAGNOSIS	0.6667	21.9
467	[3] OTHER FACTORS INFLUENCING HEALTH STATUS	0.7637	24.8
468	EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	2.1478	40.2
469	[6] PRINCIPAL DIAGNOSIS INVALID AS DISCHARGE DIAGNOSIS	0.0000	0.0
470	[6] UNGROUPABLE	0.0000	0.0
471	[5] BILATERAL OR MULTIPLE MAJOR JOINT PROCS OF LOWER EXTREMITY	1.7034	38.5
473	ACUTE LEUKEMIA W/O MAJOR O.R. PROCEDURE AGE >17	0.8537	20.0
475	RESPIRATORY SYSTEM DIAGNOSIS WITH VENTILATOR SUPPORT	2.0831	34.6
476	[4] PROSTATIC O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	1.1820	29.6
477	NON-EXTENSIVE O.R. PROCEDURE UNRELATED TO PRINCIPAL DIAGNOSIS	1.5836	35.3
479	[7] OTHER VASCULAR PROCEDURES W/O CC	0.7637	24.8
480	[6] LIVER TRANSPLANT	0.0000	0.0
481	[7] BONE MARROW TRANSPLANT	1.7034	38.5
482	[5] TRACHEOSTOMY FOR FACE,MOUTH & NECK DIAGNOSES	1.7034	38.5
484	[2] CRANIOTOMY FOR MULTIPLE SIGNIFICANT TRAUMA	0.5837	21.3
485	[7] LIMB REATTACHMENT, HIP AND FEMUR PROC FOR MULTIPLE SIGNIFICANT TR	1.1820	29.6
486	[5] OTHER O.R. PROCEDURES FOR MULTIPLE SIGNIFICANT TRAUMA	1.7034	38.5
487	OTHER MULTIPLE SIGNIFICANT TRAUMA	0.8992	26.0
488	[5] HIV W EXTENSIVE O.R. PROCEDURE	1.7034	38.5
489	HIV W MAJOR RELATED CONDITION	0.8535	21.4
490	HIV W OR W/O OTHER RELATED CONDITION	0.4919	16.6
491	[5] MAJOR JOINT & LIMB REATTACHMENT PROCEDURES OF UPPER EXTREMITY	1.7034	38.5
492	[7] CHEMOTHERAPY W ACUTE LEUKEMIA AS SECONDARY DIAGNOSIS	1.1820	29.6
493	[5] LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W CC	1.7034	38.5
494	[7] LAPAROSCOPIC CHOLECYSTECTOMY W/O C.D.E. W/O CC	1.7034	38.5
495	[6] LUNG TRANSPLANT	0.0000	0.0
496	[7] COMBINED ANTERIOR/POSTERIOR SPINAL FUSION	1.1820	29.6
497	[4] SPINAL FUSION W CC	1.1820	29.6
498	[7] SPINAL FUSION W/O CC	1.1820	29.6

TABLE 3.—FY 2006 LTC–DRGS, RELATIVE WEIGHTS AND GEOMETRIC AVERAGE LENGTH OF STAY—Continued

[Effective for discharges occurring on or after October 1, 2005 through September 30, 2006]

LTC–DRG	Description	Relative Weight	Geometric Average Length of Stay
499	[5] BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W CC	1.7034	38.5
500	[4] BACK & NECK PROCEDURES EXCEPT SPINAL FUSION W/O CC	1.1820	29.6
501	[5] KNEE PROCEDURES W PDX OF INFECTION W CC	1.7034	38.5
502	[4] KNEE PROCEDURES W PDX OF INFECTION W/O CC	1.1820	29.6
503	[2] KNEE PROCEDURES W/O PDX OF INFECTION	0.5837	21.3
504	[7] EXTENSIVE BURN OR FULL THICKNESS BURNS WITH MECH VENT 96+ HOURS WITH SKIN GRAFT.	1.7034	38.5
505	[4] EXTENSIVE BURN OR FULL THICKNESS BURNS WITH MECH VENT 96+ HOURS WITHOUT SKIN GRAFT.	1.1820	29.6
506	[4] FULL THICKNESS BURN W SKIN GRAFT OR INHAL INJ W CC OR SIG TRAUMA	1.1820	29.6
507	[3] FULL THICKNESS BURN W SKIN GRFT OR INHAL INJ W/O CC OR SIG TRAUMA	0.7637	24.8
508	FULL THICKNESS BURN W/O SKIN GRFT OR INHAL INJ W CC OR SIG TRAUMA	0.8367	29.4
509	[1] FULL THICKNESS BURN W/O SKIN GRFT OR INH INJ W/O CC OR SIG TRAUMA	0.4499	19.0
510	NON-EXTENSIVE BURNS W CC OR SIGNIFICANT TRAUMA	0.7709	24.6
511	[1] NON-EXTENSIVE BURNS W/O CC OR SIGNIFICANT TRAUMA	0.4499	19.0
512	[6] SIMULTANEOUS PANCREAS/KIDNEY TRANSPLANT	0.0000	0.0
513	[6] PANCREAS TRANSPLANT	0.0000	0.0
515	[5] CARDIAC DEFIBRILATOR IMPLANT W/O CARDIAC CATH	1.7034	38.5
518	[7] PERCUTANEOUS CARDIVASCULAR PROC W/O CORONARY ARTERY STENT OR AMI	0.7637	24.8
519	[5] CERVICAL SPINAL FUSION W CC	1.7034	38.5
520	[7] CERVICAL SPINAL FUSION W/O CC	1.1820	29.6
521	ALCOHOL/DRUG ABUSE OR DEPENDENCE W CC	0.4457	19.4
522	[7] ALCOHOL/DRUG ABUSE OR DEPENDENCE W REHABILITATION THERAPY W/O CC	0.4499	19.0
523	[7] ALCOHOL/DRUG ABUSE OR DEPENDENCE W/O REHABILITATION THERAPY W/O CC	0.4499	19.0
524	TRANSIENT ISCHEMIA	0.5043	21.1
525	[7] OTHER HEART ASSIST SYSTEM IMPLANT	1.7034	38.5
528	[7] INTRACRANIAL VASCULAR PROC W PDX HEMORRHAGE	1.7034	38.5
529	[5] VENTRICULAR SHUNT PROCEDURES W CC	1.7034	38.5
530	[7] VENTRICULAR SHUNT PROCEDURES W/O CC	1.7034	38.5
531	[3] SPINAL PROCEDURES WITH CC	0.7637	24.8
532	[3] SPINAL PROCEDURES WITHOUT CC	0.7637	24.8
533	[5] EXTRACRANIAL VASCULAR PROCEDURES WITH CC	1.7034	38.5
534	[7] EXTRACRANIAL VASCULAR PROCEDURES WITHOUT CC	1.1820	29.6
535	[7] CARDIAC DEFIB IMPLANT W CARDIAC CATH W AMI/HF/SHOCK	1.7034	38.5
536	[7] CARDIAC DEFIB IMPLANT W CARDIAC CATH W/O AMI/HF/SHOCK	1.7034	38.5
537	LOCAL EXCISION AND REMOVAL OF INTERNAL FIXATION DEVICES EXCEPT HIP AND FEMUR WITH CC.	1.1615	34.7
538	[7] LOCAL EXCISION AND REMOVAL OF INTERNAL FIXATION DEVICES EXCEPT HIP AND FEMUR WITHOUT CC.	1.1820	29.6
539	[4] LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURE WITH CC	1.1820	29.6
540	[7] LYMPHOMA AND LEUKEMIA WITH MAJOR O.R. PROCEDURE WITHOUT CC	0.5837	21.3
541	ECMO OR TRACH W MECH VENT 96+ HRS OR PDX EXCEPT FACE, MOUTH & NECK DIAG WITH MAJOR OR.	4.2287	65.6
542	TRACH W MECH VENT 96+ HRS OR PDX EXCEPT FACE, MOUTH & NECK DIAG WITHOUT MAJOR OR.	3.1869	48.2
543	[5] CRANIOTOMY W IMPLANT OF CHEMO AGENT OR ACUTE COMPLEX CNS PDX	1.7034	38.5
544	[5] MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY	1.7034	38.5
545	[5] REVISION OF HIP OR KNEE REPLACEMENT	1.7034	38.5
546	[7] SPINAL FUSION EXCEPT CERVICAL WITH CURVATURE OF SPINE OR MALIGNANCY	1.7034	38.5
547	[7] CORONARY BYPASS WITH CARDIAC CATH WITH MAJOR CV DIAGNOSIS	1.7034	38.5
548	[7] CORONARY BYPASS WITH CARDIAC CATH WITHOUT MAJOR CV DIAGNOSIS	1.7034	38.5
549	[7] CORONARY BYPASS WITHOUT CARDIAC CATH WITH MAJOR CV DIAGNOSIS	1.7034	38.5
550	[7] CORONARY BYPASS WITHOUT CARDIAC CATH WITHOUT MAJOR CV DIAGNOSIS	1.7034	38.5
551	[4] PERMANENT CARDIAC PACEMAKER IMPLANT WITH MAJOR CV DIAGNOSIS OR AICD LEAD OR GNRTR.	1.1820	29.6
552	[4] OTHER PERMANENT CARDIAC PACEMAKER IMPLANT WITHOUT MAJOR CV DIAGNOSIS	1.1820	29.6
553	[8] OTHER VASCULAR PROCEDURES WITH CC WITH MAJOR CV DIAGNOSIS	1.3255	30.6
554	[8] OTHER VASCULAR PROCEDURES WITH CC WITHOUT MAJOR CV DIAGNOSIS	1.3255	30.6
555	[4] PERCUTANEOUS CARDIOVASCULAR PROC WITH MAJOR CV DIAGNOSIS	1.1820	29.6
556	[8] PERCUTANEOUS CARDIOVASCULAR PROC WITH NON-DRUG-ELUTING STENT WITHOUT MAJOR CV DIAGNOSIS.	1.1820	29.6
557	[8] PERCUTANEOUS CARDIOVASCULAR PROC WITH DRUG-ELUTING STENT WITH MAJOR CV DIAGNOSIS.	1.1820	29.6
558	[7] PERCUTANEOUS CARDIOVASCULAR PROC WITH DRUG-ELUTING STENT WITHOUT MAJOR CV DIAGNOSIS.	1.1820	29.6
559	[7] ACUTE ISCHEMIC STROKE WITH USE OF THROMBOLYTIC AGENT	0.7637	24.8

[1] Relative weights for these LTC-DRGs were determined by assigning these cases to low-volume quintile 1.

[2] Relative weights for these LTC-DRGs were determined by assigning these cases to low-volume quintile 2.
[3] Relative weights for these LTC-DRGs were determined by assigning these cases to low-volume quintile 3.
[4] Relative weights for these LTC-DRGs were determined by assigning these cases to low-volume quintile 4.
[5] Relative weights for these LTC-DRGs were determined by assigning these cases to low-volume quintile 5.
[6] Relative weights for these LTC-DRGs were assigned a value of 0.0000.
[7] Relative weights for these LTC-DRGs were determined by assigning these cases to the appropriate low volume quintile because there are no LTCH cases in the FY 2004 MedPAR file.
[8] Relative weights for these LTC-DRGs were determined after adjusting to account for nonmonotonicity.

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Federal Register

Friday,
January 27, 2006

Part III

United States Sentencing Commission

Sentencing Guidelines for United States Courts; Notice

UNITED STATES SENTENCING COMMISSION

Sentencing Guidelines for United States Courts

AGENCY: United States Sentencing Commission.

ACTION: Notice of proposed amendments; request for public comment; notice of public hearings.

SUMMARY: (A) Proposed Temporary, Emergency Amendment Pertaining to Steroid Offenses.—Pursuant to section 994(a), (o), and (p) of title 28, United States Code, section 3 of the Anabolic Steroid Control Act of 2004, Pub. L. 108–358, and the United States Parole Commission Extension and Sentencing Commission Authority Act of 2005, Pub. L. 109–75, the Commission is considering promulgating a temporary, emergency amendment to the sentencing guidelines, policy statements, and commentary to increase the penalties for steroid offenses. This notice sets forth the proposed amendment and a synopsis of the issues addressed by the amendment. Issues for comment follow the proposed amendment.

(B) Proposed Non-Emergency Amendments.—Pursuant to section 994(a), (o), and (p) of title 28, United States Code, the United States Sentencing Commission is considering promulgating certain amendments to the sentencing guidelines, policy statements, and commentary. This notice sets forth the proposed amendments and, for each proposed amendment, a synopsis of the issues addressed by that amendment. This notice also provides multiple issues for comment, some of which are contained within proposed amendments.

The specific proposed amendments and issues for comment in this notice are as follows: (A) proposed amendment and issues for comment regarding immigration offenses, particularly offenses covered by §§ 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien), 2L1.2 (Unlawfully Entering or Remaining in the United States), 2L2.1 (Trafficking in a Document Relating to Naturalization, Citizenship, or Legal Resident Status, or a United States Passport; etc.) and 2L2.2 (Fraudulently Acquiring Documents Relating to Naturalization, Citizenship, or Legal Resident Status for Own Use); (B) proposed amendments to §§ 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition), 1B1.1 (Application Instructions), and 5K2.11 (Lesser Harms), and issues for comment pertaining to firearms offenses; (C) proposed repromulgation of the proposed temporary, emergency amendment to §§ 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy), and 3B1.3 (Hate Crime Motivation and Vulnerable Victim) set forth in Part A of this notice; (D) proposed amendment to repromulgate as a permanent amendment the temporary, emergency amendment to § 2B5.3 (Criminal Infringement of Copyright or Trademark), which became effective October 24, 2004 (see Supplement to Appendix C, (Amendment 675)); (E) proposed amendment to repromulgate as a permanent amendment the temporary, emergency amendment to § 2J1.2 (Obstruction of Justice), which became effective October 24, 2005 (see Supplement to Appendix C, (Amendment 676)); (F) proposed amendments §§ 2A1.4 (Involuntary Manslaughter), 2A5.2 (Interference with Flight Crew Member or Flight Attendant; Interference with Dispatch, Operation, or Maintenance of Mass Transportation Vehicle or Ferry), 2B1.1 (Theft, Fraud, and Property Destruction), 2K1.4 (Arson; Property Damage by Use of Explosives), and Chapter Two, Part X (Other Offenses) to implement the Safe, Accountable, Flexible, Efficient Transportation Act: A Legacy for Users, Pub. L. 109–59; (G) proposed amendments to §§ 2A6.1 (Threatening Communications), 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition), 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien), and 2M6.1 (Unlawful Production, Development, Acquisition, Stockpiling, Alteration, Use, Transfer, or Possession of Nuclear Material, Weapons, or Facilities, Biological Agents, Toxins, or Delivery Systems, Chemical Weapons, or Other Weapons of Mass Destruction; Attempt or Conspiracy) to implement the Intelligence Reform and Terrorism Prevention Act of 2004, Pub. L. 108–458; (H) proposed amendments to (i) Chapter Three (Adjustments) to implement the directive to the Commission in section 204(b) of the Intellectual Property Protection and Courts Administration Act of 2004, Pub. L. 108–482; and (ii) § 2G2.5 (Recordkeeping Offenses Involving the Production of Sexually Explicit Materials) to implement section 5(d)(1) of the CAN-SPAM Act, Pub. L. 108–187; (I) proposed amendments to (i) §§ 2B1.1 and 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources; Unlawful Sale, Purchase, Exchange, Transportation, or Receipt of Cultural Heritage Resources) to implement the Veterans' Memorial Preservation and Recognition Act of 2003, Pub. L. 108–29; (ii) § 2N2.1 (Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product) to implement the Plant Protection Act of 2002, Pub. L. 107–171; (iii) § 2T3.1 (Evading Import Duties or Restrictions (Smuggling); Receiving or Trafficking in Smuggled Property) to implement the Clean Diamond Trade Act of 2003, Pub. L. 108–19; (iv) §§ 2A1.1 (First Degree Murder), 2A1.2 (Second Degree Murder), 2A1.3 (Voluntary Manslaughter), 2A1.4 (Involuntary Manslaughter), 2A2.1 (Assault with Intent to Commit Murder; Attempted Murder), 2A2.2 (Aggravated Assault), and 2X5.1 to implement the Unborn Victims of Violence Act of 2004, Pub. L. 108–212; and (v) Chapter Two, Part X (Other Offenses) to implement several other laws that created new Class A Misdemeanor offenses; (J) proposed amendments to § 2D1.1 and Chapter Three (Adjustments) to address various guideline application issues; (K) proposed amendment to § 3C1.1 (Obstruction of Justice) that addresses three issues of circuit conflict; (L) issue for comment pertaining to attorney-client waiver in Chapter Eight (Sentencing of Organizations); (M) proposed amendment to Chapter Six (Sentencing Procedures and Plea Agreements) pertaining to crime victims' rights; and (N) proposed amendment to Chapter One, Part B (General Application Principles) pertaining to reductions in the term of imprisonment based on a Bureau of Prisons motion.

DATES: (A) Proposed Temporary, Emergency Amendment.—Written public comment on the proposed emergency amendment should be received by the Commission not later February 27, 2006, in anticipation of a vote to promulgate the emergency amendments at the Commission's March 2006 public meeting. Thereafter, written public comment on whether to repromulgate the emergency amendment as a permanent, non-emergency amendment should be received by the Commission not later than March 28, 2006.

(B) Proposed Non-Emergency Amendments.—Written public comment regarding the proposed

amendments and issues for comment set forth in this notice, including public comment regarding retroactive application of any of the proposed amendments, should be received by the Commission not later than March 28, 2006.

(C) Public Hearings.—The Commission has scheduled a public hearing on its proposed amendments for March 15, 2006, at the Thurgood Marshall Federal Judiciary Building, One Columbus Circle, NE., Washington, DC 20002–8002. A person who desires to testify at the public hearing should notify Michael Courlander, Public Affairs Officer, at (202) 502–4597, not later than February 17, 2006. Written testimony for the public hearing must be received by the Commission not later than March 1, 2006. Timely submission of written testimony is a requirement for testifying at the public hearing. The Commission requests that, to the extent practicable, commentators submit an electronic version of the comment and of the testimony for the public hearing. The Commission also reserves the right to select persons to testify at any of the hearings and to structure the hearings as the Commission considers appropriate and the schedule permits. Further information regarding the public hearing, including the time of the hearing, will be provided by the Commission on its Web site at *http://www.ussc.gov.*

In addition to the March public hearing, the Commission has scheduled two regional public hearings on the proposed immigration amendment. The first hearing will be held in San Antonio, TX, on February 21, 2006. The second hearing will be held in San Diego, CA, on March 6, 2006. Further information regarding these hearings, including the time and location, will be provided by the Commission on its Web site.

ADDRESSES: Public comment should be sent to: United States Sentencing Commission, One Columbus Circle, NE., Suite 2–500, Washington, DC 20002–8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Michael Courlander, Public Affairs Officer, Telephone: (202) 502–4597.

