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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Part 103

[INS No. 1136-90]

RIN 1115-AB17

Appeals, Precedents, Certifications, and Motions

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Final rule.

SUMMARY: This final rule amends sections of the Immigration and Naturalization Service regulations on appeals, precedent decisions, certifications, and motions, and increases the time periods within which certain appeals and briefs may be submitted. These changes are intended to make certain appeals complete when filed, to streamline the Service's review of certain decisions, and to make requirements easier for the public to understand.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Thomas W. Simmons, Chief, Administrative Appeals Unit, Immigration and Naturalization Service, 425 I Street, NW (Vermont 400), Washington, DC 20536, (202) 376-2080.

SUPPLEMENTARY INFORMATION: On July 12, 1989, the Immigration and Naturalization Service published a proposed rule with request for comments at 54 FR 29344. The Service proposed to amend its regulations on appeals and precedent decisions at 8 CFR 103.3, certifications at 8 CFR 103.4, and motions at 8 CFR 103.5. The comment period closed on August 11, 1989.

Comments on Proposed Regulations

The Service received responses from four commentors who raised several issues concerning the proposed rule. The following is a discussion of the comments and any revisions adopted as a result of them.

Increasing Time to File AAU Appeal From 15 to 30 Days

One commentor was in favor of the provision in proposed 8 CFR 103.3(a)(2)(i) increasing from 15 to 30 days the period for submitting an Administrative Appeals Unit (AAU) appeal in other than a Legalization Appeals Unit (LAU) case. (The LAU appeal period is already 30 days.) According to this commentor, the provision would benefit aliens by providing more time to consult with their representatives or attorneys about submitting an appeal.

The Service also believes this provision will be beneficial. It is, therefore, being adopted in the final rule.

Requests for Additional Time To Submit Briefs Directed To AAU

The same commentor noted that the proposed changes at 8 CFR 103.3(a)(2) would benefit the Service by allowing it to expedite the movement of appeals to the AAU. The Service proposed that a request for more time to submit a brief in support of a non-LAU AAU appeal be made directly to the AAU. The proposal provides that the AAU may allow more time for good cause shown.

Under current regulations, when the affected party desires more time, the request is made to the office which made the original decision. If more time is granted, the affected party submits the brief to that office.

The Service agrees that the new procedure, as proposed, will be beneficial. Accordingly, it is being adopted in the final rule.

Calculating the Period for Submission of AAU Appeal

With respect to the proposed changes at 8 CFR 103.3(a)(2)(i), the same commentor opposed the provision which counts the 30 days for submission of a non-LAU AAU appeal from the date of the decision. This commentor stated that a decision may be dated but not mailed until later, and expressed concern about timely delivery by the Post Office.

The commentor suggested that the 30-day period begin on the date the affected party receives the decision. The Service could then determine this date from the Post Office receipt by sending an unfavorable decision certified mail, return receipt requested. In the alternative, it was suggested that wording similar to that in the current 8 CFR 103.3(a)(1) "after the service of notification of decision" be used.

The commentor persuasively pointed out the inconvenience and unfairness which might have resulted from the proposed wording. The wording in 8 CFR 103.3(a)(2)(i) is, consequently, being amended to require that an appeal be submitted within 30 days after service of the decision. Comparable amendments are also being made in 8 CFR 103.4(a)(2) regarding notice of certification and in 8 CFR 103.5(a)(5)(ii) regarding a Service motion in a Service proceeding.

Beginning the appeal period on the date the affected party receives the decision would be difficult for the Service to administer. For example, a Post Office receipt may not be returned to the record of proceeding in a timely manner or at all. To address concern about timely mailing, however, the Service's operations instructions are being amended to require that the date of service of a decision appealable to the AAU be recorded in the record of proceeding if it is not the date of the decision.

The provision, as adopted, is consistent with the Board of Immigration Appeals (Board) and LAU provisions. It is also consistent with 8 CFR 103.5a(b) which states, "Service by mail is complete upon mailing."

8 CFR 103.5a(b) adds three days if a notice is served by mail. Under the final regulations, if an appealable decision is mailed, the affected party actually has 33 days from service of the decision to file an appeal.

Meaning of "Affected Party"

Two commentors opposed the definition of "affected party" in the proposed changes at 8 CFR 103.3(a)(1)(iii)(B). For purposes of these regulations, "affected party" (in addition to the Service) means the person or entity with legal standing in a proceeding. It does not include the beneficiary of a visa petition.

The first commentor believed the proposed wording takes away the

appeal rights of beneficiaries of visa petitions. Based on case law which the commentor did not identify, it was asserted that a constitutional issue was involved.

The proposed wording does not take away appeal rights of visa petition beneficiaries since they cannot file appeals. A visa petition proceeding has long been a proceeding between the petitioner and the Service. The beneficiary of the petition does not have any standing in such a proceeding. *See Matter of Sano,* I.D. 2999 (BIA 1985).

The second commentor believed that an applicant for extension or change of nonimmigrant classification should have standing to file an appeal because he or she has a substantial stake in the outcome of such a proceeding. Currently, such an applicant cannot file an appeal.

The suggested change with respect to extension and change of nonimmigrant classification applicants is beyond the scope of this rulemaking. As there are no compelling reasons not to adopt the wording as proposed, it is being adopted in the final rule.

Appeal by Attorney or Representative Without Proper Form G–28

The last commentor, who found that the proposed regulations improve significantly on the current regulations, noted that there is no specified period in the proposed changes at 8 CFR 103.3(a)(2)(ii)(B) for submission of a properly executed Notice of Entry of Appearance as Attorney or Representative (Form G–28). The proposal provides that, if a non-LAU AAU appeal is filed by an attorney or representative without such a form, the appeal must be returned to that person for resubmission with the form. According to the commentor, if no period is specified, cases cannot be closed efficiently.

It was recommended that submission of Form G–28 be required within 15 days of the request for its submission. Under this recommendation, if Form G–28 is not submitted, the office where the appeal is filed could then reject it as not properly filed.

The recommendation for a 15-day time limit for submission of Form G–28 is being adopted in the final rule. However, upon review, the Service has determined that it would be more efficient not to return the appeal to the attorney or representative. Therefore, additional changes in the procedure are being made.

Under the final rule at 8 CFR 103.3(a)(2)(v)(A)(*2*), the appeal, if otherwise properly filed, will not be returned to the attorney or representative. Instead, if the reviewing official at the office where the appeal is filed decides favorable action is warranted, that official will ask the attorney or representative to submit Form G–28 to the official's office within 15 days of the request. If Form G–28 is not submitted within the time allowed, the official may, on his or her own motion, make a new decision favorable to the affected party without notifying the attorney or representative.

If, on the other hand, the reviewing official decides favorable action is not warranted, that official will ask the attorney or representative to submit Form G–28 directly to the AAU. The official will forward the appeal to the AAU. The AAU will decide whether the appeal is properly filed.

The final rule remains unchanged regarding the proposal that the filing fee not be refunded with respect to an appeal filed by a person or entity not entitled to file it. The final rule at 8 CFR 103.3(a)(2)(v)(A)(*2*) clarifies that an appeal filed by an attorney or representative without a properly executed Form G–28 is included in this provision.

Official Responsible for Reviewing Appeal Before It Is Sent to AAU

The last commentor also suggested that the official responsible for reviewing a non-LAU AAU appeal before it is sent to the AAU be clarified. The final rule at 8 CFR 103.3(a)(2)(ii) provides that the official who made the unfavorable decision being appealed must review the appeal unless the affected party moves to a new jurisdiction. In that instance, the official who has jurisdiction over such a proceeding in that geographic location must review the appeal.

Withdrawal of Appeal

In addition, the last commentor suggested that written withdrawal of a non-LAU AAU appeal in proposed 8 CFR 103.3(a)(2)(viii) be sent directly to the AAU. This suggestion is not being adopted because there may be appeals which are withdrawn before they are sent to the AAU. Also, some appeals are not sent to the AAU at all if they are treated as motions. This occurs either when the reviewing official takes favorable action or the appeal is untimely but it meets the requirements of a motion to reopen or reconsider.

Jurisdiction Over a Motion

Finally, the last commentor suggested that the official who has jurisdiction over adjudicating a motion be clarified in the final rule. This issue is clarified in the final rule at 8 CFR 103.5(a)(1)(ii). The official having jurisdiction over the motion is the official who made the latest decision in the proceeding unless the affected party moves to a new jurisdiction. In that instance, the new official having jurisdiction is the official who has jurisdiction over such a proceeding in the new geographic location.

Technical Amendment

In addition to minor editorial changes, the following minor technical amendments have been made in the final rule:

- 8 CFR 103.3(a)(2)(iii) clarifies that the reviewing official is not precluded from taking favorable action on his or her own motion *after* 45 days of receipt of a non-LAU AAU appeal. Under this provision, within 45 days of receipt of the appeal, the reviewing official may treat the appeal as a motion to reopen or reconsider and take favorable action.
- 8 CFR 103.4(a)(3) permits the Service officer to whom a case is certified to suspend the 30-day period for submission of a brief if that officer takes favorable action.

Description of Final Rule

The final rule simplifies the processing of appeals and certifications within the Service's jurisdiction and extends the time periods for preparing certain cases for review after decisions are made. The final rule also consolidates into the regulations existing policies and procedures and makes the requirements and procedures easier for the public to understand. The Service believes the changes will be beneficial to the public and to the Service because they include more efficient procedures for review of certain Service decisions.

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule does not have a significant economic impact on a substantial number of small entities. This is not a major rule as defined in Section 1(b) of E.O. 12992, nor does this rule have Federalism implications warranting the preparation of a Federal Assessment in accordance with E.O. 12612.

List of Subjects in 8 CFR Part 103

Administrative practice and procedure, Aliens, Authority delegation, Organization and functions.

Accordingly, part 103, chapter I of title 8 of the Code of Federal Regulations is amended as follows:

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS; AVAILABILITY OF SERVICE RECORDS

1. The authority citation for part 103 continues to read as follows:

Authority: 5 U.S.C. 552, 552a; 8 U.S.C. 1101, 1103, 1201, 1304; 31 U.S.C. 9701; E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p. 166; 8 CFR 2.

2. Section 103.1 is amended by revising paragraph (f)(1)(v) to read as follows:

§ 103.1 Delegations of authority.

* * * * *

(f) * * *

(1) * * *

(v) Director, Administrative Appeals Unit, and

* * * * *

3. Section 103.3 is amended by removing paragraphs (d) and (e), by redesignating paragraphs (a)(2) and (a)(3) as paragraphs (a)(3) and (a)(4) respectively, by adding a new paragraph (a)(2), and by revising paragraphs (a)(1), (b), and (c) to read as follows:

§ 103.3 Denials, appeals, and precedent decisions.

(a) *Denials and appeals*—(1) *General*—(i) *Denial of application or petition.* When a Service officer denies an application or petition filed under § 103.2 of this part, the officer shall explain in writing the specific reasons for denial. If Form I–292 (a denial form including notification of the right of appeal) is used to notify the applicant or petitioner, the duplicate of Form I–292 constitutes the denial order.

(ii) *Appealable decisions.* Certain unfavorable decisions on applications, petitions, and other types of cases may be appealed. Decisions under the appellate jurisdiction of the Board of Immigration Appeals (Board) are listed in § 3.1(b) of this chapter. Decisions under the appellate jurisdiction of the Associate Commissioner, Examinations, are listed in § 103.1(f)(2) of this part.

(iii) *Appeal*—(A) *Jurisdiction.* When an unfavorable decision may be appealed, the official making the decision shall state the appellate jurisdiction and shall furnish the appropriate appeal form.

(B) *Meaning of "affected party."* For purposes of this section and §§ 103.4 and 103.5 of this part, "affected party" (in addition to the Service) means the person or entity with legal standing in a proceeding. It does not include the beneficiary of a visa petition. An affected party may be represented by an attorney or representative in accordance with part 292 of this chapter.

(C) *Record of proceeding.* An appeal and any cross-appeal or briefs become part of the record of proceeding.

(D) *Appeal filed by Service officer in case within jurisdiction of Board.* If an appeal is filed by a Service officer, a copy must be served on the affected party.

(iv) *Function of Administrative Appeals Unit (AAU).* The AAU is the appellate body which considers cases under the appellate jurisdiction of the Associate Commissioner, Examinations.

(2) *AAU appeals in other than special agricultural worker and legalization cases*—(i) *Filing appeal.* The affected party shall file an appeal on Form I–290B. Except as otherwise provided in this chapter, the affected party must pay the fee required by § 103.7 of this part. The affected party shall file the complete appeal including any supporting brief with the office where the unfavorable decision was made within 30 days after service of the decision.

(ii) *Reviewing official.* The official who made the unfavorable decision being appealed shall review the appeal unless the affected party moves to a new jurisdiction. In that instance, the official who has jurisdiction over such a proceeding in that geographic location shall review it.

(iii) *Favorable action instead of forwarding appeal to AAU.* The reviewing official shall decide whether or not favorable action is warranted. Within 45 days of receipt of the appeal, the reviewing official may treat the appeal as a motion to reopen or reconsider and take favorable action. However, that official is not precluded from reopening a proceeding or reconsidering a decision on his or her own motion under § 103.5(a)(5)(i) of this part in order to make a new decision favorable to the affected party after 45 days of receipt of the appeal.

(iv) *Forwarding appeal to AAU.* If the reviewing official will not be taking favorable action or decides favorable action is not warranted, that official shall promptly forward the appeal and the related record of proceeding to the AAU in Washington, DC.

(v) *Improperly filed appeal*—(A) *Appeal filed by person or entity not entitled to file it*—(*1*) *Rejection without refund of filing fee.* An appeal filed by a person or entity not entitled to file it must be rejected as properly filed. In such a case, any filing fee the Service has accepted will not be refunded.

(*2*) *Appeal by attorney or representative without proper Form G–28*—(*i*) *General.* If an appeal is filed by an attorney or representative without a properly executed Notice of Entry of Appearance as Attorney or Representative (Form G–28) entitling that person to file the appeal, the appeal is considered improperly filed. In such a case, any filing fee the Service has accepted will not be refunded regardless of the action taken.

(*ii*) *When favorable action warranted.* If the reviewing official decides favorable action is warranted with respect to an otherwise properly filed appeal, that official shall ask the attorney or representative to submit Form G–28 to the official's office within 15 days of the request. If Form G–28 is not submitted within the time allowed, the official may, on his or her own motion, under § 103.5(a)(5)(i) of this part, make a new decision favorable to the affected party without notifying the attorney or representative.

(*iii*) *When favorable action not warranted.* If the reviewing official decides favorable action is not warranted with respect to an otherwise properly filed appeal, that official shall ask the attorney or representative to submit Form G–28 directly to the AAU. The official shall also forward the appeal and the related record of proceeding to the AAU. The appeal may be considered properly filed as of its original filing date if the attorney or representative submits a properly executed Form G–28 entitling that person to file the appeal.

(B) *Untimely appeal*—(*1*) *Rejection without refund of filing fee.* An appeal which is not filed within the time allowed must be rejected as improperly filed. In such a case, any filing fee the Service has accepted will not be refunded.

(*2*) *Untimely appeal treated as motion.* If an untimely appeal meets the requirements of a motion to reopen as described in § 103.5(a)(2) of this part or a motion to reconsider as described in § 103.5(a)(3) of this part, the appeal must be treated as a motion, and a decision must be made on the merits of the case.

(vi) *Brief.* The affected party may submit a brief with Form I–290B.

(vii) *Additional time to submit a brief.* The affected party may make a written request to the AAU for additional time to submit a brief. The AAU may, for good cause shown, allow the affected party additional time to submit one.

(viii) *Where to submit supporting brief if additional time is granted.* If the AAU grants additional time, the affected party shall submit the brief directly to the AAU.

(ix) *Withdrawal of appeal.* The affected party may withdraw the appeal, in writing, before a decision is made.

(x) *Decision on appeal.* The decision must be in writing. A copy of the decision must be served on the affected party and the attorney or representative of record, if any.

* * * * *

(b) *Oral argument regarding appeal before AAU.*—(1) *Request.* If the affected party desires oral argument, the affected party must explain in writing specifically why oral argument is necessary. For such a request to be considered, it must be submitted within the time allowed for meeting other requirements.

(2) *Decision about oral argument.* The Service has sole authority to grant or deny a request for oral argument. Upon approval of a request for oral argument, the AAU shall set the time, date, place, and conditions of oral argument.

(c) *Service precedent decisions.* In addition to Attorney General and Board decisions referred to in § 3.1(g) of this chapter, designated Service decisions are to serve as precedents in all proceedings involving the same issue(s). Except as these decisions may be modified or overruled by later precedent decisions, they are binding on all Service employees in the administration of the Act. Precedent decisions must be published and made available to the public as described in § 103.9(a) of this part.

4. Section 103.4 is amended by revising paragraph (a) to read as follows:

§ 103.4 Certifications.

(a) *Certification of other than special agricultural worker and legalization cases.*—(1) *General.* The Commissioner or the Commissioner's delegate may direct that any case or class of cases be certified to another Service official for decision. In addition, regional commissioners, regional service center directors, district directors, officers in charge in districts 33 (Bangkok, Thailand), 35 (Mexico City, Mexico), and 37 (Rome, Italy), and the Director, National Fines Office, may certify their decisions to the appropriate appellate authority (as designated in this chapter) when the case involves an unusually complex or novel issue of law or fact.

(2) *Notice to affected party.* When a case is certified to a Service officer, the official certifying the case shall notify the affected party using a Notice of Certification (Form I-290C). The affected party may submit a brief to the officer to whom the case is certified within 30 days after service of the notice. If the affected party does not wish to submit a brief, the affected party may waive the 30-day period.

(3) *Favorable action.* The Service officer to whom a case is certified may suspend the 30-day period for submission of a brief if that officer takes action favorable to the affected party.

(4) *Initial decision.* A case within the appellate jurisdiction of the Associate Commissioner, Examinations, or for which there is no appeal procedure may be certified only after an initial decision is made.

(5) *Certification to AAU.* A case described in paragraph (a)(4) of this section may be certified to the AAU.

(6) *Appeal to Board.* In a case within the Board's appellate jurisdiction, an unfavorable decision of the Service official to whom the case is certified (whether made initially or upon review) is the decision which may be appealed to the Board under § 3.1(b) of this chapter.

(7) *Other applicable provisions.* The provisions of § 103.3(a)(2)(x) of this part also apply to decisions on certified cases. The provisions of § 103.3(b) of this part also apply to requests for oral argument regarding certified cases considered by the AAU.

* * * * *

5. Section 103.5 is amended by revising paragraph (a) to read as follows:

§ 103.5 Reopening or reconsideration.

(a) *Motions to reopen or reconsider in other than special agricultural worker and legalization cases.*—(1) *When filed by affected party.*—(i) *General.* Except where the Board has jurisdiction and as otherwise provided in part 242 of this chapter, when the affected party files a motion, the official having jurisdiction may, for proper cause shown, reopen the proceeding or reconsider the prior decision.

(ii) *Jurisdiction.* The official having jurisdiction is the official who made the latest decision in the proceeding unless the affected party moves to a new jurisdiction. In that instance, the new official having jurisdiction is the official having jurisdiction over such a proceeding in the new geographic location.

(iii) *Filing requirements.* A motion may be accompanied by a brief. It must be—

(A) In writing and signed by the affected party or the attorney or representative of record, if any;

(B) In triplicate if addressed to the Board, in duplicate if addressed to an immigration judge, without any copies if addressed to a Service officer;

(C) Accompanied by the fee required by § 103.7 of this part;

(D) Accompanied by a statement about whether or not the validity of the unfavorable decision has been or is the subject of any judicial proceeding and, if so, the court, nature, date, and status or result of the proceeding;

(E) Addressed to the official having jurisdiction; and

(F) Submitted to the office maintaining the record upon which the unfavorable decision was made for forwarding to the official having jurisdiction.

(iv) *Effect of motion or subsequent application or petition.* Unless the Service directs otherwise, the filing of a motion to reopen or reconsider or of a subsequent application or petition does not stay execution of any decision in a case or extend a previously set departure date.

(2) *Requirements for motion to reopen.* A motion to reopen must—

(i) State the new facts to be proved at the reopened proceeding; and

(ii) Be supported by affidavits or other documentary evidence.

(3) *Requirements for motion to reconsider.* A motion to reconsider must—

(i) State the reasons for reconsideration; and

(ii) Be supported by any pertinent precedent decisions.

(4) *Deficient motion in Service case.*—(i) *Motion to reopen.* A Service officer considering a motion to reopen shall reject a motion as deficient and not refund any filing fee the Service has accepted when the motion does not state the new facts to be proved or when it is not supported by affidavits or other documentary evidence.

(ii) *Motion to reconsider.* A Service officer considering a motion to reconsider shall reject a motion as deficient and not refund any filing fee the Service has accepted when the motion does not state the reasons for reconsideration.

(iii) *Correction of deficient motion.* If the affected party corrects the deficiency within 60 days of rejection of a motion, the Service officer having jurisdiction shall act upon the original motion and make a decision on the merits of the case. There is no fee for correction of a deficient motion within 60 days of its rejection as long as the filing fee has already been paid and accepted by the Service.

(5) *Motion by Service officer.*—(i) *Service motion with decision favorable to affected party.* When a Service officer, on his or her own motion, reopens a Service proceeding or reconsiders a Service decision in order to make a new decision favorable to the affected party, the Service officer shall combine the motion and the favorable decision in one action.

(ii) *Service motion with decision which may be unfavorable to affected party.* When a Service officer, on his or her own motion, reopens a Service proceeding or reconsiders a Service decision, and the new decision may be unfavorable to the affected party, the officer shall give the affected party 30 days after service of the motion to submit a brief. The officer may extend the time period for good cause shown. If the affected party does not wish to submit a brief, the affected party may waive the 30-day period.

(iii) *Proceeding before Board or immigration judge.* When a Service officer is the moving party in a proceeding before the Board or an immigration judge, a copy of the motion must be served on the affected party. The motion and proof of service must be filed with the official having jurisdiction. The affected party has 10 days from the date of service to submit a brief. This time period may be extended as provided in §§ 3.8(c) and 3.22(b) of this chapter.

(6) *Appeal to AAU from Service decision made as a result of a motion.* A field office decision made as a result of a motion may be appealed to the AAU only if the original decision was appealable to the AAU.

(7) *Other applicable provisions.* The provisions of § 103.3(a)(2)(x) of this part also apply to decisions on motions. The provisions of § 103.3(b) of this part also apply to requests for oral argument regarding motions considered by the AAU.

* * * * *

Dated: April 26, 1990.

Gene McNary,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 90-11695 Filed 5-18-90; 8:45 am]

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8 CFR Parts 103 and 210a

[INS No. 1201-90]

RIN 1115-AB05

Powers and Duties of Service Officers; Availability of Service Records; Admission or Adjustment of Status of Replenishment Agricultural Workers

AGENCY: Immigration and Naturalization Service; Justice.

ACTION: Final rule.

SUMMARY: This rule amends part 210a of 8 CFR, to conform with section 210A of the Immigration and Nationality Act, established by the Immigration Reform and Control Act of 1986 (IRCA), Public Law 99-603, and makes related conforming amendments to the existing part 103 of 8 CFR. This rule sets forth the criteria and procedures to be used to admit or adjust the status of replenishment agricultural workers (RAW) for temporary residence, should there be a determination that RAW workers are required.

EFFECTIVE DATE: This rule is effective May 21, 1990.

FOR FURTHER INFORMATION CONTACT: Janet M. Charney, Deputy Assistant Commissioner, Legalization Programs, Immigration and Naturalization Service, 425 I Street NW., Washington, DC 20536, 202-786-3658.

SUPPLEMENTARY INFORMATION: On July 17, 1989, an interim final rule with request for comments was published in the **Federal Register** at 54 FR 29875. A second interim rule was published on September 1, 1989, at 54 FR 36275, which revised certain provisions of the registration process and allowed further opportunity for comment on the July 17, 1989, interim rule. The comment period expired on October 2, 1989. The Service received 13 comments, representing the view of employer and farmworker advocacy organizations, state and federal government agencies, members of Congress, and individuals.

The Service believes that the widest range of opinions has been expressed throughout the development of this regulation and greatly appreciates these comments. Each has been considered and many commentors will see the effects of their comments in this rule. The supplementary information is arranged by subject areas which elicited comments regarding both the July 17, 1989, interim final rule and the September 1, 1989, interim rule. In addition, several incidental changes have been made to better convey the intent of the Service in this rulemaking. The Service wishes to clarify that, unlike other programs created by IRCA which provided for temporary residence by merely meeting eligibility requirements, the RAW program does not convey temporary residence as a matter of statutory entitlement. The purpose of the RAW program is to provide additional seasonal agricultural workers to U.S. agricultural employers if needed to alleviate shortages of workers. This could occur if large numbers of aliens, who gained legal residence status in the Legalization or Special Agricultural Worker programs, left seasonal agricultural work to seek other types of employment.

Registration period

Pursuant to interim rules published in the **Federal Register** on July 17, 1989, and September 1, 1989, the Service conducted a one-time only registration for the RAW program beginning on September 1, 1989. During the registration period, 610,700 aliens who believed they met eligibility requirements contained at § 210a.2 filed form I-807, *Request for Consideration as a Replenishment Agricultural Worker (RAW).* either by mail directly with the Service's central processing location, or through a participating Qualified Designated Entity (QDE). Therefore, the registrant pool for the RAW program will consist of those aliens whose forms I-807 were accepted for processing by the Service. The 610,700 I-807 cards accepted for processing were sorted into four priority categories according to responses provided on the I-807 card. The approximate distribution by priority category is: Group #1—Aliens in the United States claiming family preference to an IRCA legalized alien—84,800, Group #2—Aliens in the United States not claiming family preference to an IRCA legalized alien—447,500, Group #3—Aliens outside the United States claiming family preference to an IRCA legalized alien—8,300, and Group #4—Aliens outside the United States not claiming family preference to an IRCA legalized alien—70,100. If and when a shortage number is determined by the Secretaries of the Departments of Agriculture and Labor, the petition process will begin with random selection and notification of aliens to be invited to file petitions for temporary resident status as a RAW, starting with registrants in Group #1.

Section 210a.1(j) has been added to the rule to define the term "Registrant" as used by the Service in the post-registration period environment as an alien who: filed form I-807, *Request for Consideration as a Replenishment Agricultural Worker (RAW)*, with the Service during the registration period beginning September 1, 1989, provided that the form I-807 was filed according to regulations at § 210a.3, according to instructions provided with the form, and that the completed form was accepted by the Service for processing.

Eligibility and Priority Consideration

A sugar producer and employer of H-2A cane cutters recommends that H-2A workers should not be eligible for the RAW program or, alternatively, that only those H-2A workers whose qualifying employment was in seasonal agricultural services should be eligible. It was argued that RAW workers will not work in sugar cane because such work is not considered to be seasonal agricultural services which RAWs are

required to perform. The RAW program would, the commentor stated, be a drain on the H–2A workforce and contrary to congressional intent that the two programs not be in conflict.

The Service does not believe Congress intended to avoid conflict between the programs by making former participants in one program ineligible for the other. It purposely declined to make persons who performed qualifying work while in legal status ineligible for the SAW program. Furthermore, although field work in sugar cane is not now considered to be seasonal agricultural services, there is nothing to prohibit a RAW from working in sugar cane for the entire harvest. The law requires only that 90 days of seasonal agricultural services be performed during a year. The interests of employers who are currently dependent on foreign labor are adequately protected by the provision in the rule which defers issuance of general employment authorization to a non-immigrant alien until expiration of the non-immigrant status. When the employment contract with the non-immigrant is concluded, neither party is under an obligation to enter into a new contract.

The commentor suggested that, at a minimum, aliens in the United States pursuant to H–2A status should not be included in the first priority category. In support of this position, the commentor cited the Service's justification in the July 17, 1989, interim final rule for according priority in selection to aliens in the United States. The Service said in explanation that it would be better to legalize the status of workers already here before importing additional workers from overseas. The point made by the commenter is that there is no policy justification for including H–2A workers in this category, since they are not illegal and their inclusion would result in fewer illegal aliens being legalized. While there is some merit to this argument, the Service believes that to penalize an entire class of registrants because their qualifying work was performed in legal rather than illegal status would result in greater harm than that caused by the potential displacement of relatively few registrants in a random selection process. The Service further believes that an employer is not harmed if a former employee is free to accept an alternative offer of employment. The rule will not be changed with respect to eligibility or priority consideration for non-immigrant workers.

Changes to Petitioner's Address

Section 210a.5(c). Several commentors requested that the Service permit registrants to use "care of" addresses. Registrants should use whatever address will best ensure that they receive mail which may be sent to them by the Service. A "care of" address may be appropriate and is not prohibited by the regulation as written. The Service commends organizations who wish to help registrants in this way. However, organizations and individuals who would perform this service for RAW registrants must consider that selection may occur over a four year period. The Service cannot be responsible if mail sent to the registrant's address of record does not reach the registrant. As a reminder, address changes are made on form I–697A, Change of Address Card, which is available from any Service office. Completed I–697A cards should be mailed only to: INS, P.O. Box 6004, London, KY 40742–6004.