SUPPLEMENTARY INFORMATION: The United States Sentencing Commission is an independent agency in the judicial branch of the United States Government. The Commission promulgates sentencing guidelines and policy statements for Federal courts pursuant to 28 U.S.C. 994(a). The Commission also periodically reviews and revises previously promulgated guidelines pursuant to 28 U.S.C. 994(o) and submits guideline amendments to the Congress not later than the first day of May of each year pursuant to 28 U.S.C. 994(p).

The Commission seeks comment on the proposed amendments, issues for comment, and any other aspect of the sentencing guidelines, policy statements, and commentary. In addition to the issues for comment presented in the proposed amendments, the Commission requests comment regarding simplification of the guidelines. Specifically, with respect to the guidelines that are the subject of the following proposed amendments, should the Commission make additional amendments to simplify those guidelines, and if so, how? For example, should Specific Offense Characteristics that are infrequently applied be deleted and instead included as bases for upward departures? Should Specific Offense Characteristics that provide graduated increases for degrees of conduct be collapsed to provide a single offense level increase? For example, should a firearm enhancement that provides alternative offense level increases based on how a firearm was involved in the offense (*e.g.*, discharged, brandished, possessed, or otherwise used) provide a single offense level increase for the involvement of a firearm?

The Commission also requests public comment regarding whether the Commission should specify for retroactive application to previously sentenced defendants any of the proposed amendments published in this notice. The Commission requests comment regarding which, if any, of the proposed amendments that may result in a lower guideline range should be made retroactive to previously sentenced defendants pursuant to § 1B1.10 (Reduction in Term of Imprisonment as a Result of Amended Guideline Range).

The proposed amendments in this notice are presented in one of two formats. First, some of the amendments are proposed as specific revisions to a guideline or commentary. Bracketed text within a proposed amendment indicates a heightened interest on the Commission's part on comment and suggestions regarding alternative policy choices; for example, a proposed enhancement of [2][4][6] levels indicates that the Commission is considering, and invites comment on, alternative policy choices regarding the appropriate level of enhancement. Similarly, bracketed text within a specific offense characteristic or application note means that the Commission specifically invites comment on whether the proposed provision is appropriate. Second, the Commission has highlighted certain issues for comment and invites suggestions on how the Commission should respond to those issues.

Additional information pertaining to the proposed amendments described in this notice, including the Interim Staff Report on Immigration Reform and the Federal Sentencing Guidelines, may be accessed through the Commission's Web site at *http://www.ussc.gov.*

Authority: 28 U.S.C. 994(a), (o), (p), (x); USSC Rules of Practice and Procedure, Rule 4.4.

Ricardo H. Hinojosa,

Chair.

A. Proposed Emergency Amendment

1. Steroids

Synopsis of Proposed Amendment: This proposed amendment implements the directive in the United States Parole Commission Extension and Sentencing Commission Authority Act of 2005, Pub. L. 109–76, which requires the Commission, under emergency amendment authority, to implement section 3 of the Anabolic Steroid Control Act of 2004, Pub. L. 108–358 (the ''ASC Act''). The ASC Act directs the Commission to ''review the Federal sentencing guidelines with respect to offenses involving anabolic steroids'' and ''consider amending the * * * guidelines to provide for increased penalties with respect to offenses involving anabolic steroids in a manner that reflects the seriousness of such offenses and the need to deter anabolic steroid trafficking and use * * *.'' The Commission must promulgate an amendment not later than 180 days after the date of enactment of the United States Parole Commission Extension and Sentencing Commission Authority Act of 2005, which creates a promulgation deadline of March 27, 2006.

The proposed amendment implements the directives by increasing the penalties for offenses involving anabolic steroids. It does so by changing the manner in which anabolic steroids are treated under § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy). Currently, one unit of an anabolic steroid ''means a 10 cc vial of an injectable steroid or fifty tablets.'' The proposed amendment presents two options for increasing penalties. Option One bases the offense level in an anabolic steroid offense on the ''actual'' quantity of steroid involved in the offense and provides that one unit of an anabolic steroid means

[25][50][100] mg of an anabolic steroid, regardless of the form involved in the offense (*e.g.*, patch, cream, tablet, liquid). At 25 mg, sentencing penalties would be increased approximately 6–8 levels above current offense levels, and would closely approximate a 1:1 ratio with other Schedule III substances. At 50 mg, sentencing penalties would be increased approximately 4–6 levels above current offense levels, and at 100 mg, sentencing penalties would be increased approximately 2–4 levels above current offense levels. This option also includes a rebuttable presumption that the label, shipping manifest, or other similar documentation accurately reflects the purity of the steroid. Option Two eliminates the sentencing distinction between anabolic steroids and other Schedule III substances. Accordingly, if an anabolic steroid is in a pill, tablet, capsule, or liquid form, the court would sentence as it would in any other case involving a Schedule III substance. For anabolic steroids in other forms, the proposed amendment instructs the court that [1 unit means 25 mg and that] the court may determine the base offense level using a reasonable estimate of the quantity of anabolic steroid involved in the offense.

The proposed amendment also provide new enhancements designed to capture aggravating harms involved in anabolic steroid cases. First, the proposed amendment amends § 2D1.1 to provide an increase of two levels if the offense involved the distribution of a masking agent. A masking agent is a product added to, or taken with, an anabolic steroid to prevent the detection of the anabolic steroid in an individual's body. Second, the proposed amendment amends § 2D1.1 to provide an increase of two levels if the defendant distributed an anabolic steroid to a professional, college, or high school athlete. Third, the proposed amendment presents two options for increasing penalties for coaches who distribute anabolic steroids to their athletes. Option One provides, as an alternative to the proposed enhancement for distribution to an athlete, a two-level increase in § 2D1.1 if the defendant used the defendant's position as a coach of athletic activity to influence an athlete to use an anabolic steroid. Option Two amends Application Note 2 of § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) to include a coach who uses his or her position to influence an athlete to use an anabolic steroid in the list of special circumstances to which the two level adjustment in § 3B1.3 shall apply.

Two issues for comment follow the proposed amendment. The first pertains to whether the Commission, when it repromulgates the proposed amendment as a permanent amendment, should expand the scope of the enhancements to cover all controlled substances, not just anabolic steroids. The second issues pertains to whether the penalties for steroid offenses should be based on quantities typical of offenses involving mid- and high-level dealers.

Proposed Amendment: Section 2D1.1 is amended by redesignating subsections (b)(6) and (b)(7) as subsections (b)(8) and (b)(9), respectively; and by inserting the following after subsection (b)(5):

''(6) If the offense involved the distribution of (A) an anabolic steroid; and (B) a masking agent, increase by 2 levels.

(7) If the defendant distributed an anabolic steroid to a professional, college, or high school athlete[; Option 1(for coach): or (B) the defendant used the defendant's position as a coach of an athletic activity to influence a professional, college, or high school athlete to use an anabolic steroid], increase by 2 levels.]''.

[Option 1 (for steroids): Section 2D1.1(c) is amended in the ''*Notes to the Drug Quantity Table'' by striking subdivision (G) and inserting the following:

''(G) In the case of anabolic steroids, one 'unit' means [25][50][100] mg of an anabolic steroid, regardless of the form (*e.g.*, patch, topical cream, tablet, liquid). [There shall be a rebuttable presumption that the label, shipping manifest, or other similar documentation describing the type and purity of the anabolic steroid accurately reflects the purity of that steroid.]''.]

[Option 2 (for steroids): Section 2D1.1(c) is amended in the ''*Notes to the Drug Quantity Table'' in subdivision (F) by striking ''(except anabolic steroids)''; and by adding at the end the following:

''For an anabolic steroid that is not in a pill, capsule, tablet, or liquid form (*e.g.* patch, topical cream, aerosol), [(A) one 'unit' means [25] mg; and (B)] the court may determine the base offense level using a reasonable estimate of the quantity of anabolic steroid involved in the offense.''.

Section 2D1.1(c) is amended in the ''*Notes to the Drug Quantity Table'' by striking subdivision (G).]

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended by striking ''(b)(6)'' and inserting ''(b)(8)'' each place it appears; and by striking ''(b)(7)'' and inserting ''(b)(9)'' each place it appears.

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended by adding at the end the following:

''24. Application of Subsection (b)(6).—For purposes of subsection (b)(6), 'masking agent' means a product added to, or taken with, an anabolic steroid that prevents the detection of the anabolic steroid in an individual's body.

25. Application of Subsection (b)(7).—For purposes of subsection (b)(7):

'Athlete' means an individual who participates in an athletic activity conducted by (A) an intercollegiate athletic association or interscholastic athletic association; (B) a professional athletic association; or (C) an amateur athletic organization.

'Athletic activity' means an activity that (A) has officially designated coaches; (B) conducts regularly scheduled practices or workouts that are supervised by coaches; and (C) has established schedules for competitive events or exhibitions.

'College or high school athlete' means an athlete who is a student at an institution of higher learning (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001) or at a secondary school (as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

'Professional athlete' means an individual who competes in a major professional league.''.

The Commentary to § 2D1.1 captioned ''Background'' is amended in the ninth paragraph by striking ''(b)(6)(A)'' and inserting ''(b)(8)(A)''; and in the last paragraph by striking ''(b)(6)(B) and (C)'' and inserting ''(b)(8)(B) and (C)''.

[Option 2 (for coaches): The Commentary to § 3B1.3 captioned ''Application Notes'' is amended in Note 2 in subdivision (A) by inserting ''Postal Service Employee.—'' before ''An employee''; in subdivision (B) by inserting ''Offenses Involving 'Means of Identification'.—'' before ''A defendant''; and by adding at the end the following:

''(C) Coach of Athletic Activity.—A defendant who uses the defendant's position as a coach of an athletic activity to influence a professional, college, or high school athlete to use an anabolic steroid.

For purposes of this guideline:

(i) 'Athlete' means an individual who participates in an athletic activity conducted by (I) an intercollegiate athletic association or interscholastic athletic association; (II) a professional athletic association; or (III) an amateur athletic organization.

(ii) 'Athletic activity' means an activity that (I) has officially designated coaches; (II) conducts regularly

scheduled practices or workouts that are supervised by coaches; and (III) has established schedules for competitive events or exhibitions.

(iii) 'College, or high school athlete' means an athlete who is a student at an institution of higher learning (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001) or at a secondary school (as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(iv) 'Professional athlete' means an individual who competes in a major professional league.]''.

Issues for Comment:

(1) The Commission requests comment regarding whether, when the Commission re-promulgates the temporary, emergency amendment as a permanent amendment, it should expand the proposed enhancements in § 2D1.1(b)(6) (pertaining to masking agents) and in § 2D1.1(b)(7) (pertaining to distribution of a steroid to an athlete) to cover offenses involving any controlled substance. Specifically, the proposed amendment defines ''masking agent'' as ''a product added to, or taken with, an anabolic steroid to prevent the detection of the anabolic steroid in an individual's body.'' However, masking agents also can be taken to prevent the detection of other controlled substances. The Commission requests comment regarding whether it should expand the definition of masking agent, and thus application of the enhancement, in a manner that covers all controlled substances, not just anabolic steroids. Similarly, there are controlled substances other than anabolic steroids that enhance an individual's performance. The Commission requests comment regarding whether the proposed enhancement pertaining to distribution to an athlete should be expanded to cover offenses involving all types of controlled substances.

(2) The Commission requests comment regarding whether penalties for steroid offenses should be based on quantities typical of offenses involving mid- and high-level dealers. For more serious drug types (*e.g.*, heroin, cocaine, marihuana), the Drug Quantity Table in § 2D1.1(c) provides an offense level of 26 for quantities typical of mid-level dealers and an offense level of 32 for quantities typical of high-level dealers. These levels also correspond to the statutory mandatory minimum penalties for mid- and high-level dealers. Although there are no statutory mandatory minimum penalties establishing thresholds for steroid offenses, the Commission has been informed that a steroids dealer who provides the equivalent of one complete cycle to 10 customers is considered to be a mid-level dealer, and a dealer who provides the equivalent of one complete cycle to 30 customers is considered to be a high-level dealer. Currently, offense levels in the Drug Quantity Table for anabolic steroids and other Schedule III substances begin at level 6 and are ''capped'' at level 20. Should the Commission provide a penalty structure within this range that targets offenses involving mid- and high-level steroid dealers, and if so, what offense levels should correspond to a mid-level dealer and to a high-level dealer?

B. Proposed Non-Emergency Amendments

1. Immigration

Synopsis of Proposed Amendment: This four part proposed amendment addresses issues involving immigration offenses. These issues were identified through review of HelpLine calls to the Commission, feedback from training seminars, receipt of public comment, and information staff gathered from an immigration roundtable discussion. Part One of the proposed amendment addresses issues relating to offenses sentenced under § 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien). Part Two is a proposal to amend § 2L2.1 (Trafficking in a Document Relating to Naturalization, Citizenship, or Legal Resident Status, or a United States Passport; False Statement in Respect to the Citizenship or Immigration Status of Another; Fraudulent Marriage to Assist Alien to Evade Immigration Law) and § 2L2.2 (Fraudulently Acquiring Documents Relating to Naturalization, Citizenship, or Legal Resident Status for Own Use; False Personation or Fraudulent Marriage by Alien to Evade Immigration Law; Fraudulently Acquiring or Improperly Using a United States Passport). Part Three addresses issues relating to offenses sentenced under § 2L1.2 (Unlawfully Entering or Remaining in the United States). Part Four presents issues for comment regarding the proposed amendment.

1. Section 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien)

This part of the proposed amendment covers offenses sentenced under § 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien).

A. National Security Concerns

Currently, § 2L1.1(a)(1) provides a base offense level of level 23 if the defendant was convicted under 8 U.S.C. 1327 of a violation involving an alien who previously was deported after a conviction for an aggravated felony. Title 8, United States Code, section 1327, provides a statutory maximum term of imprisonment of 10 years for cases involving aiding or assisting certain aliens who pose a heightened risk to the safety of the citizens of the United States. However, § 2L1.1(a)(1) only applies to a limited subgroup of those convicted under § 1327. This proposal provides three options to increase punishment for those defendants who assist ''inadmissible aliens'' in illegally entering the United States. All options retain the current base offense level of 23 for a defendant who has a conviction under 8 U.S.C. 1327 in a case in which the violation involved an alien ''who previously was deported after a conviction for an aggravated felony.'' Option One provides a base offense level of 25 for a defendant who is convicted of 8 U.S.C. 1327 involving an alien who is inadmissable because of ''security or related grounds'', as defined in 8 U.S.C. 1182(a)(3). Option Two provides a specific offense characteristic with an increase of [2–6] levels for defendants who smuggle, transport, or harbor an alien who was inadmissible under 8 U.S.C. 1182(a)(3). This option is relevant conduct based.

B. Number of Aliens

The proposed amendment provides two options to amend § 2L1.1(b)(2) regarding the number of aliens involved in the offense. The first option maintains the current structure of the table, which provides a three-level increase for offenses involving six to 24 aliens, a six-level increase for offenses involving 25 to 99 aliens, and a nine-level increase for offenses involving 100 or more aliens. Option One amends the table to provide a nine-level increase for offenses involving 100 to 199 aliens, a [12]-level increase for offenses involving 200 to 299 aliens, and a [15]-level increase for offenses involving 300 or more aliens. Option Two, in part mirrors Option One by providing the same increases at the top end of the table for offenses involving 100 or more aliens. However, Option Two also provides smaller categories at the low end of the table. Offenses involving six to [15] aliens would receive an increase of three levels, [16 to 49] aliens would receive an increase of [six] levels, and [50 to 99] aliens would receive an increase of [nine] levels.

C. Endangerment of Minors

The proposed amendment presents two options and an issue for comment to address offenses in which an alien

minor was smuggled, harbored, or transported. Option One provides a [2][4][6] level increase if the defendant smuggled, transported, or harbored a minor unaccompanied by the minor's parent. Option two provides a graduated increase, based upon the age of the minor smuggled, harbored, or transported. A four-level increase is provided for a defendant who smuggles a minor under the age of 12 who is unaccompanied by his or her parent. A two-level increase is provided for a defendant who smuggles a minor unaccompanied by his or her parent who has attained the age of 12 years, but has not attained the age of 16 years.

D. Offenses Involving Death

The amendment proposes several changes to the guideline in cases in which death occurred. First, the proposed amendment removes the increase of eight levels ''if death resulted'' from the current specific offense characteristic addressing bodily injury and places this increase in a stand alone specific offense characteristic. This new specific offense characteristic would provide an increase of [10] levels. Providing a separate specific offense characteristic for death allows for cumulative enhancements in a case in which both bodily injury and death occur. Additionally, the cross reference at § 2L1.1(c)(1) is expanded to cover deaths other than murder, if the resulting offense level is greater than the offense level determined under § 2L1.1.

E. Abducting Aliens, or Holding Aliens for Ransom

A [four]-level increase and a minimum offense level of [23] is proposed for cases in which an alien was kidnapped, abducted, or unlawfully restrained, or if a ransom demand was made. This proposed amendment addresses the concern about cases in which the unlawful aliens are coerced, with or without the use of physical force, or even with direct threats, into remaining in ''safe houses'' for long periods of time through coercion, implied threat, or deception. This is done so that the smugglers can get more money from the families of the aliens or so they will provide inexpensive labor. Currently, this conduct is not covered by § 3A1.3 (Restraint of Victim) because that guideline only covers ''physical restraint''. The extent of the increase (four levels) is consistent with a similar enhancement in subsection (b)(7)(B) of § 2A4.1 (Kidnapping, Abduction, Unlawful Restraint) and the minimum offense level of 23 is consistent with § 2A4.2 (Demanding or Receiving Ransom Money), which provides a base offense level of 23 for such offenses.

2. Sections 2L2.1 (Trafficking in a Document Relating to Naturalization, Citizenship, or Legal Resident Status, or a United States Passport; etc.) and 2L2.2 (Fraudulently Acquiring Documents Relating to Naturalization, Citizenship, or Legal Resident Status for Own Use; etc.)

This part of the proposed amendment covers offenses sentenced under §§ 2L2.1 (Trafficking in a Document Relating to Naturalization, Citizenship, or Legal Resident Status, or a United States Passport; etc.) and 2L2.2 (Fraudulently Acquiring Documents Relating to Naturalization, Citizenship, or Legal Resident Status for Own Use; etc.)

A. Number of Documents

The proposed amendment provides two options in § 2L2.1 to amend the specific offense characteristic involving the number of documents and passports involved in the offense. The two options are identical to the two options presented under § 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien) to amend the specific offense characteristic (b)(2) regarding the number of aliens involved in the offense. The first option maintains the current structure of the table, which provides a three-level increase for offenses involving six to 24 documents, a six-level increase for offenses involving 25 to 99 documents, and a nine-level increase for offenses involving 100 or more documents. Option one amends the table to provide a nine-level increase for offenses involving 100 to 199 documents, a [12]-level increase for offenses involving 200 to 299 documents, and a [15]-level increase for offenses involving 300 or more documents. Option two, in part mirrors option one by providing the same increases at the top end of the table for offenses involving 100 or more documents. However, option two also provides smaller categories at the low end of the table. Offenses involving six to [15] documents would receive an increase of [three] levels, [16 to 49] documents would warrant an increase of [six] levels, and [50 to 99] documents would receive an increase of [nine] levels.

B. Fraudulently Obtaining or Using United States Passports or Foreign Passports

The proposed amendment provides a new specific offense characteristic at § 2L2.1(b)(5)(A) that provides a four-level increase in a case in which the defendant fraudulently used or obtained a United States passport. The same specific offense characteristic was added to § 2L2.2, effective November 1, 2004. Addition of this specific offense characteristic promotes proportionality between the document fraud guidelines, §§ 2L2.1 and 2L2.2. In addition, the proposed amendment also provides, at § 2L2.1(b)(1)(B) and § 2L2.2(b)(3)(B), a two-level increase if the defendant fraudulently obtained or used a foreign passport.

3. § 2L1.2 (Unlawfully Entering or Remaining in the United States)

This part of the proposed amendment addresses issues relating to offenses sentenced under § 2L1.2 (Unlawfully Entering or Remaining in the United States).

A. Alternative Approaches to Sentencing Under § 2L1.2

The current structure of § 2L1.2 requires the court, using the ''categorical approach'', to assess whether a prior conviction qualifies for a particular category under the guideline. This analysis is often complicated by lack of documentation, competing case law decisions, and the volume of cases. In addition, § 2L1.2 contains different definitions of covered offenses from the statute. Courts, then, are faced with making these assessments multiple times in the same case. The proposed amendment provides five options to address the complexity of this guideline.

The first, second, and third options amend the structure of § 2L1.2 by using the definition of aggravated felony in combination with the length of the sentence imposed for that prior felony conviction. Option one provides a 16-level increase for an aggravated felony in which the sentence of imprisonment imposed exceeded 13 months; a 12-level increase for an aggravated felony in which the sentence of imprisonment imposed was less than 13 months; and an eight-level increase for all other aggravated felonies. Option two provides a 16-level increase for an aggravated felony in which the sentence of imprisonment imposed exceeded two years; a 12-level increase for an aggravated felony in which the sentence of imprisonment imposed was at least one year, but less than two years; and an 8 level increase for all other aggravated felonies. Option three, mirroring the criminal history guidelines, provides a 16-level increase for an aggravated felony in which the sentence imposed exceeded 13 months; a 12-level increase for an aggravated felony in which the sentence imposed

was at least 60 days but did not exceed 13 months; and an 8 level increase for all other aggravated felonies.

The fourth option maintains the current structure of § 2L1.2, except that the categories of offenses delineated under this guideline are defined by 8 U.S.C.1101(a)(43), the statute providing definitions for ''aggravated felonies''. Additionally, this option provides use of length of sentence of imprisonment imposed in conjunction with ''crime of violence'' to further distinguish between the numerous types of prior convictions that fall within this category.

Finally, the fifth option provides an increased base offense level and a reduction if the prior conviction is not a felony.

4. Issues for Comment

Part 4 of the proposed amendment sets forth multiple issues for comment regarding the immigration guidelines and the proposed amendment.

Proposed Amendment:

Part 1: § 2L1.1

[**Please Note:** For ease of presentation, the proposed amendments set forth in Part 1, Subparts A through E, are drafted independently of each other. If the Commission were to vote to adopt an amendment from each Subpart, technical and conforming amendments would be made to ensure proper redesignations of subsections and application notes.]

A. National Security Concerns

[Option 1: Section 2L1.1 is amended by redesignating subsections (a)(1) and (a)(2) as subsections (a)(2) and (a)(3), respectively; and by inserting after ''Level:'' the following:

''(1) [25], if the defendant was convicted under 8 U.S.C. 1327 of a violation involving an alien who was inadmissible under 8 U.S.C. 1182(a)(3);''; and in subsection (a)(3), as redesignated by this amendment, by striking ''12'' and inserting ''[12][14]''.

The Commentary to § 2L1.1 captioned ''Application Notes'' is amended by redesignating Notes 2 through 6 as Notes 3 through 7, respectively; and by inserting after Note 1 the following:

''2. Application of Subsection (a)(1).—Subsection (a)(1) applies in cases in which the defendant is convicted under 18 U.S.C. 1327 of knowingly smuggling certain aliens inadmissible under 8 U.S.C. 1182(a)(3). Section 1327 requires that the defendant know that the alien is ineligible to be admitted into the United States, however, it does not require that the defendant have specific knowledge as to why the defendant is ineligible for admission.''.]

[Option 2 (for national security): Section 2L1.1 is amended by redesignating subsections (b)(3) through (b)(6) as subsections (b)(4) through (b)(7), respectively; and by inserting after subsection (b)(2) the following:

''(3) If the defendant smuggled, transported, or harbored an alien who was inadmissible under 8 U.S.C. 1182(a)(3), increase by [2][4][6] levels.''.]

B. Number of Aliens

[Option 1: Section 2L1.1(b)(2) is amended by striking subdivision (C) and inserting the following:

''(C) 100–199 add 9
(D) 200–299 add [12]
(E) 300 or more add [15].''.]

[Option 2: Section 2L1.1(b)(2) is amended by striking subdivisions (A) through (C) and inserting the following:

''(A) 6–[15] add 3
(B) [16–49] add [6]
(C) [50–99] add [9]
(D) [100–199] add [12]
(E) [200–299] add [15]
(F) [300 or more] add [18].''.]

The Commentary to § 2L1.1 captioned ''Application Notes'' is amended in Note 4 by inserting ''Application of Subsection (b)(2).—'' before ''If''; and by striking ''100'' and inserting ''300''.

C. Endangerment of Minors

Section 2L1.1 is amended by redesignating subsections (b)(3) through (b)(6) as subsections (b)(4) through (b)(7), respectively; and by inserting the following after subsection (b)(2):

[Option 1:

''(3) If the defendant smuggled, transported, or harbored a minor who was unaccompanied by the minor's parent, increase by [2][4][6] levels.''.]

[Option 2:

''(3) If (A) the defendant smuggled, transported, or harbored a minor who was unaccompanied by the minor's parent; and (B) the minor (i) had not attained the age of 12 years, increase by [4] levels; or (ii) had attained the age of 12 years but had not attained the age of 16 years, increase by [2] levels.''.]

D. Offenses Involving Death

Subsection (b)(6) is amended by striking ''died or''; by striking ''Death or''; by redesignating subdivisions (1) through (3) as subdivisions (A) through (C), respectively; by inserting a period after ''6 levels''; and by striking subdivision (4).

Section 2L1.1 is amended by inserting after subsection (b)(6) the following:

''(7) If the offense resulted in the death of any person, increase by [10] levels.''.

Subsection 2L1.1 is amended by striking subsection (c) and inserting the following:

''(c) Cross Reference

(1) If death resulted, apply the appropriate homicide guideline from Chapter Two, Part A, Subpart 1, if the resulting offense level is greater than that determined under this guideline.''.

E. Abducting Aliens or Holding Aliens for Ransom

Section 2L1.1(b) is amended by adding at the end the following:

''(7) If an alien was kidnapped, abducted, or unlawfully restrained, or if a ransom demand was made, increase by [4] levels. If the resulting offense level is less than level [23], increase to level [23].''.

Part 2: §§ 2L2.1 and 2L2.2

A. Number of Documents

[Option 1: Subsection 2L2.1(b)(2) is amended by striking subdivision (C) and inserting the following:

''(C) 100–199 add 9
(D) 200–299 add [12]
(E) 300 or more add [15].''.]

[Option 2: Section 2L2.1(b)(2) is amended by striking subdivisions (A) through (C) and inserting the following:

''(A) 6–[15] add 3
(B) [16–49] add [6]
(C) [50–99] add [9]
(D) [100–199] add [12]
(E) [200–299] add [15]
(F) [300 or more] add [18].''.]

The Commentary to § 2L2.1 captioned ''Application Notes'' is amended in Note 5 by inserting ''Application of Subsection (b)(2).—'' before ''If''; and by striking ''100'' and inserting ''300''.

B. Fraudulently Obtaining or Using United States Passports or Foreign Passports

Section 2L2.1(b) is amended by adding at the end the following:

''(5) If the defendant fraudulently obtained or used (A) a United States passport, increase by 4 levels; or (B) a foreign passport, increase by 2 levels.''.

Section 2L2.2(b)(3) is amended by inserting ''(A)'' after ''used'' and by inserting ''; or (B) a foreign passport, increase by 2 levels'' after ''4 levels''.

Part 3: § 2L1.2

[Option 1: Section 2L1.2(b)(1) is amended by striking subdivisions (A) and (B) and inserting the following:

''(A) a conviction for an aggravated felony for which a sentence of imprisonment exceeding 13 months was imposed, increase by 16 levels;

''(B) a conviction for an aggravated felony for which a sentence of imprisonment of 13 months or less was imposed, increase by 12 levels;''; and in subdivision (C) by inserting ''not covered by subdivision (b)(1)(A) or (b)(1)(B)'' after ''felony''.]

(Option 2: Section 2L1.2(b)(1) is amended by striking subdivisions (A) and (B) and inserting the following:

''(A) a conviction for an aggravated felony for which the sentence imposed exceeded 2 years, increase by 16 levels;

(B) a conviction for an aggravated felony for which the sentence imposed was at least 12 months but did not exceed 2 years, increase by 12 levels;''; and in subdivision (C) by inserting ''not covered by subdivision (b)(1)(A) or (b)(1)(B)'' after ''felony''.]

[Option 3: Section 2L1.2(b)(1) is amended by striking subdivisions (A) and (B) and inserting the following:

''(A) a conviction for an aggravated felony for which the sentence imposed exceeded 13 months, increase by 16 levels;

(B) a conviction for an aggravated felony for which the sentence imposed was at least 60 days but did not exceed 13 months, increase by 12 levels;''; and in subdivision (C) by inserting ''not covered by subdivision (b)(1)(A) or (b)(1)(B)'' after ''felony''.]

[**Please Note:** The following proposed Commentary amendments would be used with Options 1, 2, and 3)]:

The Commentary to § 2L1.2 captioned ''Application Notes'' is amended in Note 1 by striking subdivisions (B)(i) through (B)(viii) and inserting the following:

''(i) 'Aggravated felony' has the meaning given that term in section 101(a)(43) of the Immigration and Nationality Act (8 U.S.C. 1101(a)(43)), without regard to the date of conviction for the aggravated felony.

(ii) 'Aggravated felony not covered by subdivision (b)(1)(A) or (b)(1)(B)' means an aggravated felony for which the sentence imposed was a sentence other than imprisonment (*e.g.*, probation).

(iii) 'Felony' means any Federal, State, or local offense punishable by imprisonment for a term exceeding one year.

(iv) 'Sentence of imprisonment' has the meaning given that term in Application Note 2 and subsection (b) of § 4A1.2 (Definitions and Instructions for Computing Criminal History), without regard to the date of the conviction. The length of the sentence imposed includes any term of imprisonment given upon revocation of probation, parole, or supervised release.''.

The Commentary to § 2L1.2 captioned ''Application Notes'' is amended by striking Notes 2 and 3; and by redesignating Notes 4 through 6 as Notes 2 through 4, respectively.

[Option 4: Section 2L1.2(b) is amended in subdivision (A) by striking ''a felony'' and inserting ''an aggravated felony''; and by inserting ''for which the sentence imposed exceeded 13 months'' after ''violence''; in subdivision (B) by striking ''a felony'' and inserting ''an aggravated felony that is a (i)''; by striking the comma after ''less'' and inserting ''; (ii) crime of violence for which the sentence imposed was 13 months or less,''; and in subdivision (C) by inserting ''not covered by subdivision (b)(1)(A) or (b)(1)(B)'' after ''felony''.

The Commentary to § 2L1.2 captioned ''Application Notes'' is amended in Note 1 by striking subdivisions (B)(ii) through (B)(vi) and inserting the following:

''(ii) 'Child pornography offense' is an offense described in 8 U.S.C. 1101(a)(43)(I).

(iii) 'Crime of violence' has the meaning given that term in 18 U.S.C. 16.

(iv) 'Drug trafficking offense' has the meaning given that term in 18 U.S.C. 924(c).

(v) 'Firearms offense' is an offense described in 8 U.S.C. 1101(a)(43)(C) and (E).

(vi) 'Human trafficking offense' is an offense described in 8 U.S.C. 1101(a)(43)(K).''; and by striking subdivision (B)(viii) and inserting the following:

''(viii) 'National security or terrorism offense' is an offense described in 8 U.S.C. 1101(a)(43)(L).''.]

[Option 5: Section 2L1.2 is amended in subsection (a) by striking ''8'' and inserting ''[16][20][24]''; and by striking subsection (b)(1) and inserting the following:

''(1) If the defendant does not have a prior conviction for a felony, decrease by [8][6][4] levels.''.

The Commentary to § 2L1.2 captioned ''Application Notes'' is amended by striking Notes 1, 3, 4, and 6; by redesignating Notes 2 and 5 as Notes 1 and 2, respectively.

Part 4. Issues for Comment

(1) The proposed amendment to § 2L1.1 provides options for addressing defendants who smuggle, transport, or harbor any alien who is inadmissible under 8 U.S.C. 1182(a)(3). Certain sections of 8 U.S.C. 1182(a)(3), however, are very broad, such as subsection (a)(3)(A)(iii) (pertaining to inadmissibility due to an intent to commit ''any other unlawful activity''), or are unrelated to the national security risks associated with terrorism, such as subsections (a)(3)(D) (pertaining to membership in a totalitarian party) and (a)(3)(E) (pertaining to participants in Nazi persecutions). The Commission requests comment regarding whether it should more specifically identify, for purposes of either a heightened base offense level or a specific offense characteristic, the subsections of 8 U.S.C. 1182(a)(3) that pertain to terrorism or to other national security provisions. For example, should either a heightened base offense level or a specific offense characteristic be limited to 8 U.S.C. 1182(a)(3)(A)(i) (pertaining to espionage or sabotage), (a)(3)(A)(iii) (pertaining to overthrow of the United States Government), (a)(3)(B) (pertaining to terrorist activities), and (a)(3)(F) (pertaining to association with terrorist organizations)?

Additionally, the Commission requests comment regarding whether § 2L1.1 should provide a heightened base offense level if the defendant were convicted under 8 U.S.C. 1327 (Aiding or assisting certain aliens to enter) and a specific offense characteristic that would apply cumulatively if the defendant smuggled, transported, or harbored an alien the defendant knew to be inadmissible under 8 U.S.C. 1182(a)(3).

(2) The proposed amendment provides new specific offense characteristics that are defendant-based (*i.e.*, the defendant's liability is limited to the defendant's own conduct and conduct that the defendant aided or abetted, counseled, commanded, induced, procured, or willfully caused) rather than offense-based (*i.e.*, expanded relevant conduct). See proposed amendment, § 2L1.1(b)(3) (pertaining to smuggling inadmissible aliens) and (b)(4) (pertaining to smuggling a minor unaccompanied by the minor's parent). The Commission requests comment regarding whether these specific offense characteristics should be offense based rather than defendant based. Alternatively, should the proposed enhancement in § 2L1.1(b)(10) (pertaining to kidnapping an alien) be defendant-based rather than offense-based, as it is currently proposed?

(3) The proposed amendment to § 2L1.1 includes an enhancement for a defendant who smuggled, transported, or harbored a minor who was unaccompanied by the minor's parent. The Commission requests comment regarding whether such conduct is better addressed in the context of § 3A1.1 (Hate Crime Motivation or Vulnerable Victim).

(4) The Commission requests comment regarding whether it should increase the base offense levels in §§ 2L2.1 and 2L2.2.

(5) Currently, § 2L2.2 provides an increase of four levels if the defendant fraudulently obtained or used a United States passport. The proposed amendment would add this

enhancement to § 2L2.1 and also provide an enhancement of two levels in both §§ 2L2.1 and 2L2.2 if the defendant fraudulently obtained or used a foreign passport. As an alternative to the proposed amendment, the Commission requests comment regarding whether it should provide a [four-level] enhancement in both §§ 2L2.1 and 2L2.2 regardless of whether the passport was issued by the United States or a foreign country. Additionally, the Commission requests comment regarding whether other types of documents should be included in the enhancement. If so, what types of documents should be included? For example, should the proposed 2-level enhancement also apply in the case of a defendant who fraudulently obtains or used a driver's license?

Additionally, the Commission requests comment regarding whether it should provide an application note in §§ 2L2.1 and 2L2.2 that instructs the court not to apply § 2L2.1(b)(2), proposed § 2L2.1(b)(5), or § 2L2.2(b)(3) if the documents are so obviously counterfeit that they are unlikely to be accepted even if subjected to only minimal scrutiny. The guidelines currently provide such an application note in § 2B5.1 (Offenses Involving Counterfeit Bearer Obligations of the United States).

(6) The Commission requests comment regarding whether the prior convictions used to increase a defendant's offense level under § 2L1.2 should be subject to the rules of criminal history found at § 4A1.2. For example, if a prior conviction is too old to be counted for the purposes of criminal history, should that prior conviction also be too old to count for the purposes of § 2L1.2? Alternatively, should such a conviction be the basis for a reduction?

(7) Before May 1997, the table for number of aliens in § 2L1.1(b)(2) provided increases of two level increments. In May 1997, in response to a directive to increase the enhancement in § 2L1.1(b)(2) by at least 50 percent (see section 203 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Pub. L. 104–208), the Commission amended the table to provide increases of three level increments. At that time, the Commission also similarly amended the table in § 2L2.1 pertaining to the number of documents. The Commission requests comment regarding whether it should amend these tables to provide increases of two level increments. Any such change would be done in a manner that complies with the directive in the Illegal Immigration Reform and Immigrant Responsibility Act of 1996.

(8) As an alternative to Option 5 for amending § 2L1.2, the Commission requests comment regarding whether it should provide a guideline that is in essence an inversion of the current structure of § 2L1.2. Currently, § 2L1.2 provides increases based on the type of prior conviction. Should the Commission consider multiple reductions based on the type of prior conviction?

2. Firearms

Synopsis of Proposed Amendment: This proposed amendment addresses various issues pertaining to the firearms guideline, § 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition), and to other firearm provisions in the guidelines.