Work Authorization

Sections 210a.5(d), 210a.5(i) and 210a.7(c). To minimize confusion and administrative problems, the Service has decided that initial work authorization provided either on a fee receipt for a petition filed under this part, or temporary work authorization issued by the Service on Form I–688A, for a case which has been continued, will be for a fixed period of six (6) months.

Interview Process

Section 210a.5(g). The Service wishes to clarify in this rule that pursuant to discretionary authority contained in 8 CFR 103.2(b)(1), petitioners shall be entitled to supply translators at interviews related to determining eligibility for RAW status, but that interviews will not be rescheduled or delayed for production of translators. In addition, persons providing translation for a petitioner at an interview must certify in writing to the Service that the translation they have given is accurate, and that they are competent to translate from the language spoken by the petitioner. The rule has been revised to include this provision.

Inability To Establish Family Relationship at Interview

Section 210a.5(h). One commentor questioned the manner in which petitions would be "held in abeyance" if a petitioner claimed priority consideration for RAW status, based on a family relationship to an alien legalized under IRCA, and was not able to support that claim. The final rule has been modified to provide that, if a claim to family relationship to an alien legalized under IRCA cannot be substantiated by the petitioner at the time of his or her initial interview, the petition will be denied without prejudice for failure to establish the claimed family relationship. The petitioner again becomes a registrant in the group not claiming preference based on family relationship, with the same chance for selection as others in that group. The fee will be waived if this person is again selected to petition. To accord such persons more favorable treatment would not be fair to registrants who had not sought preference in selection.

Expedited Filing of Petition for RAW Status

Section 210a.5(i). Two comments were received with respect to the expedited filing procedure. Concern was expressed about the ability of the Service to have officers available to determine the credibility of petitioner's claims to having performed agricultural work. The expedited petition procedure, contained at section 210a.5(i), has been amended to permit deferral of the examination of the petitioner's claim to having performed qualifying employment until the review of the petition at the service center has been completed, if officers trained to determine the credibility of petitioner's claims regarding performance of qualifying agricultural work are not available earlier. Petitioners found credible at this second interview, who are otherwise eligible, may be granted temporary resident status at that time. They will, of course, have been issued employment authorization at the first interview after establishing their identity, age, admissibility as an immigrant, and family relationship to an IRCA legalized alien, if that was claimed for preference in selection.

Standard of Proof

Section 210a.6(a). The rule presently provides that, if the petitioner is not credible at his or her interview and the petition is denied for this reason, only then would documents establishing performance of the 20 man-days of qualifying agricultural employment become necessary as part of an appeal of the denial. Although not specifically commented upon, the Service would like to clarify the standard of proof that will be applied to adjudicating petitions for RAW status. This rule has been revised to provide that a petitioner seeking temporary resident status under section 210A of the Act has the burden to prove his or her eligibility by a preponderance of the evidence. While there is no bright line test for "preponderance of the evidence," the determination as to whether or not a petitioner has submitted sufficient evidence to meet

his or her burden of proof, under section 210A of the Act, will depend upon the factual circumstances of each case. Therefore, the application of the preponderance of the evidence standard may require examination of each piece of relevant evidence, including testimony, and a determination as to whether such evidence, either by itself or when viewed within the totality of the evidence, establishes that something to be proved is probably true. The petitioner must satisfy the examining officer at an interview regarding the credibility of claims to performance of qualifying employment. To summarize on this point, the use of documents to establish eligibility for temporary residence as a RAW is clearly intended by the Service to be the exception rather than the rule, as was the case for the now-concluded Legalization and Special Agricultural Worker programs.

Employment Documentation

Section 210a.6(d). Several commentors urged the Service to provide that determinations regarding performance of qualifying employment will be made only on the basis of documentary proof, and to permit such proof to include affidavits from persons other than employers. These commentors also urged that the Service provide for the issuance of subpoenas, under 8 CFR 287.4, to compel production of employment records for petitioners to ensure that they will not be precluded from establishing entitlement by factors beyond their control. The Service believes that, in many instances, records of the qualifying employment performed by petitioners were not kept and that it might be very difficult for such petitioners to produce documentary evidence of work performed several years ago, illegally, and far from home. Moreover, the Service does not wish to make the establishment of qualifying employment unduly burdensome on petitioners by requiring documentary proof, or for petitioners to feel compelled to purchase false documents, which experience with the SAW program has shown, would be readily available. The Service believes that an interview by a specially trained Service officer will provide for expeditious approval of eligible petitioners with minimal burden on the petitioner or the Service. The regulations provide that, if the petitioner is not credible, only then will documents establishing performance of the 20 man-days of qualifying agricultural employment become necessary. Absent a requirement for documentation, there is no need for the Service to assume the significant administrative burdens of extending the subpoena issuance provisions of 8 CFR 287.4, or to broaden the ability to submit affidavits to persons other than employers. Accordingly, the rule will not be changed.

Notice of Intent to Deny

Section 210a.7(d). One commentor stated that it would be harsh to cut off temporary work authorization during the pendency of a Notice of Intent to Deny or before a final decision is made on the petition by the Service, and urged the Service to reconsider this position. The commentor stated that employers, having hired a petitioner on the strength of the temporary work authorization on a fee receipt, would terminate the alien's employment if work authorization is revoked or cancelled. The Service has considered this issue and has decided to revise the rule to provide that, when a Notice of Intent to Deny is issued, employment authorization will be continued. Section 210a.7(c) has also been revised to include a Notice of Intent to Deny as an action which constitutes continuance of a case. Petitioners whose cases are continued at an interview will be issued employment authorization on form I–688A for six (6) months from the date of the interview. This allows time for a reply to the Notice of Intent to Deny and the appeals process, if the decision is to deny the petition.

To ensure consistency with other Service programs, as provided by 8 CFR 103.2(b)(2), the rule has been changed to provide that a Notice of Intent to Deny will be issued only when a petitioner is the subject of adverse information, considered by the Service in arriving at a decision concerning the petition, and of which the petitioner is unaware. Petitioners will be advised by the Service, in writing, and will be offered 30 days to rebut this adverse information and present evidence in his or her behalf before a decision is made by the Service.

Proof of Performance of Seasonal Agricultural Services

Section 210a.8(d). One commentor urged that FLSA (Fair Labor Standards Act) and MSAWPA (Migrant and Special Agricultural Worker Protection Act) generated documents depicting employment history be specifically referenced in the regulation as the type of records that will meet INS documentary requirements.

The commentor also stated that RAWs should not have to rely exclusively on INS' discretion to secure essential evidence. The regulation, at § 210a.8(d)(2), currently incorporates these documents by reference. Accordingly, there is no need to revise the rule.

Securing RAW Employment Records

Section 210a.8(f). A commentor criticized the preconditions to the Service issuing a subpoena under 8 CFR 287.4, to obtain employment records on behalf of a RAW, as being overly restrictive. The commentor urged the Service to accept the filing and prosecution of actions to obtain work records or judicial declarations regarding employment as legitimate efforts by RAWs to meet their burden of proving performance of required work in seasonal agricultural services. In addition, the commentor stated that the Service should not begin deportation proceedings where the alien has initiated and is satisfactorily pursuing litigation to obtain either employment records or a judicial determination as to employment history. The Service has considered these comments and feels that it remains the responsibility of each RAW to obtain and retain required documentary proof of performance of required work. The Service believes that a RAW who conscientiously collects and maintains proof of employment in seasonal agricultural services, and who takes actions to ensure that his or her employer complies with requirements for issuing documentary proof of employment, will have little difficulty establishing the performance of this work to the Service.

Issuance and Reissuance of Temporary Resident Card (Form I–688)

Section 210a.7(b) and section 210a.8(g). Several commentors urged that the Service ensure annual verification of required work-days of employment in perishable agriculture by issuing temporary resident cards for a period of twelve (12) months at a time. The commentors pointed out that this would better meet the intent of Congress than the previous plan to issue two I–688 cards. Under the previous plan, the first I–688 card would be issued for 18 months. Upon a finding by the Service that the work-days in seasonal agricultural services required during the first 12 month period has been completed, a second I–688 would be issued. That card would be valid through the end of the 36 month period of temporary residence. The Service has evaluated comments received, reviewed the logistics of the verification process, and believes that annual verification can be implemented; but, must be staggered to allow time for automated verification using employment data supplied by the Department of Labor.

Therefore, § 210a.7(b) has been revised to provide that the first temporary resident card (Form I–688) will be issued with a validity of 15 months from the filing/fee date of the RAW petition. Section 210a.8(g) has been revised to provide that, after the conclusion of the first 12-month period from the filing/fee date of the petition, if performance of required work-days has been verified through records available to the Service or established by the RAW, a second I–688 will be issued with a validity of 12 months from the expiry of the first I–688. After the conclusion of the second 12-month period from the filing/fee date, if performance of required work-days has been established as before, a third I–688 will be issued with a validity of 12 months from the expiry of the second I–688. After the third 12 month period from the filing/fee date of the RAW petition, the RAW becomes eligible to adjust to permanent residence, provided that performance of required work-days has been established as provided by § 210a.9.

Other Issues

Section 210a.1. One commentor suggested the Service clarify the use of the term "fiscal year" within the context of this regulation. The term is now defined at § 210a.1(e).

Section 210a.5(j). The Service has amended the rule to provide that a petition may be denied where a petitioner fails to pursue a petition by not providing required information or by not appearing within the time allowed. This will better enable the Service to complete processing on all petitions, and to invite additional registrants to petition for RAW status as needed, to the maximum extent practicable, within the current fiscal year, to satisfy shortage number requirements.

Section 210a.7(c). One commentor questioned what would become of a petition if the family member, to whom a family relationship is claimed for the purpose of establishing a priority preference, has an application for temporary residence filed under IRCA which remains pending. The Service will hold the processing of a petition in abeyance where a claim to IRCA family preference is made and the relative's IRCA application is pending. This continuance will be accompanied by work authorization.

Section 210a.8(e). The Service clarifies in this rule that the waiver of the requirement that an alien perform the required work-days of employment in seasonal agricultural work to maintain status as a RAW pertains only to aliens who have been adjusted to temporary resident status as a RAW. The interim final rule published on July 17, 1989, inadvertently implied that this waiver might apply to other aliens.

Section 210a.5. In response to questions which have been asked, regarding how the Service will handle a situation where an alien who has filed an application for the SAW program then files a RAW petition, the Service wishes to clarify that any petition or application placed before the Service for adjudication may be withdrawn by a petitioner or applicant at any stage in the adjudicative process. This is relevant to those aliens seeking temporary resident status in the RAW program who have applications for temporary resident status under part 210 (SAW) pending a final decision by the Service at the time they file a RAW petition. Temporary residence under the SAW provisions of IRCA has fewer requirements for maintaining status than does the RAW program. Moreover, status as a permanent resident can be gained more quickly under the SAW provisions than in the RAW program. While eligible aliens are not prohibited from seeking temporary resident status under both the SAW and RAW provisions of IRCA, the Service restates the ability of a RAW petitioner to voluntarily withdraw a concurrent petition for temporary resident status as a RAW.

One commentor urged the Service to develop a mechanism to identify RAW applicants who have applications pending under the SAW program and to adjudicate the SAW application immediately, rather than hold up a RAW slot. The Service is moving to adjudicate all pending SAW applications as soon as possible and will cross reference RAW registrants with pending SAW applicants to ensure that these SAW cases are adjudicated rapidly.

Another commentor stated that the regulations continued to omit an explanation of the emergency procedures provided for in section 210A(a)(7) of the Act regarding a general procedure for an emergency increase in the number of RAWs. Regulations promulgated separately by the Secretaries of Agriculture and Labor, at 7 CFR part 1e and 29 CFR part 503, set forth the method for procedure for determining the need for an emergency increase in the size of the current shortage number, as required by section 210A(a)(7) of the Act. Section 210a.5(i) of this regulation presently provides a mechanism for processing RAW petitions expeditiously if the Service determines that exigent circumstances exist, and that an expedited process for return of petitions for selected aliens should be employed. No further explanation is required.

One commentor stated that the Service should specify clearly that participating QDEs will be notified when INS sends a notice to the applicant, because QDEs often have other family and friends who can help locate the alien. QDEs, as well as attorneys, will be sent copies of notices for an alien, provided the QDE number is provided on the I–807 registration card or I–805 petition where indicated, and in the case of attorneys, Form G–28 has been filed with the Service.

In accordance with 5 U.S.C. 605(b), the Commissioner of the Immigration and Naturalization Service certifies that this rule does not have a significant adverse economic impact on a substantial number of small entities. This rule is not a major rule within the meaning of 1(b) of E.O. 12291, nor does this rule have federalism implications warranting the preparation of a Federal Assessment in accordance with Executive Order 12612.

The information collection requirements contained in this rule have been cleared by Office of Management and Budget under the provisions of the Paperwork Reduction Act.

List of Subjects

8 CFR Part 103

Aliens, Delegations of Authority, Fees, Availability of Service Records.

8 CFR Part 210a

Aliens, Temporary resident status, Reporting and recordkeeping requirements, Permanent resident status.

The interim rules published at 54 FR 29875–29888 on July 17, 1989, and at 54 FR 36275–36277 on September 1, 1989, amending parts 103 and 210a, are adopted as final with the following changes:

PART 103—POWERS AND DUTIES OF SERVICE OFFICERS; AVAILABILITY OF SERVICE RECORDS

1. The authority citation for Part 103 continues to read as follows:

Authority: 8 U.S.C. 552, 552a; 8 U.S.C. 1101, 1103, 1201, 1304; 31 U.S.C. 9701; E.O. 12356, 47 FR 14874, 15557; 3 CFR, 1982 Comp., p. 166; 8 CFR 2.

§ 103.1 [Amended]

2. In § 103.1, paragraph (n)(4) is amended by replacing the word "of" immediately after the word "jurisdiction" with the word "over."

§ 103.3 [Amended]

3. In § 103.3, paragraph (a)(3)(i) is amended by removing the words "or termination" after the word "denial" and, before the phrase "on Form I–692", replacing the term "brief is desired" with the term "brief if desired".

§ 103.5 [Amended]

4. In § 103.5, paragraph (c)(1) is amended by changing the term "regional proceeding facility" to "regional processing facility."

5. Part 210a is revised to read as follows:

PART 210a—REPLENISHMENT AGRICULTURAL WORKERS

Sec.

210a.1 Definition of terms used in this part.
210a.2 Eligibility and priority consideration.
210a.3 Registration process.
210a.4 Admissibility.
210a.5 Petition for temporary resident status.
210a.6 Evidence.
210a.7 Decision and appeal.
210a.8 Status, benefits and obligations.
210a.9 Adjustment to permanent resident status.

Authority: 8 U.S.C. 1103; 8 CFR part 2.

§ 210a.1 Definition of terms used in this part.

(a) *Act.* The Immigration and Nationality Act, as amended by the Immigration Reform and Control Act of 1986, Public Law 99–603.

(b) *ADIT. Alien Documentation, Identification and Telecommunications card, Form I–89.* Used to collect key data concerning an alien. When processed together with an alien's photographs, fingerprints and signature, this form becomes the source document for generation of Form I–551 Alien Registration Receipt Card.

(c) *Agricultural employment.* The term "agricultural employment" has the meaning of "agricultural labor and services" as defined by the Department of Labor at 20 CFR 655.100(c)(1).

(d) *Application under IRCA.* The term "application under IRCA" means an application filed by any alien with the Immigration and Naturalization Service under section 245a (legalization) and 210 (Special Agricultural Worker) of the Immigration and Nationality Act and section 202 (Cuban/Haitian adjustees) of the Immigration Reform and Control Act of 1986 (IRCA).

(e) *Fiscal Year.* The term "fiscal year" refers to the twelve (12) month period beginning on October 1 and ending on September 30 of the following calendar year.

(f) *Man-day.* The term "man-day" is used to quantify work performed for the purpose of establishing eligibility under § 210a.2(a)(1)(iii) of this part; and means the performance, during any day, of not less than one (1) hour of agricultural employment or seasonal agricultural services for wages paid on any day in which piece rate work was performed. Work for more than one employer in a single day shall be counted as no more than one man-day for purposes of this part.

(g) *Public cash assistance.* Public cash assistance means income or needs-based monetary assistance to include, but not limited to, supplemental security income received by the alien or his or her immediate family members through federal, state or local programs designed to meet subsistence levels. It does not include assistance in kind, such as food stamps, public housing, or other non-cash benefits, nor does it include work-related compensation or certain types of medical assistance (Medicare, Medicaid, emergency treatment, services to pregnant women or children under 18 years of age, or treatment in the interest of public health).

(h) *Participating Qualified Designated Entity (QDE).* The term "participating qualified designated entity" means those entities designated pursuant to sections 210 and 245A of the Act, who have entered into new cooperative agreements with the Service to specifically participate in the RAW program. Only QDEs in good standing with the Service are eligible to participate in the RAW program.

(i) *Service Center.* Service offices established in each of the four Service regions to process or adjudicate applications for adjustment of status under sections 210, 210A, 245A(a) or 245A(b)(1) of the Act.

(j) *Registrant.* An alien who filed form I–807, Request for Consideration as a Replenishment Agricultural Worker (RAW), with the Service during the registration period beginning September 1, 1989, provided that the form I–807 was filed according to regulations as § 210a.3 of this part, according to instructions provided with the form, and that the completed form was accepted by the Service for processing.

(k) *Replenishment Agricultural Worker (RAW).* Any individual granted temporary resident status or permanent resident status under section 210A(c) of the Act.

(l) *Seasonal Agricultural Services.* Defined in section 210(h) of the Act as the performance of field work related to planting, cultivating, cultural practices, growing and harvesting of fruits and vegetables of every kind and other perishable commodities, as defined by the Secretary of Agriculture. Regulations further defining these terms can be found at 7 CFR part 1d.

(m) *Secretaries.* The term "Secretaries" means the Secretaries of Labor and Agriculture.

(n) *Shortage number.* The number, if any, of replenishment agricultural workers to be adjusted or admitted to the United States during a fiscal year as determined by the Departments of Labor and Agriculture under the provisions of section 210A (a) and (b) of the Act. The numerical limitations of sections 201 and 202 of the Act do not apply to the admission or adjustment of aliens for lawful temporary or permanent resident status under section 210A(c) of the Act.

(o) *Special Agricultural Worker (SAW).* Any individual granted temporary or permanent resident status under section 210(a) of the Act.

(p) *Work-day.* The term "work-day" quantifies the work required of RAWs in order to maintain temporary resident status as described in § 210a.8(b) of this part and means a calendar day during which at least four (4) hours of work in seasonal agricultural services is performed.

Note: The term "work-day" is used here in lieu of the statutory term "man-day" to conform with its usage in Department of Labor regulations at 29 CFR 502 and to distinguish between the term "man-day" as defined elsewhere in this section.

§ 210a.2 Eligibility and priority consideration.

(a) *Eligibility.* (1) An alien eligible for status as an alien lawfully admitted for temporary residence under section 210A(c) of the Act is one who:

(i) Is eighteen (18) years of age or older;

(ii) Is admissible to the United States as an immigrant, or if inadmissible, has had the grounds of excludability waived in accordance with the provisions of § 210a.4(d) of this part;

(iii) Has performed at least 20 man-days of employment in agricultural work in the United States during any 12 consecutive months during the period beginning May 1, 1985, and ending on November 30, 1988; and

(iv) Certifies that he or she is able and intends to perform seasonal agricultural services as required under § 210a.8(b) of this part.

(2) An alien who entered the United States illegally after November 30, 1988, is not eligible for RAW status.

(b) *Priority consideration.* General registration is limited to aliens who meet the eligibility criteria as provided at § 210a.2(a) of this part. Registrants will be selected at random and invited to petition in accordance with the

following priority classes in descending order (i.e.; if there are sufficient numbers of registrants to meet a shortage number in the higher priority class, registrants in the lower priority class will not be considered for selection, but, will be held for possible future selection):

(1) Aliens, in the United States, who have performed at least 20 man-days of employment in agricultural work in the United States, during any 12 consecutive months during the period beginning May 1, 1985, and ending on November 30, 1988, and who meet all the eligibility criteria provided at § 210a.2(a) of this part.

(2) Aliens, outside the United States, who have performed at least 20 man-days of employment in agricultural work in the United States during any 12 consecutive months during the period beginning May 1, 1985, and ending on November 30, 1988, and who meet all the eligibility criteria provided at § 210a.2(a) of this part.

(c) *Family preference.* (1) Within each of the two (2) registration priority classes, preference in selection will be given to the qualified spouses and unmarried sons or daughters (18 years of age or older) of aliens who have filed an application under IRCA, which has been approved or is pending. Any marriage or adoption which created the claimed family relationship must have occurred on or before November 30, 1988.

(2) Registrants will be sorted into the two (2) priority classes and within each class, into family preference and non-preference groups.

(3) If the petitioner fails to establish eligibility for the priority status accorded by the claimed family relationship, or if the IRCA application of the relative is denied, the procedure at § 210a.5(h) of this part will be followed.

§ 210a.3 Registration process.

(a) *General.* The general registration is intended to provide an adequate number of persons to satisfy shortage number requirements for several years. Registrant's names in excess of the current year's shortage number requirement will be retained for potential future selection. Aliens who are not yet eighteen (18) years of age but who will become eighteen (18) during the period October 1, 1989, through September 30, 1993, may register. These registrants will not be selected to petition for temporary resident status as a RAW until they have turned eighteen (18) years of age.

(b) *Registration period.* The Service conducted a general registration period between September 1, 1989, and November 30, 1989.

(c) *Obtaining registration Form (I–807).* Registration cards (Form I–807) will be available from all Service district, legalization and sub-offices. Registration forms will also be available from participating QDEs. Persons residing outside the United States can obtain a registration card only from a participating QDE. Non-participating QDEs, farmworker and grower organizations, non-profit community groups and public agencies may also receive cards for distribution to aliens within the United States upon approval of a request to the Regional commissioner of the Service having jurisdiction over the area of the proposed distribution.

(d) *Filing of registration Form (I–807).* (1) Aliens must mail their registration card only to the address provided in the instructions accompanying the registration card and pre-printed on the registration card and accompanying envelope. All registration cards shall be submitted by regular domestic or international surface or airmail to the address provided on the registration card. Participating QDEs operating overseas may be exempted from the requirement to use regular mail when forwarding cards of aliens registered overseas. An alternate means of delivery may be approved by the Service upon written request from the QDE.

(2) A separate registration card must be filed by each eligible registrant. Only one registration card per registrant will be accepted. If more than one registration card is discovered, all but one will be disqualified and destroyed.

(e) *Filing or registration fee.* The required registration fee of ten dollars ($10.00) shall be submitted to the Service in the envelope provided with the registration card. All fees for registration shall be paid in United States funds in the form of a money order, cashier's check, or bank check made payable to the Immigration and Naturalization Service. No personal checks or currency will be accepted. Each registration card must be accompanied by a separate fee. Group payment of registration fees is not permitted unless specifically approved in advance by the Service on a case by case basis. Registration fees will not be waived or refunded under any circumstances.

(f) *Appeal.* The decision of the Service regarding acceptance of a form I–807 registration card shall be final. No appeal shall lie from failure to be registered, or as a registrant, to be placed in a priority class, or to be given family preference.

(g) *No benefit for registration.* Neither employment authorization nor any other benefit shall derive from filing a registration card, being placed in a registry pool, or being invited to petition for RAW status.

(h) *Invitation to petition.* (1) If a shortage number is announced after completion of the registration period, registrants will be invited to petition for temporary residence as a RAW, up to the shortage number.

(2) Invitations to submit a petition and necessary materials will be mailed to registrants who are eighteen (18) years of age or older in the order of their random selection from the registration pool, beginning with registrants selected at random from the group claiming family relationship to IRCA legalized aliens in the first registration priority class. The invitation process will continue through priority classes, in order, with successive random selection of registrants until the shortage number for that year is reached.

(3) Registrants in excess of the current shortage number will be retained for future random selection and invitation to petition for temporary resident status as a RAW.

§ 210a.4 Admissibility.

(a) *General.* An alien seeking temporary resident status as a replenishment agricultural worker must be admissible to the United States as an immigrant. This means that the alien must not be excludable under the provisions of section 212(a) of the Act. However, section 210A(e) of the Act provides that certain grounds of excludability are not applicable, that certain grounds may be waived, and that other grounds cannot be waived.

(b) *Grounds of exclusion not to be applied.* The following paragraphs of section 212(a) of the Act shall not apply to petitioners for temporary resident status: (14), workers entering without Labor Certification; (20), immigrants not in possession of a valid entry document; (21), visas issued without compliance with section 203; (25), illiterates; and (32), graduates of non-accredited medical schools.

(c) *Special rule for determination of public charge.* Section 212(a)(15) of the Act shall not apply to an alien who demonstrates a history of employment in the United States evidencing self-support without reliance on public cash assistance. Consideration of the use of the special rule for determination of public charge will occur only after a determination is made that a petitioner appears to be subject to the provisions of section 212a(15) of the Act. The alien

will not be considered to be reliant on public cash assistance received by an immediate family member unless the alien's sole means of support was incident to the eligibility for cash assistance by the family member.

(d) *Waiver of grounds for exclusion.* (1) Except as provided in paragraph 9(e) of this section, the Service may waive any other provision of section 212(a) of the Act only in the case of individual aliens for humanitarian purposes, to assure family unity, or when the granting of such a waiver is in the public interest. When an application for waiver of grounds of excludability is filed jointly with a petition for temporary residence under this part, it shall be accepted for adjudication at the service center. If an alien is found to be excludable on grounds which may be waived as set forth in this paragraph, during the petition interview, then he or she shall be advised of the procedures for applying for a waiver of grounds of excludability. If an application for waiver of grounds of excludability is filed at the time of the initial petition interview, it shall be accepted at the interview office and adjudicated under the designated authority of the district director where filed. If an application for waiver of grounds of excludability is filed subsequent to the initial petition interview, it shall be filed with and adjudicated by the Service processing facility with jurisdiction over the alien's place of residence, unless otherwise directed by the Service. District directors and directors of service centers are delegated authority to adjudicate applications for waivers of grounds of excludability.

(2) Applications for grounds of excludability are filed on Form I–690. All applications for waivers of grounds of excludability must be accompanied by the correct fee in the exact amount. All fees for applications must be in the form of a money order, cashier's check, or bank check. No personal checks or currency will be accepted. Fees will not be waived or refunded under any circumstances.

(3) The applicant will be notified of the decision on the application for waiver in writing and, if denied, the reason therefore. The applicant may appeal the decision within thirty (30) days after service of the notice pursuant to the provisions of § 103.3(a)(3) of this chapter.

(e) *Grounds of exclusion that may not be waived.* The following provisions of section 212(a) of the Act may not be waived:

(1) Paragraphs (9) and (10) (relating to criminals);

(2) Paragraph (23) (relating to narcotics), except for a single offense of simple possession of thirty grams or less of marijuana;

(3) Paragraphs (27), (28), and (29) (relating to national security and members of certain organizations);

(4) Paragraph (33) (relating to those who assisted in the Nazi persecutions).

(f) *Exchange visitors.* An alien who was at any time a nonimmigrant exchange visitor (as defined in section 101(a)(15)(J) of the Act), must establish that he or she was not subject to the two-year foreign residence requirement of section 212(e) of the Act, or has fulfilled that requirement or has received a waiver of such requirement. Requests for waiver of this requirement must be filed with the District Director having jurisdiction over the alien's place of residence and must be approved by the Service prior to the petition interview.

§ 210a.5 Petition for temporary resident status.

(a) *General.* Registrants who have been selected pursuant to § 210a.3 of this part will be invited to petition for temporary resident status as a RAW. To address the variety of circumstances which might be expected to occur during the RAW program, there are two different procedures for the return of completed petition packages. Participating Qualified Designated Entities (QDEs) are authorized to assist petitioners with the preparation of their petitions and, if identified by a valid QDE number, will be advised of determinations on such petitions.

(b) Registrants who are invited to petition will be sent petition materials consisting of:

(1) Instructions in English and Spanish for completing all required forms;

(2) Petition for Temporary Resident Status as a Replenishment Agricultural Worker (RAW) Section 210A of the Immigration and Nationality Act, Form I–805;

(3) Change of Address Card for Replenishment Agricultural Workers (RAW), Form I–697A;

(4) Fingerprint card, Form FD–258;

(5) Medical Examination of Aliens Seeking Adjustment of Status (P.L. 99–603), Form I–693; and

(6) ADIT photo instruction sheet.

(c) *Changes to petitioner's address.* (1) The petition package will be mailed to the address supplied on the registration form. If a registrant changes address prior to an invitation to petition, it is his or her responsibility to notify the Service of a change of address on Form I–697A, and to file a separate notice of a change of address with the postal service, so that the petition package may be forwarded to the current address.