First, the proposed amendment addresses offenses involving a weapon described in 18 U.S.C. 921(a)(30), which expired on September 13, 2004. Although possession of such a weapon is no longer covered by 18 U.S.C. 921, possession of certain weapons, particularly by a prohibited person, may still be considered an aggravating factor warranting an increase in the base offense level. The proposed amendment presents two options for providing increases for possession of weapons previously covered by 18 U.S.C. 921(a)(30). Currently, § 2K2.1 has four base offense level provisions that are triggered by the offense involving such a weapon. Under Option One, each of the four base offense level provisions would be based on whether ''the offense involved a firearm that is a high-capacity, semiautomatic firearm.'' ''High-capacity, semiautomatic firearm'' would be defined as ''a semiautomatic firearm that has a magazine capacity of more than [15] cartridges.'' Option Two would provide an upward departure if the offense involved a high-capacity semiautomatic firearm. The proposed amendment also presents an issue for comment regarding this definition and whether any similar changes should be made to § 5K2.17 (High-capacity, Semiautomatic Firearms).

Second, the proposed amendment provides a [2-][4-]level enhancement in § 2K2.1 if the defendant engaged in the trafficking of [2–24] firearms, and a [6-][8-] level enhancement if the defendant engaged in the trafficking of [25 or more] firearms. Although there is no definition of trafficking in the firearm statutes, the proposed amendment borrows from the statutory definition of ''traffic'' found in other sections of the United States Code (see, *e.g.*, 18 U.S.C. 1028(d)(12), and 2318). The proposed amendment, however, modifies the statutory definition in two ways. The first modification pertains to consideration and two options are presented. Option One would result in application of the enhancement whenever a firearm was transferred as consideration for anything of value. (This option would be consistent with the statutory definitions of ''traffic''.) Option Two would result in application of the enhancement only if the transfer was made for pecuniary gain. The second modification is to include ongoing schemes to transport or transfer firearms to another individual, even if nothing of value was exchanged. The proposed amendment also presents an issue for comment regarding the proposed definition of ''trafficking''.

Third, the proposed amendment modifies § 2K2.1(b)(4) to increase the penalties for offenses involving altered or obliterated serial numbers. Under the proposed amendment, a 2-level enhancement would continue to apply to offenses involving a stolen firearm. However, the proposed amendment would provide a 4-level enhancement for offenses involving altered or obliterated serial numbers. The 4-level increase reflects the difficulty in tracing firearms with altered or obliterated serial numbers. The proposed amendment also makes slight technical changes to the corresponding application note.

Fourth, the proposed amendment addresses a circuit conflict pertaining to application of §§ 2K2.1(b)(5) and (c)(1), specifically with respect to the meaning of use of a firearm ''in connection with'' another offense in the context of burglary and drug offenses. The majority of circuits have adopted a standard consistent with *Smith* v. *United States*, 508 U.S. 223 (1993), in which the Supreme Court determined the scope of ''in relation to'' as that term is used in 18 U.S.C. 924(c). The proposed amendment accordingly provides that §§ 2K2.1(b)(5) and (c)(1) apply if the firearm facilitated, or had the potential of facilitating, another felony offense or another offense, respectively. However, the courts are split as to how this standard then applies with respect to burglary and drug offenses. For ease of presentation, the proposed amendment presents options in terms of whether the presence of a firearm by mere coincidence during the course of a burglary or drug offense ''facilitated or had the potential of facilitating'' another offense. Option One provides that the mere presence of a firearm during the course of burglary or a drug offense is

sufficient because the firearm emboldens the defendant. Option Two states that the mere presence of a firearm is not sufficient except in a drug offense. Accordingly, the enhancement in § 2K2.1(b)(5), or the cross reference in § 2K2.1(c)(1) would not apply in the case of a defendant who takes a firearm during a burglary, but it would apply in a drug offense because the mere presence of a firearm in a drug offense increases the risk of violence. Option Three provides that the mere presence is not enough to trigger either § 2K2.1(b)(5) or § 2K2.1(c)(1). (Please note that the proposed definitions of ''another felony offense'' and ''another offense'', as well as the upward departure note, are not new—the proposed language is a technical reworking of current Application Notes 4, 11, and 15.)

Fifth, the proposed amendment modifies § 5K2.11 (Lesser Harms) to prohibit a downward departure in any case in which a defendant is convicted under 18 U.S.C. 922(g).

Finally, the proposed amendment addresses the circuit conflict regarding whether pointing or waving a firearm at a specific person constitutes ''brandishing'' or ''otherwise using''. The proposed amendment presents three options. Option One combines brandished and otherwise used with respect to firearms under the theory that the same risk of harm, and the same fear, exists whether a firearm is generally waved about or specifically pointed at a particular individual. Under this approach, otherwise using and brandishing with respect to a firearm would result in the same sentencing increase in §§ 2B3.1 (Robbery) and 2B3.2 (Extortion by Force or Threat of Injury or Serious Damage). However, the proposed amendment would maintain the distinction between otherwise using or brandishing with respect to other dangerous weapons. Additionally, this option provides that generally waving a firearm would constitute otherwise used. Following this option, the proposed amendment presents an issue for comment regarding whether the Commission, if it adopts this approach, should make similar changes to other guidelines that have an enhancement for brandishing and otherwise using a firearm. Option Two presents the majority and minority circuit court views. The majority view holds that generally waiving or pointing a firearm constitutes brandishing but pointing a firearm at a specific individual to make an explicit or implicit threat, or as a means of forcing compliance, constitutes otherwise used. The minority view holds that pointing a firearm, even if it is pointed at a specific person, is brandishing. In the non-firearms context, otherwise used necessarily includes the most extreme thing that can be done with a weapon (*i.e.*, using it to injure or attempt to injure a victim). Accordingly, these courts hold a firearm must similarly be used to injure or attempt to injure a victim in order to constitute otherwise used, and to hold otherwise would be to obliterate the guidelines' definition of otherwise used.

Proposed Amendment

(A) 18 U.S.C. 921(a)(30)

[Option 1:

Section 2K2.1(a) is amended by striking subdivision (1) and inserting the following:

''(1) 26, if (A) the offense involved a firearm that is a high-capacity, semiautomatic firearm, or that is described in 26 U.S.C. 5845(a); and (B) the defendant committed any part of the instant offense subsequent to sustaining at least two felony convictions of either a crime of violence or a controlled substance offense;''; by striking subdivision (3) and inserting the following:

''(3) 22, if (A) the offense involved a firearm that is a high-capacity, semiautomatic firearm, or that is described in 26 U.S.C. 5845(a); and (B) the defendant committed any part of the instant offense subsequent to sustaining one felony conviction of either a crime of violence or a controlled substance offense;''; by striking subdivision (4)(B) and inserting the following:

''(B) the offense involved a firearm that is a high-capacity, semiautomatic firearm, or that is described in 26 U.S.C. 5845(a); and the defendant (i) was a prohibited person at the time the defendant committed the instant offense; or (ii) is convicted under 18 U.S.C. 922(d);''; and by striking subdivision (5) and inserting the following:

''(5) 18, if the offense involved a firearm that is a high-capacity, semiautomatic firearm, or that is described in 26 U.S.C. 5845(a);''.

The Commentary to § 2K2.1 captioned ''Application Notes'' is amended in Note 1 by inserting after the paragraph that begins '' 'Firearms' has'' the following:

''High-capacity, semiautomatic firearm'' means a semiautomatic firearm that has a magazine capacity of more than [15] cartridges.''.]

[Option 2:

Section 2K2.1(a) is amended in subdivision (1) by inserting ''(A)'' after ''26, if''; by striking ''or 18 U.S.C. 921(a)(30),'' and inserting a colon; and by inserting ''(B)'' before ''the defendant''; in subdivision (3) by inserting ''(A)'' after ''22, if''; by striking ''or 18 U.S.C. 921(a)(30),'' and inserting a colon; and by inserting ''(B)'' before ''the defendant''; in subdivision (4)(B) by striking ''or 18 U.S.C. 921(a)(30)''; and in subdivision (5) by striking ''or 18 U.S.C. 921(a)(30)''.

The Commentary to § 2K2.1 captioned ''Application Notes'' is amended by striking Note 11, as redesignated by Part D of this proposed amendment, and inserting the following:

''11. Upward Departure Provision.''—An upward departure may be warranted in any of the following circumstances: (A) the offense involved a high-capacity, semiautomatic firearm; (B) the number of firearms substantially exceeded 200; (C) the offense involved multiple National Firearms Act weapons (*e.g.*, machineguns, destructive devices), military type assault rifles, non-detectable (''plastic'') firearms (defined at 18 U.S.C. 922(p); (D) the offense involved large quantities of armor-piercing ammunition (defined at 18 U.S.C. 921(a)(17)(B)); or (E) the offense posed a substantial risk of death or bodily injury to multiple individuals (see Application Note 8). For purposes of this guideline, 'high-capacity, semiautomatic firearm' means a semiautomatic firearm that has a magazine capacity of more than [15] cartridges.''.]

Issue for Comment: The proposed amendment uses as a basis for providing enhanced base offense levels or, alternatively, for an upward departure. The Commission requests comment regarding whether there is an alternative definition that it should consider. Additionally, are there other categories of firearms or types of firearms that should form the basis for either an enhanced base offense level or for an upward departure? Finally, should the Commission make similar changes to the definition of ''high-capacity, semiautomatic firearm'' in § 5K2.17 (High-Capacity, Semiautomatic Firearms)?

(B) Trafficking SOC

Section 2K2.1(b) is amended by adding at the end the following:

''(7) If the defendant engaged in the trafficking of (A) [[2]–24] firearms, increase by [2][4] levels; or (B) [25 or more] firearms, increase by [6][8] levels.''.

The Commentary to § 2K2.1 captioned ''Application Notes'', as amended by Part D of this proposed amendment, is amended by adding at the end the following:

''13. Application of Subsection (b)(7).—

(A) Definition of 'Trafficking'.—For purposes of subsection (b)(7), 'trafficking' means transporting, transferring, or otherwise disposing of, [firearms][a firearm] to another individual, (i) [as consideration for anything of value][for pecuniary gain]; or (ii) as part of an ongoing unlawful scheme, even if nothing of value was exchanged.

(B) Use of the Term 'Defendant'.—Consistent with § 1B1.3 (Relevant Conduct), the term 'defendant' limits the accountability of the defendant to the defendant's own conduct and conduct that the defendant aided or abetted, counseled, commanded, induced, procured, or willfully caused.''.

Issue for Comment: The Commission requests comment regarding whether the definition of trafficking should be restricted to offenses in which the defendant knew, had reason to believe, or was wilfully blind to the fact, that the transfer would be to an individual whose possession or receipt would be unlawful. Additionally, should the definition include receiving firearms from another individual.

(C) Stolen and Altered or Obliterated Serial Numbers

Section 2K2.1(b) is amended by striking subdivision (4) and inserting the following:

''(4) (Apply the greater):

(A) If any firearm was stolen, increase by 2 levels; or

(B) If any firearm had an altered or obliterated serial number, increase by 4 levels.''.

The Commentary to § 2K2.1 captioned ''Application Notes'' is amended by striking Note 8, as redesignated by Part D of this amendment, and inserting the following:

''8. Application of Subsection (b)(4).—

(A) Interaction with Subsection (a)(7).—If the only offense to which § 2K2.1 applies is 18 U.S.C. 922(i), (j), or (u), or 18 U.S.C. 924(l) or (m) (offenses involving a stolen firearm or stolen ammunition) and the base offense level is determined under subsection (a)(7), do not apply the adjustment in subsection (b)(4)(A). This is because the base offense level takes into account that the firearm or ammunition was stolen. However, it the offense involved a firearm with an altered or obliterated serial number, apply subsection (b)(4)(B).

Similarly, if the offense to which § 2K2.1 applies is 18 U.S.C. 922(k) or 26 U.S.C. 5861(g) or (h) (offenses involving an altered or obliterated serial number) and the base offense level is determined under subsection (a)(7), do not apply the adjustment in subsection (b)(4)(B). This is because the base offense level takes into account that the firearm had an altered or obliterated serial number. However, it the offense involved a stolen firearm or stolen ammunition, apply subsection (b)(4)(A).

(B) Knowledge or Reason to Believe.—Subsection (b)(4) applies regardless of whether the defendant knew or had reason to believe that the firearm was stolen or had an altered or obliterated serial number.''.

(D) ''In Connection with'' in Burglary and Drug Offenses

The Commentary to § 2K2.1 captioned ''Application Notes'' is amended by striking Notes 4, 11, and 15; and by redesignating Notes 5 through 10 as Notes 4 through 9, respectively; and by redesignating Notes 12 through 14 as Notes 10 through 12, respectively.''.

The Commentary to § 2K2.1 captioned ''Application Notes'', as amended by Part (B) of this amendment, is amended by adding at the end the following:

''14. 'In Connection With'.—

(A) In General.—Subsections (b)(5) and (c)(1) apply if the firearm or ammunition facilitated, or had the potential of facilitating, another felony offense or another offense, respectively.

[Option One (mere coincidence enough because emboldens defendant):

(B) 'Mere Coincidence'.—Subsection (b)(5) and (c)(1) apply in a case in which the firearm is present by mere coincidence because the firearm has the potential of facilitating another felony offense, or another offense, respectively. For example, subsections (b)(5) and (c)(1) would apply in a case in which a defendant who, during the course of a burglary, finds and takes the firearm, even if the defendant did not engage in any other conduct with that firearm during the course of the burglary. Similarly, in a case involving a drug offense, the mere presence of a firearm is sufficient for application of subsections (b)(5) and (c)(1).]

[Option Two (mere coincidence not enough except in drug cases):

(B) 'Mere Coincidence'.—Except as provided in subdivision (C), application of subsection (b)(5) or (c)(1) requires that the firearm be present by more than mere coincidence. For example, neither subsection (b)(5) nor subsection (c)(1) would apply in a case in which a defendant who, during the course of a burglary, finds and merely takes the firearm, without engaging in any other conduct with that firearm during the course of the burglary. However, if the defendant subsequently engages in conduct that is separate and distinct from the initial taking of the firearm, subsection (b)(5) or subsection (c)(1) would apply.

(C) Application in Drug Cases.—In a case involving a drug offense, the mere presence of a firearm is sufficient for application of subsections (b)(5) and (c)(1) because of the increased risk of violence when a firearm is present during a drug offense. For example, subsections (b)(5) and (c)(1) would apply in the case of a defendant who, in the course of a drug trafficking offense, keeps a firearm in close proximity to the drugs, to drug-manufacturing materials, or to drug paraphernalia.]

[Option Three (mere coincidence not enough):

(B) 'Mere Coincidence'.—Application of subsection (b)(5) or (c)(1) requires that the firearm be present by more than mere coincidence. For example, neither subsection (b)(5) nor subsection (c)(1) would apply in a case in which a defendant who, during the course of a burglary, finds and merely takes the firearm, without engaging in any other conduct with that firearm during the course of the burglary. Similarly, in a case involving a drug offense, the mere presence of a firearm is not sufficient for purposes of applying subsection (b)(5) or (c)(1); there must be some indication that the firearm was used or possessed to protect the defendant engaged in the drug offense or to protect the drugs from theft.]

[**Please Note:** Subdivisions (C) and (D) to be used with Options One, Two, and Three]

(C) Definitions.—

'Another felony offense', for purposes of subsection (b)(5), means any Federal, State, or local offense, other than the explosive or firearms possession or trafficking offense, punishable by imprisonment for a term exceeding one year, regardless of whether a criminal charge was brought, or a conviction obtained.

'Another offense', for purposes of subsection (c)(1), means any Federal, State, or local offense other than the explosive or firearms possession or trafficking offense.

(D) Upward Departure Provision.—In a case in which the defendant used or possessed a firearm or explosive to facilitate another firearms or explosives offense (*e.g.*, the defendant used or possessed a firearm to protect the delivery of an unlawful shipment of explosives), an upward departure under § 5K2.6 (Weapons and Dangerous Instrumentalities) may be warranted.]''.

(E) Lesser Harms and Felon in Possession

Section 5K2.11 is amended in the second paragraph by adding at the end the following:

''However, lesser harms is not an appropriate basis for a downward departure in any case in which a defendant is convicted under 18 U.S.C. 922(g), even if the possession of a firearm were brief or existed because the defendant was disposing, or attempting to dispose of, a firearm.''.

(F) ''Brandished'' or ''Otherwise Used''

[Option 1 (Combining Brandished and Otherwise Used plus modified majority view):

The Commentary to § 1B1.1 captioned ''Application Notes'' is amended in Note 1 in subdivision (I) by adding at the end the following:

''For example, using a firearm or a bat to hit a victim would constitute 'otherwise used'. Additionally, with respect to a firearm, generally pointing or waving a firearm in a threatening manner constitutes 'otherwise used'.''.

Section 2B3.1(b)(2) is amended in subdivision (B) by inserting ''brandished or'' after ''firearm was''; and in subdivision (C) by striking ''brandished or'' before ''possessed,''.

Section 2B3.2(b)(3) is amended in subdivision (A)(ii) by inserting ''brandished or '' after ''firearm was''; and in subdivision (A)(iii) by striking ''brandished or'' before ''possessed''.].

[Option 2 (presenting majority and minority views):

[(Option 2A) (majority view): The Commentary to § 1B1.1 captioned ''Application Notes'' is amended in Note 1 by striking subdivision (C) and inserting the following:

''(C) 'Brandished' with reference to a dangerous weapon (including a firearm) means (i) all or part of the weapon was displayed; (ii) a weapon was generally pointed or waved in a threatening manner; or (iii) the presence of the weapon was otherwise made known to another person, in order to intimidate that person, regardless of whether the weapon was directly visible to that person. Although the dangerous weapon does not have to be directly visible, the weapon must be present.''; and in subdivision (I) by adding at the end the following:

''Pointing a firearm at a specific individual, or group of individuals, to make an explicit or implicit threat, or as a means of forcing compliance, constitutes 'otherwise used'.''.]

[Option 2B (Minority View): The Commentary to § 1B1.1 captioned ''Application Notes'' is amended in subdivision (I) by adding at the end the following:

''Use of a dangerous weapon (including a firearm) to injure or attempt to injure a victim would constitute 'otherwise used'. For example, using a firearm or a bat to hit a victim would constitute 'otherwise used' but pointing a firearm at a specific individual would not constitute 'otherwise used'.''.]

Issue for Comment: The proposed amendment provides an option for consolidating the enhancements for otherwise used and brandishing with respect to a case involving a firearm. The Commission requests comment regarding whether, if it adopts this approach in §§ 2B3.1 (Robbery) and 2B3.2 (Extortion by Force or Threat of Injury or Serious Damage), it should also adopt this approach in §§ 2A2.2 (Aggravated Assault) and 2E2.1 (Making or Financing an Extortionate Extension of Credit; Collecting an Extension of Credit by Extortionate Means).