(2) If a petition package is returned as undeliverable by the postal service because of an insufficient address or because the registrant has moved and left no forwarding address, he or she will lose the opportunity to petition and will be placed back into the registration pool from which he or she was selected. If a registrant is selected a second time and the petition package is again returned as undeliverable, the registrant will be disqualified from further consideration.

(d) *Acceptance of completed petition package.* (1) For a petition to be accepted, petition form I–805 must be completed and returned to the Service within 60 days of the date of the invitation to petition letter according to the instructions supplied, together with the one hundred seventy-five dollar ($175.00) fee as prescribed by § 103.7(b)(1), and completed fingerprint card.

(2) Following the receipt and acceptance of a petition as provided in paragraph (d)(1) of this section, the petitioner will be sent a fee receipt. The fee receipt will provide temporary work authorization for six (6) months from the date the petition is accepted by the Service, except that petitioners who have received work authorization incident to non-immigrant status, as provided at § 274a.12(b) of this chapter, shall be granted work authorization under this section the day following the expiration of the petitioner's prior employment authorization obtained under § 274a.12(b) of this chapter.

(e) *Filing of fee.* The required fee of one hundred seventy-five dollars ($175.00) shall be submitted at the time the petition is returned to the Service, except as provided in paragraph (i) of this section. All fees for petitions shall be in the form of a money order, cashier's check, or bank check made payable to the Immigration and Naturalization Service. The petitioner's RAW registration number shall be written on the fee payment. No personal checks or currency will be accepted. Fees will not be refunded under any circumstances.

(f) *Complete petition.* (1) Invited registrants will have sixty (60) days from the date of the invitation to petition letter to complete the filing of an acceptable petition by submitting the completed petition together with the one hundred seventy-five dollar ($175.00) fee as required by § 103.7(b)(1), and completed fingerprint card.

(2) If an acceptable petition has not been received by the Service within 60

days of the date of the invitation to petition letter, the petition fee and all other materials which are submitted after the 60 day period expires will not be accepted and will be returned to the registrant unprocessed. Registrants who fail to return petitions on time will lose their chance at petitioning and will be placed back into the priority class from which they were selected. If a registrant is selected again and fails to respond a second time, that registrant will be disqualified from further consideration.

(g) *Interview.* Except as otherwise provided in paragraph (i) of this section, registrants will be invited to appear for an interview at an INS office or U.S. consulate for the purpose of petitioning for admission or adjustment to temporary resident status under this part. At that time, the petitioner must submit proof of identity and age, two ADIT photographs, proof of family relationship to an IRCA legalized alien (if claimed), and the results of the medical examination on Form I-693. The immigration or consular officer shall judge the sufficiency of the documents submitted and the truthfulness of the petitioner's claims to the performance of qualifying employment. Petitioners shall be entitled to supply interpreters at an interview. Interpreters supplied by a petitioner shall certify to the Service in writing that the translation is accurate and that he or she is competent to translate from the language in which the written and/or oral evidence is provided. Additional documentation and statements from the petitioner may be required, including the filing of additional requests for waiver of a ground(s) of exclusion, to establish eligibility under this part.

(h) *Inability to establish IRCA family relationship.* Where a petitioner is unable to substantiate a claim to family preference and fraud has not been established, the petition will be denied without prejudice. The petitioner will lose his or her present chance at petitioning and will be placed into the priority class of qualifying aliens not claiming a priority based on family relationship. In this case, the petitioner may again be selected at random and invited to petition. Temporary employment authorization obtained incident to the original petition will be terminated. Fees will not be refunded; however, if the alien is subsequently selected from the non-family pool of registrants, the fee for the filing of a second petition will be waived.

(i) *Expedited interview and petition filing.* If the Service determines that exigent circumstances exist, petitioners may be instructed to comply with the following expedited procedure in the invitation to petition letter.

(1) The Service will mail a petition package to the address supplied on the registration form, accompanied by a letter which invites the registrant to petition and to appear as soon as possible at any Service office designated to accept RAW petitions. The registrant must appear with the invitation letter, completed I–805 petition, two ADIT photographs, correct fee, proof of identity, age, and proof of family relationship to an IRCA legalized alien, if claimed at registration.

(2) On appearing at a listed Service office and after acceptance of the petition fee, the petitioner will receive a fee receipt and will be interviewed with respect to identity, age, and family relationship to an IRCA legalized alien if preference in selection was claimed on that basis. A determination regarding the truthfulness of claims to performance of qualifying employment may be made at this interview, or deferred to a later date. A petitioner who appears eligible will be granted six (6) months employment authorization on Form I–688A. If the petition is still pending upon expiration of the employment authorization, it may be extended beyond the original six (6) month period. Petitioners who have employment authorization incident to non-immigrant status, pursuant to § 274a.12(b) of this chapter, will not be granted employment authorization under this section until the day following the expiration of the employment authorization obtained incident to the non-immigrant status.

(3) The petitioner must return the fingerprint card, 1 ADIT photograph, any waiver(s) of ground(s) of excludability required, and the results of the required medical examination on Form I–693, to the Service, in the envelope that was provided with the petition package, within sixty (60) days from the date of the invitation to petition letter. Petition materials received by the Service after sixty (60) days will be returned to the petitioner unprocessed.

(4) If all required documentation and evidence is provided to the Service within the sixty (60) day period beginning with the date of the invitation to petition, the petitioner will be informed in writing of the Service's decision regarding the petition. If the petition is approved, the petitioner will be instructed to return to a Service office to exchange Form I–688A for a Temporary Resident Card (Form I–688). If the petition is denied, the petitioner will be informed in writing of his or her appeal rights and procedures to be followed in accordance with § 210a.7(g) of this part.

(5) An alien who fails to appear for the interview within 60 days of the date of the invitation to petition will lose this opportunity to petition, but may be selected at random again. Petition materials received by the Service after sixty (60) days will be returned to the petitioner unprocessed.

(j) *Failure to pursue petition.* (1) Where a petitioner timely files his or her petition, but fails to return requested documentation within the number of days allowed in this section, the petition will be denied for failure to pursue his or her petition for temporary residence.

(2) When an alien fails to report to a scheduled second or subsequent interview, the petition will be denied.

§ 210a.6 Evidence.

(a) *Proof of eligibility*—(1) *General.* Proof of identity and age, proof of claimed family relationship to an IRCA legalized alien, results of the required medical examination (Form I–693) and two ADIT photographs shall be provided to the Service at the time of the petition interview, except as provided in § 210a.5(i) of this part. Although not required, documentation of claimed qualifying employment may also be presented at this time.

(2) *Burden and standard of proof.* An alien seeking admission or adjustment of status under this part has the burden of establishing, by a preponderance of the evidence, each of the eligibility requirements set forth in § 210a.2(a) of this part, the basis for placement in a priority class as provided in § 210a.2(b) of this part, and family relationship as provided in § 210a.2(c) of this part, if claimed on the registration form.

(b) *Proof of identity and age.* (1) The petitioner may establish identity and age by submitting the following documents:

(i) Passport;

(ii) Birth certificate;

(iii) Any national identity document from the alien's country of origin bearing a photograph and/or fingerprint (e.g., "cedula", "cartilla", "carte d'identite", etc.);

(iv) Driver's license or similar document issued by the state, if it contains a photograph;

(v) Baptismal record or marriage certificate;

(vi) Affidavits; or,

(vii) Such other documentation which may establish the identify and age of the petitioner.

(2) *Assumed names.* (i) In cases where a petitioner claims to have met any of the eligibility criteria under an assumed

name, the petitioner has the burden of proving that the petitioner was, in fact, the person who used that name. The petitioner's true identity is established pursuant to the requirements of paragraph (b)(1) of this section. The assumed name must appear in documents provided by the petitioner to establish eligibility. To meet the requirements of this paragraph, documentation must be submitted to prove that the assumed name was, in fact, used by the petitioner.

(ii) *Proof of common identity.* The most persuasive proof of common identity is a document issued in the assumed name which identifies the petitioner by photograph, fingerprint or detailed physical description. Other evidence which will be considered are affidavit(s) by a person or persons other than the petitioner, made under oath, which identify the affiant by name and address, state the affiant's relationship to the petitioner and the basis of the affiant's knowledge of the petitioner's use of the assumed name. Affidavits accompanied by a photograph, which have been identified by the affiant as the individual known to affiant under the assumed name in question, will carry greater weight.

(c) *Evidence of family relationship*—(1) *Spouse of legalized alien.* If the petitioner is the spouse of a legalized alien, then a certificate of marriage between the petitioner and legalized alien is required. If either the husband or wife was married before, then documents must be submitted to show that all previous marriages were legally ended (e.g., divorce decree, death certificate).

(2) *Unmarried son or daughter of a legalized alien.* (i) If the legalized alien is the mother, then the birth certificate of the unmarried son or daughter showing the name of the mother is required.

(ii) If the legalized alien is the father, a certificate of marriage of the parents and the unmarried son or daughter's birth certificate showing the names of the parents must be provided.

(iii) If the legalized alien is the stepparent, the unmarried son or daughter's birth certificate showing the names of both natural parents, the marriage certificate of the parent to the stepparent, and proof of legal termination of their prior marriages must be provided.

(iv) if the unmarried son or daughter was born out of wedlock, and the father is the legalized alien, the parent/child relationship must be established by providing the unmarried son or daughter's birth certificate showing the father's name, and evidence that he supported the child.

(v) If the unmarried son or daughter is the adoptive child of a legalized alien, a certified copy of the adoption decree, the legal custody decree, if the custody of the unmarried son or daughter was obtained before adoption, and a statement showing the dates and places the unmarried son or daughter and adoptive parent lived together must be submitted.

(vi) If the umarried son or daughter has previously been married, a certified copy of the divorce or annulment decree, or other document that terminated the prior marriage, must be submitted.

(3) *Documents not available.* If the documents listed in this section are not available, the following evidence may be submitted. The Service may require a statement from the appropriate authority certifying that the needed document is not available (blood test may be required):

(i) *Church record.* A certificate under the seal of the church of baptism, dedication, or comparable rite showing the date and place of the child's birth, date of the religious ceremony, and the names of the child's parents;

(ii) *School record.* A letter from the authorities of the first school attended showing the date of admission to the school, the child's date and place of birth, and the names and places of birth of the parents, if shown in the school records;

(iii) *Census record.* State or federal census record showing the name, place of birth, and date of birth or the age of the person listed;

(iv) *Affidavits.* Written statements sworn to or affirmed by two persons who were living at the time who have personal knowledge of the event the petitioner is trying to prove. The affidavit must include the affiant's full name, address, date and place of birth, and his or her relationship to the petitioner, if any; full information concerning the event; and complete details concerning how the person acquired knowledge of the event.

(d) *Employment documentation.* Upon request or instruction by the Service, documents which may be submitted to establish performance of qualifying employment include: government employment records; records maintained by agricultural producers, farm labor contractors, collective bargaining organizations and other groups or organizations which maintain records of employment; worker identification issued by employers or collective bargaining organizations; union membership cards or other union records such as dues receipts; other records of the applicant's involvement with organizations providing services to farm workers; work records such as pay stubs, piece work receipts, W–2 forms; certification of filing income tax returns on IRS Form 6166; state verification of the filing of state income tax returns; or affidavits from employers.

(e) *Documents*—(1) *Original documents.* When documents are required, original documents must be presented wherever possible, except the following: Official government records; employment or employment related records maintained by employers, unions or collective bargaining organizations; medical records; school records maintained by a school or school board; or other records maintained by a party other than the applicant. Copies of records maintained by parties other than the petitioner which are presented in evidence must be certified as true and complete by such parties and must bear their seal or signature or the signature and title of persons authorized to act in their behalf. If at the time of the interview the return of orignial documents is desired by the petitioner, then they must be accompanied by notarized copies or copies certified true and complete by a qualified designated entity, or by the petitioner's attorney or accredited representative, in the format prescribed at 8 CFR 204.2(j) (1) or (2).

(2) At the discretion of the district director, original documents, even if accompanied by certified copies, may be temporarily retained for forensic examination by the Service. Original documents will be retained only for the period of time necessary to determine their authenticity. Documents will be returned to petitioners at a Service office whenever possible and will be returned by mail at the option of the petitioner.

(3) *Documents in a foreign language.* Documents in a language other than English must be accompanied by a summary translation into English. A summary translation is a condensation or abstract of the document's text but includes all pertinent facts. The translator must certify that the translation is accurate, and that he or she is competent to translate from the language in which the original document is written.

(f) *Medical examination.* A petitioner under this part must be examined by a designated civil surgeon at no expense to the government. The medical report setting forth the findings concerning the mental and physical condition of the applicant shall be incorporated into the

record on Form I–693, Medical Examination of Aliens Seeking Adjustment of Status. This form will be sent to the petitioner with the petition package. The results of the medical examination on Form I–693 must be submitted at the time of the interview, except as provided in § 210a.5(i) of this part. Any petitioner certified under paragraphs (1), (2), (3), (4), or (5) of section 212(a) of the Act may appeal to a Board of Medical Officers of the U.S. Public Health Service, as provided in section 234 of the Act and part 235 of this chapter.

(g) *Confidentiality of information.* Information furnished pursuant to registration or petitioning under this part will not be used to deport or prosecute any person unless fraud is discovered during the registration or petition processes, an alien has failed to maintain status as a RAW, or a person is the subject of an outstanding criminal arrest warrant.

§ 210a.7 Decision and appeal.

(a) *General.* Based on all information provided with the petition, at the interview, or as otherwise provided in § 210a.5(i), a district director or the director of a service center may decide to approve, continue, or deny a petition for adjustment to temporary resident status as a RAW.

(b) *Approval.* If the petitioner has submitted a complete petition, has been interviewed, has established his or her admissibility and eligibility, and record check(s) initiated by the Service are returned without adverse information concerning the petitioner, the petition shall be approved by the Service. The petitioner will be issued Form I–688, Temporary Resident Card, valid for a period of fifteen (15) months from the filing date of the petition. Employment authorization will be extended for 12 months from the 15-month anniversary date of temporary resident status upon a finding by the Service that the alien has completed the required work-days of employment in seasonal agricultural services as provided in § 210a.8 of this part during the petitioner's first 12 months in temporary resident status, and for an additional 12 months from the expiry of the second expiration date, upon a finding that the petitioner has completed the required employment during the petitioner's second 12-month period in temporary resident status.

(c) *Continuance—General.* Except as provided in § 210a.5(i) of this part, a petitioner who has provided all required evidence to meet the burden of proof but in whose case the Service has not completed required record checks or other processing, a claim to IRCA family preference is made and the relative's IRCA application is pending, or a Notice of Intent to Deny is issued, may be granted a six (6) month period of employment authorization on Form I–688A (Employment Authorization Card). This card may be renewed, extended or reissued at the direction of the district director. Petitioners who have received employment authorization incident to non-immigrant status pursuant to § 274a.12(b) of this chapter will not be granted employment authorization under this section until the day following the expiration of the employment authorization obtained incident to the non-immigrant status.

(d) *Notice of Intent to Deny.* The Service shall issue a Notice of Intent to Deny where a petitioner is the subject of adverse information, of which the petitioner is unaware, that would render him or her ineligible if the Service relied on this information in making a decision on the petition. This notice is a statement by the Service that specifies the basis for the intended denial of the petition and what additional evidence is required to prevent denial of the petition. Petitioners will be granted thirty (30) days to return to the Service with the required evidence. If the petitioner fails to meet the burden of proof by the end of this thirty (30) day period, the petition will be denied.

(e) *Denial.* When a petition for temporary resident status as a RAW is denied, the petitioner will be given written notice setting forth the specific reasons for the denial on Form I–692. Form I–692 shall also contain advice to the petitioner that he or she may appeal the decision and that such appeal must be taken within thirty (30) days after service of the notification of the decision, accompanied by any additional new evidence, and a copy of a supporting brief if desired. The Form I–692 shall additionally provide a notice to the petitioner that if he or she fails to file an appeal from the decision, the Form I–692 will serve as a final notice of ineligibility.

(f) *Reopening or reconsideration of decisions.* The director of a service center may *sua sponte* reopen any proceeding under this part within his or her jurisdiction, and may render a new decision. This decision may reverse a prior favorable decision when it is determined that there is evidence of fraud during the registration or petition processes, and the petitioner was not entitled to the status granted. If the decision of the director, after reconsideration, is to deny the petition, the petitioner shall be accorded the due process provisions contained in paragraphs (d), (e) and (g) of this section related to the notice of intent to deny, denial and appeal processes.

(g) *Appeal process.* Denial of a petition for status as a RAW and denial of an application for waiver of grounds of excludability may be appealed to the Associate Commissioner, Examinations (Administrative Appeals Unit) using Form I–694. Any appeal, with the required fee of fifty dollars ($50.00), shall be filed with the service center within thirty (30) days after service of the Notice of Denial in accordance with the procedures of 8 CFR 103.3(a)(3). The thirty (30) day period includes any time required for service or receipt by mail.

(h) *Date of adjustment.* (1) The status of an alien whose petition for temporary resident status is approved by the Service shall be adjusted to that of a lawful temporary resident as of the date the petition was accepted by the Service, as provided for in § 210a.5(d)(1) of this part.

(2) An exception to paragraph (h)(1) of this section occurs if an alien has been granted employment authorization incident to non-immigrant status pursuant to § 274a.12(b) of this chapter. The date of adjustment for these petitioners will be the day following the expiration of the employment authorization obtained incident to non-immigrant status.

(i) *Fraud or willful misrepresentation.* If, during the petition process, fraud or willful misrepresentation of a material fact is found in the registration and/or petition processes, a Notice of Intent to Deny will be issued and, if not answered satisfactorily or within the time allowed, the petition will be denied. If the petitioner is in the United States, he or she will be subject to deportation under section 241 of the Act and/or referral to the United States Attorney for possible prosecution.

(j) In the Case of a petition which was denied for failure of the petitioner to meet the priority class standard from which he or she was selected, absent a finding of fraud, the petitioner will be placed into the next lower priority class for which he or she appears eligible. If selected again, a new petition may be required; however, the petition fee will be waived.

§ 210a.8 Status, benefits and obligations.

(a) *Employment and travel authorization.* (1) An alien whose petition for temporary residence has been approved under section 210A(c) of the Act has the right to reside in the United States, to travel abroad (including commuting from a residence abroad), and to accept employment in the United States in the same manner as

an alien lawfully admitted for permanent residence. Employment and travel abroad will be authorized for such aliens on Temporary Resident Card (Form I–688).

(2) An alien who has been granted temporary work authorization incident to a continuance during the petition interview process will be issued an Employment Authorization Card (Form I–688A) for the duration of the approved period of employment. Travel outside the United States is authorized by Form I–688A.

(b) *Obligation to perform seasonal agricultural services.* (1) An alien who has obtained temporary resident status as a replenishment agricultural worker must establish to the Service, as set forth in this section, that he or she has performed ninety (90) work-days of seasonal agricultural services in each of three successive twelve (12) month periods following the date the alien's status was adjusted, unless the required number of work days has been adjusted pursuant to paragraph (c) of this section.

(2) An alien granted lawful permanent residence on the basis of temporary residence under section 210A(c) of the Act may not be naturalized as a citizen of the United States under any provision in Title III of the Act, unless the alien has performed ninety (90) work-days of seasonal agricultural services in each of two (2) additional years beyond the three (3) twelve (12) month periods required by paragraph (b)(1) of this section.

(3) A replenishment agricultural worker who fails to establish to the Service that he or she has fulfilled the requirements of section 210A(d)(5)(A) of the Act, to perform seasonal agricultural services in any one of the twelve (12) month periods, shall be subject to deportation proceedings under section 241(a)(20) of the Act.

(c) *Adjustment of required work-days.* (1) The number of work-days of required employment in seasonal agricultural services during a fiscal year is subject to reduction, by the Department of Labor and the Department of Agriculture, under section 210A(a)(8) of the Act. The Secretaries will make a determination in this regard and will publish a notice of any such adjustment in the **Federal Register.**

(2) A RAW whose 12-month period during which the required employment must be performed falls in two fiscal years, shall be required to meet the lesser work-day standard which is in effect during that 12-month period.

(d) *Proof of performance of seasonal agricultural services.* (1) The burden is on the RAW temporary resident or permanent resident to collect, maintain, and have available for inspection evidence that he or she has performed the requisite number of work-days of seasonal agricultural services for each year as described in this section.

(2) Such evidence may consist of certificates provided to employees by employers, as required in section 210A(b)(2) of the Act, and under Department of Labor regulations located at 29 CFR 502.13; or the same type of documentation as may be submitted under section 210(b)(3) of the Act.

(3) Aliens are required to establish performance of required work-days in seasonal agricultural services annually for each of the three 12-month periods of temporary residence.

(e) *Waiver of requirement to perform work.* Where a RAW temporary resident is unable to perform the 90 work days of seasonal agricultural services required by the Act and this part, because of extraordinary, unusual, and unique circumstances such as disabling injury, disease or condition which is beyond an alien's control, the Service may waive this requirement.

(f) *Securing RAW employment records.* (1) When a RAW temporary resident or permanent resident alleges that an employer refuses to provide him or her with records relating to his or her employment and the petitioner has reason to believe such records exist, the Service shall attempt to secure such records.

(2) Prior to any attempt by the Service to secure the employment records, the following conditions must be met: the alien must be in approved temporary resident status as a Replenishment Agricultural Worker; the alien must have made reasonable attempts to secure the documentation from the employer; the alien's testimony must support credibly his or her claim; and, the Service must determine that temporary resident status is in jeopardy in the absence of employer records.

(3) Provided each of the conditions in paragraph (f)(2) of this section have been met, and after unsuccessful attempts by the Service for voluntary compliance, district directors shall issue a subpoena in accordance with 8 CFR 287.4, in such cases where the employer or farm labor contractor refuses to release the needed employment records.

(g) *Reissuance of Temporary Resident Card (Form I–688).* (1) Upon a finding by the Service that the work-days in seasonal agricultural services required during the first twelve (12) month period following the acceptance date of the RAW petition have been completed, a second Temporary Resident Card (Form I–688) shall be issued and will be valid for twelve (12) months from the expiry of the I–688 issued for the first 12-month period. Upon a finding by the Service that a RAW has completed the work-days in seasonal agricultural services required during the second twelve (12) month period following the filing date of the RAW petition, a third Temporary Resident Card (Form I–688) will be issued and will be valid for twelve (12) months from the expiry of the I–688 issued for the second 12-month period.

(2) Form I–688 shall not be issued, reissued or extended and shall lose its validity if the temporary resident status of the alien has been terminated as provided in paragraph (i) of this section.

(h) *Ineligibility for immigration benefits.* An alien who is admitted as, or whose status is adjusted to that of, a lawful temporary resident under section 210A(c) of the Act is not entitled to submit a petition pursuant to section 203(a)(2) of the Act, or receive any other benefit or consideration accorded under the Act to aliens lawfully admitted for lawful permanent residence, except as provided in paragraph (a) of this section.

(i) *Termination of temporary resident status.* (1) Upon a finding by the Service that an alien is deportable under sections 235, 236, 237 or 241 of the Act as amended, to include failure to meet the work-day requirement of section 210A(d)(5)(A) of the Act, the Service shall issue an Order to Show Cause and place the alien in deportation proceedings. Temporary resident status as a replenishment agricultural worker shall be terminated upon a finding by an Immigration Judge that an alien is deportable.

(2) *Retention of Form I–688.* The alien shall be entitled to retain his or her I–688 Temporary Resident Card while deportation proceedings are pending and until a determination is made by an immigration judge that the alien is deportable. This card shall be reissued or extended as required during the period of time that the deportation proceedings are pending.

(3) *Surrender of Form I–688.* An alien whose status as a temporary resident has been terminated as a consequence of an order of deportation by an immigration judge shall, upon demand, promptly surrender Form I–688, Temporary Resident Card, to the district director having jurisdiction over the alien's place of residence, or, in the case of a commuter, employment.

§ 210a.9 Adjustment to permanent resident status.

The status of an alien lawfully admitted to the United States for temporary residence as a RAW shall be adjusted to that of an alien lawfully

admitted to the United States for permanent residence only after performance of the required work-days in seasonal agricultural services has been verified by the Service. However, once adjustment of status has been approved by the Service, the effective date of permanent residence shall be as of the end of the three (3) year period that began on the date the alien was granted such temporary resident status.

Dated: April 26, 1990.

Gene McNary,

Commissioner, Immigration and Naturalization Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 109 and 509

[Docket No. 88N-0006]

RIN 0905-AC73

Action Levels for Added Poisonous or Deleterious Substances in Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its procedural regulations governing unavoidable food and feed contaminants (including food-packaging materials) to (1) Make it clear that action levels, as defined in the final rule, constitute prosecutorial guidance rather than substantive rules, (2) remove the provisions of the regulations in 21 CFR parts 109 (human food) and 509 (animal feed) providing for exemptions to action levels, and (3) provide for substantive rules, called regulatory limits, establishing levels of unavoidable added poisonous or deleterious substances in food and feed that adulterate the food and feed. The amendments to the procedural regulations are being made in response to a court decision that invalidated FDA action levels, as previously defined, on the ground that they were substantive rules that had not been promulgated in accordance with notice and comment procedures.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: John R. Wessel, Office of Regulatory Affairs (HFC-6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1815.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 21, 1989 (54 FR 16128), FDA proposed to (1) amend its regulations creating and describing action levels to make it clear that action levels constitute prosecutorial guidance rather than substantive rules, and (2) remove the provisions of regulations providing for exemptions to action levels in 21 CFR parts 109 (human food) and 509 (animal feed). FDA proposed these changes in its procedural regulations for unavoidable food and feed contaminants (including food-packaging materials) because of a court decision that relied on those regulations in invalidating the action levels. Specifically, on May 15, 1987, the D.C. Circuit held that FDA action levels, as then defined, were legislative rules rather than general statements of policy within the meaning of the Administrative Procedure Act (5 U.S.C. 551(5)) and, therefore, had to be promulgated in accordance with the notice and comment procedures of that statute (*CNI* v. *Young*, 818 F.2d 943 (D.C. Cir. 1987)). Because FDA's action levels were issued without such procedures, the court found the action levels to be "invalid." *Id.* at 950.

Before the circuit court's decision, and beginning with the enactment of the Federal Food, Drug, and Cosmetic Act (the act) in 1938 (21 U.S.C. 301 *et seq.*), FDA regulated the presence of unavoidable added poisonous or deleterious substances in food and feed, such as aflatoxins in corn, principally by using what the agency viewed as general statements of policy—publicly available prosecutorial guidelines—that it termed "action levels." These action levels announced the amount of a particular added contaminant that FDA regarded as resulting in adulteration under section 402(a)(1) of the act (21 U.S.C. 342(a)(1)). That section provides that a food is adulterated if it bears or contains an added poisonous or deleterious substance that "may render [the food] injurious to health."

As the first step in responding to the circuit court's decision, FDA issued a notice in the **Federal Register** of February 19, 1988 (53 FR 5043), stating that its current action levels are not binding on the courts, the public (including food and feed producers), or the agency (including individual FDA employees), and that action levels do not have the "force of law" of substantive rules. The notice said that if a food bears or contains an unavoidable added poisonous or deleterious substance in an amount below the action level for that substance, FDA is not precluded from recommending to the Department of Justice (see 21 U.S.C. 337; *Ewing* v. *Mytinger & Casselberry, Inc.*, 339 U.S. 594, 598-599 (1950)) that court enforcement action be instituted against the food or the persons responsible for its shipment, and the Government is not barred from bringing such an action. Action levels do not create a legal immunity from prosecution for food or feed producers, nor do action levels grant to food or feed producers a legal privilege to ship in interstate commerce food or feed with added contaminants up to the applicable action levels. At the same time, as stated in the notice, if a food or feed bears or contains an unavoidable poisonous or deleterious substance in an amount in excess of the action level for that substance, FDA is not required to recommend court proceedings, and the Government is not required to bring such proceedings.

The proposed amendments to FDA's procedural regulations in 21 CFR parts 109 and 509 reiterated these points (April 21, 1989; 54 FR 16128 to 16130) and, as the agency's second step in responding to the circuit court's decision, would eliminate the language and provisions in these regulations on which the circuit court relied in determining that the action levels were substantive rules.

Interested persons were given until June 20, 1989, to comment on the proposal. FDA received two comments on the proposed rule. A summary of the comments and FDA's response follows:

1. One comment suggested that although the proposed amendments to the regulations would satisfy the circuit court's ruling, they were deficient in that the proposed amendments did not describe the agency's authority to regulate unavoidable food or feed contaminants through an informal rulemaking process under section 402(a)(1) of the act and the Administrative Procedure Act (5 U.S.C. 553). Therefore, the comment identified, and urged FDA to include in any final rule, three possible ways that the agency can regulate unavoidable added poisonous or deleterious substances in food and feed: (1) Tolerances pursuant to sections 406 and 701(e) of the act; (2) action levels pursuant to FDA's authority to issue prosecutorial guidelines; and (3) regulations in accordance with the Administrative Procedure Act. The comment then proposed several changes in parts 109 and 509 to accommodate this objective. Each of these proposed changes is discussed below.

FDA agrees with the suggestion that any final rule should set forth a description of the agency's authority to provide for substantive rules established

by informal rulemaking as well as for tolerances and action levels. As the agency stated in the preamble to the proposed rule (54 FR 16129), it may establish by notice and comment (informal) rulemaking under sections 402(a)(1) and 701(a) of the act levels of added poisonous or deleterious substances in food or feed that may render the food or feed injurious to health and, thus, adulterated within the meaning of section 402(a)(1) of the act. *CNI* v. *Young, supra; Young* v. *CNI*, 106 S. Ct. 2360 (1986), reversing *CNI* v. *Young*, 757 F. 2d 354 (D.C. Cir. 1985). FDA explained that if it establishes such levels, it will call them "regulatory limits," to distinguish them from action levels, as defined in the February 19, 1988 (53 FR 5043) notice, and in this final rule, and that regulatory limits will be binding on the courts, the public (including food and feed producers), and the agency (including individual agency employees) (54 FR 16129; April 21, 1989). FDA is using the term "regulatory limit" rather than "regulation," as suggested by the comment, because tolerances under sections 406 and 701(e) of the act are established by regulation, albeit by formal rather than informal rulemaking.

In issuing the proposed amendments to the procedural regulations, the agency's primary concern was to eliminate the language and provisions that could lead to any misinterpretation that action levels were substantive rules. For this reason, the agency did not provide a reference to regulatory limits in the text of the proposed amendments. However, consistent with the preamble to the proposed rule and as urged by the comment, FDA now believes that the final rule should address the three regulatory options identified by the comment for dealing with unavoidable food and feed contaminants and the general circumstances in which each option may be used. Accordingly, the final rule incorporates additional provisions for regulatory limits that FDA may establish for unavoidable added poisonous or deleterious substances, as follows:

(a) Parts 109 and 509 are amended by redesignating subpart C as subpart D and reserving it, and by adding and reserving a new subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances—[Reserved].

(b) Sections 109.4 and 509.4 are amended by revising the section headings to read "Establishment of tolerances, regulatory limits, and action levels"; by revising paragraph (b); by redesignating paragraph (c) as paragraph (d), and revising it to remove the reference "subpart C" and to replace it with "subpart D"; and by adding a new paragraph (c).

(c) As revised, §§ 109.4(b) and 509.4(b) provide for the establishment of a regulatory limit for an added poisonous or deleterious substance under the criteria of § 109.6 or 509.6, as appropriate, and under sections 402(a)(1) and 701(a) of the act.

Reliance on the criteria set out in §§ 109.6 and 509.6 and the first clause of section 402(a)(1) of the act were suggested by the comment, and FDA is adopting the suggestion. The comment also suggested that the Administrative Procedure Act (5 U.S.C. 553) be cited as the authority for regulatory limits. The agency believes that, although the Administrative Procedure Act is certainly applicable to the promulgation of regulatory limits, specific citation to it is unnecessary because section 701(a) of the act is FDA's substantive rulemaking authority. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973); *National Ass'n of Pharmaceutical Manufacturers* v. *FDA*, 637 F. 2d 877 (2d Cir. 1981); *National Confectioners Ass'n* v. *Califano*, 569 F. 2d 690 (D.C. Cir. 1978); *National Nutritional Foods Ass'n* v. *Weinberger*, 512 F. 2d 688 (2d Cir.), *cert. denied*, 423 U.S. 825 (1975).

(d) FDA is not adding to new §§ 109.4(c)(1) and 509.4(c)(1) the phrase "and therefore subject to enforcement action by the agency" after the word "adulterated," as suggested by the comment, because such language is unnecessary.

(e) Sections 109.6 and 509.6 are amended by revising paragraph (a); by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and revising them; and by adding a new paragraph (c).

(f) For the reasons discussed above, the term "regulatory limit" is added to §§ 109.6(a) and 509.6(a), after the word "tolerance" in the second sentence.

(g) In new §§ 109.6(c) and 509.6(c), FDA is setting out the criteria it will use when determining whether to establish a regulatory limit for an added poisonous or deleterious substance in food or feed. These criteria are: the substance cannot be avoided by current good manufacturing practices; there is no tolerance established for the substance in the particular food or feed under sections 406, 408, or 409 of the act; and there is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food or feed is adulterated within the meaning of section 402(a)(1) of the act.

(h) Redesignated §§ 109.6(d) and 509.6(d) have been revised by adding the sentence: "An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act." This addition is intended to make clear that action levels are not binding on the agency, the courts, or the regulated industry.

(i) Redesignated §§ 109.6(e) and 509.6(e) have been revised by adding "of the act," after "section 408 or 409" in the first sentence. This editorial change is intended to clarify that the references are to section 408 or 409 of the Federal Food, Drug, and Cosmetic Act.

(j) Sections 109.7 and 509.7 are revised to add to the term "regulatory limits" after the word "tolerances" in paragraph (b).

2. As discussed in the preamble to the proposed rule (54 FR 16128 at 16129), FDA is deleting §§ 109.8 and 509.8 in their entirety. No comments were received concerning the deletion of these sections which provided for exemptions from action levels.

As the agency emphasized in the preamble to the proposed rule, notwithstanding the deletion of §§ 109.8 and 509.8, FDA "enjoys complete discretion not to employ the enforcement provisions" of the act. *CNI* v. *Young*, 818 F. 2d at 950, citing *Heckler* v. *Chaney*, 470 U.S. 821 (1985). Those "provisions authorize, but do not compel, FDA to undertake enforcement activity; they 'commit complete discretion to [FDA] to decide how and when they should be exercised.'" *Schering Corp.* v. *Heckler*, 779 F. 2d 683, 686 (D.C. Cir. 1985), quoting *Heckler* v. *Chaney*, 470 U.S. at 835.

3. One comment acknowledged that the ageney should not issue a tolerance where technological or other changes might require a change in that tolerance in the near future but urged FDA to make it clear that the prospect of such changes would not limit the circumstances in which it would adopt regulatory limits. The comment also advocated that FDA build into the regulation the flexibility to allow for lowering a regulatory limit when technological or other circumstances change. The comment further suggested

that, with this flexibility, the Government could prosecute where an added contaminant was present in an amount below an established regulatory limit, but that the Government would be required to prove its case in court. According to the comment, all these suggestions could be implemented by adding the words "In the case of tolerances" at the beginning of §§ 109.6(b) and 509.6(b).

Regulatory limits are established by informal rulemaking, tolerances by formal rulemaking. Because of the differences in rulemaking procedures, a regulatory limit can be changed more easily than a tolerance. FDA believes that the criteria in new §§ 109.6(c) and 509.6(c) that will be used when determining whether to establish a regulatory limit will make it clear that the prospect of technological changes will not preclude the agency from establishing such a limit. FDA also believes that §§ 109.6(c) and 509.6(c) are flexible enough to allow for a change in a regulatory limit (either a lowering or raising) when technological or other circumstances change. The agency does not agree, however, that consideration should be given to prosecuting where an added poisonous or deleterious substance is present in an amount below the regulatory limit for it. A regulatory limit will define a level of an added contaminant that will render a food or feed adulterated within the meaning of section 402(a)(1) of the act. Such a limit will be binding on the food and feed industry as well as on FDA and the courts. Thus, the agency would not be acting legally or in good faith by prosecuting a food or feed firm that shipped in interstate commerce a product that contained an added contaminant at a level less than the applicable regulatory limit. In addition, such an action would defeat the purpose of issuing a regulatory limit in the first place.

4. One comment expressed disappointment that FDA has not used "its full regulatory authority to monitor dangerous, unavoidable contaminants such as aflatoxin in food." Indeed, according to both of the comments that FDA received, by using action levels instead of either formal or informal rulemaking, FDA is, as one comment stated, "requiring itself to prove its case in court each time the industry contests its efforts to remove food products that are contaminated with aflatoxin above its action level." Both comments claimed that the agency's use of action levels results in a significant, unnecessary expenditure of resources and a diminishment in the protection of the public. The comments further claimed that proceeding with substantive rules instead of action levels would give industry a greater incentive to comply with section 402(a)(1) of the act. One of the comments also urged FDA to review all its action levels and to identify those contaminants in addition to aflatoxin which present "a serious threat to the public health." Once the substances are identified, the comment argued that FDA should then initiate rulemaking proceedings to set legal limits at the lowest possible levels.

FDA agrees that having substantive rules in place for unavoidable food and feed contaminants would ease the Government's burden of proof in the agency's enforcement actions. FDA has already established tolerances under sections 406 and 701(e) of the act for unavoidable polychlorinated biphenyls (PCB's) in food and feed, including food-packaging materials (see 21 CFR 109.30 and 509.30). It has also issued a notice of proposed rulemaking to establish regulatory limits for lead in ceramicware (54 FR 23485; June 1, 1989). The agency recognizes that it may be desirable to subject other unavoidable food and feed contaminants to regulatory limits rather than action levels. It further recognizes that, as a practical matter, current resources and scientific information do not permit the agency to immediately achieve that objective. Instead, FDA is proceeding to initiate appropriate rulemaking on a case-by-case basis as resources and the scientific information allow.

5. One comment recommended that FDA establish regulations (i.e., regulatory limits) in lieu of action levels for aflatoxins and presumably other unavoidable added poisonous or deleterious substances in food and feed in accordance with the informal rulemaking provisions of the Administrative Procedure Act.

This comment is not relevant to this proceeding which is intended to clarify FDA's procedural regulations. As stated in FDA's response to comment 4 above, the agency acknowledges that regulatory limits may have some advantages over action levels for regulating unavoidable added poisonous or deleterious substances in food or feed. For example, FDA is considering whether regulatory limits are appropriate for aflatoxins.

FDA also recognizes that circumstances may exist in which an action level may be more appropriate than a regulatory limit or tolerance. Thus, the amended procedural regulations continue to provide for action levels as one of the options for regulating unavoidable added poisonous or deleterious substances in food or feed.

6. One comment offered a number of general statements about action levels. For example, the comment took issue with FDA's announcement that action levels are not binding on the courts, the public, or the agency. The comment argued that action levels are, in fact, binding because they permit FDA to act upon a violation of the action levels by declaring that contamination found above the stated level is legally adulterated.

FDA believes that this comment and its underlying arguments are based on a misunderstanding about the effect of action levels on a determination of adulteration. FDA cannot simply declare a food or feed that contains a contaminant above an action level to be adulterated. Instead, the Government must prove in court that a food or feed contains a particular level of a contaminant and that that level may render the food or feed injurious to health. The fact that a level of contamination may exceed an action level does not lessen the Government's burden of proof, compel the court to decide in the Government's favor, or force industry to behave in a certain way. Moreover, the same comment stated that "[a]ction levels are less effective because they force FDA to prove that corn contaminated above its set action level is adulterated * * * each time it files a complaint to enforce the level established." FDA not only agrees with this conclusion but believes that it is consistent with the agency's position that action levels are not binding on the courts, the public (including food and feed producers) or FDA (including individual agency employees).

Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule of April 21, 1989 (54 FR 16128). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the environment and that an environmental impact statement is not required.

Economic Impact

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency

has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, FDA has previously analyzed the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as defined by the Order. The agency has not received any new information or comments that would alter its previous determination.

List of Subjects in 21 CFR

Part 109

Food packaging, Foods, Polychlorinated biphenyls (PCB's).

Part 509

Animal foods, Packaging and containers, Polychlorinated biphenyls (PCB's).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 109 and 509 are amended as follows:

PART 109—UNAVOIDABLE CONTAMINANTS IN FOOD FOR HUMAN CONSUMPTION AND FOOD-PACKAGING MATERIAL

1. The authority citation for 21 CFR part 109 continues to read as follows:

Authority: Secs. 306, 402, 406, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 336, 342, 346, 346a, 348, 371).

Subpart D [Redesignated from Subpart C]

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances—[Reserved]

2. Part 109 is amended by redesignating subpart C as subpart D and reserving it, and by adding and reserving a new subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances—[Reserved].

3. Section 109.4 is amended by revising the section heading, by revising paragraph (b), by redesignating paragraph (c) as paragraph (d) and revising it, and by adding a new paragraph (c) to read as follows:

§ 109.4 Establishment of tolerances, regulatory limits, and action levels.

* * * * *

(b) When appropriate under the criteria of § 109.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c) (1) When appropriate under the criteria of § 109.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the **Federal Register** as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

4. Section 109.6 is amended by revising paragraph (a), by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and revising them; and by adding a new paragraph (c) to read as follows:

§ 109.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive, will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

* * * * *

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

(1) The substance cannot be avoided by current good manufacturing practices.

(2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

(3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(d) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.

(e) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 of the act, if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

5. Section 109.7 is amended by revising paragraph (b) to read as follows:

§ 109.7 Unavoidability.

* * * * *

(b) Compliance with tolerances, regulatory limits, and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances, regulatory limits, or action levels. The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 109.8 [Removed]

6. Section 109.8 *Exemptions* is removed from subpart A.

PART 509—UNAVOIDABLE CONTAMINANTS IN ANIMAL FOOD AND FOOD-PACKAGING MATERIAL

7. The authority citation for 21 CFR part 509 continues to read as follows:

Authority: Secs. 306, 402, 406, 408, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 336, 342, 346, 346a, 348, 371).

Subpart D [Redesignated from Subpart C]

Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances—[Reserved]

8. Part 509 is amended by redesignating subpart C as subpart D and reserving it, and by adding and reserving a new Subpart C—Regulatory Limits for Added Poisonous or Deleterious Substances—[Reserved].

9. Section 509.4 is amended by revising the section heading, by revising paragraph (b), by redesignating paragraph (c) as paragraph (d) and revising it, and by adding a new paragraph (c) to read as follows:

§ 509.4 Establishment of tolerances, regulatory limits, and action levels.

* * * * *

(b) When appropriate under the criteria of § 509.6, and under section 402(a)(1) of the act, a regulatory limit for an added poisonous or deleterious substance, which may be a food additive, may be established by regulation in subpart C of this part under the provisions of sections 402(a)(1) and 701(a) of the act. A regulatory limit may prohibit any detectable amount of the substance in food. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(c)(1) When appropriate under the criteria of § 509.6, an action level for an added poisonous or deleterious substance, which may be a food additive, may be established to define a level of contamination at which a food may be regarded as adulterated.

(2) Whenever an action level is established or changed, a notice shall be published in the **Federal Register** as soon as practicable thereafter. The notice shall call attention to the material supporting the action level which shall be on file with the Dockets Management Branch before the notice is published. The notice shall invite public comment on the action level.

(d) A regulation may be established in Subpart D of this part to identify a food containing a naturally occurring poisonous or deleterious substance which will be deemed to be adulterated under section 402(a)(1) of the act. These regulations do not constitute a complete list of such foods.

10. Section 509.6 is amended by revising paragraph (a); by redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and revising them; and by adding a new paragraph (c) to read as follows:

§ 509.6 Added poisonous or deleterious substances.

(a) Use of an added poisonous or deleterious substance, other than a pesticide chemical, that is also a food additive will be controlled by a regulation issued under section 409 of the act when possible. When such a use cannot be approved under the criteria of section 409 of the act, or when the added poisonous or deleterious substance is not a food additive, a tolerance, regulatory limit, or action level may be established pursuant to the criteria in paragraphs (b), (c), or (d) of this section. Residues resulting from the use of an added poisonous or deleterious substance that is also a pesticide chemical will ordinarily be controlled by a tolerance established in a regulation issued under sections 406, 408, or 409 of the act by the U.S. Environmental Protection Agency (EPA). When such a regulation has not been issued, an action level for an added poisonous or deleterious substance that is also a pesticide chemical may be established by the Food and Drug Administration. The Food and Drug Administration will request EPA to recommend such an action level pursuant to the criteria established in paragraph (d) of this section.

* * * * *

(c) A regulatory limit for an added poisonous or deleterious substance in any food may be established when each of the following criteria is met:

(1) The substance cannot be avoided by current good manufacturing practices.

(2) There is no tolerance established for the substance in the particular food under sections 406, 408, or 409 of the act.

(3) There is insufficient information by which a tolerance may be established for the substance under section 406 of the act or technological changes appear reasonably possible that may affect the appropriateness of a tolerance. The regulatory limit established represents the level at which food is adulterated within the meaning of section 402(a)(1) of the act.

(d) An action level for an added poisonous or deleterious substance in any food may be established when the criteria in paragraph (b) of this section are met, except that technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future. An action level for an added poisonous or deleterious substance in any food may be established at a level at which the Food and Drug Administration may regard the food as adulterated within the meaning of section 402(a)(1) of the act, without regard to the criteria in paragraph (b) of this section or in section 406 of the act. An action level will be withdrawn when a tolerance or regulatory limit for the same substance and use has been established.

(e) Tolerances will be established under authority appropriate for action levels (sections 306, 402(a), and 701(a) of the act, together with section 408 or 409 of the act, if appropriate) as well as under authority appropriate for tolerances (sections 406 and 701 of the act). In the event the effectiveness of a tolerance is stayed pursuant to section 701(e)(2) of the act by the filing of an objection, the order establishing the tolerance shall be deemed to be an order establishing an action level until final action is taken upon such objection.

11. Section 509.7 is amended by revising paragraph (b) to read as follows:

§ 509.7 Unavoidability.

* * * * *

(b) Compliance with tolerances, regulatory limits, and action levels does not excuse failure to observe either the requirement in section 402(a)(4) of the

act that food may not be prepared, packed, or held under insanitary conditions or the other requirements in this chapter that food manufacturers must observe current good manufacturing practices. Evidence obtained through factory inspection or otherwise indicating such a violation renders the food unlawful, even though the amounts of poisonous or deleterious substances are lower than the currently established tolerances, regulatory limits, or action levels.The manufacturer of food must at all times utilize quality control procedures which will reduce contamination to the lowest level currently feasible.

§ 509.8 [Removed]

12. Section 509.8 *Exemptions* is removed from subpart A.

Dated: January 31, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–11632 Filed 5–18–90; 8:45 am]

BILLING CODE 4160–01–M

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 813

RIN 0701–AA29

Schedule of Fees for Copying, Certifying, and Searching Records and Other Documentary Material

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is revising part 813 of chapter VII, title 32, of the Code of Federal Regulations. This revision updates the schedule of fees the public is charged for services rendered by DOD components related to copying, certifying and searching records and other documentary material. The intended effect of this revision is to make available to the public updated information and to clarify policy and procedures. It implements DOD Instruction 7230.7.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Turner, SAF/AAIA, Pentagon, Washington, DC 20330–1000, telephone (202) 697–3491.

SUPPLEMENTARY INFORMATION: This regulation implements a DOD instruction on the schedule of fees and rates charged for copying, certifying and searching records and other documentary material. The Department of the Air Force will apply the same schedule of fees and rates as that applied by the Department of Defense in 32 CFR part 288. Therefore this part is published as a final rule.

The Department of the Air Force has determined that this regulation is not a major rule as defined by Executive Order 12291, is not subject to the relevant provisions of the Regulatory Flexibility Act of 1980 (Pub.L. 96–354), and does not contain reporting or recordkeeping requirements under the criteria of the Paperwork Reduction Act of 1980 (Pub.L. 96–511).

List of Subjects in 32 CFR Part 813

Freedom of information.

Accordingly, 32 CFR, chapter VII, is amended by revising part 813 as set forth below:

PART 813—SCHEDULE OF FEES FOR COPYING, CERTIFYING AND SEARCHING RECORDS AND OTHER DOCUMENTARY MATERIAL

Sec.

813.0 Purpose.
813.1 Assessing charges.
813.2 Sales charge.
813.3 Service fees.
813.4 Collecting and depositing fees.
813.5 Schedule of fees and rates.

Authority: 10 U.S.C. 8013.

§ 813.0 Purpose.

This part tells what fees you may collect for copying, certifying, and searching records and other documentary material when authorized for release. It is derived from Air Force Regulation 4–37 and implements DOD Instruction 7230.7 (part 288 of this title). This part applies to all Air Force activities, including Air National Guard and US Air Force Reserve.

§ 813.1 Assessing charges.

Before assessing fees, read 32 CFR part 812 on non-user charge transactions, waived or reduced charges and user charge exclusions. Do not use this schedule for records furnished under the Freedom of Information Act (part 806 of this chapter) or the Privacy Act (part 806b of this chapter). Part 811 of this chapter prescribes procedures and prices for the release, dissemination and sale of Air Force visual information materials.

§ 813.2 Sales charge.

You may charge for any service or sale that conveys a special benefit to the recipient beyond any benefits that accrue to the general public. For guidance see part 812 of this chapter.

§ 813.3 Service fees.

Use the fee schedule in part 288 of this title to set fees for services provided. The fees in this schedule include postage and other administrative costs.

§ 813.4 Collecting and depositing fees.

Persons responsible for collecting and depositing fees must comply with part 812 of this chapter, AFRs 177–101 and 177–108,[1] and other Accounting and Finance directives that apply.

§ 813.5 Schedule of fees and rates.

The schedule of fees and rates that the Air Force applies are the same as the Department of Defense (see 32 CFR 288.10).

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 90–11647 Filed 5–18–90; 8:45 am]

BILLING CODE 3910–01–M

32 CFR 836

Release of Information Relating to Criminal Proceedings

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Final rule.

SUMMARY: The Department of the Air Force is amending title 32, chapter VII of the CFR by removing Part 836, Release of Information Relating to Criminal Proceedings. This rule is removed because it has limited applicability to the general public. This action is the result of departmental review. The intended effect is to insure that only regulations which substantially affect the public are maintained in the Air Force portion of the Code of Federal Regulations.

EFFECTIVE DATE: June 20,1990.

FOR FURTHER INFORMATION CONTACT: Ms. Patsy J. Conner, Air Force Federal Register Liaison Officer, SAF/AAIA, Pentagon, Washington, DC 20330–1000, telephone (202–694–3431).

SUPPLEMENTARY INFORMATION: Accordingly, 32 CFR, Chapter VII, is amended by removing Part 836.

Authority: 10 U.S.C. 8013.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 90–11646 Filed 5–18–90; 8:45 am]

BILLING CODE 3910–01–M

[1] Air Force publications are available through NTIS, 5285 Port Royal Road, Springfield, VA 22161.

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 228

[FRL-3780-4]

Ocean Dumping; Designation of Disposal Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA today is designating a dredged material disposal site located offshore of the mouth of the Coquille River, Oregon, for the disposal of dredged material removed from the Coquille River navigation project and vicinity. This action is necessary to provide an acceptable ocean dumping site for the current and future disposal of this material. This site designation is for an indefinite period of time, but the site is subject to continuing monitoring to ensure that unacceptable, adverse environmental impacts do not occur.

DATES: This designation will become effective on June 20, 1990.

ADDRESSES: John Malek, Ocean Dumping Coordinator, Region 10, WD-138.

The file supporting this designation is available for public inspection at the following locations:

EPA Public Information Reference Unit (PIRU), Room 2904 (rear), 401 M Street Southwest, Washington, DC.
EPA Region 10, 1200 Sixth Avenue, Seattle, Washington
U.S. Army Corps of Engineers, North Pacific Division, U.S. Custom House, 220 Northwest Eighth, Portland, Oregon
U.S. Army Corps of Engineers, Portland District, Multnomah Building, 319 Southwest Pine, Portland, Oregon

FOR FURTHER INFORMATION CONTACT: John Malek, 206/442-1286.

SUPPLEMENTARY INFORMATION:

A. Background

Section 102(c) of the Marine Protection, Research, and Sanctuaries Act of 1972, as amended, 33 U.S.C. 1401 *et seq.* ("the Act"), gives the Administration the authority to designate sites where ocean dumping may be permitted. On October 1, 1986, the Administrator delegated the authority to designate ocean dumping sites to the Regional Administrator of the Region in which the site is located. This site designation is being made pursuant to that authority.

The EPA Ocean Dumping Regulations (40 CFR chapter I, subchapter H, § 228.4) state that ocean dumping site will be designated by publication in part 228. A list of "Approved and Final Ocean Dumping Sites" was published on January 11, 1977 (42 FR 2461 *et seq.*) and was last updated on February 2, 1990 (55 FR 3688 *et seq.*). That list established an interim site in the vicinity of the Coquille River entrance. An adjusted site, located approximately 450 meters north-northwest of the interim site, has been selected for formal designation.

B. EIS Development

Section 102(c) of the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et. seq.*, (NEPA) requires that Federal agencies prepare an Environmental Impact Statement (EIS) on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment. The object of NEPA is to build into agency decision-making processes careful consideration of all environmental aspects of proposed actions. While NEPA does not apply to EPA activities of this type, EPA has voluntarily committed to prepare EIS's in connection with ocean dumping site designations such as this. 39 FR 16186 (May 7, 1974).

EPA Region 10 prepared Draft and Final EIS entitled "Coquille Ocean Dredged Material Disposal Site (ODMDS) Designation." Five letters of comment were submitted, which EPA assessed and responded to in the final EIS. As a separate but concurrent action, a notice of availability of the final EIS has been published in the **Federal Register.** Anyone desiring a copy of the final EIS may obtain one from the address given above.

The action discussed in the final EIS is designation for continuing use of an ocean disposal site for dredged material. The purpose of the designation is to provide an environmentally acceptable location for ocean disposal of dredged material. The appropriateness of ocean disposal is determined on a case-by-case basis as part of the process of issuing permits for ocean disposal.

The final EIS presented the information to support designation of an ocean dredged material disposal site (ODMDS) in the Pacific Ocean off the mouth of the Coquille River in the State of Oregon. The designated ODMDS is an adjusted location lying north-northeast of the previous interim-designated site. Site designation studies were conducted by the Portland District, Corps of Engineers, in consultation with EPA Region 10. The adjusted ODMDS was judged to be a safer location with less potential for adverse environmental effects. No significant or long-term adverse environmental effects are predicted to result from the designation. The designated ODMDS would continue to receive sediments dredged by the Corps of Engineers to maintain the federally-authorized navigation project at Coquille River, Oregon, and other dredged materials authorized in accordance with section 103 of the Marine Protection, Research, and Sanctuaries Act of 1972 (MPRSA). Before any disposal may occur, a specific evaluation by the Corps must be made using EPA's ocean dumping criteria. EPA makes an independent evaluation of the proposal and has the right to disapprove the actual disposal.

The former, interim-designated site is hereby rescinded.

The study and final designation process were conducted in accordance with the Act, the Ocean Dumping Regulations, and other applicable Federal environmental legislation.

This final rulemaking notice fills the same role as the Record of Decision required under regulations promulgated by the Council on Environmental Quality for agencies subject to NEPA.

C. Site Designation

On November 10, 1988, EPA proposed designation of the adjusted site for the continuing disposal of dredged material. The public comment period for the proposed rule and draft EIS were concurrent and closed on December 27, 1988. Five letters of comment were received specifically referencing the draft EIS. No comments were received specifically referencing the proposed rule. These comments were responded to in the final EIS. The majority of comments provided clarification and were not considered substantive. No one raised serious concern regarding designation or management of the Coquille site.

The site is located approximately 1 nautical mile offshore of the Coquille River, Oregon, and occupies an area approximately 150 acres (.17 square nautical miles). Water depths within the area average 18.3 meters. The coordinates of the site are as follows:

43° 08' 26" N.	124° 26' 44" W.
43° 08' 03" N.	124° 26' 08" W.
43° 08' 13" N.	124° 27' 00" W.
and 43° 07' 50" N.	124° 26' 23" W.
43° 08' 08" N.	124° 26' 34" W.
	(centroid)

If at any time disposal operations at the site cause unacceptable adverse impacts, further use of the site will be restricted or terminated.

D. Regulatory Requirements

Five general criteria are used in the selection and approval of ocean disposal sites for continuing use. Sites

are selected so as to minimize interference with other marine activities, to keep any temporary perturbations from the dumping from causing impacts outside the disposal site, and to permit effective monitoring to detect any adverse impacts at an early stage. Where feasible, locations off the Continental Shelf are chosen. If at any time disposal operations at a site cause unacceptable adverse impacts, appropriate action will be taken by EPA. Such action would include additional restrictions on site use and a requirement for more intensive monitoring; however, the use of that site might be terminated and suitable alternate disposal sites identified and designated. The general criteria are given in § 228.5 of the EPA Ocean Dumping Regulations, and § 228.6 lists eleven specific factors used in evaluating a proposed disposal site to assure that the general criteria are met.

The site, as discussed below under the eleven specific factors, is acceptable under the five general criteria, except for the preference for sites located off the Continental Shelf. EPA has determined, based on the information presented in the EIS, that a site off the Continental Shelf is not feasible and that no environmental benefits would be obtained by selecting such a site instead of the site being designated in this action. Historical disposal at the existing interim site has not resulted in substantial adverse effects to living resources of the ocean or to other uses of the marine environment.

The characteristics of the adjusted site being designated are reviewed below in terms of the eleven factors and in comparison to the now-rescinded interim site.