3. Steroids

Synopsis of Proposed Amendment: This proposed amendment would repromulgate the proposed temporary, emergency amendment set forth in Part A of this Notice as a permanent amendment. The proposed amendment implements the directive in the United States Parole Commission Extension and Sentencing Commission Authority Act of 2005, Pub. L. 109–76, which requires the Commission, under emergency amendment authority, to implement section 3 of the Anabolic Steroid Control Act of 2004, Pub. L. 108–358 (the ''ASC Act''). The ASC Act directs the Commission to ''review the Federal sentencing guidelines with respect to offenses involving anabolic steroids'' and ''consider amending the * * * guidelines to provide for increased penalties with respect to offenses involving anabolic steroids in a manner that reflects the seriousness of such offenses and the need to deter anabolic steroid trafficking and use * * *.''

The proposed amendment implements the directives by increasing the penalties for offenses involving anabolic steroids. It does so by changing the manner in which anabolic steroids are treated under § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy). Currently, one unit of an anabolic steroid ''means a 10 cc vial of an injectable steroid or fifty tablets.'' The proposed amendment presents two options for increasing penalties. Option One bases the offense level in an anabolic steroid offense on the ''actual'' quantity of steroid involved in the offense and provides that one unit of an anabolic steroid means [25][50][100] mg of an anabolic steroid, regardless of the form involved in the offense (*e.g.*, patch, cream, tablet, liquid). At 25 mg, sentencing penalties would be increased approximately 6–8 levels above current offense levels, and would closely approximate a 1:1 ratio with other Schedule III substances. At 50 mg, sentencing penalties would be increased approximately 4–6 levels above current offense levels, and at 100 mg, sentencing penalties would be increased approximately 2–4 levels above current offense levels. This option also includes a rebuttable presumption that the label, shipping manifest, or other similar documentation accurately reflects the purity of the steroid. Option Two eliminates the sentencing distinction between anabolic steroids and other Schedule III substances. Accordingly, if an anabolic steroid is in a pill, tablet, capsule, or liquid form, the court would sentence as it would in any other case involving a Schedule III substance. For anabolic steroids in other forms, the proposed amendment instructs the court that [1 unit means 25 mg and that] the court may determine the base offense level using a reasonable estimate of the quantity of anabolic steroid involved in the offense.

The proposed amendment also provide new enhancements designed to capture aggravating harms involved in anabolic steroid cases. First, the proposed amendment amends § 2D1.1 to provide an increase of two levels if the offense involved the distribution of a masking agent. A masking agent is a product added to, or taken with, an anabolic steroid to prevent the detection of the anabolic steroid in an individual's body. Second, the proposed amendment amends § 2D1.1 to provide an increase of two levels if the defendant distributed an anabolic steroid to a professional, college, or high school athlete. Third, the proposed amendment presents two options for increasing penalties for coaches who distribute anabolic steroids to their athletes. Option One provides, as an alternative to the proposed enhancement for distribution to an athlete, a two-level increase in § 2D1.1 if the defendant used the defendant's position as a coach of athletic activity to influence an athlete to use an anabolic steroid. Option Two amends Application Note 2 of § 3B1.3 (Abuse of Position of Trust or Use of Special Skill) to include a coach who uses his or her position to influence an athlete to use an anabolic steroid in the list of special circumstances to which

the two level adjustment in § 3B1.3 shall apply.

Three issues for comment follow the proposed amendment. The first pertains to whether the Commission, when it repromulgates the proposed amendment as a permanent amendment, should expand the scope of the enhancements to cover all controlled substances, not just anabolic steroids. The second issue pertains to whether the penalties for steroid offenses should be based on quantities typical of offenses involving mid- and high-level dealers. The third issue pertains to whether the Commission should amend the guidelines to address offenses involving human growth hormone (HGH) and if so, how.

Proposed Amendment: Section 2D1.1 is amended by redesignating subsections (b)(6) and (b)(7) as subsections (b)(8) and (b)(9), respectively; and by inserting the following after subsection (b)(5):

''(6) If the offense involved the distribution of (A) an anabolic steroid; and (B) a masking agent, increase by 2 levels.

(7) If the defendant distributed an anabolic steroid to a professional, college, or high school athlete[; Option 1(for coach): or (B) the defendant used the defendant's position as a coach of an athletic activity to influence a professional, college, or high school athlete to use an anabolic steroid], increase by 2 levels.''.

[Option 1 (for steroids): Section 2D1.1(c) is amended in the ''*Notes to the Drug Quantity Table'' by striking subdivision (G) and inserting the following:

''(G) In the case of anabolic steroids, one ''unit'' means [25][50][100] mg of an anabolic steroid, regardless of the form (*e.g.*, patch, topical cream, tablet, liquid). [There shall be a rebuttable presumption that the label, shipping manifest, or other similar documentation describing the type and purity of the anabolic steroid accurately reflects the purity of that steroid.]''.]

[Option 2 (for steroids): Section 2D1.1(c) is amended in the ''*Notes to the Drug Quantity Table'' in subdivision (F) by striking ''(except anabolic steroids)''; and by adding at the end the following:

''For an anabolic steroid that is not in a pill, capsule, tablet, or liquid form (*e.g.* patch, topical cream, aerosol), [(A) one ''unit'' means [25] mg; and (B)] the court may determine the base offense level using a reasonable estimate of the quantity of anabolic steroid involved in the offense.''.

Section 2D1.1(c) is amended in the ''*Notes to the Drug Quantity Table'' by striking subdivision (G).]

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended by striking ''(b)(6)'' and inserting ''(b)(8)'' each place it appears; and by striking ''(b)(7)'' and inserting ''(b)(9)'' each place it appears.

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended by adding at the end the following:

''24. Application of Subsection (b)(6).—For purposes of subsection (b)(6), ''masking agent'' means a product added to, or taken with, an anabolic steroid that prevents the detection of the anabolic steroid in an individual's body.

25. Application of Subsection (b)(7).—For purposes of subsection (b)(7):

'Athlete' means an individual who participates in an athletic activity conducted by (A) an intercollegiate athletic association or interscholastic athletic association; (B) a professional athletic association; or (C) an amateur athletic organization.

'Athletic activity' means an activity that (A) has officially designated coaches; (B) conducts regularly scheduled practices or workouts that are supervised by coaches; and (C) has established schedules for competitive events or exhibitions.

'College or high school athlete' means an athlete who is a student at an institution of higher learning (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001) or at a secondary school (as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

'Professional athlete' means an individual who competes in a major professional league.''.

The Commentary to § 2D1.1 captioned ''Background'' is amended in the ninth paragraph by striking ''(b)(6)(A)'' and inserting ''(b)(8)(A)''; and in the last paragraph by striking ''(b)(6)(B) and (C)'' and inserting ''(b)(8)(B) and (C)''.

[Option 2 (for coaches): The Commentary to § 3B1.3 captioned ''Application Notes'' is amended in Note 2 in subdivision (A) by inserting ''Postal Service Employee.—'' before ''An employee''; in subdivision (B) by inserting ''Offenses Involving 'Means of Identification'.—'' before ''A defendant''; and by adding at the end the following:

''(C) Coach of Athletic Activity.—A defendant who uses the defendant's position as a coach of an athletic activity to influence a professional, college, or high school athlete to use an anabolic steroid.

For purposes of this guideline:

(i) 'Athlete' means an individual who participates in an athletic activity conducted by (I) an intercollegiate athletic association or interscholastic athletic association; (II) a professional athletic association; or (III) an amateur athletic organization.

(ii) 'Athletic activity' means an activity that (I) has officially designated coaches; (II) conducts regularly scheduled practices or workouts that are supervised by coaches; and (III) has established schedules for competitive events or exhibitions.

(iii) 'College, or high school athlete' means an athlete who is a student at an institution of higher learning (as defined in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001) or at a secondary school (as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(iv) 'Professional athlete' means an individual who competes in a major professional league.]''.

Issues for Comment:

(1) The Commission requests comment regarding whether, when the Commission re-promulgates the temporary emergency amendment as a permanent amendment, it should expand the proposed enhancements in § 2D1.1(b)(6) (pertaining to masking agents) and in § 2D1.1(b)(7) (pertaining to distribution of a steroid to an athlete) to cover offenses involving any controlled substance. Specifically, the proposed amendment defines ''masking agent'' as ''a product added to, or taken with, an anabolic steroid to prevent the detection of the anabolic steroid in an individual's body.'' However, masking agents also can be taken to prevent the detection of other controlled substances. The Commission requests comment regarding whether it should expand the definition of masking agent, and thus application of the enhancement, in a manner that covers all controlled substances, not just anabolic steroids. Similarly, there are controlled substances other than anabolic steroids that enhance an individual's performance. The Commission requests comment regarding whether the proposed enhancement pertaining to distribution to an athlete should be expanded to cover offenses involving all types of controlled substances.

(2) The Commission requests comment regarding whether penalties for steroid offenses should be based on quantities typical of offenses involving mid- and high-level dealers. For more serious drug types (*e.g.*, heroin, cocaine, marihuana), the Drug Quantity Table in § 2D1.1(c) provides an offense level of 26 for quantities typical of mid-level dealers and an offense level of 32 for

quantities typical of high-level dealers. These levels also correspond to the statutory mandatory minimum penalties for mid- and high-level dealers. Although there are no statutory mandatory minimum penalties establishing thresholds for steroid offenses, the Commission has been informed that a steroids dealer who provides the equivalent of one complete cycle to 10 customers is considered to be a mid-level dealer, and a dealer who provides the equivalent of one complete cycle to 30 customers is considered to be a high-level dealer. Currently, offense levels in the Drug Quantity Table for anabolic steroids and other Schedule III substances begin at level 6 and are ''capped'' at level 20. Should the Commission provide a penalty structure within this range that targets offenses involving mid- and high-level steroid dealers, and if so, what offense levels should correspond to a mid-level dealer and to a high-level dealer?

(3) Application Note 4 of § 2N2.1 (Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product) states that ''[t]he Commission has not promulgated a guideline for violations of 21 U.S.C. 333(e) (offenses involving human growth hormone).'' The Commission requests comment regarding whether it should specifically address offenses involving the distribution of human growth hormone (HGH), and if so, how.

4. Intellectual Property

Synopsis of Proposed Amendment: This proposed amendment proposes to re-promulgate as a permanent amendment the temporary, emergency amendment that implemented the directive in section 105 of the Family Entertainment and Copyright Act of 2005, Pub. L. 109–9. The emergency amendment became effective on October 24, 2005.

The directive instructs the Commission to ''review and, if appropriate, amend the Federal sentencing guidelines and policy statements applicable to persons convicted of intellectual property rights crimes * * *''

''In carrying out [the directive], the Commission shall—

(1) take all appropriate measures to ensure that the Federal sentencing guidelines and policy statements * * * are sufficiently stringent to deter, and adequately reflect the nature of, intellectual property rights crimes;

(2) determine whether to provide a sentencing enhancement for those convicted of the offenses [involving intellectual property rights], if the conduct involves the display, performance, publication, reproduction, or distribution of a copyrighted work before it has been authorized by the copyright owner, whether in the media format used by the infringing party or in any other media format;

(3) determine whether the scope of 'uploading' set forth in application note 3 of section 2B5.3 of the Federal sentencing guidelines is adequate to address the loss attributable to people who, without authorization, broadly distribute copyrighted works over the Internet; and

(4) determine whether the sentencing guideline and policy statements applicable to the offenses [involving intellectual property rights] adequately reflect any harm to victims from copyright infringement if law enforcement authorities cannot determine how many times copyrighted material has been reproduced or distributed.''

Pre-Release Works

The proposed amendment provides a separate two-level enhancement if the offense involved a pre-release work. The enhancement and the corresponding definition use language directly from 17 U.S.C. 506(a) (criminal infringement). The amendment adds language to Application Note 2 that explains that in cases involving pre-release works, the infringement amount should be determined by using the retail value of the infringed item, rather than any premium price attributed to the infringing item because of its pre-release status. The proposed amendment addresses concerns that distribution of an item before it is legally available to the consumer is more serious conduct than distribution of other infringing items and involves a harm not addressed by the current guideline.

Uploading

The concern underlying the uploading directive pertains to offenses in which the copyrighted work is transferred through file sharing, particularly peer-to-peer models. The Department of Justice has explained that Application Note 3, which expands on the definition of ''uploading'', may be read to exclude peer-to-peer activity from application of the current enhancement in § 2B5.3(b)(2) for offenses that involve the manufacture, importation, or uploading of infringing items. In particular, the concern pertains to the third sentence, which reads, ''For example, this subsection applies in the case of illegally uploading copyrighted software to an Internet site, but it does not apply in the case of downloading or installing that software on a hard drive on the defendant's personal computer.'' The proposed amendment builds on the current definition of ''uploading'' to include making an infringing item available on the Internet by storing an infringing item as an openly shared file (*i.e.*, a file that is stored on a peer-to-peer network). The proposed amendment also clarifies that uploading does not include merely downloading or installing infringing items on a hard drive of the defendant's computer unless the infringing item is an openly shared file. By clarifying the definition of uploading in this manner, Application Note 3, which is a restatement of the uploading definition, is no longer necessary and the proposed amendment deletes the application note from the guideline.

Indeterminate Number

The proposed amendment addresses the final directive by amending Application Note 2, which sets forth the rules for determining the infringement amount. The proposed note provides that the court may make a reasonable estimate of the infringement amount using any relevant information including financial records in cases in which the court cannot determine the number of infringing items. The Commission's empirical analysis of cases sentenced under this guideline suggests that courts often determine the infringement amount in this manner. This proposed amendment simply codifies into the guideline the practice currently employed by the courts.

New Offense

Finally, the proposed amendment provides a reference in Appendix A (Statutory Index) for the new offense at 18 U.S.C. 2319B. This offense is proposed to be referenced to § 2B5.3.

Proposed Amendment: Section 2B5.3(b) is amended by redesignating subsections (b)(2) through (b)(4) as subsections (b)(3) through (b)(5), respectively; and by inserting after subsection (b)(1) the following:

''(2) If the offense involved the display, performance, publication, reproduction, or distribution of a work being prepared for commercial distribution, increase by 2 levels.''.

The Commentary to § 2B5.3 captioned ''Application Notes'' is amended in Note 1 by striking the last paragraph and inserting the following:

'''Uploading' means making an infringing item available on the Internet or a similar electronic bulletin board with the intent to enable other persons to (A) download or otherwise copy the infringing item; or (B) have access to the

infringing item, including by storing the infringing item as an openly shared file. 'Uploading' does not include merely downloading or installing an infringing item on a hard drive on a defendant's personal computer unless the infringing item is an openly shared file.

'Work being prepared for commercial distribution' has the meaning given that term in 17 U.S.C. 506(a)(3).''.

The Commentary to § 2B5.3 captioned ''Application Notes'' is amended in Note 2 in subdivision (A) by inserting after subdivision (v) the following:

''(vi) The offense involves the display, performance, publication, reproduction, or distribution of a work being prepared for commercial distribution. In a case involving such an offense, the 'retail value of the infringed item' is the value of that item upon its initial commercial distribution.''; and by inserting after subdivision (D) the following:

''(E) Indeterminate Number of Infringing Items.—In a case in which the court cannot determine the number of infringing items, the court need only make a reasonable estimate of the infringement amount using any relevant information, including financial records.''.

The Commentary to § 2B5.3 captioned ''Application Notes'' is amended by striking Note 3; and by redesignating Notes 4 and 5 as Notes 3 and 4, respectively.

Appendix A (Statutory Index) is amended by inserting after the line reference to ''18 U.S.C. 2319A'' the following:

''18 U.S.C. 2319B2B5.3''.

5. Terrorism/Obstruction of Justice

Synopsis of Proposed Amendment: This proposed amendment re-promulgates as a permanent amendment the temporary, emergency amendment that responded to section 6703 of the Intelligence Reform and Terrorism Prevention Act of 2004 (the ''Act''), Pub. L. 108–458. That amendment became effective on October 24, 2005.

The Act directed the Commission ''to provide for an increased offense level for an offense under sections 1001(a) and 1505 of title 18, United States Code, if the offense involves international or domestic terrorism, as defined in section 2331 of such title.'' The Act also increased the penalties for offenses under 18 U.S.C. 1001 (false statements) and 1505 (obstruction of proceedings before departments, agencies, and committees of the United States) from not more than 5 years to not more than 8 years if the offense involves international or domestic terrorism. The Commission was subsequently directed by the United States Parole Commission Extension and Sentencing Commission Authority Act of 2005 Pub. L. 109–76 to promulgate an amendment under emergency amendment authority not later than November 27, 2005. See Supplement to Appendix C (Amendment 676).

The proposed amendment provides a 12-level enhancement in § 2J1.2 (Obstruction of Justice) if the defendant is convicted under 18 U.S.C. 1001 or 1505 and the enhanced statutory sentencing provision pertaining to international or domestic terrorism applies. The proposed amendment also provides an application note that instructs the court not to apply the new enhancement if an adjustment under § 3A1.4 (Terrorism) applies.

Proposed Amendment: Section 2J1.2(b) is amended by striking subdivision (1) and inserting the following:

''(1) (Apply the greater):

(A) If the offense involved causing or threatening to cause physical injury to a person, or property damage, in order to obstruct the administration of justice, increase by 8 levels.

(B) If (i) defendant was convicted under 18 U.S.C. 1001 or 1505; and (ii) the statutory maximum term of imprisonment relating to international terrorism or domestic terrorism is applicable, increase by 12 levels.''.

The Commentary to § 2J1.2 captioned ''Statutory Provisions'' is amended by striking ''18 U.S.C. 1503'' and inserting the following:

''18 U.S.C. 1001 when the statutory maximum term of imprisonment relating to international terrorism or domestic terrorism is applicable, 1503''.

The Commentary to § 2J1.2 captioned ''Application Notes'' is amended in Note 1 by inserting after ''Definitions.—For purposes of this guideline:'' the following:

'''Domestic terrorism'' has the meaning given that term in 18 U.S.C. 2331(5).

International terrorism'' has the meaning given that term in 18 U.S.C. 2331(1).''.

The Commentary to § 2J1.2 captioned ''Application Notes'' is amended by striking Note 2 and inserting the following:

''2. Chapter Three Adjustments.—

(A) Inapplicability of Chapter Three, Part C.—For offenses covered under this section, Chapter Three, Part C (Obstruction) does not apply, unless the defendant obstructed the investigation, prosecution, or sentencing of the obstruction of justice count.

(B) Interaction with Terrorism Adjustment.—If § 3A1.4 (Terrorism) applies, do not apply subsection (b)(1)(B).''.

Appendix A (Statutory Index) is amended in the line referenced to ''18 U.S.C. 1001'' by inserting '', 2J1.2 when the statutory maximum term of imprisonment relating to international terrorism or domestic terrorism is applicable'' after 2B1.1''.