1. *Geographical position, depth of water, bottom topography, and distance from coast.* 40 CFR 228.6(a)(1). The interim site lies in 12 to 25 meters of water, 450 meters offshore from the entrance to the Coquille River. Corner coordinates are:

43° 07′ 54″ N.	124° 27′ 04″ W.
43° 07′ 30″ N.	124° 26′ 27″ W.
43° 07′ 20″ N.	124° 26′ 40″ W.
and 43° 07′ 44″ N.	124° 27′ 17″ W.

The interim site's center is on a 280 degree azimuth from the river mouth. In general, the interim site lies just north of the submerged extension of Coquille Point on bottom contours sloping at about 60 feet per mile.

The adjusted ODMDS lies 1,150 meters north-northeast of the interim ODMDS. Bottom contours and depths at the adjusted site are similar to those at the interim ODMDS. The adjusted site has the following corner and centroid coordinates:

43° 08′ 26″ N.	124° 26′ 44″ W.
43° 08′ 03″ N.	124° 26′ 08″ W.
43° 08′ 13″ N.	124° 27′ 00″ W.
and 43° 07′ 50″ N.	124° 26′ 23″ W.
43° 08′ 08″ N.	124° 26′ 34″ W.
	(centroid)

2. *Location in relation to breeding, spawning, nursery, feeding, or passage areas of living resources in adult and juvenile phases.* 40 CFR 228.6(a)(2). Aquatic resources are described in detail in the final EIS, appendix A. The interim and adjusted sites are located in the nearshore area, and contain an abundance of aquatic life characteristic of nearshore, sandy, wave-influenced regions common along the coasts of the Pacific Northwest. The dominant commercially and recreationally important macroinvertebrate species in the area are shellfish, Dungeness crab, and squid. Recently, the Oregon Department of Fish and Wildlife (ODFW) has identified a squid spawning area that overlays the adjusted site. Numerous species of birds and marine mammals occur in the pelagic nearshore and shoreline habitats.

The nearshore area off the Coquille River supports a variety of pelagic and demersal fish species. Pelagic species include anadromous salmon, steelhead, cutthroat trout, striped bass, and shad which migrate through the estuary to upriver spawning areas. Although migratory species are present throughout the year, individual species are present only during certain times of the year. Demersal species present include English sole, sanddab, and starry flounder which spawn in the inshore coastal area in the summer. The species of invertebrates inhabiting the sandy portions of the area are the more motile psamnitic (sand-dwelling) forms which tolerate or require high sediment flux. Past and anticipated future disposal activities are not expected to significantly effect this community beyond the initial physical impacts of disposal. Abundances of some benthic organisms were higher at the adjusted site than at the interim site.

The interim site contains submerged rocky habitats and is immediately adjacent to neritic reefs. These are unusual features along the coast and support a variety of aquatic organisms, including bull kelp (*Nerocystis lutkeana*) and its associated fish and invertebrate community. Pelagic species associated with the neritic reefs to the east and south of the estuary and jetties include both resident and non-resident species. The shallower reefs are dominated by black rockfish while the deeper reefs are dominated by lingcod, yellow rockfish and black rockfish. These rocky areas also have a very different benthic composition from the surrounding, sandy environments. Past disposal activity does not appear to have significantly impacted this community.

The ocean waters contain many nearshore pelagic organisms which include zooplankton and meroplankton (fish, crab and other invertebrate larvae). These organisms generally display seasonal changes in abundance and, since they are present over most of the coast, are not critical to overall coastal populations. Based on evidence from previous zooplankton and larval fish studies, no impacts to organisms in the water column are predicted. Portland District requested an endangered species listing from U.S. Fish and Wildlife Service (USFWS) and National Marine Fisheries Service (NMFS). The brown pelican and the gray whale represent the only species which were listed. Based on previous biological assessments conducted along the Oregon coast regarding impacts to the brown pelican and the gray whale, no impact to either species is anticipated from the project. Letters of concurrence are included in appendix F of the Draft EIS.

In summary, both the interim and adjusted ODMDS contain living resources that could be affected by disposal activities. Evaluation of past disposal activities do not indicate that unacceptable adverse effects to these resources have occurred. The interim site contains and is in close proximity to submerged rocks and reefs with rich and varied aquatic communities. There is no evidence that past disposal has seriously impacted these communities, and in the absence of any other disposal location the interim site would be considered an acceptable site. However, the adjusted site represents a potentially less impacting location and its use is considered environmentally preferable.

3. *Location in relation to beaches and other amenity areas.* 40 CFR 228.6(a)(3). The southeast corner of the adjusted site is approximately 1,150 meters from the end of the north jetty. Both the interim and adjusted ODMDS are far enough removed that use of either site would not affect these amenities.

4. *Types and quantities of wastes proposed to be disposed of, and proposed method of release, including methods of packing the waste, if any.* 40 CFR 228.6(a)(4). The final designated ODMDS will receive dredged materials transported by either government or private contractor hopper dredges. The current dredges available for use at Coquille have hopper capacities from 800 to 4,000 cy. This would be the range

in volumes of dredged material disposed of in any one dredging/disposal cycle. Upwards of 100,000 cy of material can be placed at the site in one dredging season by any combination of private and government dredgers. The dredges would be under power and moving while disposing. This allows the ship to maintain steerage.

The material dredged from the entrance channel consists of medium to fine grain marine sands. The dredged material shows a wider variation in median grain size and tends to be slightly coarser than the ambient sediments at the proposed disposal site. The differences are small enough that the sediments are considered compatible. The occasional gravel sized sediments occur in such small quantities and so infrequently as to cause no problems. All sediments destined for ocean disposal is subject to specific evaluation, including independent review by EPA. Past sediments discharged at the interim ODMDS have been clean sands that met the exclusion criteria (40 CFR 227.13(b)).

5. *Feasibility of surveillance and monitoring.* 40 CFR 228.6(a)(5). The proximity of the proposed disposal site to shore facilities creates an ideal situation for shore-based monitoring of disposal activities to ensure that material is actually discharged at the disposal site. There is routinely a Coast Guard vessel patrolling the entrance and nearshore areas so surveillance can also be accomplished by surface vessel.

Following formal designation of an ODMDS for Coquille, EPA and the Corps will develop a site management plan which will address the need for post-disposal monitoring. Several research groups are available in the area to perform any required field monitoring. The work could be performed from small surface research vessels at a reasonable cost.

6. *Dispersal, horizontal transport and vertical mixing characteristics of the area, including prevailing current direction, and velocity.* 40 CFR 228.6(a)(6). The nearshore circulation at Coquille is influenced by the complex bathymetry and geology. Bottom currents have been observed by video camera and were recorded in April-May 1985. Currents were toward the north and offshore with velocity under .5 feet/second. The area at Coquille is exposed to normal wave action typical of this portion of the Pacific Ocean. The material dredged from the entrance channel at Coquille River is fine to medium sand. For the range of depths and grain sizes found at either of the Coquille ODMDS sites there is essentially constant mobility of bottom sediment due to wave action. This wave-induced motion is not responsible for net transport, but, once in motion, bottom sediments can be affected by other forces such as gravity or directional currents. Sediments dicharged at either of the ODMDS would be expected to join the littoral movement and disperse gradually out of the site.

7. *Existence and effects of current and previous discharges and dumping in the area (including cumulative effects).* 40 CFR 228.6(a)(7). The 10 year range of disposal has varied from 25,000 to 116,000 cy; on average, about 59,000 cy are annually discharged to the ocean. Future volumes are expected to be similar, although probably showing some increase as other disposal options are exhausted.

No biological information has been found to exist regarding the interim site prior to any disposal having occurred. It is expected that no significant impacts to the interim site have occurred beyond the yearly, site-specific effects of disposal. Beyond the observation that abundances of some benthic organisms are lower inside the interim ODMDS than other locations outside (which may be related to past disposal), there appear to be no apparent disposal effects.

No pre- or post-disposal studies on water or sediment quality have been performed. Sediments disposed in the past are identical to sediments collected in close proximity to the interim site and have met the exclusion criteria for testing.

8. *Interference with shipping, fishing, recreation, mineral extraction, desalination, fish and shellfish culture, areas of special scientific importance, and other legitimate uses of the ocean.* 40 CFR 228.6(a)(8). The Draft EIS identified no legitimate uses of the ocean that would be interfered with as a result of designation of an ODMDS or its use. The following paragraphs summarize conclusions:

Commercial Fishing: Two commercial fisheries occur in the inshore area: Salmon trawling and Dungeness crab fishing. The length of the salmon fishing season varies each year depending upon the established quota; however, it normally extends from July to September. During this period, the potential exists for conflicts between the dredge and fishing boats. The Coast Guard and ODFW indicated that this had never been a problem to their knowledge. The Dungeness crab season extends from December 1 to August 15 each year; however, most of the crabbing occurs prior to June and usually ends early because of the increase in soft shell crabs in the catch which are not marketable. As a result, most crab fishing is done outside of the normal dredging season and it is unlikely that a conflict would result. ODFW has idenified a potential squid fishery in the area. No fishery exists at present, but stocks may be sufficient to support a fishery if a market develops. There are no commercial fish or shellfish aquaculture operations that would currently be impacted by use of the existing disposal site.

Recreational Fishing: Both private party and charterboat recreational fishing for salmon and rock and reef fish occurs in the inshore area off Coquille River. The sports salmon fishing season coincides with the commerical season and extends from summer until the quota for the area is reached. Most of the sports fishery occurs along the south reef because of navigational hazards on the north reef. Potential exists for recreational fishing boats to conflict with dredging and disposal operations; however, none has been reported to date. It is unlikely that any significant conflict will develop in the near future.

Offshore Mining Operations: No offshore mining presently occurs; although, considerations for offshore mining and oil/gas leases are in the development stages. The disposal site is not expected to interfere with such proposed operations, as most exploration programs are scheduled for the outer continental shelf.

Navigation: No conflicts with commercial navigation traffic have been recorded in the more than 60-year history of hopper dredging activity. The probable reason for this is the light commercial traffic through the Coquille navigation channel. Interviews with Coast Guard personnel also did not produce any instances of conflicts with either commercial or recreational traffic. Navigation hazards exist within the immediate area (e.g., rock outcroppings/reefs) which have been considered in positioning the adjusted ODMDS. Ships cannot navigate within the area south of the interim disposal site.

Scientific: There are no identified scientific study locations. However, three is a permanent wave buoy several miles offshore in 70 meter water depth. This buoy is part of a Pacific Coast wave data network operated by Scripps for the Corps of Engineers.

Coastal Zone Management: In reviewing proposed ODMDS for consistency with the Coastal Zone Management (CZM) plan, they are evaluated against Oregon's Statewide Goal 19 (Ocean Resources). Local Jurisdiction does not extend beyond the

baseline for territorial seas and, therefore, local plans do not address offshore sites. Goal 19 requires that agencies determine the impact of proposed projects or actions. Paragraph 2.g of Goal 19 specifically addresses dredged material disposal. The requirements of the ocean dumping regulations are broad enough to meet the needs of Goal 19. Therefore, the designation of this site for ocean disposal of dredged material following the ocean dumping regulations would be consistent with Goal 19 and the State of Oregon's Coastal Zone Management Plan.

Pursuant to an Office of Water policy memorandum dated October 23, 1989, EPA has evaluated the proposed site designation for consistency with the State's approved coastal zone management program. EPA has determined that the designation of this site is consistent to the maximum extent practicable with the State coastal management program. The State of Oregon has concurred with this determination (appendix F of final EIS). In addition, as part of the NEPA process, EPA has consulted with the State of Oregon regarding the effects of the dumping at the site on the State coastal zone. EPA has taken the State's comments into account in preparing the final EIS for the site, in determining whether the proposed site should be designated, and in determining whether restrictions or limitations should be placed on the use of the site.

9. *The existing water quality and ecology of the site as determined by available data or by trend assessment of baseline surveys.* 40 CFR 228.6(a)(9). Water quality off the mouth of the Coquille River is considered excellent, typical of unpolluted seawater along the Pacific Northwest coast. No short- or long-term impacts on water quality are expected to be associated with disposal operations. The offshore area is a northwest Pacific Ocean mobile sand community bordered by a neritic reef system. Evaluation of the interim ODMDS in light of past disposal did not indicate any significant adverse effects to those communities. Designation and use of the adjusted ODMDS is not expected to have significant ecological consequences and provides additional distance from the reef community.

10. *Potentiality for the development or recruitment of nuisance species in the disposal site.* 40 CFR 228.6(a)(10). It is highly unlikely that any nuisance species could be transported or attracted to the disposal site as result of dredging and disposal activities.

11. *Existence at or in close proximity to the site of any significant natural or cultural features of historical importance.* 40 CFR 228.6(a)(11). The neritic reefs off the Oregon coast comprise a unique ecological feature. They support a wide variety of invertebrates and fish species as well as bull kelp communities. These areas are partially sheltered from wave action and receive nutrients from both the ocean and the estuaries are usually highly productive.

Potential areas of shipwrecks were evaluated. Given the characteristics of the Coquille Bar, onshore current patterns, and hard sand bottom, and the fact that the ship channel over the bar has been actively maintained by dredging and removal of wrecks from the 1860's to present, it is unlikely that any wrecks have survived in the vicinity of the disposal site. Based on this information it is unlikely that any significant cultural resources will be affected by the continued use of the disposal site. The existing information and supplementary side scan sonar data was reviewed by the State Historic Preservation Office (SHPO). SHPO concurred with the Corps' findings of no cultural resources concerns. The SHPO letter of concurrence is included in the Final EIS.

E. Action

The EIS concluded that the adjusted site may be appropriately designated for use. The adjusted site is compatible with the general criteria and specific factors used for site evaluation.

The designation of the Coquille River ODMDS as an EPA approved Ocean Dumping Site is being published as final rulemaking. Management of this site will be delegated to the Regional Administrator of EPA Region 10.

It should be emphasized that, if an ocean dumping site is designated, such a designation does not constitute or imply EPA's approval of actual disposal of material at sea. Before ocean dumping or dredged material at the site may commence, the Corps of Engineers must evaluate a permit application according to EPA's ocean dumping criteria. EPA has the right to disapprove the actual dumping, it determines that environmental concerns under the Act have not been met.

F. Regulatory Assessments

Under the Regulatory Flexibility Act, EPA is required to perform a Regulatory Flexibility Analysis for all rules which may have a significant impact on a substantial number of small entities. EPA has detemined that this action will not have a significant impact on small entities since the site designation will only have the effect of providing a disposal option for dredged material. Consequently, this rule does not necessitate preparation of a Regulatory Flexibility Analysis.

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This action will not result in an annual effect on the economy of $100 million or more or cause any other effects which would result in its being classified by the Executive Order as a "major" rule. Consequently, this rule does not necessitate preparation of a Regulatory Analysis.

This Proposed Rule does not contain any information collection requirements subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Part 228

Water pollution control.

Dated: April 23, 1990.

Thomas P. Dunne,

Acting Regional Administrator for Region 10.

In consideration of the foregegoing, subchapter H of chapter I of title 40 is amended as set forth below.

PART 228—[AMENDED]

1. The authority citation for part 228 continues to read as follows:

Authority: 33 U.S.C. sections 1412 and 1418.

2. Section 228.12 is amended by removing from paragraph (a)(3) the entry for "Coquille River Entrance," and adding paragraph (b)(71) to read as follows:

§ 228.12 Delegation of management authority for ocean dumping sites.

* * * * *

(b) * * *

(71) Coquille River Entrance—Region 10. Location: 43°08'26" N., 124°26'44" W.; 43°08'03" N., 124°26'08" W.; 43°08'13" N., 124°27'00" W.; and 43°07'50" N., 124°26'23" W.

Size: 0.17 square nautical miles.

Depth: 18.3 meters (average).

Primary Use: Dredged material.

Period of Use: Continuing use.

Restrictions: Disposal shall be limited to dredged material from the Coquille Estuary and River and adjacent areas.

[FR Doc. 90-11723 Filed 5-18-90; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 721

[OPTS-50572A; FRL-3765-5]

1,3-Benzenediamine, 4-(1,1-Dimethylethyl)-ar-Methyl; Determination of Significant New Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is promulgating a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) for the chemical substance: 1,3-benzenediamine, 4-(1,1-dimethylethyl)-*ar*-methyl, which was the subject of premanufacture notice (PMN) P-85-929 and a TSCA section 5(e) consent order issued by EPA. EPA believes that this substance may be hazardous to human health and that the uses described in this rule may result in significant human exposure. As a result of this rule, certain persons who intend to manufacture, import, or process this substance for a significant new use must notify EPA at least 90 days before commencing that activity. The required notice will provide EPA with the opportunity to evaluate the intended uses and, if necessary, prohibit or limit those activities before they occur.

DATES: This rule shall become effective on August 3, 1990. In accordance with 40 CFR 23.5 (50 FR 7271), this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern "daylight" time on June 4, 1990.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-545, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD: (202) 554-0551.

SUPPLEMENTARY INFORMATION: This rule describes significant new uses and recordkeeping requirements for certain persons who intend to manufacture, import, or process the chemical substance: 1,3-benzenediamine, 4-(1,1-dimethylethyl)-*ar*-methyl, which was the subject of PMN P-85-929 and a TSCA section 5(e) consent order issued by EPA. EPA believes that this substance may be hazardous to human health and that the uses described in this rule may result in significant human exposure. A requirement to notify EPA at least 90 days before commencing significant new uses would provide EPA with the opportunity to evaluate the intended uses and, if necessary, prohibit or limit those activities before they occur. This rule was proposed in the **Federal Register** of May 31, 1989 (54 FR 23228).

I. Authority

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use.

Persons subject to the final SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5) and the regulations at 40 CFR part 720. Once EPA receives a SNUR notice, EPA may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities on which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires EPA to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR part 707. Persons who intend to import a chemical substance are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. Persons who import a substance identified in a final SNUR must certify that they are in compliance with the SNUR requirements. The EPA policy in support of the import certification appears at 40 CFR part 707.

II. Applicability of General Provisions

In the **Federal Register** of September 5, 1984 (49 FR 35011), EPA promulgated general regulatory provisions applicable to SNURs (40 CFR part 721, Subpart A). On July 27, 1988 (53 FR 28354), and July 27, 1989 (54 FR 31298), EPA promulgated amendments to the general provisions. The general provisions are discussed in the three documents in detail, and interested persons should refer to those documents for further information. These general provisions apply to this SNUR, except as discussed in this preamble and as set forth in § 721.555. On August 17, 1988 (53 FR 31252), EPA promulgated the "User Fee Rule" (40 CFR part 700) under the authority of TSCA section 26(b). Provisions requiring persons submitting significant new use notices to submit certain fees to EPA are discussed in detail in that **Federal Register** document.

III. Summary of this Rule

The chemical substance which is the subject of this rule is identified as 1,3-benzenediamine, 4-(1,1-dimethylethyl)-*ar*-methyl. EPA is designating the following as significant new uses of the substance: Use other than for applications where it will be completely reacted (cured or used as a chemical intermediate); disposal of the substance other than by incineration or landfill; any manner or method of manufacture, import, or processing without establishing a program whereby: (1) Persons who may be exposed dermally to the substance wear gloves, eye protection, and protective clothing, and persons who may be exposed by inhalation during manufacture wear a National Institute for Occupational Safety and Health approved, category 23C respirator, (2) potentially exposed individuals are informed of the possible hazards and required protective equipment; (3) containers of the substance which may be distributed in commerce are labeled; and (4) exceeding a specified production limit prior to completion of certain tests. This rule requires persons intending to manufacture, import, or process 1,3-benzenediamine, 4-(1,1-dimethylethyl)-*ar*-methyl to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for the significant new uses described above.

IV. Background

The Agency proposed a SNUR for this substance which was published in the **Federal Register** of May 31, 1989 (54 FR 23228). The background of the PMN and the reasons for proposing the SNUR are set forth in the preamble to the proposed rule. The PMN submitter initially claimed the following as confidential business information (CBI): chemical identity, production volume, use information, process information, and portions of a mixture. The PMN submitter subsequently withdrew the confidentiality claim for chemical identity. For purposes of clarity, the substance will be referred to by its specific name and PMN number. The PMN submitter currently intends to manufacture the substance for applications where it will be completely reacted (cured or used as a chemical intermediate).

EPA received comments only from the submitter of PMN P-85-

929. A summary of the comments, EPA's responses, and subsequent actions based on those comments are described below.

In the comments it was noted that the proposed SNUR for P–85–929 provided that use other than as a chain extender for reaction injection molding polyurethane elastomers would be a significant new use. This was more restrictive than the uses permitted under the consent order for P–85–929 which allows uses where the PMN substance is completely reacted (cured or used as a chemical intermediate). Accordingly, EPA has changed the final rule to define a significant new use as any use other than where the PMN substance is completely reacted (cured or used as a chemical intermediate).

The comments also noted there were several places where restrictions imposed by the SNUR were different than those required by the original section 5(e) order. These areas included disposal, use of respirators during manufacture, and the required warning statement. The commenter also requested that EPA clarify the status of the section 5(e) consent order once this rule is effective.

Persons subject to a section 5(e) consent order for a particular chemical substance that is also subject to an effective SNUR are exempted from submitting SNUNs by 40 CFR 721.45(i) of the General Provisions to Significant New Use Rules (53 FR 28354, July 27, 1988). In general, persons subject to a section 5(e) consent order must comply with provisions of the order even when they differ from the corresponding SNUR. EPA has modified the consent order for P–85–929 so that the PMN submitter will be subject to identical distribution and use restrictions as persons subject to the SNUR for P–85–929.

EPA agrees that the language defining the warning label should be the same for the section 5(e) consent order as the SNUR for P–85–929. Accordingly, EPA has modified the label requirements in the section 5(e) order to match the language in the SNUR. The PMN submitter has agreed to these modifications to the section 5(e) consent order. In the case of the disposal and respirator requirements, EPA will modify the provisions in the SNUR to match those in the section 5(e) consent order.

The final comments concern the significant new use defined as certain required toxicity testing if a certain aggregrate volume is manufactured or imported. The commenter agreed with EPA's approach of not disclosing the aggregrate limit on manufacture or import in the rule because the PMN submitter claimed production volume of the substance as confidential business information. The commenter stated that the detailed provisions of the consent order regarding toxicity testing for P–85–929 should be incorporated in the SNUR. The commenter also stated that other manufacturers and importers of P–85–929 should not be allowed to rely on testing generated under the consent order.

The SNUR requires a manufacturer or importer to submit the toxicity test data required under the order for P–85–929 before exceeding the production volumes specified in the consent order, unless they submit a SNUN to EPA. This provision will allow EPA to address adequately toxicity testing issues, including the detailed testing provisions required by the order and the potential for unnecessarily duplicative testing. Upon receipt of such a SNUN, EPA may contact previous PMN or SNUN submitters of the same chemical substance to inquire regarding the status of testing efforts and to coordinate such efforts among the interested submitters. Also, upon receipt of such a SNUN, EPA may, depending on the circumstances, issue a section 5(e) order to the SNUN submitter which may include detailed testing provisions. The detailed testing provisions in the consent order are essentially designed to ensure that toxicity data submitted to EPA is scientifically valid and are unnecessary to include in the SNUR because, as discussed below, persons who decide to conduct the relevant studies before submitting a SNUN should follow TSCA Good Laboratory Practice standards at 40 CFR part 792 and should consult EPA before selecting a protocol.

V. Objectives and Rationale for the Rule

To determine what would constitute significant new uses of P–85–929, EPA considered relevant information about the toxicity of the substance, likely exposures associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. Based on these considerations, EPA wishes to achieve the following objectives with regard to the significant new uses that are designated in this rule:

1. EPA wants to ensure that it will receive notice of any company's intent to manufacture, import, or process P–85–929 for a significant new use before that activity begins.

2. EPA wants to ensure that it will have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing, importing, or processing P–85–929 for the significant new use.

3. EPA wants to ensure that it will be able to regulate prospective manufacturers, importers, or processors of P–85–929 before a significant new use of that substance occurs, provided that the degree of potential health and environmental risk or exposure is sufficient to warrant such regulation.

Based on test data on the structural analogues 2,4-diaminotoluene and 2,6-diaminotoluene, EPA has determined that any significant exposure may present a risk of cancer and chronic organ and systemic effects to workers. Given EPA's concerns about P–85–929, EPA believes that unrestricted manufacture, import, processing, distribution in commerce, use, and disposal of the substance may present an unreasonable risk of injury to human health.

Section 5(a)(2) of TSCA does not require EPA to find that a significant new use "may present" or "will present" an unreasonable risk. Rather, the statute requires that EPA provide for a "consideration of all relevant factors." EPA believes that the data described in this preamble and in the preamble to the proposed rule are sufficient to support the conclusion that the significant new uses of P–85–929 present a potentially significant increase in the magnitude of exposure.

VI. Recordkeeping

To ensure compliance with this rule and to assist enforcement efforts, EPA is requiring, under its authority in sections 5 and 8(a) of TSCA, that in addition to meeting the requirements in § 721.17, the records described in § 721.555 (b)(2) be maintained for 5 years after the date of their creation by persons who manufacture, import, or process P–85–929.

These recordkeeping requirements would apply to all manufacturers, importers, and processors, including small manufacturers, importers, and processors, because the small business exemption of section 8(a) of TSCA is not applicable when the chemical substance which is the subject of the rule also is the subject of a section 5(e) order. EPA considered omitting these specific recordkeeping requirements, but believes compliance monitoring for this SNUR would be made more difficult without them.

VII. Applicability to Uses Occurring Before Effective Date of the Final Rule

When determining that a use is a significant "new" use, EPA intends that the use not be currently ongoing. In this case, P–85–929 has recently undergone premanufacture review. The notice

submitter has sent EPA a Notice of Commencement of Manufacture and the substance was added to the Inventory on November 16, 1989. The section 5(e) order prohibits the notice submitter from undertaking the activities which EPA is designating as significant new uses. Therefore, EPA concluded that these uses are not presently ongoing. However, since the chemical substance identified in this SNUR has been added to the Inventory, it may be manufactured, imported, or processed by other persons for a significant new use as defined in this rule.

EPA believes that the intent of section 5(a)(1)(B) is best served by designating a use as a significant new use as of the proposal date of the SNUR rather than as of the promulgation of the final rule. If uses begun during the proposal period of a SNUR were considered ongoing, any person could defeat the SNUR by initiating a proposed significant new use before the rule became final. This would make it extremely difficult for EPA to establish SNUR notice requirements.

Thus, persons who began commercial manufacture, import, or processing of P–85–929 for a significant new use between proposal and promulgation of this rule must cease that activity before the effective date of this rule. To resume their activities, these persons must comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires.

EPA, not wishing to unnecessarily disrupt the commercial activities of persons who manufacture, import, or process for a proposed significant new use prior to promulgation of a final SNUR, has promulgated a new § 721.45(h) (July 27, 1988, 53 FR 28354) to allow for advance SNUR compliance (i.e., compliance prior to the date of promulgation).

VIII. Determining when Use is Designated in the Rule

EPA has designated a significant new use at production volumes which are confidential. EPA believes it is appropriate to keep this information confidential to protect the interest of the original notice submitter.

Therefore, EPA will reveal the production volumes described in § 721.555(a)(2)(iv) only to a manufacturer or importer who has shown a *bona fide* intent to manufacture or import the substance. To establish a *bona fide* intent, the person must submit the information required under § 721.11(b). EPA will make a determination as to whether the person has established a *bona fide* intent to manufacture or import the substance. If the person has established a *bona fide* intent, EPA will inform the person of the production volumes which would constitute a significant new use.

IX. Test Data and Other Information

EPA recognizes that, under TSCA section 5, persons are not required to develop any particular test data before submitting a SNUN. Rather, persons are only required to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them.

However, in view of the potential health risks that may be posed by a significant new use of this substance, EPA suggests potential SNUN submitters consider conducting tests that would permit a reasoned evaluation of the potential risks posed by this substance when utilized for an intended use. EPA believes that the results of a 2–year rodent bioassay outlined under 40 CFR 798.3300 and a 90–day subchronic study outlined under 40 CFR 798.2650 would adequately characterize possible cancer and chronic health effects, respectively, of the substance. The section 5(e) consent order negotiated with the PMN submitter prohibits the submitter from exceeding specific production volume limits without completing these studies. Under the consent order, the PMN submitter is required to submit each study at least 12 weeks before it reaches the applicable specified production volume limit. The order contains detailed procedures for dealing with situations where the resulting data are invalid or equivocal, or show that the substance will present an unreasonable risk of injury under the exposure limitations in the order. This SNUR uses the same production volume limits as the consent order; exceeding those production volume limits without submitting the required test data is defined as a significant new use.

EPA believes it is likely that the PMN submitter will conduct the 2–year rodent bioassay and 90–day subchronic study before reaching the production volume limits and before any other person subject to this SNUR would reach the limits in the SNUR. Accordingly, before beginning to conduct either study, a person subject to this SNUR should contact EPA to determine whether the required study has already been produced. These studies may not be the only means of addressing the potential risks. SNUR notices submitted for significant new uses without such test data may increase the likelihood that EPA will take action under section 5(e).

EPA encourages persons to consult with EPA before selecting a protocol for testing the substance. Published test guidelines (e.g., 40 CFR part 798) provide general guidance for development of test protocols, but are not themselves acceptable protocols. As part of this prenotice consultation, EPA will discuss the test data it believes necessary to evaluate a significant new use of the substance. Test data should be developed according to TSCA Good Laboratory Practice standards at 40 CFR part 792. Failure to do so may lead EPA to find such data to be insufficient to evaluate reasonably the health effects of the substance.

EPA urges SNUR notice submitters to provide detailed information on human exposure that will result from the significant new uses. In addition, EPA encourages persons to submit information on potential benefits of the substance and information on risks posed by the substance compared to risks posed by substitutes.

X. Economic Analysis

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacture, import, processing, distribution in commerce, use, and/or disposal of this chemical substance. EPA's complete economic analysis is available in the public record.

XI. Rulemaking Record

EPA has established a record for this rulemaking (docket control number OPTS–50572A). The record includes basic information considered by EPA in developing this rule. EPA will supplement the record with additional information as it is received. The record now includes the following:

1. PMN P–85–929.
2. The **Federal Register** notice of receipt of the PMN.
3. The section 5(e) consent order.
4. The proposed SNUR.
5. The modification to 5(e) consent order.
6. Public comments to the proposed SNUR.
7. The economic analysis of the proposed rule.
8. The engineering support document.
9. The exposure support document.
10. The toxicology support document.

A public version of this record containing sanitized copies from which CBI has been deleted is available to the public in the TSCA Public Docket Office from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The TSCA Public Docket Office is located in Rm. NE–G004, 401 M St., SW., Washington, DC.

XII. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "major" and therefore requires a Regulatory Impact Analysis. EPA has determined that this rule is not a "major rule" because it will not have an effect on the economy of $100 million or more and it will not have a significant effect on competition, costs, or prices. While there is no precise way to calculate the total annual cost of compliance with this rule, EPA believes that the cost will be low. EPA believes that, because of the nature of the rule and the substance involved, there will be few significant new use notices submitted. Furthermore, while the expense of a notice and the uncertainty of possible EPA regulation may discourage certain innovation, that impact will be limited because such factors are unlikely to discourage an innovation that has high potential value.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA has determined that this rule will not have a significant impact on a substantial number of small businesses. EPA cannot determine whether parties affected by this rule are likely to be small businesses. However, EPA expects to receive few SNUR notices for the substance. Therefore, EPA believes that the number of small businesses affected by this rule will not be substantial even if all the SNUR notice submitters were small firms.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, and has assigned OMB control number 2070–0012. Public reporting burden for this collection of information is estimated to average 8 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM 223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, D.C. 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503, marked "Attention: Desk Officer for EPA."

List of Subjects in 40 CFR Part 721

Chemicals, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, Significant new uses.

Dated: May 9, 1990.

Victor J. Kimm,

Acting Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR part 721 is amended as follows:

PART 721—[AMENDED]

1. The authority citation for part 721 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2625(c).

2. By adding a new § 721.555 to read as follows:

§ 721.555 1,3-Benzenediamine, 4-(1,1-dimethylethyl)-ar-methyl.

(a) *Chemical substance and significant new uses subject to reporting.* (1) The following chemical substance, referred to by its PMN number and chemical name, is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section: P–85–929; 1,3-Benzenediamine, 4-(1,1-dimethylethyl)-*ar*-methyl.

(2) The significant new uses are:

(i) Use other than for applications where the substance will be completely reacted (cured or used as a chemical intermediate).

(ii) Any method of disposal other than by landfill, incineration, or for wastewater from vent scrubbers, steam vacuum ejectors, pad washings, equipment washouts, and stormwater runoffs, wastewater treatment in permitted industrial wastewater treatment facilities. Each method of disposal must meet all applicable local, State, and Federal laws and regulations.

(iii) Any manner or method of manufacturing, importing, or processing without establishing a program whereby:

(A) Any person who may be exposed dermally to the substance wears:

(*1*) Gloves which have been determined to be impervious to the substance under the conditions of exposure, including the duration of exposure. This determination is made either by testing the gloves under the conditions of exposure or by evaluating the specifications provided by the manufacturer of the gloves. Testing or evaluation of specifications includes consideration of permeability, penetration, and potential chemical and mechanical degradation by the substance and associated chemical substances.

(*2*) Clothing which covers any other exposed areas of the arms, legs, and torso.

(*3*) Chemical safety goggles or equivalent eye protection.

(B) Any person who may be exposed to the substance through inhalation during manufacture, in addition to the dermal protective equipment described in paragraph (a)(2)(iii)(A) of this section, wears at a minimum, a National Institute for Occupational Safety and Health approved, category 23C respirator, organic vapor type. Use of the respirator must be according to 29 CFR 1910.134 and 30 CFR part 11. If a full-face type respirator is selected and worn, the chemical safety goggles requirement in paragraph (a)(2)(iii)(A)(*3*) of this section is waived.

(C)(*1*) All persons who may be exposed to the substance are informed, in writing, and by presenting the information as part of a training program in safety meetings at which attendance is recorded, by means of the following statement:

WARNING: Avoid all contact. Chemicals similar in structure to [insert appropriate name] have been found to cause chronic organ and systemic effects and cancer in laboratory animals. To protect yourself, you must wear chemical safety goggles or equivalent eye protection, impervious gloves, and protective clothing while handling this material.

(*2*) During manufacture, the warning statement in paragraph (a)(2)(iii)(C)(*1*) of this section shall include the additional following statement:

Respirators are required during clean-up or loading of bulk material.

(D) All persons that receive the PMN substance are notified by means of a Material Safety Data Sheet ("MSDS") which includes, at a minimum, the language specified in paragraph (a)(2)(iii)(C)(*1*) of this section, and specifies the requirements for protective equipment in paragraph (a)(2)(iii)(A) and (a)(2)(iii)(B) of this section.

(E) Each container of the substance distributed in commerce has affixed to it a label which includes a Warning Statement which consists, at a minimum, of the language specified in paragraph (a)(2)(iii)(C)(*1*) of this section. The first word of the Warning Statement is capitalized, and the type size of the first word is no smaller than 6–point type for a label 5 square inches or less in area, 10–point type for a label above 5 but no greater than 10 square inches in area, 12–point type for a label above 10

but no greater than 15 square inches in area, 14–point type for a label above 15 but no greater than 30 square inches in area, or 18–point type for a label over 30 square inches in area. The type size of the remainder of the Warning Statement is no smaller than 6–point type. All required label text is of sufficient prominence, and is placed with such conspicuousness relative to other label text and graphic material, to ensure that the Warning Statement is read and understood by the ordinary individual under customary conditions of purchase and use.

(iv) Manufacturing and importing the substance for any use at greater than the aggregate volumes allowed under the consent order issued for Premanufacture Notice P–85–929, without submitting to EPA the corresponding scientifically valid toxicity test data required under that order, developed according to EPA's Good Laboratory Practice standards at 40 CFR part 792 and EPA's testing guidelines at 40 CFR 798.2650 and 798.3300.

(b) *Specific requirements.* The provisions of Subpart A of this part apply to this section except as modified by this paragraph.

(1) *Determining whether a use is a significant new use.* (i) Any person who intends to manufacture or import the substance identified in paragraph (a)(1) of this section shall, before commencing any manufacture or import, submit to EPA the information required under § 721.11(b).

(ii) EPA will review this information to determine whether the person has a *bona fide* intent to manufacture or import the substance. If EPA determines that the person has a *bona fide* intent to manufacture or import the substance, EPA will tell the person the specific production volumes which would constitute a significant new use under paragraph (a)(2)(iv) of this section.

(iii) A disclosure to a person with a *bona fide* intent to manufacture or import the substance of the specific production volumes which would constitute a significant new use under paragraph (a)(2)(iv) of this section will not be considered public disclosure of confidential business information under section 14 of the Act.

(2) *Recordkeeping.* In addition to the requirements of § 721.40, manufacturers, importers, and processors must maintain the following records for 5 years after the date they are created:

(i) Any determination that gloves are impervious to the substance.

(ii) Names of persons who have attended safety meetings in accordance with paragraph (a)(2)(iii)(C) of this section, the dates of such meetings, and copies of any written information provided in accordance with paragraph (a)(2)(iii)(C) of this section.

(iii) Copies of any MSDSs used.

(iv) Names and addresses of all persons to whom the substance is sold or transferred including shipment destination address if different, the date of each transfer, and the quantity of substance sold or transferred on such date.

(v) Copies of any labels used.

(vi) Any names used for the substance and the corresponding dates of use.

(vii) Quantities of the substance manufactured or imported, with the corresponding dates of manufacture or import.

(viii) Quantities of the substance purchased in the United States by processors of the substance, names and addresses of suppliers, and corresponding dates of purchase.

(ix) Information on disposal of the substance, including dates waste material is disposed of, location of disposal sites, volume of disposed solid material, estimated volume of any disposed liquid wastes containing the substance, and method of disposal.

(Approved by the Office of Management and Budget under OMB control number 2070–0012)

[FR Doc. 90–11610, Filed 5–18–90; 8:45 a.m.]
BILLING CODE 6560–50–D

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 171, 172, 173, 175, and 176

[Docket No. HM–126C: Amdt. Nos. 171–102, 172–116, 173–213, 175–45, and 176–28]

RIN 2137–AA88

Emergency Response Communication Standards; Extension of the Effective Date

AGENCY: Research and Special Programs Administration, (RSPA), DOT.

ACTION: Final rule; extension of the effective date.

SUMMARY: RSPA is extending the effective date of the final rule published in the **Federal Register** on June 27, 1989 (54 FR 27138) and January 10, 1990 (55 FR 870) under docket HM–126C. RSPA is experiencing a delay in printing the revised 1990 DOT "Emergency Response Guidebook" (ERG), which may be used to comply with certain emergency response information requirements in this rule. The extension will provide the necessary time for RSPA to print the ERG and make available proof copies for commercial reproduction. Additionally, the extension will provide commercial sources the time necessary to print and distribute the ERG to those choosing to use it as a compliance tool.

EFFECTIVE DATES: The effective date of the final rule published under Docket HM–126C on June 27, 1989 (54 FR 27138) and January 10, 1990 (55 FR 870) are changed from June 4, 1990 to September 17, 1990.

FOR FURTHER INFORMATION CONTACT: Helen L. Engrum, Standards Division, Office of Hazardous Materials Transportation, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590–0001. Telephone: (202) 366–4488.

SUPPLEMENTARY INFORMATION: The final rule under Docket HM–126C amended the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180) to include new requirements for additional emergency response information on shipping papers and packages and maintenance of emergency response information on transportation vehicles and at transportation facilities. As a result of eleven petitions for reconsideration of certain aspects of the final rule entitled "Emergency Response Communication Standards", published in the **Federal Register** on June 27, 1989 (54 FR 27138), on January 10, 1990, a correction final rule was published in the **Federal Register** (55 FR 870) under Docket HM–126C.

The January 10, 1990 correction final rule made several changes including: Revising the definition of "technical name"; use of waste codes as technical names for certain waste hazardous materials; providing an exception for one year from requirements for marking technical names on packages filled prior to June 4, 1990; and extending the effective date from April 2, 1990 until June 4, 1990.

One consideration for extending the effective date from April 2, 1990 until June 4, 1990, was the unavailability of the 1990 edition of the ERG. RSPA is experiencing a delay in printing the 1990 ERG and it will not be available and distributed commercially by the current June 4, 1990 effective date. Accordingly, the effective date of the final rule as published in the **Federal Register** on June 27, 1989 (54 FR 27138) and the correction final rule published on January 10, 1990 (55 FR 870) are extended from June 4, 1990 until September 17, 1990. If further significant delays are experienced, RSPA will

consider a further extension of the effective date.

Additionally, RSPA received three petitions for reconsideration of certain aspects of the final rule, published January 10, 1990 (55 FR 870), from Government Services Institute Incorporated (GSI), the Petroleum Marketers Association of America (PMAA), and the Ocean Carrier Dangerous Goods Coalition. In view of this extension from June 4, 1990 to September 17, 1990, RSPA will be afforded the additional time needed to adequately respond to the three petitions for reconsideration in a subsequent document that will be published in the **Federal Register**.

Issued in Washington, DC on May 15, 1990 under the authority delegated in 49 CFR part 1.

Travis P. Dungan,

Administrator, Research and Special Programs Administration.

[FR Doc. 90–11726 Filed 5–18–90; 8:45 am]

BILLING CODE 4910–60–M

Proposed Rules

Federal Register
Vol. 55, No. 98
Monday, May 21, 1990

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.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 401

[Docket No. 8011S; Amdt. No. 36]

General Crop Insurance Regulations; Safflower Endorsement

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the General Crop Insurance Regulations (7 CFR part 401), effective for the 1991 and succeeding crop years, to amend the Safflower Endorsement with respect to cancellation and termination dates, and the date by which contract changes are required to be filed in the agent's office. The intended effect of this rule is to provide cancellation and termination dates more in keeping with safflower growing practices in California, and to provide a date by which programs changes must be filed in the agent's office which are consistent with such new dates.

DATES: Written comments, data, and opinions on this proposed rule must be submitted not later than June 20, 1990.

ADDRESSES: Written comments on this proposed rule should be sent to Peter F. Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250, telephone (202) 447-3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512–1. This action does not constitute a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is February 1, 1994.

David Gabriel, Acting Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons and will not have a significant economic impact on a substantial number of small entities.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR 3015, subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

The current cancellation and termination date for safflowers in California is February 15. Safflower plantings are generally completed in January or February and may be well established by February 15. FCIC herein proposes to move the cancellation and termination date to December 31. In order to provide that any contract changes are filed timely to be effective for California safflower growers, and allow an appropriate amount of time for applications to be accepted, it is necessary that FCIC move the contract change date from the present November 30 to August 31 of the previous calendar year.

Accordingly, FCIC proposes to amend the General Crop Insurance Regulations (7 CFR Part 401) to provide cancellation and termination dates more in keeping with safflower growing practices in California, and to provide a date by which programs changes must be filed in the agent's office to be consistent with such new dates.

FCIC is soliciting public comment on this proposed rule for 30 days following publication in the **Federal Register**. Written comment should be sent to Peter F. Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250.

All written comments received pursuant to this proposed rule will be available for public inspection and copying in the Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

List of Subjects in 7 CFR Part 401

Crop insurance; Safflowers.

Proposed Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation proposes to amend the General Crop Insurance Regulations (7 CFR part 401), proposed to be effective for the 1991 and succeeding crop years, in the following instances:

PART 401—[AMENDED]

1. The authority citation for 7 CFR part 401 continues to read as follows:

Authority: 7 U.S.C. 1506, 1516.

2. 7 CFR 401.123 is amended by revising paragraphs 8 and 9, to read as follows:

§ 401.123 Safflower seed crop endorsement.

* * * * *

8. *Cancellation and Termination Dates.*

The cancellation and termination dates for California are December 31. For all other states, the cancellation and termination dates are April 15.

9. *Contract Changes*

Contract changes will be available at your service office by August 31 prior to the cancellation date for California, and by

December 31 prior to the cancellation date for all other states.

* * * * *

Done in Washington, DC on May 14, 1990.

David Gabriel,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 90-11644 Filed 5-18-90; 8:45 am]

BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 920

[Docket No. FV-90-138]

Kiwifruit Grown in California; Order Directing That a Referendum be Conducted; Determination of Representative Period for Voter Eligibility; and Designation of Referendum Agents to Conduct the Referendum

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Referendum order.

SUMMARY: This document directs that a referendum be conducted among eligible growers of kiwifruit grown in California to determine whether they favor continuance of the marketing order regulating the handling of kiwifruit grown in the production area.

DATES: The representative production period is from August 1, 1989, through May 31, 1990. The referendum will be conducted from June 4 through June 22, 1990.

FOR FURTHER INFORMATION CONTACT: Robert F. Matthews, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525-S, Washington, DC 20090-6456; Telephone: 202-447-2431.

SUPPLEMENTARY INFORMATION: Pursuant to Marketing Order No. 920 (7 CFR part 920), and the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (17 U.S.C. 601-674), hereinafter referred to as the Act, it is hereby directed that a referendum be conducted within the period June 4 through June 22, 1990, among the growers in the production area who, during the period August 1, 1989, through May 31, 1990 (which period is hereby determined to be a representative period for purposes of such referendum), were engaged in the production of kiwifruit covered by the said marketing order to ascertain whether continuance of the order is favored by the growers.

Section 920.63 of the order provides that the Secretary shall conduct a continuance referendum within the period beginning May 15 and ending July 15, 1990, to determine if continuance of the order is favored by growers.

The Secretary of Agriculture has determined that continuance referenda are an effective means for ascertaining whether growers favor continuation of marketing order programs. The Secretary would consider termination of the order if less than two-thirds of the growers of kiwifruit voting in the referendum and growers of less than two-thirds of the volume of kiwifruit represented in the referendum favor continuance. However, in evaluating the merits of continuance versus termination, the Secretary will not only consider the result of the continuance referendum but also all other relevant information concerning the operation of the order and the relative benefits and disavantages to growers, handlers, and consumers in order to determine whether continued operation of the order would tend to effectutate the declared policy of the Act.

In any event, section 8c(16)(B) of the Act requires the Secretary to terminate an order whenever the Secretary finds that a majority of all growers favor termination, and such majority produced for market more than 50 percent of the commodity covered by such order.

In accordance with the Paperwork Reduction Act of 1980 [44 U.S.C. chapter 35], the ballot material that will be used in the referendum herein ordered has been submitted to and approved by the Office of Management and Budget (OMB) and has been assigned OMB No. 0581-0149. It has been estimated that it will take an average of 20 minutes for each of the approximately 1,225 growers to participate in the voluntary referendum balloting.

Robert J. Curry and Gary D. Olson, California Marketing Field Office, Fruit and Vegetable Division, Agricultural Marketing Service, USDA, are hereby designated as referendum agents of the Secretary of Agriculture to conduct such referendum. The procedure applicable to the referendum shall be the "Procedure for the Conduct of Referenda in Connection with Marketing Orders for Fruits, Vegetables, and Nuts Pursuant to the Agricultural Marketing Agreement Act of 1937, as Amended (7 CFR part 900.400 *et seq.*).

Copies of the text of the aforesaid marketing order may be examined in the office of the referendum agents at 2202 Monterey Street, suite 102B, Fresno, California 93721, or in the Office of the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525-S, Washington, DC 20090-6456.

Ballots to be cast in the referendum may be obtained from the referendum agent and from his appointees.

Authority: Agricultural Marketing Agreement Act of 1937, as amended Secs. 1-19, 48 Stat. 31, as amended; 7 U.S.C. 601-674.

Dated: May 15, 1990.

Jo Ann R. Smith,

Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 90-11693 Filed 5-18-90; 8:45 am]

BILLING CODE 3410-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Ch. I

[Docket No. 90N-0056]

Parenteral Drug Products Containing Aluminum as an Ingredient or a Contaminant; Notice of Intent and Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is considering proposing a rule that would: (1) Specify an upper limit of aluminum for large volume parenterals, and (2) require the aluminum content to be labeled for certain small volume parenterals and pharmacy bulk packages. The agency is considering these actions because of reports linking the use of parenteral drug products containing aluminum to morbidity and mortality among premature infants, individuals with renal insufficiency, and patients receiving long-term parenteral nutrition. This notice gives interested persons an opportunity to submit comments on these possible actions and requests information and data on related issues and problems.

DATES: Written comments by August 20, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Adele S. Seifried, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8046.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has become increasingly concerned about aluminum content in parenteral drug products, including alumium present as a contaiminant. A number of reports in the scientific literature have suggested that neonates and other patient populations may be at high risk of exposure to unsafe amounts of aluminum in drug products. Moreover, many drug products that are used routinely in parenteral therapy have been reported to contain levels of aluminum sufficiently high to cause clinical manifestations.

FDA has held several meetings to discuss risks posed by aluminum in human drug products. The agency's Advisory Committee on Endocrinologic and Metabolic Drug Products (the committee) met on March 3, 1986, to discuss the problems posed by aluminum content in parenteral drug products. The committee recommended that parenteral drug products intended for repeated use or given in large volumes over a short period of time be tested for aluminum levels. The committee also recommended that the agency establish an aluminum contamination limit. Several committee members suggested appropriate safe intake levels ranging from 30 to 80 micrograms per day. To explore these recommendations, FDA sponsored two additional meetings.

On November 6, 1986, the agency held a public workshop to discuss aluminum toxicity in clinical medicine, existing aluminum monitoring, clinical effects of aluminum loading, and methodology for quantitative aluminum determination in parenteral products. At this meeting, several speakers concluded that a limit of 90 to 100 micrograms per day for adults is a more appropriate range than the lower level of 30 micrograms suggested earlier.

On June 25 and 26, 1987, the Allergenic Products Advisory Committee of the Center for Biologics Evaluation and Research met to discuss the safety of the aluminum component of alum-precipitated allergenic extracts. The Allergenic Products Advisory Committee noted the absence of conclusive evidence that alum-precipitated extracts are more effective than aqueous extracts of the same allergen for treatment of allergic disease. The agency will address the Allergenic Products Advisory Committee's comments separately.

At this time, the agency is not seeking comments regarding the aluminum content of biological drug products licensed under section 351 of the Public Health Service Act. FDA sets limits for aluminum in biological products in 21 CFR 610.15(a). There are some biological drug products in which the aluminum content cannot be reduced or eliminated due to inherent differences from other drug products in composition and manufacturing methods. Since biological drug products are not usually incorporated in total parenteral nutrition, FDA is not soliciting comments on the aluminum content of biological drug products via this notice.

II. Human Exposure to Aluminum

Aluminum in ionic form is found in plant and animal tissues of all kinds and in natural bodies of water. The amount of aluminum an individual ingests depends greatly on geographic location and eating habits.

Although aluminum is sometimes added as an excipient to drug products, it is usually found in parenteral drug products as a contaminant, i.e., as a component not added deliberately to the drug product. The main source of aluminum contamination is the drug substance. Aluminum is also leached from glass containers and closures during autoclaving and storage. In most cases, changes in processing and screening of raw materials can significantly reduce aluminum contamination of drug products.

Current studies suggest that in healthy individuals the plasma aluminum level is less than 10 micrograms per liter and that total body aluminum is probably less than 35 milligrams. Based on urinary excretion of aluminum, it appears that the gastrointestinal tract acts as an efficient barrier to absorption and that relatively little aluminum that is ingested actually reaches body tissues. Although aluminum intoxication is not commonly identified clinically, it can be serious in selected patient populations and may conceivably be more common than is recognized. Moreover, when aluminum-containing products are administered parenterally, the protective mechanism of the gastrointestinal tract is bypassed (Refs. 1 through 4).

Patient Populations at Risk

FDA is concerned that certain populations of patients may be exposed to excess aluminum parenterally. FDA is specifically concerned about three groups of patients: (1) Patients with renal failure on chronic hemodialysis or continuous ambulatory peritoneal dialysis (CAPD); (2) patients receiving long-term total parenteral nutrition, especially those with compromised renal function; and (3) premature neonates and neonates who have immature or impaired renal function and require total parenteral nutrition. The reasons for the agency's concerns about these patient populations are discussed below.

1. *Renal failure patients.* Aluminum-related osteodystrophy and encephalopathy have been reported in patients on CAPD (Refs. 1 through 11). Aluminum-related encephalopathy has been reasonably well controlled by reducing the aluminum content of dialysis water and restricting the use of aluminum compounds prescribed as phosphate binders.

Renal or uremic osteodystrophy is a broad and imprecise term for various skeletal abnormalities associated with renal failure. Aluminum-related osteodystrophy in patients with renal failure on hemodialysis has been somewhat controlled by removal of aluminum from dialysis water.

2. *Patients on long-term total parenteral nutrition.* Several studies suggest that fundamental abnormalities in bone remodeling occur during long-term total parenteral nutrition, although the relationship between aluminum deposition and the bone diseases associated with long-term total parenteral nutrition remains controversial (Refs. 11 and 12). Little has been written concerning aluminum loading or aluminum-associated osteodystrophy in renally compromised patients receiving total parenteral nutrition but not on hemodialysis or continuous ambulatory peritoneal dialysis. A study of bone disease in such a patient group is needed.

3. *Premature infants.* Toxic blood levels of aluminum have not been established in this group; however, bone and neurological abnormalities have been reported in neonates having blood aluminum levels in excess of 100 micrograms per liter. Premature infants are particularly susceptible to aluminum loading from parenteral fluids because of reduced renal capacity, higher intake of fluids per unit body weight than in adults and older children, and greater need for calcium and phosphate. Because they receive relatively large amounts of calcium and phosphate solutions, parenteral fluids that are the most heavily contaminated with aluminum, premature infants are more likely than others to develop aluminum levels that cause toxicity (Refs. 1 and 11 through 18).

III. Possible Future Actions on Which Comment is Sought

1. *Large volume parenterals.* FDA is considering whether to specify by regulation an upper limit for aluminum content of large volume parenterals. The

specification currently being considered is 25 micrograms per liter or 25 parts per billion for large volume drug products for parenteral nutrition. The 25 micrograms per liter limit is based primarily on a calculation that an intake of 3 liters per day would result in a total exposure under 100 micrograms per day, an amount within the 90 to 100 micrograms per day range recommended at the 1986 FDA workshop as a safe daily burden for healthy individuals. In addition, information provided to the agency indicates that most of the currently marketed large volume parenteral drug products will meet this specification. The agency is soliciting comments regarding acceptable levels for parenteral drug products that do not meet this specification, including CAPD drug products, hemodialysis drug products, antibiotics, and other drug products marketed as large volume parenterals. FDA is also considering requiring the package insert for large volume parenterals to contain a warning statement about the potential aluminum toxicity of total parenteral nutrition mixtures in the risk groups described above. It should be noted that the upper safe level of aluminum in large volume parenterals administered to neonates and renal-impaired patients has not yet been established. This notice seeks additional data and information regarding both safe levels and unsafe levels of aluminum in large volume parenteral drug products.

2. *Small volume parenterals and pharmacy bulk packages.* For small volume parenterals and pharmacy bulk packages, the agency is considering a different approach than imposing upper limits on aluminum content. FDA is considering requiring the immediate container labels for each lot of certain small volume parenterals and pharmacy bulk packages to state the exact amount of aluminum present at time of release, or, alternately, the maximum amount of aluminum present. This labeling requirement would apply only to solutions intended for use, and identified by the agency as being commonly used in the preparation of total parenteral nutrition solutions, and to all regularly used additives (i.e., vitamins, minerals, trace elements, etc.), regardless of aluminum levels detected. The agency is soliciting comments on which drug products or components should be included on a list of those commonly used in the preparation of total parenteral nutrition solutions.

FDA is considering taking this approach for small volume parenterals and pharmacy bulk packages to permit the person administering the drug to calculate the total aluminum exposure the patient receives from multiple parenteral sources. This calculation is especially important because additives appear to be the major contributor of aluminum to total parenteral nutrition mixtures. Requiring disclosure of actual aluminum levels in commonly used additives intended for use in parenteral nutrition solutions would also allow the user to make appropriate substitutions to prepare "low aluminum" parenteral solutions for use in patients who are in high risk groups. Accurate calculations of total aluminum exposure could not be made if the labeling of small volume parenterals stated only a safe upper limit on aluminum rather than stating the exact or the maximum amount of aluminum actually present. In addition, becasue many small volume parenteral additives exceed the large volume parenteral proposed limit of 25 parts per billion, enforcement of a limit would remove many parenterals from the marketplace. The agency seeks additional data and information regarding safe levels of aluminum content in small volume parenteral drug products and pharmacy bulk packages.

3. *Assay methodology.* For products subject to premarket approval, the agency is considering whether to allow manufacturers to develop their own validated assay methods and submit them for approval. Criteria to be considered in the selection of an aluminum release assay would include accuracy, sensitivity, specificity, and reproducibility when applied to each of the tested drug products. An aluminum assay method should be validated by normal scientific procedures. For drug applications requiring supplements to provide for new assay methodology, the agency's "Guideline for Submitting Samples and Analytical Data for Methods Validation" may be consulted for assistance. The agency welcomes comments on assay methodology. FDA is also involved with the United States Pharmacopeia in deciding whether assays for aluminum determination in parenteral drug products should be adopted under the compendium.

4. *Units of measurements.* FDA believes that a standard unit of measurement (i.e., parts per billion, parts per million, milligrams, and micrograms) should be specified to avoid confusion and errors, and that the same unit of measurement should be used to describe the drug being administered, the amount of aluminum present, and the maximum exposure limit per day. It has also been recommended that both mass and molar concentrations be stated in the labeling. The agency welcomes comments on this matter.

IV. References

The following references have been place on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Sedman, A. B. et al., "Evidence of Aluminum Loading in Infants Receiving Intravenous Therapy," *The New England Journal of Medicine*, 312:1337–1343, 1985.

2. Alfrey, A. C., "Aluminum," *Advances in Clinical Chemistry*, 23:69–91, 1983.

3. Greger, J. L., and M. J. Baier, "Excretion and Retention of Low or Moderate Levels of Aluminum by Human Subjects," *Food and Chemical Toxicology*, 21:473–477, 1983.