6. Transportation

Synopsis of Proposed Amendment: This proposed amendment implements a number of provisions of the Safe, Accountable, Flexible, Efficient Transportation Act: A Legacy for Users, Pub. L. 109–59 (hereinafter the ''Transportation Act''). Specifically:

(A) Section 3042 of the Transportation Act amends the definition of ''mass transportation'' in 18 U.S.C. 1993 so that it now refers to ''public transportation'' and expands the definition to include the control of mass transportation vehicles.

The proposed amendment responds to section 3042 by revising §§ [2A1.4 (Involuntary Manslaughter)], 2A5.2 (Interference with Flight Crew Member of Flight Attendant; Interference with Dispatch, Operation, or Maintenance of Mass Transportation Vehicle or Ferry) and 2K1.4 (Arson; Property Damage by Use of Explosives) so that the guideline term definition of ''mass transportation'' mirrors the statutory change to ''public transportation''. It also proposes to amend the heading of Chapter Two, Part A, Subpart 5 to reflect the revised terminology and proposes to amend the heading of § 2A5.2 to include the control of mass transportation vehicle, in conformance with the amendments to 18 U.S.C. 1993 made by section 3042.

(B) Section 4102 of the Transportation Act amends 49 U.S.C. 31310 to provide increased penalties for out-of-service violations and false records related to commercial vehicle safety. The Transportation Act creates a new criminal penalty of up to one year imprisonment for employers who knowingly and willfully allow or require employees to violate ''out-of-service'' orders (''OOS orders''). The Secretary of Transportation's statutory authority for issuing OOS orders is predicated upon a finding that a regulatory violation ''poses an imminent hazard to safety.'' The term ''imminent hazard'' is defined as ''any condition'likely to result in serious injury or death. . . .'' Previously, the statute imposed only a maximum fine of $10,000 for knowingly requiring or allowing an employee to operate an out of service commercial motor vehicle.

According to the Senate's report language on this provision, it is

increasingly more difficult for enforcement officers to monitor out of service vehicles, particularly when the orders cover entire fleets of commercial motor vehicles. As such, ''Many OOS orders are violated.'' Congress intends the new penalty provisions—including increased fines for violating OOS orders—to deter such violations in the future.

In response, the proposed amendment references the new criminal provision at 49 U.S.C. 31310 to a new guideline already proposed for Class A misdemeanors. (See proposed amendment relating to the implementation of miscellaneous enacted legislation.)

(C) Section 4210 of the Transportation Act creates a new section at 49 U.S.C. 14915 covering penalties for failure to give up possession of household goods. Failure to give up household goods is defined as ''the knowing and willful failure, in violation of a contract, to deliver to, or unload at, the destination of a shipment of household goods that is subject to jurisdiction under subchapter I or III of chapter 135 of this title, for which charges have been estimated by the motor carrier providing transportation of such goods, and for which the shipper has tendered a payment described in clause (i), (ii), or (iii) of section 13707(b)(3)(A).''. The criminal penalty for failure to give up possession of household goods is a term of imprisonment of up to two years.

The proposed amendment refers this new offense to § 2B1.1, the guideline covering fraud, theft, and property destruction.

(D) The proposed amendment provides an issue for comment regarding whether the Commission should amend the guidelines to implement section 7121 of the Transportation Act, which pertains to the transportation of hazardous waste, and if so how.

Proposed Amendment

(A) Implementation of Section 3042 of Transportation Act

The Commentary to § 2A1.4 captioned ''Application Note'' is amended in Note 1 in the paragraph that begins '''Means of transportation''' by striking ''mass transportation'' and inserting ''public transportation''; and by striking '''Mass transportation''' and inserting '''Public transportation'''.

Chapter 2, Part A, Subpart 5, is amended in the heading by striking ''MASS'' and inserting ''PUBLIC''.

Section 2A5.2 is amended in the heading by inserting ''Control,'' after ''Operation,''; and by striking ''Mass'' and inserting ''Public''.

Section 2A5.2(a) is amended in subdivisions (1)(B) and (2)(B) by striking ''mass'' and inserting ''public'' each place it appears.

The Commentary to § 2A5.2 captioned ''Application Note'' is amended in Note 1 in the last paragraph by striking '''Mass'' and inserting '''Public''.

Section 2K1.4(a) is amended by striking ''mass'' and inserting ''public'' each place it appears.

The Commentary to § 2K1.4 captioned ''Application Note'' is amended in Note 1 by striking ''Mass'' and inserting ''Public''.

(B) Implementation of Section 4102 of Transportation Act

[**Please Note:** This amendment proposes to add a statutory reference to the guideline proposed for Class A Misdemeanors in Proposed Amendment 9 (Miscellaneous Laws), Part E.]

Chapter Two, Part X, Subpart 5, as amended by Proposed Amendment 9, Part E, is further amended in the Commentary to § 2X5.2 captioned ''Statutory Provisions'' by inserting ''; 49 U.S.C. 31310(i)(2)(D)'' after ''14133''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to ''18 U.S.C. 30170'' the following:

''49 U.S.C. 31310(i)(2)(D) 2X5.2''.

(C) Implementation of Section 4210 of the Transportation Act

The Commentary to § 2B1.1 captioned ''Statutory Provisions'' is amended by inserting ''14915,'' before ''30170,''.

Appendix A (Statutory Provisions) is amended by inserting after the line referenced to 49 U.S.C. 14912 the following:

''49 U.S.C. 149152 B1.1''.

Issue for Comment: The Commission requests comment on how it should implement provisions of the Safe, Accountable, Flexible, Efficient Transportation Act: A Legacy for Users, Pub. L. 109–59 (hereinafter the ''Transportation Act'') relating to the transportation of hazardous materials. Specifically, the Commission requests comment regarding whether, and if so how, the Commission should amend the guidelines to implement section 7121 of the Transportation Act.

Section 7121 of the Transportation Act amends 49 U.S.C. 5124, which criminalizes knowing or willful violations of chapter 51 of title 49, United States Code, regarding the transportation of hazardous materials, in two ways. First, it defines ''knowing,'' ''willful,'' and ''reckless'' violations of the Hazardous Materials Act. Second, it provides a new ten year maximum for aggravated felonies in which a defendant knowingly or willfully violated the hazardous materials act (or its accompanying regulations), a release of hazardous materials occurs, and such a release results in death or serious bodily injury. Section 7127 of the Transportation Act added section 5124 to the provisions set forth in 18 U.S.C. 3663 that allow the Department of Justice to seek restitution.

Offenses under 49 U.S.C. 5124 currently are referenced to § 2Q1.2 (Mishandling of Hazardous or Toxic Substances or Pesticides; Recordkeeping, Tampering, and Falsification; Unlawfully Transporting Hazardous Materials in Commerce). The Commission amended § 2Q1.2 in 2004 to provide for a 2-level increase for offenses involving the unlawful transportation of hazardous materials. This enhancement is to apply whenever a defendant is convicted under 49 U.S.C. 5124 or 49 U.S.C. 46312 and is intended to capture the increased risk of harm associated with these types of offenses. Is this enhancement adequate to account for the seriousness of conduct involving the unlawful transportation of hazardous materials and/or the increased risk of harm associated with these offenses, particularly for offenses involving the knowing, willful, and/or reckless transportation of hazardous materials?

7. Implementation of the Intelligence Reform and Terrorism Prevention Act of 2004

Synopsis of Proposed Amendment: This proposed amendment implements a number of provisions of the Intelligence Reform and Terrorism Prevention Act of 2004, Pub. L. 108–458. Specifically:

(A) Section 5401 of the Act adds a new subsection (a)(4) to 8 U.S.C. 1324 that increases the otherwise applicable penalties by up to ten years for bringing aliens into the United States if (A) the conduct is part of an ongoing commercial organization or enterprise; (B) aliens were transported in groups of 10 or more; and (C)(1) aliens were transported in a manner that endangered their lives; or (2) the aliens presented a life-threatening health risk to people in the United States.

Criminal penalties for violations of 8 U.S.C. 1324 include fines and terms of imprisonment ranging from 1 year for knowingly bringing in an alien who does not have permission to enter the country, 8 U.S.C. 1324(a)(2)(A), up to life if a death occurs during a violation, 8 U.S.C. 1324(a)(1)(B)(iv). Offenses under 18 U.S.C. 1324 are referenced to

§ 2L1.1 (Smuggling, Transporting, or Harboring an Unlawful Alien).

In response to the new offense, the proposed amendment provides three options. Option One amends § 2L1.1 by adding a specific offense characteristic to account for offenses of conviction under 8 U.S.C. 1324(a)(4). Option Two amends § 2L1.1 by adding a specific offense characteristic to account for offenses that involve an ongoing commercial organization or enterprise. Option Three provides an upward departure for such conduct.

(B) Section 6702 of the Act creates a new offense at 18 U.S.C. 1038 (False Information and Hoaxes), which provides as follows:

(1) In General—Whoever engages in any conduct with intent to convey false or misleading information under circumstances where such information may reasonably be believed and where such information may indicate that an activity has taken, is taking, or will take place that would constitute a violation of chapter 2, 10, 11B, 39, 40, 44, 111, or 113B of this title, section 236 of the Atomic Energy Act of 1954 (42 U.S.C. 2284) or section 46502, the second sentence of section 46504, section 46505(b)(3) or (c), section 46506 if homicide or attempted homicide is involved, or section 60123(b) of title 49, shall—

(A) be fined under this title or imprisoned not more than 5 years, or both;

(B) if serious bodily injury results, be fined under this title or imprisoned not more than 20 years, or both; and

(C) if death results, be fined under this title or imprisoned for any number of years up to life or both.

(2) Armed Forces—Any person who makes a false statement, with intent to convey false or misleading information, about the death, injury, capture, or disappearance of a member of the Armed Forces of the United States during a war or armed conflict in which the United States is engaged—

(A) shall be fined under this title or imprisoned not more than 5 years, or both;

(B) if serious bodily injury results, shall be fined under this title or imprisoned not more than 20 years, or both; and

(C) if death results, shall be fined under this title or imprisoned for any number of years or for life or both.

The proposed amendment references the new offense to § 2A6.1 (Threatening or Harassing Communications) and adds a cross reference to § 2M6.1 (Unlawful Production, Development, Acquisition, Stockpiling, Alteration, Use, Transfer, or Possession of Nuclear Material, Weapons, or Facilities, Biological Agents, Toxins, or Delivery Systems, Chemical Weapons, or Other Weapons of Mass Destruction; Attempt or Conspiracy) if the conduct supports a threat to use a weapon of mass destruction.

(C) Section 6803 creates a new offense at 18 U.S.C. 832, relating to participation in nuclear, and weapons of mass destruction, threats to the United States. The new offense reads in part as follows:

(a) Whoever, within the United States or subject to the jurisdiction of the United States, willfully participates in or knowingly provides material support or resources (as defined in section 2339A) to a nuclear weapons program or other weapons of mass destruction program of a foreign terrorist power, or attempts or conspires to do so, shall be imprisoned for not more than 20 years.

(b) There is extraterritorial Federal jurisdiction over an offense under this section.

(c) Whoever without lawful authority develops, possesses, or attempts or conspires to develop or possess a radiological weapon, or threatens to use or uses a radiological weapon against any person within the United States, or a national of the United States while such national is outside of the United States or against any property that is owned, leased, funded, or used by the United States, whether that property is within or outside of the United States, shall be imprisoned for any term of years or for life.

Section 6803 also adds this new offense to the list of predicate offenses at 18 U.S.C. 2332b(g)(5)(B)(i) and amends §§ 57(b) and 92 of the Atomic Energy Act of 1954 (42 U.S.C. 2077(b)) to cover the participation of an individual in the development of special nuclear material.

The proposed amendment references 18 U.S.C. 832 to § 2M6.1.

(D) Section 6903 of the Act creates a new offense at 18 U.S.C. 2332g (Missile Systems Designed to Destroy Aircraft) prohibiting the production or transfer of missile systems designed to destroy aircraft. Specifically, section 2332g reads in part:

(a) Unlawful Conduct

(1) In general. Except as provided in paragraph (3), it shall be unlawful for any person to knowingly produce, construct, otherwise acquire, transfer directly or indirectly, receive, possess, import, export, or use or possess and threaten to use—

(A) an explosive or incendiary rocket or missile that is guided by any system designed to enable the rocket or missile to—

(i) seek or proceed toward energy radiated or reflected from an aircraft or toward an image locating an aircraft; or

(ii) otherwise direct or guide the rocket or missile an aircraft;

(B) any device designed or intended to launch or guide a rocket or missile described in subparagraph (A); or

(C) any part or combination of parts designed or redesigned for use in assembling or fabricating a rocket, missile, or device described in subparagraph (A) or (B).

The new offense conduct provides for different criminal penalties. First, any individual who ''violates, attempts, or conspires to violate, subsection (a),'' the criminal penalties range from a fine of no more than two million dollars along with a statutory minimum term of imprisonment of 25 years to life. See 18 U.S.C. 2332g(c)(1). Second, any person who in the course of a violation of subsection (a) who ''uses, attempts or conspires to use, or possesses or threatens to use,'' any item(s) described in subsection (a) will be fined no more than two million dollars in addition to receiving a statutory minimum sentence of 30 years to life. See 18 U.S.C. 2332g(c)(2). Finally, if the death of another person results from a violation of subsection (a), the offender will be fined no more than two million dollars and will be given a sentence of life imprisonment. See 18 U.S.C. 2332g(c)(3).

The proposed amendment references 18 U.S.C. 2332g to § 2K2.1 (Unlawful Receipt, Possession, or Transportation of Firearms or Ammunition; Prohibited Transactions Involving Firearms or Ammunition) because the types of weapon described in the offense would seem to be covered as destructive devices under 26 U.S.C. 5845(a).

(E) Section 6905 of the Act creates a new offense at 18 U.S.C. 2332h prohibiting the production, transfer, receipt, possession, or threat to use, any radiological dispersal device. Section 2332h reads in part as follows:

(a) Unlawful Conduct

(1) In general. Except as provided in paragraph (2), it shall be unlawful for any person to knowingly produce, construct, otherwise acquire, transfer directly or indirectly, receive, possess, import, export, or use, or possess and threaten to use—

(A) any weapon that is designed or intended to release radiation or radioactivity at a level dangerous to human life; or

(B) any device or other object that is capable of and designed or intended to endanger human life through the release of radiation or radioactivity.

The new offense conduct provides for different criminal penalties. First, any individual who ''violates, attempts, or conspires to violate, subsection (a),'' the criminal penalties range from a fine of no more than two million dollars along with a statutory minimum term of imprisonment of 25 years to life. See 18 U.S.C. 2332h(c)(1). Second, any person who in the course of a violation of subsection (a) who ''uses, attempts or conspires to use, or possesses or threatens to use,'' any item(s) described in subsection (a) will be fined no more than two million dollars in addition to receiving a statutory minimum sentence of 30 years to life. See 18 U.S.C. 2332h(c)(2). Finally, if the death of another person results from a violation of subsection (a), the offender will be fined no more than two million dollars and will be given a sentence of life imprisonment. See 18 U.S.C. 2332h(c)(3).

The proposed amendment references 18 U.S.C. 2332h to § 2M6.1 because of the nature of the offense. Section 2M6.1 covers conduct dealing with the production of certain types of nuclear, biological or chemical weapons or other weapons of mass destruction, including weapons of mass destruction that, as defined in 18 U.S.C. 2332a, are designed to release radiation or radioactivity at levels dangerous to human life.

(F) Section 6906 of the Act creates a new offense prohibiting the production, acquisition, transfer, or possession of, or the threat to use, the variola virus. Specifically, 18 U.S.C. 175c (Variola Virus), reads, in part:

(a) Unlawful Conduct

(1) In general. Except as provided in paragraph (2), it shall be unlawful for any person to knowingly produce, engineer, synthesize, acquire, transfer directly or indirectly, receive, possess, import, export, or use, or possess and threaten to use, variola virus.

The new offense conduct provides for different criminal penalties. First, any individual who ''violates, attempts, or conspires to violate, subsection (a),'' the criminal penalties range from a fine of no more than two million dollars along with a statutory minimum term of imprisonment of 25 years to life. See 18 U.S.C. 175c(c)(1). Second, any person who in the course of a violation of subsection (a) who ''uses, attempts or conspires to use, or possesses or threatens to use,'' any item(s) described in subsection (a) will be fined no more than two million dollars in addition to receiving a statutory minimum sentence of 30 years to life. See 18 U.S.C. 175c(c)(2). Finally, if the death of another person results from a violation of subsection (a), the offender will be fined no more than two million dollars and will be given a sentence of life imprisonment. See 18 U.S.C. 175c(c)(3).

The proposed amendment references 18 U.S.C.175c to § 2M6.1. The variola virus may be used as a biological agent or toxin and, therefore, should be covered under this guideline.

(G) The proposed amendment provides an issue for comment regarding whether the Commission should define the term ''ongoing commercial organization'' and if so, how.

Proposed Amendment

(A) Implementation of Section 5401 of the Act

Section 2L1.1(b) is amended by adding at the end the following:

''(7) If [Option One: the defendant was convicted under 8 U.S.C. 1324(a)(4)] [Option Two: the offense was part of an ongoing commercial organization or enterprise], increase by [2] levels.''.

[Option Three:

The Commentary to § 2L1.1 captioned ''Application Notes'' is amended by adding at the end the following:

''7. Offenses Involving Ongoing Commercial Organizations or Enterprises.—If [the defendant was convicted under 8 U.S.C. 1324(a)(4)] [the offense involved an ongoing commercial organization or enterprise], an upward departure may be warranted.]''.

(B) Implementation of Section 6702 of the Act

Chapter Two, Part A, Subpart 6, is amended in the heading by inserting ''HOAXES,'' after ''COMMUNICATIONS,''.

Section 2A6.1 is amended in the heading by adding at the end ''; Hoaxes''; by adding after subsection (b) the following:

''(c) Cross Reference

(1) If the offense involved any conduct evidencing an intent to carry out a threat to use a weapon of mass destruction, as defined in 18 U.S.C. 2332a(c)(2)(B), (C), and (D), apply § 2M6.1 (Weapons of Mass Destruction), if the resulting offense level is greater than that determined under this guideline.''; and in the Commentary captioned ''Statutory Provisions'' by inserting ''1038,'' after ''879,''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 1037 the following:

''18 U.S.C. 1038 2A6.1''.

(C) Implementation of Section 6803 of the Act

The Commentary to § 2M6.1 captioned ''Statutory Provisions'' is amended by inserting ''832,'' after ''831,''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 831 the following:

''18 U.S.C. 832 2M6.1''.

(D) Implementation of Section 6903 of the Act

The Commentary to § 2K2.1 captioned ''Statutory Provisions'' is amended by inserting '', 2332g'' after ''(k)–(o)''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 2332f the following:

''18 U.S.C. 2332g 2K2.1''.