4. Gorsky, J. E. et al., "Metabolic Balance of Aluminum Studied in Six Men," *Clinical Chemistry*, 25:1739–1743, 1979.

5. Pierides, A. M. et al., "Hemodialysis Encephalopathy with Osteomalacic Fractures and Muscle Weakness," *Kidney International*, 18:115–124, 1980.

6. Andreoli, S. P., J. A. Smith, and J. M. Bergstein, "Aluminum Bone Disease in Children: Radiographic Features from Diagnosis to Resolution," *Radiology*, 156:663–667, 1985.

7. Charhon, S. A. et al., "Serum Aluminum Concentration and Aluminium Deposits in Bone in Patients Receiving Haemodialysis," *British Medical Journal*, 290:1613–1614, 1985.

8. Sedman, A. B. et al., "Encephalopathy in Childhood Secondary to Aluminum Toxicity," *The Journal of Pediatrics*, 105:836–838, 1984.

9. O'Hare, J. A., and D. J. Murnaghan, "Reversal of Aluminum-induced Hemodialysis Anemia by a Low-aluminum Dialysate," *New England Journal of Medicine*, 306:654–656, 1982.

10. O'Connor, M. O. et al., "Aluminum-related Bone Disease," *American Journal of Clinical Pathology*, 86:168–174, 1986.

11. de Vernejoul, M. C. et al., "Multifactorial Low Remodeling Bone Disease During Cyclic Total Parenteral Nutrition," *Journal of Clinical Endocrinology and Metabolism*, 60:109–113, 1985.

12. Heyman, M. B. et al., "Aluminum Does Not Accumulate in Teenagers and Adults on Prolonged Parenteral Nutrition Containing Free Amino Acids," *Journal of Parenteral and Enteral Nutrition*, 10:86–87, 1986.

13. Creber, E. et al., "Parenteral Nutrition Solutions," *The Medical Journal of Australia, 143:368–369, 1985.*

14. McGraw, M. et al., "Aluminum Content of Milk Formulae and Intravenous Fluids Used in Infants," *The Lancet*, 1:157, 1986.

15. Fell, G. S., A. Shenkin, and D. J. Halls, "Aluminum Contamination of Intravenous Pharmaceuticals, Nutrients, and Blood Products," *The Lancet*, 1:380, 1986.

16. Puntis, J. W. L., K. Hall, and I. W. Booth, "Plasma Aluminum and Prolonged Parenteral Nutrition in Infancy," *The Lancet*, 2:1332–1333, 1986.

17. Koo, W. W. K. et al., "Response to Aluminum in Parenteral Nutrition During

Infancy," *Journal of Pediatrics*, 109:877–883, 1986.

18. American Academy of Pediatrics Committee on Nutrition, "Aluminum Toxicity in Infants and Children," *Pediatrics*, 78:1150–1154, 1986.

V. Request for Comments, Data, and Information

The agency is interested in receiving data on safe and unsafe levels of aluminum in large volume parenterals, small volume parenterals, and pharmacy bulk packages. The agency is also interested in receiving comments on assay methodology, on units of measurement, and on which drug products should be included in the content disclosure requirement, and suggestions for appropriate warning language.

In addition to submitting data, comments, or suggestions regarding the issues discussed above or related concerns, the agency is interested in receving data concerning the economic effects of any of the actions discussed above.

Persons interested in commenting on the intent to propose labeling requirements on parenteral drug products containing aluminum may, on or before August 20, 1990, submit to the Dockets Management Branch (address above) written comments on this notice of intent. Two copies of any comments 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. These comments will be considered in determining whether further agency action is appropriate. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 10, 1990.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90–11708 Filed 5–18–90; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 312

[Docket No. 89N–0510]

Investigational New Drug, Antibiotic and Biological Drug Product Applications; Proposed Amendment to Sections on Clinical Hold and Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration is proposing to amend two provisions of its regulations governing investigational new drug (IND) applications to include additional grounds for placing an investigation on "clinical hold" and for terminating an IND. Under these proposed amendments, the agency may require a sponsor to cease distributing an experimental drug in an open, nonconcurrently controlled investigation if any of several specified conditions exist. These amendments are necessary as part of the Public Health Service (PHS) efforts to make promising drugs more widely available to people with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV)-related disease who lack satisfactory alternative therapies, while at the same time assuring that the adequate and well-controlled clinical trials essential to establishing the safety and effectiveness of new drugs are carried out expeditiously. These amendments would help to implement the proposed PHS policy on expanded availability of investigational new drugs through a parallel track mechanism for people with AIDS or HIV-related disease published elsewhere in this issue of the **Federal Register**.

DATES: Written comments by July 20, 1990.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Phillip L. Chao, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8049.

SUPPLEMENTARY INFORMATION: Published elsewhere in this issue of the **Federal Register** is a notice issued by the Public Health Service proposing its policy on expanded availability of investigational new drugs through a parallel track mechanism for people with AIDS or HIV-related disease. That notice explains a procedure to make promising investigational new drugs available to people with AIDS or HIV-related disease who are not able to take or are failing on standard therapy and who are not able to participate in ongoing controlled clinical trials.

Under the "parallel track" mechanism, eligible physicians and patients would be able to participate in open, nonconcurrently controlled studies (i.e., studies in which all patients receive the investigational drug and there is no comparison group) and receive promising investigational drugs at an early stage in the drug development process. Such open, nonconcurrently controlled studies are ordinarily not designed to provide substantial evidence of effectiveness but are designed to provide significant safety data, representing a wider patient experience than is usually possible in other, more rigorously designed studies. Under the parallel track mechanism it is possible that an investigational drug being investigated for an HIV-related condition may be made available in a large open study even earlier than under the treatment IND mechanism, initiated by regulation in 1987.

While there is general agreement among interested groups on the desirability of providing increased early availability of investigational drugs for HIV-related conditions through open studies without concurrent control groups, there is also consensus that adequate safeguards need to be in place for the patients and for the drug development process. The PHS policy statement addresses the importance of adequate informed consent procedures and continuing education so that participating physicians and their patients may consider all appropriate available information. The policy statement also addresses general criteria for termination of parallel track studies. To be certain that adequate safeguards are maintained, FDA is amending the IND regulations to include specific grounds for placing such studies on clinical hold or terminating them. (A study without a concurrent control group will not be considered adequate and well-controlled for purposes of this rule simply because the sponsor asserts that the data from the study will be compared with an historical control. The burden will be on the sponsor in such a case to demonstrate that the study was prospectively designed, and is being conducted, to permit a valid comparison with an adequately documented historical control group.)

Existing regulations at 12 CFR 312.42(b) (1) and (2) specify various reasons for placing phase 1, phase 2, or phase 3 studies on clinical hold. Generally stated, these reasons include exposure of subjects to unreasonable and significant risk; unqualified investigators; misleading, erroneous, or incomplete investigator brochures; and insufficient information in the IND to assess the risks to subjects. For phase 2 or phase 3 trials an additional reason for clinical hold is a deficiently designed protocol. Because open, nonconcurrently controlled studies take place within the IND context and are usually phase 2 or phase 3 studies, these existing regulations would already apply. Nevertheless, in order that there be no doubt as to the applicability of all these grounds for placing on hold open, nonconcurrently controlled studies

designed to provide expanded early access, regardless of the "phase" designation, the agency is directly including these clinical hold criteria in new § 312.42(b)(4)(i).

In addition, interested persons have expressed considerable concern that increased early access to an investigational drug through open, nonconcurrently controlled studies might make it difficult, in certain cases, to enroll patients in, or to complete, adequate and well-controlled studies of the drug. There is general agreement among all interested groups that maintaining the ability to carry out adequate and well-controlled trials expeditiously is essential because without such trials it is not possible to determine whether the drug is safe and effective. If the evidence for such a determination is never developed, or is not developed expeditiously, individuals with the disease for which the drug is intended may suffer unnecessarily. Should the open, nonconcurrently controlled trials delay development of information that the drug is actually ineffective or unsafe, those receiving the drug in the open, nonconcurrently controlled trial will be exposed to it, and kept from other alternatives, for a longer period than necessary.

On the other hand, should the open, nonconcurrently controlled trials delay development of proof that the drug is safe and effective, general marketing will be delayed and those patients not enrolled in the trials will be deprived of a useful drug. There is therefore a consensus that open, nonconcurrently controlled trials should be permitted only so long as they do not interfere with the successful enrollment in and completion of adequate and well-controlled studies.

Concerns were also raised during the promulgation of the treatment IND regulations that distributing an investigational drug under a treatment IND would lead to delays in the testing and marketing of promising therapies. To protect the integrity and timeliness of the clinical testing process and to assure that distribution under a treatment IND did not become a substitute for obtaining marketing approval, FDA included in the treatment IND regulations authority to place a treatment protocol on clinical hold or to terminate the treatment IND if the sponsor was not pursuing marketing approval with due diligence (21 CFR 312.42(b)(3(ii)(C) and 312.44(b)(3)(ii)). The agency described "active pursuit of marketing approval" as including timely enrollment of patients in the controlled clinical trials and successful, prompt completion of the steps necessary for drug approval. (See 52 FR 19466 at 19470 and 19471; May 22, 1987.)

There is, however, no clear authority to place an open, nonconcurrently controlled trial that is not under a treatment IND on clinical hold, or to terminate the sponsor's IND, where the open, nonconcurrently controlled trial is interfering with enrollment in, or the conduct or completion of, adequate and well-controlled investigations of the drug. In addition, § 312.42(b)(3)(ii)(C) is intended to address lack of diligence by the sponsor in enrolling patients in a controlled trial, rather than interference in enrollment that is an unintended byproduct of an open, nonconcurrently controlled trial. Accordingly, FDA is proposing to add 21 CFR 312.42(b)(4)(ii) to make clear the agency's authority to halt an open, nonconcurrently controlled trial that is interfering with an adequate and well-controlled trial, whether or not the interference is caused by any lack of diligence on the part of the sponsor. The agency notes that the imposition of a clinical hold on an open, nonconcurrently controlled study may, depending on the factual context, result only in a bar to the enrollment of additional patients. Already-enrolled patients could, in such a case, continue to receive the drug.

In determining whether there is reasonable evidence that the conduct or completion of an adequate and well-controlled trial has been impeded, FDA would look to whether enrollment is proceeding at the expected rate and whether an adequate number of enrolled patients are completing the trial. To assist in monitoring the progress of controlled trials, FDA would generally require that a protocol for a controlled clinical trial of a drug for which an open, nonconcurrently controlled study of the drug is also proposed, contain estimated times for full enrollment, estimated drop-out rates, and an expected date of completion of the trial. When an unexpectedly slow rate of enrollment or an unusually high drop-out rate that is not attributable to adverse drug experience occurred and there was an ongoing open, nonconcurrently controlled study of the drug, this would ordinarily be considered reasonable evidence that the open, nonconcurrently controlled study is interfering in the conduct or completion of the adequate and well-controlled trial.

In order that the open, nonconcurrently controlled studies not impede development of safe and effective therapy for the particular indication and patient population, under proposed § 312.42(b)(4)(ii) such studies may be placed on hold if they are interfering with the adequate and well-controlled studies on either the same investigational drug or on another drug being studied for the same use in the same population.

In some instances the manufacturer of the investigational drug that is being studied under a parallel track protocol may not be able to produce sufficient quantities of the drug for all of the patients eligible to participate in the controlled and open, nonconcurrently controlled trials. To make certain that in such a case the lack of sufficient drug supply does not jeopardize the study designed to be adequate and well-controlled, proposed § 312.42(b)(4)(iii) specifies insufficient quantities of the drug as an independent ground for placing the open, nonconcurrently controlled studies on clinical hold.

As discussed above, expanded access to promising investigational drugs through open, nonconcurrently controlled trials under the parallel track mechanism is provided to severely ill patients with HIV-related disease who have no satisfactory alternative therapy. Interested persons have raised additional concerns about the appropriateness of continued expanded availability of such investigational drugs in various situations. A principal reason for permitting expanded access would be that the available data showed the investigational drug to be promising. If, however, the drug has been studied in one or more adequate and well-controlled investigations and the results of those investigations strongly suggest that the drug lacks effectiveness, it may no longer be appropriate to have expanded access through an open, nonconcurrently controlled study for that drug. Therefore, FDA has added proposed § 312.42(b)(4)(iv) to authorize placing an open, nonconcurrently controlled trial on clinical hold when one or more controlled trials strongly suggest lack of effectiveness.

In addition, if another drug approved or being studied for the same indication in the same population has demonstrated a better potential benefit/risk balance, there may no longer be adequate justification for expanded access through an open, nonconcurrently controlled study of a drug. While judgments concerning potential risks and potential benefits may be difficult to make at such an early stage of drug development, such judgments based on as much information as is available are appropriate in determining whether expanded access should be continued. If another drug has demonstrated lower

toxicity or greater potential effectiveness for the same indication in the same population, then the perceived promise of the drug in a open, nonconcurrently controlled trial may change. The agency recognizes that in the absence of a direct comparison between two drugs, or at least of controlled studies of both drugs, it will often be difficult to determine the relative toxicity or effectiveness of two drugs. Where evidence of relative toxicity or effectiveness is available, however, it may be appropriate to place the open, nonconcurrently controlled trial on clinical hold. Proposed § 312.42(b)(4)(v) makes explicit the agency's authority to place the investigation on hold because of such information about another drug.

Similarly, if a competing version of the same drug itself has received marketing approval for use in the same population for the same indication, there is no longer adequate justification for expanded availability. Of course, once a drug has received approval for the same indication in the same population, the parallel track mechanism is no longer needed to provide availability of that same drug, and the open protocol is appropriately terminated. Proposed § 312.42(b)(4)(vi) explicitly provides that an open, nonconcurrently controlled study may be placed on hold if the drug has been approved for the same indication in the same population.

As discussed above, in promulgating the treatment IND regulations, FDA included authority to terminate the treatment protocol if the sponsor of the controlled clinical trial was not actively pursuing marketing approval of the investigational drug with due diligence (21 CFR 312.42(b)(3)(ii)(C) and 312.44(b)(3)(ii)). These provisions were intended to ensure that the drug developer would seek timely and expeditious marketing approval through actions intended to advance the progress of the IND and subsequent marketing approval (52 FR 19466 at 19470).

For reasons similar to those stated in the treatment IND rule, it is also important for FDA to specify its authority to terminate open protocol studies being conducted at an early stage in drug development because the sponsor is failing to actively pursue marketing approval with due diligence. FDA's interpretation of this "active pursuit" requirement reflects the agency's belief that it is important for the drug developer's efforts not only to be sincere but also to be effective, i.e., to have a reasonable chance of being successful. Such efforts would include timely enrollment of patients in controlled trials as well as prompt carrying out of other steps needed for approval.

Although the "active pursuit" ground for placing an open, nonconcurrently controlled trial on clinical hold may overlap with the ground regarding interfering with or impeding the conduct of the controlled trial, it is being listed as an independent ground to make sure that those additional situations that may not concern the controlled trials in this manner are also covered. For example, timely compliance with all IND obligations, such as adverse reaction and annual reporting obligations, would be considered in determining whether a sponsor was actively pursuing marketing approval. Proposed § 312.42(b)(4)(vii) would be interpreted to ensure that the open protocol studies do not create disincentives to the expeditious development and marketing of promising therapies.

Finally, proposed § 312.42(b)(4)(viii) would allow the Commissioner to place an open, nonconcurrently controlled study on hold by determining that, in the public interest, the study should not be conducted or continued. The agency's experience has shown that it is not always possible to predict with precision each situation that might arise affecting the appropriateness of an expanded availability trial. It is difficult to create an exhaustive list of reasons to place such a trial on clinical hold in order to adequately protect not only the patients involved but also the procedures for developing important new therapies as expeditiously as possible. In order to be certain that the Commissioner may place an open, nonconcurrently controlled study on clinical hold if the public interest calls for such action, proposed § 312.42(b)(4)(viii) provides the appropriate flexibility.

Interested persons may, on or before July 20, 1990, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement in required.

Economic Impact

The agency has examined the economic impact of this proposed rule and has determined that it does not require either a regulatory impact analysis, as specified in Executive Order 12291, or a regulatory flexibility analysis, as defined in the Regulatory Flexibility Act (Pub. L. 96–354). The proposed amendments to the regulations governing investigational new drugs provide additional grounds for placing an investigation on clinical "hold" and for terminating an IND.

These proposed amendments would be applicable where the agency permits promising drugs to be more widely available during the same period that adequate and well-controlled studies are being conducted. These additional grounds for clinical holds and IND termination are necessary safeguards to the authorized open studies designed to provide expanded early access to investigational drugs. The proposed amendments do not impose additional requirements on sponsors and will not require the expenditure of significant resources.

Accordingly, the agency concludes that the proposed rule is not a major rule as defined in Executive Order 12291. Further, the agency certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities, as defined in the Regulatory Flexibility Act.

Paperwork Reduction Act of 1980

This proposed rule does not contain new collection of information requirements. Section 312.44, which would be amended under this proposal, contains collection of information requirements that were previously submitted for review to the Director of the Office of Management and Budget (OMB) under section 3504 of the Paperwork Reduction Act of 1980 and approved under OMB control number 0910–0014.

List of Subjects in 21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, it is proposed that 21 CFR Part 312 be amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 505, 506, 507, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 371); sec 351, of the Public Health Service Act (42 U.S.C. 262).

2. Section 312.42 is amended by adding new paragraph (b)(4) to read as follows:

§ 312.42 Clinical holds and requests for modification.

* * * * *

(b) * * *

(4) *Clinical hold of any study that is not designed to be adequate and well-controlled.* FDA may place a proposed or ongoing investigation that is not designed to be adequate and well-controlled on clinical hold if it finds that:

(i) Any of the conditions in paragraph (b)(1) or (b)(2) of this section apply; or

(ii) There is reasonable evidence the investigation that is not designed to be adequate and well-controlled is impeding enrollment in, or otherwise interfering with the conduct or completion of, a study that is designed to be an adequate and well-controlled investigation of the same or another investigational drug; or

(iii) Insufficient quantities of the investigational drug exist to adequately conduct both the investigation that is not designed to be adequate and well-controlled and the investigations that are designed to be adequate and well-controlled; or

(iv) The drug has been studied in one or more adequate and well-controlled investigations that strongly suggest lack of effectiveness; or

(v) Another drug under investigation or approved for the same indication and available to the same patient population has demonstrated a better potential benefit/risk balance; or

(vi) The drug has received marketing approval for the same indication in the same patient population; or

(vii) The sponsor of the study that is designed to be an adequate and well-controlled investigation is not actively pursuing marketing approval of the investigational drug with due diligence; or

(viii) The Commissioner determines that it would not be in the public interest for the study to be conducted or continued.

* * * * *

3. Section 312.44 is amended by adding new paragraph (b)(1)(xi) and by revising paragraph (b)(2)(i) to read as follows:

§ 312.44 Termination.

* * * * *

(b) * * *

(1) * * *

(xi) The sponsor fails to delay a proposed investigation under the IND or to suspend an ongoing investigation that has been placed on clinical hold under § 312.42(b)(4).

(2) * * *

(i) Any of the conditions in paragraph (b)(1)(i) through (b)(1)(xi) of this section apply; or

* * * * *

Dated: February 22, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90–11821 Filed 5–18–90; 8:45 am]

BILLING CODE 4160–01–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2700

Rule of Procedure

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The Federal Mine Safety and Health Review Commission is extending the time for comments on its proposed rules revising its present rules of procedure. The proposed rules were published at 55 FR 4853, February 12, 1990 and provided that written comments were to be submitted on or before May 14, 1990. Several requests have been made to the Commission for a 30-day extension of time. Accordingly, the Commission shall extend the time for comments concerning its proposed rules to June 13, 1990.

DATES: Written comments must be submitted on or before June 13, 1990.

ADDRESSES: Comments may be mailed to L. Joseph Ferrara, General Counsel, Office of the General Counsel, Federal Mine Safety and Health Review Commission, 1730 K Street, NW., 6th Floor, Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: L. Joseph Ferrara at 202–653–5610, (202–708–9300 for TDD Relay). These are not toll-free numbers.

Ford B. Ford,

Chairman, Federal Mine Safety and Health Review Commission.

[FR Doc. 90–11703 Filed 5–18–90; 8:45 am]

BILLING CODE 6735–01–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD8–90–05]

Drawbridge Operation Regulations: LA Carpe Bayou, LA

AGENCY: U.S. Coast Guard, DOT.

ACTION: Proposed rule.

SUMMARY: At the request of the Louisiana Department of Transportation and Development (LDOTD), the Coast Guard is considering a change in the regulation governing the operation of the vertical lift span bridge on State Route 661 across La Carpe Bayou, mile 7.5 at Houma, Terrebonne Parish, Louisiana, by permitting the draw to open on signal if at least four hours advance notice is given. This change is an addition to the present regulation which requires that the draw need not be opened for the passage of vessels during the vehicular rush hour periods from 7 to 8:30 a.m. and from 4:30 to 6 p.m., Monday through Friday, except holidays. This proposal is being made because of the recent decline in vessel passages. This action should relieve the bridge owner of the burden of having a person constantly available at the bridge for operations of the draw, while still providing for the reasonable needs of navigation.

DATES: Comments must be received on or before July 5, 1990.

ADDRESSES: Comments should be mailed to Commander (ob), Eighth Coast Guard District, 501 Magazine Street, New Orleans, Louisiana 70130–3396. The comments and other materials referenced in this notice will be available for inspection and copying in room 1115 at this address. Normal office hours are between 8 a.m. and 3:30 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: John Wachter, Bridge Administration Branch, at the address given above, telephone (504) 589–2965.

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting written views, comments, data or arguments. Persons submitting comments should include their names and addresses, identify the bridge, and give reasons for concurrence with or any recommended change in the proposal. Persons desiring acknowledgment that their comments have been received

should enclose a stamped, self-addressed postcard or envelope.

The Commander, Eighth Coast Guard District, will evaluate all communications received and determine a course of final action on this proposal. This proposed regulation may be changed in the light of comments received.

Drafting Information

The drafters of this notice are John Wachter, project officer, and LT J.A. Wilson, project attorney.

Discussion of Proposed Regulation

The vertical clearance of the bridge in the closed position is 3 feet above mean high water and 6 feet above mean low water. Traffic through the bridge consists of commercial boats, fishing vessels and pleasure craft. Data submitted by the LDOTD show that the bridge has not been used by marine traffic since November 1987.

Considering the length of time that the bridge has not been required to open, the Coast Guard feels that the current on-site attendance at the bridge can be discontinued and that the bridge can be placed on four hours advance notice for an opening outside of the vehicular rush hour closure periods presently in effect.

The advance notice for opening of the draw would be given by placing a collect call any time to the LDOTD in Bridge City, Louisiana, telephone 1–800–256–1599. From afloat, this contact may be made by radiotelephone through a public coast station.

The LDOTD recognizes that there may be an unusual occasion to open the bridge on less than four hours notice for an emergency or to operate the bridge on demand for an isolated but temporary surge in waterway traffic, and has committed to doing so if such an event should occur.

Economic Assessment and Certification

This proposed regulation is considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034, February 26, 1979).

The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. The basis for this conclusion is that no vessels have used this bridge since November 1987, as evidenced by the data provided by the LDOTD. Since the economic impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 117

Bridges.

Proposed Regulation

In consideration of the foregoing, the Coast Guard proposes to amend part 117 of title 33, Code of Federal Regulations, as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46 and 33 CFR 1.05–1(g).

2. Section 117.460 is revised to read as follows:

§ 117.460 La Carpe Bayou.

The draw of the S661 bridge, mile 7.5, shall open on signal if at least four hours advance notice is given, except that, the draw need not be opened for the passage of vessels Monday through Friday except holidays from 7 a.m. to 8:30 a.m. and 4:30 p.m. to 6 p.m.

Dated: May 3, 1990.

W.F. Merlin,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 90–11727 Filed 5–18–90; 8:45 am]

BILLING CODE 4910–14–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–3780–2]

Approval and Promulgation of Implementation Plans; Illinois

AGENCY: United States Environmental Protection Agency (USEPA).

ACTION: Proposed rule.

SUMMARY: USEPA is proposing to approve a request by Illinois to revise its State Implementation Plan (SIP) for ozone. This revision will reduce emissions of volatile organic compounds (VOC) from gasoline by requiring the reduction of its Reid Vapor Pressure (RVP) in July and August. The intended effect of this action is to make reasonable further progress towards attainment of the ozone National Ambient Air Quality Standard (NAAQS) as expeditiously as practicable, as required under the Clean Air Act.

DATES: Comments must be received by June 20, 1990.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Cheryl L. Newton, at (312) 886–6081, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch, 230 South Dearborn Street, Chicago, Illinois 60604

Illinois Environmental Protection Agency, Division of Air Pollution Control, 2200 Churchill Road, Springfield, Illinois 62706

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.) Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR–26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Cheryl L. Newton, U.S. Environmental Protection Agency, Region V, Air and Radiation Branch (5AR–26), 230 South Dearborn Street, Chicago, Illinois 60604, (312) 886–6081.

SUPPLEMENTARY INFORMATION: On April 6, 1990, the Illinois Environmental Protection Agency (IEPA) submitted a revision to its SIP to USEPA that revises subpart Y: Gasoline Distribution, title 35 of the Illinois Administrative Code (IAC). Subpart Y, § 215.585, entitled "Gasoline Volatility Standards," prohibits persons from selling, supplying or transporting from a bulk plant or terminal for use in Illinois, gasoline having an RVP greater than 9.5 pounds per square inch (psi), from July 1 through August 31, beginning in 1990 and continuing each year thereafter.

Background

On April 27, 1989, the Illinois Pollution Control Board (Board) accepted for hearing a proposed rule submitted by the Chicago Lung Association (CLA) which limits the RVP of gasoline sold in Illinois during the applicable control period to 9.0 psi beginning in 1990. During the course of its rulemaking action, the Board split the gasoline volatility rule docket into two separate proposals, Docket (A) and Docket (B). In Docket (A) (R88–30) (A)), the Board proposed a 9.5 psi volatility limitation statewide between July 1 and August 31 of each summer, beginning in 1990, and determined that an economic impact study need not be conducted. In Docket (B), proceeding on a separate track, the Board will consider a 9.0 psi volatility limitation statewide; however, an economic impact study is required.

On February 15, 1990, the Board adopted R88–30 (A) as an amendment to 35 IAC 215. USEPA reviewed the final adopted rule and determined that, as adopted, two sections of the rule were not consistent with USEPA requirements for approval. One section allowed the use of a test method which has not been approved by USEPA; the other section granted IEPA discretion to approve alternate test methods without Federal comment or approval. Subsequently, on March 16, 1990, USEPA submitted a Motion to Reconsider Decision to the Board, requesting that the Board correct the two noted deficiencies.

On March 22, 1990, the Board incorporated the appropriate revisions to the R88–30 (A) through an emergency rulemaking action, and on April 6, 1990, IEPA formally submitted the emergency rule adopted as part of proceeding R88–30 (A) as a SIP revision.[1] The emergency rule addressed the deficiencies noted by USEPA and also corrected language in two other subsections where the published rule inadvertently contained language from the first notice, rather than the final adopted rule. USEPA, today, is proposing to approve the Board's emergency rule for the period in which it is in effect.

Phase I of the Federal Volatility Regulation

USEPA published a notice of final rulemaking on March 22, 1989, (54 FR 11868), which also requires the control of RVP. The USEPA rule calls for control of the volatility of gasoline nationally. The national rule requires that, beginning in 1989, the maximum allowable RVP in Illinois will be 10.5 psi. (During July and August, the maximum allowable RVP in Illinois south of 40 degrees latitude is 9.5 psi.) The Federal standard will be enforced each year beginning June 1 (for retail users and other end users of gasoline) or May 1 (for all other points in the distribution system). In 1989 enforcement began 100 days and 70 days (respectively) after the publication date of the final rule. Enforcement ends at all points in the system on September 16 of each year.

[1] Pursuant to section 27(c) of the (Illinois) Environmental Protection Act and § 5.02 of the Illinois Administrative Procedure Act, the Board may adopt a temporary emergency rule for 150 days without utilizing the usual rulemaking procedural steps. The 150 days will encompass the regulatory control period of July and August of 1990 and will allow time for consideration of other steps to address USEPA's concerns for next year. The Board indicated that it may permanently address USEPA's comments in subdocket (B) of the volatility regulation for implementation in 1991. Subdocket (B) has already been proposed and is awaiting the preparation of an economic impact study.

The USEPA regulation would normally preempt the State provision under section 211(c)(4) of the Clean Air Act (Act). However, section 211(c)(4)(C) of the Act provides for approval of State control of fuel or fuel additives if the control is part of the SIP and it is necessary to achieve the primary or secondary NAAQS for which the plan is in effect.