(E) Implementation of Section 6905 of the Act

The Commentary to § 2M6.1 captioned ''Statutory Provisions'' is amended by inserting '', 2332h'' before ''; 42 U.S.C.''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 2332f the following:

''18 U.S.C. 2332h 2M6.1''

(F) Implementation of Section 6906 of the Act

The Commentary to § 2M6.1 captioned ''Statutory Provisions'' is amended by inserting ''175c,'' after ''175b,''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 175b the following:

''18 U.S.C. 175c 2M6.1''.

(G) Issue for Comment

Issue for Comment: Section 5401 of the Intelligence Reform and Terrorism Prevention Act of 2004 added a new subsection (a)(4) to 8 U.S.C. 1324 that increases the otherwise applicable penalties by up to 10 years if, among other things, the conduct is part of an ongoing commercial organization. However, the Act did not provide a definition of the term ''ongoing commercial organization.'' If the Commission were to promulgate one of the proposed options that relies on this term as a basis for a sentencing increase (either by application of a specific offense characteristic or as an upward departure), should the Commission define the term ''ongoing commercial organization'' and if so, how?

8. False Domain Names and CAN–SPAM

Synopsis of Proposed Amendment: This proposed amendment (A) implements the directive to the

Commission in section 204(b) of the Intellectual Property Protection and Courts Administration Act of 2004; and (B) implements the new offense in section 5(d) of the Controlling the Assault of Non-Solicited Pornography and Marketing Act of 2003 (''CAN–SPAM Act'') (15 U.S.C. 7704(d)).

False Registration of Domain Name

Section 204(b) of the Intellectual Property Protection and Courts Administration Act of 2004 directs the Commission—

to ensure that the applicable guideline range for a defendant convicted of any felony offense carried out online that may be facilitated through the use of a domain name registered with materially false contact information is sufficiently stringent to deter commission of such acts * * * In carrying out this [directive], the Sentencing Commission shall provide sentencing enhancements for anyone convicted of any felony offense furthered through knowingly providing or knowingly causing to be provided materially false contact information to a domain name registrar, domain name registry, or other domain name registration authority in registering, maintaining, or renewing a domain name use in connection with the offense.

The proposed amendment implements this directive by providing a new guideline in Chapter Three (Adjustments) for cases in which a statutory enhancement under 18 U.S.C. 3559(f)(1) applies. Section 3559(f)(1), created by section 204(a) of the Intellectual Property Protection and Courts Administration Act of 2004, doubles the statutory maximum term of imprisonment, or increases the maximum sentence by seven years, whichever is less, if a defendant who is convicted of a felony offense knowingly falsely registered a domain name and used that domain name in the course of the offense. Basing the adjustment in the new guideline on application of the statutory enhancement in 18 U.S.C. 3559(f)(1) satisfies the directive.

CAN–SPAM

Section 5(d)(1) of the CAN–SPAM Act prohibits the transmission of commercial electronic messages that contain ''sexually oriented material'' unless such messages include certain marks, notices, and information. Specifically, the statute requires that the sender of a commercial e-mail message containing sexually oriented material:

(a) include in the subject heading of the e-mail the ''marks and notices'' prescribed by the Federal Trade Commission; and

(b) include in the message initially viewable to the recipient (i) the FTC's marks and notices; (ii) clear and conspicuous identification that the message is an advertisement or solicitation; (iii) clear notice of the recipient's option to decline to receive further messages from the sender; and (iv) the sender's valid physical postal address.

The sender of a commercial e-mail message that contains sexually oriented material within the meaning of the statute is exempted from these notice and labeling requirements only ''if the recipient has given prior affirmative consent to the receipt of the message.'' Otherwise, a sender who ''knowingly'' transmits sexually oriented commercial messages e-mail without including the required marks and information shall be fined under title 18, United States Code, or imprisoned not more than 5 years, or both.

The proposed amendment references the new offense, found at 15 U.S.C. 7704(d), to § 2G2.5 (Recordkeeping Offenses Involving the Production of Sexually Explicit Materials). Currently, § 2G2.5 applies to violations of 18 U.S.C. 2257, which requires producers of sexually explicit materials to maintain detailed records regarding their production activities and to make such records available for inspection by the Attorney General in accordance with applicable regulations. Although offenses under 15 U.S.C. 7704(d) do not involve the recording and reporting functions at issue in cases currently sentenced under § 2G2.5, section 7704(d) offenses are essentially regulatory in nature and in this manner are similar to other offenses sentenced under § 2G2.5. In addition to the statutory reference changes, the proposed amendment also expands the heading of § 2G2.5 specifically to cover offenses under 15 U.S.C. 7704(d).

Proposed Amendment:

(A) False Registration of Domain Name

Proposed Amendment: Chapter Three, Part C is amended in the heading by adding at the end ''AND RELATED ADJUSTMENTS''.

Chapter Three, Part C is amended by adding at the end the following:

''§ 3C1.3. False Registration of Domain Name

If a statutory enhancement under 18 U.S.C. 3559(f)(1) applies, increase by [1][2][3][4] levels.

Commentary

Background: This adjustment implements the directive to the Commission in section 204(b) of Pub. L. 108–482.''.

(B) CAN–SPAM

Proposed Amendment: Section 2G2.5 is amended in the heading by adding at the end ''; Failure to Provide Required Marks in Commercial Electronic Email''.

The Commentary to § 2G2.5 captioned ''Statutory Provision'' is amended by striking ''Provision'' and inserting ''Provisions''; and by inserting ''15 U.S.C. 7704(d);'' after the colon.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 15 U.S.C. 6821 the following:

''15 U.S.C. 7704(d)2G2.5''.

9. Miscellaneous Laws

Synopsis of Proposed Amendment: This proposed amendments implements miscellaneous enacted laws as follows:

(A) The Veterans' Memorial Preservation and Recognition Act of 2003, section 2, created a new offense at 18 U.S.C. 1369 that prohibits the destruction of Veterans' Memorials, with a ten-year statutory maximum. Previously, in response to the Veteran's Cemetery Protection Act of 1997, the Commission added a two-level enhancement at § 2B1.1(b)(6) for vandalizing a National Cemetery.

The proposed amendment refers the new offense to both §§ 2B1.1 (Theft, Property Destruction, and Fraud) and 2B1.5 (Theft of, Damage to, or Destruction of, Cultural Heritage Resources). Reference to both guidelines mirrors the treatment of other offenses involving property damage to veterans' memorials. The proposed amendment also provides an increase of [2][4][6] levels in §§ 2B1.1 and 2B1.5 if the offense involved a veterans' memorial.

(B) The Plant Protection Act of 2002 increased penalties under 7 U.S.C. 7734, for knowingly importing or exporting plant, plant products, biological control organisms, and like products for distribution or sale. The statutory maximum for the first offense is five years, and for subsequent offenses, ten years.

Appendix A (Statutory Index) currently references 7 U.S.C. 7734 to § 2N2.1 (Violations of Statutes and Regulations Dealing With Any Food, Drug, Biological Product, Device, Cosmetic, or Agricultural Product), which has a base offense level of 6. The proposed amendment provides two options in response to the increased penalties. Option One increases the base offense level in consideration of the increased statutory penalties. Option Two provides an upward departure provision within the guideline. This option recommends an upward departure because of the expected

infrequency of plant protection offenses and because it provides the court with a viable tool to account for the harm involved during the commission of these offenses on a case-by-case basis.

(C) The Clean Diamond Trade Act of 2003 created a new offense at 19 U.S.C. 3901, related to the import and export of rough diamonds or any transaction by a United States citizen anywhere, or any transaction that occurs in whole or in part within the United States. The new offense prohibits an import or export of rough diamonds that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in the Act. The statutory maximum is ten years.

This offense involves importing ''conflict'' diamonds into the United States for profits used towards the overthrow or subverting of legitimate governments in Sierra Leone, Angola, Liberia, and the Democratic Republic of Congo. The diamonds, referred to as ''blood diamonds'' or ''conflict diamonds,'' are imported or exported without being controlled by a process known as the Kimberley Process Certification Scheme, which legitimizes the quality and original source of the diamond. The violation occurs when the diamonds are imported/exported without first being certified through this process or when a United States citizen enters into a transaction involving these diamonds without the proper certification. The profits from the sale of these rough diamonds are used to fund rebel and military activities in the countries mentioned earlier.

The proposed amendment references the new offense to § 2T3.1 (Evading Import Duties or Restrictions (Smuggling); Receiving or Trafficking in Smuggled Property). The proposed amendment also revises introductory commentary more specifically to indicate that uncertified diamonds are contraband covered by § 2T3.1 even if other types of contraband are covered by other, more specific guidelines.

(D) The Unborn Victims of Violence Act of 2004 (''Laci & Conner'' Law) created a new offense at 18 U.S.C. 1841 for causing a death or serious bodily injury to a child in utero while engaging in conduct violative of any one of several enumerated offenses. Under 18 U.S.C. 1841(a)(1) and (a)(2)(A), the statutory maximum for the conduct that ''caused the death of, or bodily injury to a child in utero shall be the penalty provided under Federal law for that conduct had that injury or death occurred to the unborn child's mother.'' Otherwise, under 18 U.S.C. 1841(a)(2)(C), if the person engaging in the conduct intentionally kills or attempts to kill the unborn child that person shall be punished under sections 18 U.S.C. 1111, 1112, and 1113 for intentionally killing or attempting to kill a human being.

The proposed amendment references 18 U.S.C. 1841(a)(2)(C) to the guidelines designated in Appendix A for 18 U.S.C. 1111, 1112, and 1113.

The proposed amendment references 18 U.S.C. 1841(a)(1) to § 2X5.1 (Other Offenses). Reference is made to § 2X5.1 because, under 18 U.S.C. 1841(a)(2)(A), the punishment for the offender is determined by the penalty for the conduct which caused the death or injury to a child in utero had that injury or death occurred to the unborn child's mother. For example, if the offender committed aggravated sexual abuse against the unborn child's mother and it caused the death of a child in utero, the punishment for the offender would be the same as the penalty for aggravated sexual abuse, not the penalty for first or second degree murder. There are approximately 65 other statutes listed under 18 U.S.C. 1841(b) that require a similar approach. Properly designating guidelines for these offenses would be challenging, and perhaps confusing.

In order to permit the courts to determine the most analogous guideline on a case-by-case basis, a special instruction is provided in § 2X5.1 that the most analogous guideline for these offenses is the guideline that covers the underlying offense conduct.

(E) The Farm Security and Rural Investment Act of 2002, created a new offense at 7 U.S.C. 2156 that prohibits the interstate movement of animals for animal fighting, with a one year statutory maximum.

The Social Security Administration Act created a new offense under 42 U.S.C. 1129(a) for prohibiting corrupt or forcible interference with the administration of the Social Security Administration Act. The statutory maximum is one year if the offense was committed only by threats of force, otherwise the statutory maximum is three years.

The Consumer Product Protection Act of 2002 created a new offense under 18 U.S.C. 1365(f) for prohibiting the illegal tampering with a consumer product with a statutory maximum of one year for the first offense, and three years for subsequent offenses.

The Justice for All Act of 2004 created a new offense under 42 U.S.C. 14133 for prohibiting the misuse or unauthorized disclosure of DNA analyses. The maximum penalty is one year.

The Video Voyeurism Prevention Act of 2004 created a new offense under 18 U.S.C. 1801 for prohibiting the knowing capture of an image of an individual's ''private area'' without that individual's consent, under circumstances in which the individual has a reasonable expectation of privacy. The statutory maximum for this offense is one year.

To address these Class A misdemeanors offenses, the proposed amendment creates a new guideline at § 2X5.2 (Class A Misdemeanors) that covers all Class A misdemeanors not otherwise provided for in a more specific Chapter Two guideline. The amendment assigns a base offense level of 6 for such offenses, which is the offense level typically applicable to Class A misdemeanor and regulatory offenses. A specific offense characteristic is provided for repeated violations.

Proposed Amendment:

(A) The Veterans' Memorial Preservation and Recognition Act of 2003

Section 2B1.1(b)(6) is amended by inserting ''or veterans' memorial'' after ''national cemetery''; and by striking ''2'' and inserting ''[2][4][6]''.

The Commentary to § 2B1.1 captioned ''Statutory Provisions'' is amended by inserting ''1369,'' after ''1363,''.

The Commentary to § 2B1.1 captioned ''Application Notes'' is amended in Note 1 by inserting after the paragraph that begins '' 'Trade secret' '' the following paragraph:

'' 'Veterans' memorial' means any structure, plaque, statue, or other monument described in 18 U.S.C. 1369(a).''.

Section 2B1.5(b)(2) is amended by inserting ''or veterans' memorial'' after ''cemetery''; and by striking ''2'' and inserting ''[2][4][6]''.

The Commentary to § 2B1.5 captioned ''Statutory Provisions'' is amended by inserting ''1369,'' after ''1361,''.

The Commentary to § 2B1.5 captioned ''Application Notes'' is amended in Note 3 in subdivision (B) by striking ''has the meaning given that term'' and inserting ''and 'veterans' memorial' have the meaning given those terms''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 1366 the following:

''18 U.S.C. 13692B1.1, 2B1.5''.

(B) The Plant Protection Act of 2002

[Option One: Section 2N2.1 is amended by striking subsection (a) and inserting the following:

''(a) Base Offense Level:

(1) [8][10], if the defendant was convicted under 7 U.S.C. 7734; or

(2) 6, otherwise.''.]

[Option Two: The Commentary to § 2N2.1 captioned ''Application Notes''

is amended by striking Note 3 and inserting the following:

''3. Upward Departure Provisions.—The following are circumstances under which an upward departure may be warranted:

(A) Death or bodily injury, extreme psychological injury, property damage or monetary loss resulted. See Chapter Five, Part K (Departures).

(B) The defendant was convicted under 7 U.S.C. 7734.''.]

(C) The Clean Diamond Trade Act of 2003

Chapter Two, Part T, Subpart 3 is amended in the ''Introductory Commentary'' in the first sentence by inserting ''and 3901,'' after ''1708(b),''; in the second sentence by inserting ''intended to deal with some types of contraband, such as certain uncertified diamonds, but is'' after ''It is''; and by striking ''importation of contraband'' and inserting ''importation of other types of contraband''; and in the last sentence by inserting ''not specifically covered by the Subpart'' after ''stolen goods''; and by inserting ''if there is not another more specific applicable guideline'' after ''upward''.

The Commentary to § 2T3.1 captioned ''Statutory Provisions'' is amended by inserting '', 3901'' after ''1708(b)''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 19 U.S.C. 2401f the following:

''19 U.S.C. 3901 2T3.1''.

(D) The Unborn Victims of Violence Act of 2004

The Commentary to § 2A1.1 captioned ''Statutory Provisions'' is amended by inserting ''1841(a)(2)(C),'' after ''1111,''.

The Commentary to § 2A1.2 captioned ''Statutory Provisions'' is amended by inserting ''1841(a)(2)(C),'' after ''1111,''.

The Commentary to § 2A1.3 captioned ''Statutory Provisions'' is amended by inserting ''1841(a)(2)(C),'' after ''1112,''.

The Commentary to § 2A1.4 captioned ''Statutory Provisions'' is amended by inserting ''1841(a)(2)(C),'' after ''1112,''.

The Commentary to § 2A2.1 captioned ''Statutory Provisions'' is amended by inserting ''1841(a)(2)(C),'' after ''1751(c),''.

The Commentary to § 2A2.2 captioned ''Statutory Provisions'' is amended by inserting ''1841(a)(2)(C),'' after ''1751(e),''.

Section 2X5.1 is amended by striking ''(b)'' after ''18 U.S.C. 3553''; and by adding at the end the following:

''If the defendant is convicted under 18 U.S.C. 1841(a)(1), apply the guideline that covers the conduct the defendant is convicted of having engaged in, as that conduct is described in 18 U.S.C. 1841(a)(1) and listed in 18 U.S.C. 1841(b).''.

The Commentary the § 2X5.1 is amended by inserting before ''Application Note:'' the following:

''Statutory Provision: 18 U.S.C. 1841(a)(1).''.

The Commentary the § 2X5.1 captioned ''Application Note'' is amended by striking ''Note'' and inserting ''Notes''; in Note 1 by inserting ''In General.—'' before ''Guidelines''; and by adding at the end the following:

2. Convictions under 18 U.S.C. 1841(a)(1).—

(A) In General.—If the defendant is convicted under 18 U.S.C. 1841(a)(1), the Chapter Two offense guideline that applies is the guideline that covers the conduct the defendant is convicted of having engaged in, *i.e.*, the conduct of which the defendant is convicted that violates a specific provision listed in 18 U.S.C. 1841(b) and that results in the death of or bodily injury to a child in utero at the time of the offense of conviction.

(B) Upward Departure Provision.—For offenses under 18 U.S.C. 1841(a)(1), an upward departure may be warranted if the offense level under the applicable guideline does not provide an adequate sentence to account for the death of or serious bodily injury to the child in utero.''.

The Commentary to § 2X5.1 captioned ''Background'' is amended by striking ''That statute'' and all that follows through ''subsection (a)(2).''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 18 U.S.C. 1832 the following:

''18 U.S.C. 1841(a)(1) 2X5.1

18 U.S.C. 1841(a)(2)(C) 2A1.1, 2A1.2, 2A1.3, 2A1.4, 2A2.1, 2A2.2''.

(E) Guideline for Class A Misdemeanors

Chapter Two, Part X, Subpart 5 is amended in the heading by inserting ''FELONY'' after ''OTHER'' and by adding at the end ''AND CLASS A MISDEMEANORS''.

Section 2X5.1 is amended in the heading by inserting ''Felony'' after ''Other''.

Section 2X5.1 is amended by striking ''or Class A misdemeanor''; by striking ''(b)'' after ''18 U.S.C. 3553''; and by adding at the end the following:

''If the offense is a Class A misdemeanor that has not been referenced in Appendix A (Statutory Index) to a specific offense guideline, apply § 2X5.2 (Class A Misdemeanors (Not Covered by another Specific Offense Guideline)).''.

Chapter Two, Part X, Subpart 5 is amended by adding at the end the following:

''§ 2X5.2. Class A Misdemeanors (Not Covered by Another Specific Offense Guideline)

(a) Base Offense Level: 6

(b) Specific Offense Characteristic:

(1) If the defendant committed the instant offense of conviction subsequent to sustaining a conviction under the same provision of law as the instant offense of conviction, increase by 2 levels.

Commentary

Statutory Provisions: 7 U.S.C. 2156; 18 U.S.C. 1365(f), 1801; 42 U.S.C. 1129(a), 14133.

Application Note:

1. In General.—This guideline applies to Class A misdemeanors that are specifically referenced in Appendix A (Statutory Index) to this guideline. This guideline also applies to Class A misdemeanors that have not been referenced in Appendix A to another specific offense guideline in Chapter Two. Do not apply this guideline to a Class A misdemeanor that has been referenced in the Statutory Index to a guideline other than this one.''.

Appendix A (Statutory Index) is amended by inserting after the line referenced to 7 U.S.C. 2024(c) the following:

''7 U.S.C. 2156 2X5.2''; by inserting after the line referenced to 18 U.S.C. 1121 the following:

''18 U.S.C. 1129(a) 2X5.2''; by inserting after the line referenced to 18 U.S.C. 1365(e) the following:

''18 U.S.C. 1365(f) 2X5.2''; by inserting after the line referenced to 18 U.S.C. 1792 the following:

''18 U.S.C. 1801 2X5.2''; and by inserting after the line referenced to 42 U.S.C. 9603(d) the following:

''42 U.S.C. 14133''.

Issue for Comment: The Commission requests comment regarding whether it should reference to proposed § 2X5.2 any other Class A misdemeanor offense currently referenced in Appendix A to a guideline that does not provide a higher offense level than proposed § 2X5.2. Are there additional Class A misdemeanor offenses not currently referenced in Appendix A that should be included in Appendix A and referenced to proposed § 2X5.2?

10. Application Issues

Synopsis of Proposed Amendment: This proposed amendment addresses several issues of guideline application identified through inquiries made on the Commission's Helpline and at guideline seminars. The proposed

amendment would make the following changes:

(A) Modifies the cross reference in § 2D1.1 (Unlawful Manufacturing, Importing, Exporting, or Trafficking (Including Possession with Intent to Commit These Offenses); Attempt or Conspiracy) to allow the court to apply § 2A1.2 (Second Degree Murder) for cases in which the conduct involved is second degree murder. Currently the cross reference only allows the court to apply § 2A1.1(First Degree Murder) even if the conduct does not constitute first degree murder. The proposed amendment also adds language that the cross reference to § 2A1.1 or § 2A1.2 should be applied if the offense level is greater than that determined under § 2D1.1.

(B) Adds to Chapter Three a new guideline, § 3C1.3 (Offenses Committed While on Release), which provides a three-level adjustment in cases in which the statutory sentencing enhancement at 18 U.S.C. 3147 (Penalty for an offense committed while on release) applies. Currently, § 2J1.7 (Commission of an Offense While on Release) corresponds to the statutory enhancement at 18 U.S.C. 3147 and provides for a three-level enhancement that is added to the offense level for the offense the defendant committed while on release. However, despite its reference in Appendix A (Statutory Index), 18 U.S.C. 3147 is not a statute of conviction, so there is no basis for requiring application of Appendix A. Accordingly, § 2J1.7 may be overlooked. Creating a Chapter Three adjustment for 18 U.S.C. 3147 cases is consistent with other adjustments currently in Chapter Three, all of which also apply to a broad range of offenses. The proposed amendment also eliminates commentary regarding a notice requirement. The majority of circuit courts have found that there is no notice requirement in order for 18 U.S.C. 3147 to apply.

(C) Deletes from the Drug Quantity Table in § 2D1.1 language that indicates the court should apply ''the equivalent amount of Schedule I or II Opiates'' (in the line referenced to Heroin), ''the equivalent amount of Schedule I or II Stimulants'' (in the line referenced to Cocaine), and ''the equivalent amount of Schedule I or II Hallucinogens'' (in the line referenced to LSD). Although Application Note 10 sets forth the marihuana equivalencies for substances not specifically referenced in the Drug Quantity Table, some guideline users erroneously calculate the base offense level without converting the controlled substance to its marihuana equivalency. For example, instead of converting 10 KG of morphine (an opiate) to 5000 KG of marihuana and determining the base offense level on that marihuana equivalency (resulting in a BOL of 34), some guideline users are determining the base offense level on the 10 KG of morphine (resulting in a BOL of 36). The proposed amendment would delete the problematic language and also clarify in Application Note 10 that, for cases involving a substance not specifically referenced in the Drug Quantity Table, the court is to determine the base offense level using the marihuana equivalency for that controlled substance.

Proposed Amendment:

(A) Cross Reference to Murder Guidelines

Proposed Amendment: Section 2D1.1(d) is amended by inserting ''or § 2A1.2 (Second Degree Murder), as appropriate, if the resulting offense level is greater than that determined under this guideline'' after ''Murder)''.

(B) § 2J1.7 (Commission of Offense While on Release)

Proposed Amendment: The Commentary to § 1B1.1 captioned ''Application Notes'' is amended by striking Note 6 and by redesignating Note 7 as Note 6.

Chapter Two, Part J is amended by striking section § 2J1.7.

Chapter Three, Part C is amended in the heading by adding at the end ''AND RELATED ADJUSTMENTS''.

Chapter Three, Part C is amended by adding at the end the following:

''3C1.3. Commission of Offense While on Release

If a statutory sentencing enhancement under 18 U.S.C. 3147 applies, increase the offense level by 3 levels.

Commentary

Application Note:

1. Under 18 U.S.C. 3147, a sentence of imprisonment must be imposed in addition to the sentence for the underlying offense, and the sentence of imprisonment imposed under 18 U.S.C. 3147 must run consecutively to any other sentence of imprisonment. Therefore, the court, in order to comply with the statute, should divide the sentence on the judgment form between the sentence attributable to the underlying offense and the sentence attributable to the enhancement. The court will have to ensure that the ''total punishment'' (*i.e.*, the sentence for the offense committed while on release plus the sentence enhancement under 18 U.S.C. 3147) is in accord with the guideline range for the offense committed while on release, as adjusted by the enhancement in this section. For example, if the applicable adjusted guideline range is 30–37 months and the court determines 'total punishment' of 36 months is appropriate, a sentence of 30 months for the underlying offense plus 6 months under 18 U.S.C. 3147 would satisfy this requirement.

Background: ''This guideline enables the court to determine and implement a combined 'total punishment' consistent with the overall structure of the guidelines, while at the same time complying with the statutory requirement.''.

(C) ''or Equivalent Amount''

Proposed Amendment: Section 2D1.1(c) is amended by striking ''(or the equivalent amount of other Schedule I or II Opiates)'' each place it appears; by striking ''(or the equivalent amount of other Schedule I or II Stimulants)'' each place it appears; and by striking ''(or the equivalent amount of other Schedule I or II Hallucinogens)'' each place it appears.

The Commentary to § 2D1.1 captioned ''Application Notes'' is amended in Note 10 in the first paragraph by striking the third and fourth sentences and inserting the following:

''In the case of a controlled substance that is not specifically referenced in the Drug Quantity Table, determine the base offense level as follows:

(A) use the Drug Equivalency Tables to convert the quantity of the controlled substance involved in the offense to its equivalent quantity of marihuana;

(B) find the equivalent quantity of marihuana in the Drug Quantity Table; and

(C) use the offense level that corresponds to the equivalent quantity of marihuana as the base offense level for the controlled substance involved in the offense.

(See also Application Note 5.) For example, in the Drug Equivalency Tables, one gram of a substance containing oxymorphone, a Schedule I opiate, converts to an equivalent quantity of five kilograms of marihuana. In a case involving 100 g of oxymorphone, the equivalent quantity of marihuana would be 5000 KG, which corresponds to a base offense level of 28 in the Drug Quantity Table.''.

11. Circuit Conflicts (§ 3C1.1)

Synopsis of Proposed Amendment: This proposed amendment addresses a circuit conflict regarding whether pre-investigative conduct can form the basis of an adjustment under § 3C1.1 (Obstructing or Impeding the Administration of Justice). The First, Seventh, Tenth, and District of Columbia Circuits have concluded that

pre-investigation conduct can be used to support an obstruction adjustment. *See United States* v. *McGovern*, 329 F.3d 247, 252 (1st Cir. 2003) (holding that the submission of false run sheets to Medicare and Medicaid representatives qualified for the enhancement even though the administrative audits were not part of a criminal investigation because there was a ''close connection between the obstructive conduct and the offense of conviction''); *United States* v. *Snyder*, 189 F.3d 640, 649 (7th Cir. 1999) (holding that adjustment was appropriate in case in which defendant made pre-investigation threat to victim and did not withdraw his threat after the investigation began, thus obstructing justice during the course of the investigation); *United States* v. *Mills*, 194 F.3d 1108, 1115 (10th Cir. 1999) (holding that destruction of tape that occurred before an investigation began warranted application of the enhancement for obstruction of justice because the defendant knew an investigation would be conducted and understood the importance of the tape in that investigation); *United States* v. *Barry*, 938 F.2d 1327, 1333–34 (D.C. Cir. 1991) (''Given the commentary and the case law interpreting § 3C1.1, we conclude that the enhancement applies if the defendant attempted to obstruct justice in respect to the investigation or prosecution of the offense of conviction, even if the obstruction occurred before the police or prosecutors began investigating or prosecuting the specific offense of conviction.''). The Fourth, Sixth, and Eighth Circuits have held that pre-investigation conduct cannot support application of the obstruction of justice adjustment. *See United States* v. *Self*, 132 F.3d 1039 (4th Cir. 1997) (conduct occurring before any investigation begins is not encompassed within obstruction of justice provision of Sentencing Guidelines); *United States* v. *Baggett*, 342 F.3d 536, 542 (6th Cir. 2003) (holding that the obstruction of justice enhancement could not be justified on the basis of the threats that the defendant made to the victim prior to the investigation, prosecution, or sentencing of the offense); *United States* v. *Stolba*, 357 F.3d 850, 852–53 (8th Cir. 2004) (holding that an obstruction adjustment is not available when destruction of documents occurred before an official investigation had commenced); *see also United States* v. *Clayton*, 172 F.3d 347, 355 (5th Cir. 1999) (holding that defendant's threats to witnesses warrant the enhancement under § 3C1.1, but stating in dicta that the guideline ''specifically limits applicable conduct to that which occurs during an investigation * * *.'').

The proposed amendment would permit application of § 3C1.1 to pre-investigative conduct if that conduct was intended to prevent or hinder the investigation, prosecution, or sentencing of the instant offense of conviction. Consistent with current application of the adjustment, the pre-investigative conduct also must relate to the offense of conviction and all relevant conduct or to a closely related offense.

The proposed amendment also addresses two other circuit conflicts by amending Application Note 4(b) to include ''perjury in the course of a civil proceeding (if the perjury pertains to conduct comprising the offense of conviction)'' and ''false statements on a financial affidavit in order to obtain court appointed counsel'' as examples of conduct to which § 3C1.1 normally would apply.

Proposed Amendment: Section 3C1.1 is amended by striking ''If'' and all that follows through ''2 levels.'' and inserting the following:

''If—

(1) the defendant willfully obstructed or impeded, or attempted to obstruct or impede, the administration of justice;

(2) the conduct or attempted conduct described in subdivision (1) occurred (A) prior to the investigation of the instant offense of conviction, and was intended to prevent or hinder the investigation, prosecution, or sentencing of the instant offense of conviction; or (B) during the course of the investigation, prosecution, or sentencing of the instant offense of conviction; and

(3) the conduct or attempted conduct described in subdivision (1) related to (A) the defendant's offense of conviction and any relevant conduct; or (B) a closely related offense,

increase by 2 levels.''.

The Commentary to § 3C1.1 captioned ''Application Notes'' is amended by striking Note 1 and inserting the following:

''1. In General.—Subdivision (3) makes clear that, in order for an adjustment under this section to apply, the obstructive or attempted obstructive conduct must be related to the defendant's offense of conviction and any relevant conduct, or to an otherwise closely related case, such as the case of a co-defendant.''.

The Commentary to § 3C1.1 captioned ''Application Notes'' is amended in Note 2 by inserting ''Limitations on Applicability of Adjustment.—'' before ''This provision''; in Note 3 by inserting ''Covered Conduct Generally.—'' before ''Obstructive''; in Note 4 by inserting ''Examples of Covered Conduct.—'' before ''The following''; in Note 5 by inserting ''Examples of Conduct Not Covered.—'' before ''Some types''; in Note 6 by inserting '' 'Material' Evidence Defined.—'' before '' 'Material' evidence''; in Note 7 by inserting ''Inapplicability of Adjustment in Certain Circumstances.—'' before ''If the defendant''; in Note 8 by inserting ''Grouping.—'' before ''If the defendant''; and in Note 9 by inserting ''Accountability for § 1B1.3(a)(1)(A) Conduct.—''.

The Commentary to § 3C1.1 captioned ''Application Notes'' is amended in Note 4 in subdivision (b) by inserting '', including during the course of a civil proceeding pertaining to conduct constituting the offense of conviction'' after ''perjury''; by striking the period at the end of subdivision (j) and inserting a semi-colon; and by adding at the end the following:

''(k) threatening the victim of the offense in order to prevent the victim from reporting the conduct constituting the offense of conviction;

(l) making false statements on a financial affidavit in order to obtain court-appointed counsel.''.

12. Chapter Eight—Privilege Waiver

Issue for Comment: The Commission has been asked to reconsider a portion of its 2004 amendments to Chapter Eight, the Organizational Sentencing Guidelines, namely, a single sentence of commentary at § 8C2.5(g). Section 8C2.5 provides for the calculation of the culpability score for defendant organizations, and subsection (g) provides for graduated decreases in the culpability score if a defendant organization has self-reported, cooperated with the authorities, and accepted responsibility. In 2004, the Commission added the following sentence to the commentary:

Waiver of attorney-client privilege and of work product protections is not a prerequisite to a reduction in culpability score under subdivisions (1) and (2) of subsection (g) [Self-Reporting, Cooperation, and Acceptance of Responsibility] unless such waiver is necessary in order to provide timely and thorough disclosure of all pertinent information known to the organization.

In the Reason for Amendment (see Supplement to Appendix C (Amendment 673)), the Commission stated that it expects such waivers will be required on a limited basis, consistent with statements of the Department of Justice in the United States Attorneys' Bulletin, November 2003, Volume 51, Number 6, pp. 1 and 8.

In light of requests to modify or remove this language submitted to the

Commission in the past year, the Commission listed as one of its priorities for the current amendment cycle, the ''review and possible amendment'' of the waiver language in Application Note 12. At its public meeting on November 15, 2005, the Commission heard testimony from five representatives on behalf of various organizations (the American Bar Association, the Association of Corporate Counsel, National Association of Manufacturers, the Chemistry Council, the Chamber of Commerce, the National Association of Criminal Defense Lawyers, and former officials of the Department of Justice) about what they perceived as the unintended but potentially deleterious effects on the criminal justice process of this commentary language.

Accordingly, the Commission solicits comment on the following: (1) whether this commentary language is having unintended consequences; (2) if so, how specifically has it adversely affected the application of the sentencing guidelines and the administration of justice; (3) whether this commentary language should be deleted or amended; and (4) if it should be amended, in what manner.

13. Crime Victims' Rights

Synopsis of Proposed Amendment: As part of the Justice for All Act of 2004, Pub. L. 108–405, Congress provided crime victims various rights during the criminal justice process. These rights are set forth at 18 U.S.C. 3771. Included is the ''right to be reasonably heard at any public proceeding in the district court involving release, plea, sentencing, or any parole proceeding.'' 18 U.S.C. 3771(a)(4). This proposed amendment amends Chapter Six (Sentencing Procedures and Plea Agreements) to provide a policy statement regarding crime victims' rights.

Proposed Amendment: Chapter Six is amended in the heading by striking ''AND'' and inserting a comma; and by adding at the end '', AND CRIME VICTIMS' RIGHTS''.

Chapter Six, Part A is amended by adding at the end the following:

''§ 6A1.5. Crime Victims' Rights (Policy Statement).

In any case involving the sentencing of a defendant for an offense against a crime victim, the court shall ensure that the crime victim is afforded the rights described in 18 U.S.C. 3771 and in any other provision of Federal law pertaining to the treatment of crime victims.

Commentary

Application Note:

1. Definition.—For purposes of this policy statement, 'crime victim' has the meaning given that term in 18 U.S.C. 3771(e).''.

14. Reductions in Term of Imprisonment Based on Bureau of Prisons Motion

Synopsis of Proposed Amendment: This proposed amendment implements the directive in 28 U.S.C. 994(t) that the Commission ''in promulgating general policy statements regarding the sentence modification provisions in section 3582(c)(1)(A) of title 18, shall describe what should be considered extraordinary and compelling reasons for sentence reduction, including the criteria to be applied and a list of specific examples.''

The proposed amendment provides a new policy statement at § 1B1.13 (Reduction in Term of Imprisonment as a Result of Motion by Director of Bureau of Prisons). The policy statement restates the statutory bases for a reduction in sentence under 18 U.S.C. 3582(c)(1)(A). In addition, the policy statement provides that in all cases there must be a determination made by the court that the defendant no longer is a danger to the community. Proposed Application Note 1 has two purposes. First, it provides a rebuttable presumption with respect to a Bureau of Prisons motion for a reduction based on extraordinary and compelling reasons. Second, as stated in 28 U.S.C. 994(t), the Note states that rehabilitation of the defendant alone shall not be considered an extraordinary and compelling reason warranting a reduction.

Proposed Amendment: Chapter One, Part B is amended by adding at the end the following:

''1B1.13. Reduction in Term of Imprisonment as a Result of Motion by Director of Bureau of Prisons (Policy Statement).

Upon motion of the Director of the Bureau of Prisons under 18 U.S.C. 3582(c)(1)(A), the court may reduce a term of imprisonment if, after considering the factors set forth in 18 U.S.C. 3553(a), the court determines that—

(1) (A) an extraordinary and compelling reason warrants the reduction; or

(B) the defendant is (i) at least 70 years old; and (ii) has served at least 30 years in prison pursuant to a sentence imposed under 18 U.S.C. 3559(c) for the offense or offenses for which the defendant is imprisoned;

(2) the defendant is not a danger to the safety of any other person or to the community pursuant to 18 U.S.C. 3142(g); and

(3) the reduction is consistent with this policy statement.

Commentary

Application Notes:

1. Application of Subdivision (1)(A).—

(A) Extraordinary and Compelling Reasons.—A determination made by the Director of the Bureau of Prisons that a particular case warrants a reduction for extraordinary and compelling reasons shall be considered as such for purposes of subdivision (1)(A).

(B) Rehabilitation of the Defendant.—Pursuant to 28 U.S.C. 994(t), rehabilitation of the defendant is not, by itself, an extraordinary and compelling reason for purposes of subdivision (1)(A).

2. Application of Subdivision (3).—Any reduction made pursuant to a motion by the Director of the Bureau of Prisons for the reasons set forth in subdivisions (1) and (2) is consistent with this policy statement.

Background: This policy statement implements 28 U.S.C. 994(t).''.

Issue for Comment: The Commission requests comment regarding:

(1) Whether the provisions of subdivision (1)(B) should be expanded to cover defendants who are at least 70 years old and have served at least 30 years in prison pursuant to a sentence imposed under any statute provided that the sentence imposed for offense(s) for which the defendant is imprisoned was not life imprisonment.

(2) If the Commission does so expand subdivision (1)(B) as described in paragraph (1), should certain offenses be excluded from application of subdivision (1)(B), such as terrorism offenses or sexual offenses involving minors.

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