Criteria for Approval

Section 211(c)(4)(A) of the Act, in describing Federal preemption authority, states:

> Except as otherwise provided in subparagraph (B) or (C), no State (or political subdivision thereof) may prescribe or attempt to enforce, for the purposes of motor vehicle emission control, any control or prohibition respecting use of a fuel or fuel additive in a motor vehicle or motor vehicle engine—(i) if the Administrator has found that no control or prohibition under paragraph (1) is necessary and has published his findings in the **Federal Register**, or (ii) if the Administrator has prescribed under paragraph (1) a control or prohibition applicable to such fuel or fuel additive, unless (the) State prohibition or control is identical to the prohibition or control prescribed by the Administrator.

Thus, in light of the new Federal volatility rule, State control would normally be preempted. However, USEPA may still approve certain State provisions for limits on RVP of fuel where a finding under section 211(c)(4) is made which would authorize USEPA approval and, thus, eliminate the preemption problem. As set forth below, section 211(c)(4)(C) authorizes USEPA to approve into the SIP a State-adopted fuel control measure that would otherwise be preempted by USEPA national action if USEPA finds that the State control "is necessary to achieve" the standard that the SIP implements.

Section 211(c)(4)(C) of the Act, in setting forth the circumstances under which an exception to Federal preemption of State regulation may occur, states:

> A State may prescribe and enforce, for purposes of motor vehicle emission control, a control or prohibition respecting the use of a fuel or fuel additive in a motor vehicle or motor vehicle engine if an applicable implementation plan for such State under section 110 so provides. The Administrator may approve such provision in an implementation plan, or promulgate an implementation plan containing such a provision, only if he finds that the State control is necessary to achieve the national primary or secondary ambient air quality standard which the plan implements.

In the August 1, 1988, **Federal Register** (53 FR 30220) discussion of USEPA's approval of a State oxygenated fuels program in the Maricopa County, Arizona, SIP, USEPA interpreted this language as requiring the Agency to find that a fuel control requirement was essential to achieve timely attainment of the primary standard for carbon monoxide. USEPA said further that a fuel control measure may be "necessary" for timely attainment (1) if no other measures that would bring about timely attainment exist, or (2) if such other measures do exist and are technically possible to implement, but are unreasonable or impracticable.[2] Otherwise, no fuel control would ever be "necessary," since for any area there is at least one measure—namely, required shutdowns and prohibitions on driving—that would result in timely attainment of the NAAQS. It is doubtful that Congress would have intended to bar USEPA from approving State fuel controls into a SIP based on the availability of such drastic alternatives.

USEPA has since taken action on State RVP control measures based on its findings in the Maricopa County, Arizona, rulemaking. All comments were received and addressed and, in 1989, USEPA approved State control of RVP as SIP revisions for Massachusetts (54 FR 19173), Rhode Island and Connecticut (54 FR 23650), New Jersey (54 FR 25572), and New York (54 FR 26030). An additional SIP revision is pending for the State of Maine.

Evaluation of How the Illinois Revision Satisfies the "Necessary" Criterion

As a result of a suit filed by the State of Wisconsin under Section 304 of the Act,[3] on January 18, 1989, USEPA was

[2] Although the 9th Circuit Court of Appeals vacated this SIP approval on other grounds, the Court did not comment adversely on USEPA's findings related to Federal preemption. (See *Delaney v. USEPA*, 9th Cir. No. 88–7368, Slip Op., March 1, 1990.)

[3] In April 1987, the State of Wisconsin filed a suit under Section 304 of the Act in the United States District Court for the Eastern District of Wisconsin against Lee M. Thomas, then USEPA Administrator (Civil Action No. 87–C–395). Subsequent to William K. Reilly assuming the duties of Administrator of the USEPA, William K. Reilly was substituted as named defendant for Lee Thomas. Two counts of the complaint alleged that USEPA had failed to perform a non-discretionary duty to approve or disapprove the greater Chicago area ozone SIPs of Illinois and Indiana. Two other counts requested the Court to order USEPA to develop a Federal Implementation Plan (FIP) for the northeastern Illinois and northwestern Indiana portions of the Chicago-Gary-Lake County (IL), IL-IN-WI consolidated Metropolitan Statistical Area (CMSA) within 6 months. The complaint also sought an injunction compelling USEPA to impose and enforce a moratorium on the construction and modification of major stationary sources in the Illinois and Indiana portions of the CMSA. While litigation was in progress, USEPA published final disapprovals of the ozone SIPs for Illinois on October 17, 1988, and

Continued

ordered to develop a Federal Implementation Plan (FIP) for the northeastern Illinois and northwestern Indiana portions of the Chicago-Gary-Lake County (IL), IL–IN–WI Consolidated Metropolitan Statistical Area (CMSA). During negotiations that eventually resulted in a settlement agreement, USEPA proceeded to initiate work on a FIP on a schedule to meet the Court's original deadline. On July 11, 1989, USEPA published a **Federal Register** notice (54 FR 29063) containing a 1988 emissions inventory for the Chicago area and an Empirical Kinetic Modeling Approach (EKMA) modeling analysis of the area which predicted the level of emission reductions needed to achieve the ozone NAAQS. The EKMA modeling analysis indicates a VOC emission reduction target of 71 percent of the 1988 base year inventory.[4]

According to the MOBILE 4 emission factor model for motor vehicle emissions, the Illinois RVP regulation, which reduces the volatility of gasoline from 10.5 to 9.5 psi during July and August, would reduce mobile source VOC emissions during July and August north of 40 degrees latitude by an estimated additional 177.9 tons per day (TPD) in the Chicago area between 1990 and 1992. This reduction estimate amounts to 7.0 percent of the total 1988 VOC inventory in the Chicago area. (Phase I of the Federal volatility regulation, which reduced gasoline volatility from 11.5 to 10.5 in the Chicago area, will result in an estimated 219.6 TPD VOC emission reduction between 1990 and 1992 or 8.6 percent of the 1988 base year inventory.) This estimate may understate the actual reductions in motor vehicle emissions because it does not include the emission reductions that would result from decreased running losses associated with lower volatility gasoline. Running losses are evaporative emissions from the gasoline tank and fuel system that occur while the car is being driven and which result from an overload of the evaporative control system or escape through the fuel tank filler cap.

The Illinois RVP regulation would achieve further VOC emission reductions from stationary gasoline sources. Evaporative VOC emissions from the manufacture, storage, and distribution of gasoline products would be reduced as a result of a reduction in gasoline volatility.

The VOC strategies identified by USEPA during development of the ozone FIP for the Chicago CMSA as having the greatest potential for significant future VOC reductions are:

Measure	Tons reduced (TPD) [1]	Percent of 1988 Chicago area inventory
Reducing RVP from 10.5 to 9.0	223.2	8.7
Generic rule for non-CTG sources	131.5	5.2
Motor vehicle and mobile equipment non-assembly coating operations	47.1	1.8
Automobile refueling (Stage II)	37.7	1.5
Architectural surface coatings	38.9	1.5
Volatile Organic Liquid Storage	33.3	1.3
Surfade coating of miscellaneous metal parts and products	29.8	1.2
Surface coating of paper, fabric and film	22.5	0.9
Graphic Arts	15.4	0.6
Solvent metal cleaning	8.2	0.3
Petroleum refinery wastewater treatment	3.2	0.1
Total	590.8	23.2

[1] Reductions reflect the cumulative benefit of each measure in the near term (i.e., reductions achieved by the year 1995 relative to the 1988 base year levels.) The emission reductions are based on 100 percent rule effectiveness. Actual effectiveness for certain rules may vary between 80 and 100 percent, and the potential emission reductions would be lessened accordingly.

No other categories of available controls individually appear to yield reductions of more than one percent of the 1988 VOC inventory. Further, the cumulative total of: (1) the other control strategies, if found practicable, (2) the above controls, if all controls were 100 percent effective, and (3) existing control programs (i.e., USEPA's Federal Motor Vehicle Control Program, Phase I National RVP control, and the recently promulgated National Emission Standard for Hazardous Air Pollutants for benzene (54 FR 38044)) yield approximately a 47 percent reduction. This leaves at least a 24 percent shortfall from the reduction target of 71 percent noted above. The State is considering changes to its motor vehicle inspection and maintenance (I/M) program along with other measures as pat of the Post-1987 ozone SIP planning process which will help somewhat reduce the shortfall. USEPA estimates that potential reductions of the total 1988 VOC inventory that could be obtained with enhancements to the current Illinois I/M program range from 0.8 percent for a moderately-enhanced program to 2.6 percent for a highly-enhanced program. Thus, even if such I/M program enhancements are implemented, a shortfall will still exist necessitating the implementation of other measures to achieve attainment.

Although the Illinois RVP regulation is not as stringent as the rule considered by USEPA in the preparation of the FIP, by reducing RVP to 9.5 psi from the current Federal limit of 10.5 psi, Illinois would be able to obtain reductions of approximately 177.9 TPD in July and August between 1990 and 1992. Therefore, even with USEPA's Phase I RVP regulation requiring control to 10.5 psi beginning in 1989, the State regulation will still have a significant impact. It will provide approximately an additional 7.0 percent reduction during July and August beyond the current Federal reduction.

Thus, Illinois' RVP program meets the appropriate test of being "necessary" to achieve attainment of the ozone NAAQS. The fact that the State RVP regulation might not by itself fill the remaining shortfall, and hence, by itself achieve the standard, does not mean the rule would not be "necessary" to achieve the standard within the meaning of section 211(c)(4)(C).

USEPA believes that if Congress had intended USEPA to approve a State fuel-content rule only if it were necessary and sufficient to achieve the standard, then it would have used that language in section 211(c)(4)(C). USEPA believes that the "necessary to achieve" standard must be interpreted to apply to measures which are needed to reduce ambient levels (thus bringing the area closer to achieving the NAAQS) when no other reasonable measures are available to achieve this reduction. A contrary application of "necessary to achieve" in this situation would mean that measures which result in significantly improved air quality are nonetheless unacceptable (even though no other reasonable measures are available) just because they are insufficient to actually result in attainment.

Enforceability

USEPA's review of the State's originally adopted rule revealed that

for Indiana on November 18, 1988. The Court, on January 18, 1989, ordered USEPA to develop a FIP within 14 months.

Subsequent to this, USEPA, Illinois, and Wisconsin entered into a settlement agreement. On November 6, 1989, the Court ordered all further proceedings stayed pending performance of the settlement agreement. The settlement agreement provides USEPA with additional time to promulgate a FIP for the Chicago area based on a more sophisticated air quality modeling study. While the study is being conducted, interim emission reductions are required by the settlement agreement.

[4] The settlement agreement, as discussed in the previous footnote, provides USEPA with additional time to promulgate a FIP for the Chicago area based on a more sophisticated air quality modeling study. However, at Illinois' request, USEPA is rulemaking on the State's volatility regulation utilizing the best information currently available.

two sections were not consistent with USEPA requirements for approval. One section allowed the use of a test method which has not been approved by USEPA; the other section granted IEPA discretion to approve alternate test methods without Federal comment or approval.

On March 16, 1990, USEPA submitted a Motion to Reconsider Decision to the Board requesting that the Board correct the noted deficiencies. On March 22, 1990, the Board incorporated the appropriate revisions to the volatility regulation through an emergency rulemaking action. Therefore, USEPA finds that its prior concerns have been addressed and that the regulation is approvable because it is now fully enforceable.

USEPA believes that the Illinois volatility regulation is approvable because it is necessary to enable the Chicago area to ultimately achieve the ozone NAAQS and it will help the area make reasonable further progress. However, before the State can take emission reduction credits for its fuel volatility program, the State must provide proof that the rule has been implemented and is, in fact, achieving the anticipated emission reductions. The State will need to provide a description of its enforcement program and evidence that appropriate financial and manpower resources have been allocated.

Conclusion

USEPA is proposing to approve this revision to the Illinois SIP for ozone to control gasoline volatility. USEPA is also proposing to make a finding that this SIP revision meets the requirements of Section 211(c)(4)(C) of the Act for an exeption to Federal preemption.

Under 5 U.S.C. 605(b), I certify that this SIP revision will not have a significant impact on a substantial number of small entities. (See 46 FR 8709.)

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

List of Subjects in 40 CFR Part 52

Air pollution control, Environmental protection, Hydrocarbons, Intergovernmental relations, Ozone.

Authority: 42 U.S.C. 7401–7642.

Date: May 1, 1990.

Robert Springer,

Acting Regional Administrator.

[FR Doc. 90–11724 Filed 5–18–90; 8:45 am]

BILLING CODE 6560–50–M

48 CFR Parts 1527 and 1552

[FRL–3779–4]

Acquisition Regulation

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: This rule deletes from the EPA Acquisition Regulation (EPAAR) coverage on data rights that essentially duplicates the FAR. This rule retains only EPAAR coverage on the purposes for which limited rights data may be disclosed outside of EPA. The rule is necessary to comply with the FAR's prohibition against repeating or restating FAR material in agency acquisition regulations.

DATES: Written comments should be received on or before June 20, 1990.

ADDRESSES: Comments should be addressed to: Environmental Protection Agency, Procurement and Contracts Management Division (PM–214F), 401 M Street, SW., Washington, DC 20460, attn: Marilyn Torpey.

FOR FURTHER INFORMATION CONTACT: Marilyn Torpey on telephone (202) 245–3941 (FTS 245–3941).

SUPPLEMENTARY INFORMATION:

A. Background

Part 1527 of the EPA Acquisition Regulation (EPAAR) presently provides policies and procedures with respect to rights in data and copyrights, and requirements for data. The proposed rule removes EPAAR coverage in parts 1527 and 1552 that essentially duplicates existing Federal Acquisition Regulation (FAR) coverage in part 27.

This rule retains a portion of existing EPAAR section 1552.227–71 concerning the purposes for which limited rights data, as defined in FAR 27.401, may be disclosed outside of EPA. The existing portion of EPAAR is authorized by FAR 27.404(d)(1). The retained portion is redesignated under this rule as 1527.404.

B. Executive Order 12291

The Office of Management and Budget (OMB) Bulletin No. 85–7, dated December 14, 1984, establishes the requirements for OMB review of agency acquisition regulations. This regulation does not fall within any of the categories cited in the bulletin requiring OMB review.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this proposed rule does not contain information collection requirements requiring the approval of OMB under 44 U.S.C. 3501, et seq.

D. Regulatory Flexibility Act

The EPA certifies that this proposed rule does not exert a significant economic impact on a substantial number of small entities because the proposed change does not impose any new requirements on contractors, large or small. An initial regulatory flexibility analysis has therefore not been performed.

List of Subjects in 48 CFR Parts 1527 and 1552

Government Procurement, Contracting by negotiation, Solicitation provisions and Contract clauses.

For the reasons set out in the preamble, parts 1527 and 1552 of title 48 Code of Federal Regulations are proposed to be amended as follows:

1. The authority citation for parts 1527 and 1552 continues to read as follows:

Authority: Section 205(c), 63 Stat. 390, as amended, 40 U.S.C. 486(c)).

PART 1527—AMENDED

2. Part 1527 is amended by adding Subpart 1527.4 consisting of section 1527.404 to read as follows:

Subpart 1527.4—Rights in Data and Copyrights

1527.404 Basic rights in data clause.

The Contracting Officer shall insert in the *Limited Rights Notice* when using Alternate II of FAR 52.227–14 the following purposes for disclosure of limited rights data outside the Government.

(a) Use (except for manufacture) by support service contractors;

(b) Evaluation by nongovernment evaluators;

(c) Use (except for manufacture) by other contractors participating in the Government's program of which the specific contract is a part, for information and use in connection with the work performed under each contract;

(d) Emergency repairs or overhaul work;

(e) Release to a foreign government, or instrumentality thereof, as the interests of the United States Government may require, for information or evaluation, or for emergency repair or overhaul work by such government.

Subpart 1527.70—[Amended]

3. Subpart 1527.70 is removed.

PART 1552—[AMENDED]

4. Part 1552 is amended by removing sections 1552.227–70 through 1552.227–75.

Dated: May 10, 1990.

John C. Chamberlin,

Director, Office of Administration.

[FR Doc. 90–11611 Filed 5–18–90; 8:45 am]

BILLING CODE 6560–50–M

INTERSTATE COMMERCE COMMISSION

49 CFR Parts 1105, 1106, 1150, and 1152

[Ex parte No. 55 (Sub No. 22A)]

Implementation of Environmental Laws

AGENCY: Interstate Commerce Commission.

ACTION: Proposed rule; extension of comment period.

SUMMARY: In a notice of proposed rules published in the **Federal Register** on March 30, 1990, at 55 FR 11973 the Commission proposed to make revisions to 49 CFR parts 1105, 1106, 1150 and 1152 to revise and clarify the information to be provided in environmental and historic reports. The Association of American Railroads (AAR) requests that the due date for comments be extended 30 days. AAR states that the extension is necessary to consolidate its members' views into one statement and to circulate it for their approval prior to filing. Because the new date is reasonable and will help ensure the development of a complete record, the extension is granted. The new due date will be June 28, 1990.

DATES: Comments are due on or before June 28, 1990.

ADDRESSES: An original and 15 copies of comments in Ex Parte No. 55 (Sub-No. 22A) should be sent to: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 275-7245 [TDD for hearing impaired: (202) 275-1721]

Decided: May 14, 1990.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 90–11636 Filed 5–18–90; 8:45 am]

BILLING CODE 7035–01–M

Notices

Federal Register
Vol. 55, No. 98
Monday, May 21, 1990

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

Agricultural Stabilization and Conservation Service

Feed Grain Donations for the Navajo Tribe of the Navajo Indian Reservation in Arizona, New Mexico and Utah

Pursuant to the authority set forth in section 407 of the Agricultural Act of 1949, as amended (7 U.S.C. 1427) and Executive Order 11336, I have determined that:

1. The chronic economic distress of the needy members of the Navajo Tribe of the Navajo Reservation in Arizona, New Mexico and Utah continues to be materially increased and become acute because of severe and prolonged drought, thereby creating a serious shortage of feed and causing increased economic distress. This reservation is designated for Indian use and is utilized by members of the Navajo Tribe for grazing purposes.

2. The use of feed grain or products thereof made available by the Commodity Credit Corporation (CCC) for livestock feed for such needy members of the Tribe will not displace or interfere with normal marketing of agricultural commodities.

3. Based on the above determinations, I hereby declare the reservation and grazing lands of the Tribe to be acute distress areas and authorize the donation of feed grain owned by the CCC to livestock owners who are determined by the Bureau of Indian Affairs, United States Department of the Interior, to be needy members of the tribe utilizing such lands. These donations by the CCC are extended for the period May 1, 1990, and shall be made available thorugh June 30, 1990, or such other date as may be stated in a notice issued by the USDA.

Signed at Washington, DC, on May 15, 1990.

Keith D. Bjerke,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 90–11694 Filed 5–18–90; 8:45 am]

BILLING CODE 3410–05–M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Automated Manufacturing Equipment Technical Advisory Committee; Partially Closed Meeting

A meeting of the Automated Manufacturing Equipment Technical Advisory Committee will be held June 14 & 15, 1990, in the Herbert C. Hoover Building, room 1617F, 14th & Pennsylvania Avenue, NW., Washington, DC. The General Session of the meeting will convene at 1 p.m. on June 14, 1990. The meeting will reconvene in Executive Session at 8:30 a.m. on June 15. The Committee advises the Office of Technology and Policy Analysis with respect to technical questions that affect the level of export controls applicable to automated manufacturing equipment and related technology.

Agenda

General Session June 14, 1990–1 p.m.

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Foreign availability review.
4. Report on the Joint Factory Communications and Computer Subcommittee.
5. Discussion of the following ECCN's:
   - 1091 (Numerical control equipment)
   - 1088 (Gear making or finishing machinery)
   - 1370 (Machines for turning optical-quality surfaces)
   - 1371 (Anti-friction bearings)
   - 1532 (Precision liner and angular measuring systems and specially designed components).
6. Review of Core List.
7. New business.

Executive Session June 15, 1990—8:30 a.m.

8. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent that time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting. However, to facilitate distribution of public presentation materials to the Committee members, the Committee suggests that presenters forward the public presentation materials two weeks prior to the meeting date to the following address: Lee Ann Carpenter, Technical Support Staff, OTPA/BXA, room 4069A, U.S. Department of Commerce, 14th & Pennsylvania Ave. NW., Washington, DC 20230.

The Assistant Secretary for Administration, with the concurrence of the General Counsel, formally determined on January 5, 1990, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings of the Committee and of any Subcommittees thereof, dealing with the classified materials listed in 5 U.S.C., 552b(c)(1) shall be exempt from the provisions relating to public meetings found in section 10(a)(1) and (a)(3), of the Federal Advisory Committee Act. The remaining series of meetings or portions thereof will be open to the public.

A copy of the Notice of Determination to close meetings or portions of meetings of the Committee is available for public inspection and copying in the Central Reference and Records Inspection Facility, room 6628, U.S. Department of Commerce, Washington, DC 20230. For further information or copies of the minutes, contact Lee Ann Carpenter on (202) 377–2583.

Dated: May 14, 1990.

Betty Anne Ferrell,

Director, Technical Advisory Committee Unit.

[FR Doc. 90–11650 Filed 5–18–90; 8:45 am]

BILLING CODE 3510–DT–M

International Trade Administration

[C-122-404]

Live Swine From Canada; Preliminary Results of Countervailing Duty Administrative Reviews

AGENCY: International Trade Administration/Import Administration, Commerce.

ACTION: Notice of Preliminary Results of Countervailing Duty Administrative Reviews.

SUMMARY: The Department of Commerce has conducted two administrative reviews of the countervailing duty order on live swine from Canada. We preliminarily determine the net subsidy for sows and boars to be *de minimis* for the period April 1, 1986 to March 31, 1987 and Can$0.0068/lb. for the period April 1, 1987 to March 31, 1988. We preliminarily determine the net subsidy for all other live swine to be Can$0.0060/lb. for the period April 1, 1986 to March 31, 1987 and Can$0.0071/lb. for the period April 1, 1987 to March 31, 1988. We invite interested parties to comment on these preliminary results.

EFFECTIVE DATE: May 21, 1990.

FOR FURTHER INFORMATION CONTACT: Sylvia Chadwick or Maria MacKay, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

SUPPLEMENTARY INFORMATION:

Background

On August 15, 1985, the Department of Commerce (the Department) published in the Federal Register (50 FR 32880) a countervailing duty order on live swine from Canada. On August 28, 1987 and August 25, 1988, the Government of Canada requested administrative reviews of the order. We published the initiation of review on September 21, 1987 (52 FR 35466) for the period April 1, 1986 through March 31, 1987, and on September 27, 1988 (53 FR 37618) for the period April 1, 1987 through March 31, 1988. On January 13, 1989, the petitioner submitted new allegations. In accordance with section 355.31(c)(1)(ii) of the Department Regulations, we reviewed these allegations for only the period April 1, 1987 through March 31, 1988. The Department has now conducted the administrative reviews in accordance with section 751(a) of the Tariff Act of 1930 (the Tariff Act).

Scope of Review

The United States, under the auspices of the Customs Cooperation Council, has developed a system of tariff classification based on the international harmonized system of customs nomenclature. On January 1, 1989, the United States fully converted to the *Harmonized Tariff Schedule* (HTS), as provided for in section 1201 *et seq.* of the Omnibus Trade and Competitiveness Act of 1988. All merchandise entered, or withdrawn from warehouse, for consumption on or after that date is now classified solely according to the appropriate HTS item number(s).

Imports covered by these reviews are shipments of Canadian live swine. During the periods of review, such merchandise was classifiable under item 100.8500 of the *Tariff Schedules of the United States Annotated.* Such merchandise is currently classifiable under HTS item numbers 0103.91.00 and 0103.92.00. The written description remains dispositive.

The reviews cover 35 programs administered during the periods April 1, 1986 through March 31, 1987 (fiscal year 1986/87) and April 1, 1987 through March 31, 1988 (fiscal year 1987/88).

Analysis of Programs

Federal Programs

1. Agricultural Stabilization Act

The Agricultural Stabilization Act (ASA) of 1957-58 was passed by the federal government to provide for the price stabilization of named and designated agricultural commodities. On June 27, 1985, ASA was amended by Bill C-25, which increased the number of commodities on the named list and changed the methodology used to calculate stabilization payments. See *Notice of Preliminary Results of Countervailing Duty Administrative Review, Live Swine from Canada* (53 FR 22189; June 14, 1988). No changes were made to the ASA during the periods of review.

Named commodities, including cattle, hogs, lambs and wool; industrial milk and industrial cream; corn and soybeans; and spring wheat, winter wheat, oats and barley not produced in the designated area as defined in the Canadian Wheat Board Act; are statutorily guaranteed eligibility for payouts from ASA whereas any other commodity is required to be designated by the Governor in Council and requires a separate, yearly appropriation vote by Parliament. The distinction between named and designated commodities indicates that preferential benefits from ASA are provided to named commodities. Also, only 13 commodities received ASA benefits in FY 1986/87 and 14 in 1987/88. In accordance with section 771(5) of the Tariff Act, we preliminarily determine that the ASA is countervailable because benefits from ASA are provided to a specific enterprise or industry or group of enterprises or industries.

Although the ASA did not make payments for hogs produced during the periods of review, ASA's annual reports showed payments were made in both FY 1987 and FY 1988 for hogs produced in previous years. ASA payments are made on a per hundredweight (cwt.) basis. We used 220 pounds as the average weight of slaughter hogs (excluding sows and boars) in Canada. Payments are made only on indexed slaughter hogs. Indexing is a method of grading hog carcasses according to lean meat percentage, loin fat and weight. Because sows and boars are not indexed, they are not eligible for payments from ASA.

Producers in three provinces (Prince Edward Island, Quebec and Ontario) received payments from ASA in FY 1987. To calculate the benefits from ASA, we allocated the ASA payments made in FY 1987 over the total live weight of swine (minus sows and boars) produced in the three provinces' in FY 1987. We then multiplied the result by the three provinces, share of total Canadian exports of live swine (minus sows and boars) to the United States. We made the same calculation for ASA payments made to four provinces (Nova Scotia, Quebec, Saskatchewan, and Alberta) in FY 1988. On this basis, we preliminarily determine the benefit for live swine to be Can$0.0013/lb. during the period April 1, 1986 through March 31, 1987; and less than Can$0.0001/lb. during the period April 1, 1987 through March 31, 1988. Because sows and boars are not eligible for payments from ASA, we preliminarily determine the benefit from this program to be zero for sows and boars during both periods of review.

2. Feed Freight Assistance Program

The Feed Freight Assistance Program is administered by the Canadian Livestock Feed Board (the Board) under the Livestock Feed Assistance Act of 1966 (LFA). The Board acts to ensure: (1) The availability of feed grain to meet the needs of livestock feeders; (2) the availability of adequate storage space for feed grain in Eastern Canada; and (3) the stabilization and equalization of feed grain prices in Eastern Canada, British Columbia, the Yukon and Northwest Territories. Eligibility for the program is restricted to: (1) Feed grain millers in "designated areas" (Manitoba, Saskatchewan, Alberta and parts of British Columbia) whose grain is sold for livestock feed; and (2) livestock

owners in parts of Eastern Canada, British Columbia, the Yukon Territory, and the Northwest Territories who purchase grain that will be fed to their livestock. The feed grain must be transported and stored outside the farm where it is grown, and moved through commercial channels. Commercial channels are defined as transactions that provide an invoice, weight certificate, grade certificate, and bill of lading. Payments for feed grain transportation are set per ton according to the destination of the grain and on a product-specific basis. During both FY 1986/87 and FY 1987/88, payments were made to feed grain users for both transportation assistance and storage of feed grain.

Because this program is limited to feed grain millers in the above described "designated areas" whose grain is fed to livestock, and to livestock owners in parts of Eastern Canada and British Columbia, in the Yukon and Northwest Territories, we determine that it is limited to a specific enterprise or industry, or group of enterprises or industries, and is therefore countervailable.

Five percent of all feed grains receiving assistance under this program were sold to benefit live swine producers in grain deficit regions throughout Canada. Therefore, we allocated 5 percent of the total payouts made during each of the periods of review over total Canadian hog production for a benefit of Can$0.0002/lb. for FY 1986/87 and Can$0.0002/lb. for FY 1987/88, for all live swine.

Federal/Provincial Programs

1. National Tripartite Red Meat Stabilization Program

Bill C–25 amended the ASA to authorize the Minister of Agriculture, with the approval of the Governor in Council, to enter into tripartite agreements with the provinces and/or producers to provide price stabilization schemes for any natural or processed product of agriculture. The Minister may enter into a tripartite agreement only after determining that the agreement will not give a financial advantage to some producers in the production or marketing of the product not enjoyed by other producers of the same product in Canada, and will not provide an incentive to overproduce.

In January 1986, Ontario, Alberta, and Saskatchewan signed agreements on hogs. Manitoba signed an agreement on February 25, 1986. The four agreements were implemented July 1, 1986. Under the terms of the Tripartite Agreements on Hogs, all hog producers in participating provinces receive the same level of support per unit; the cost of the scheme is shared between Canada, the province and the producer; producer participation in the scheme is voluntary; the provinces may not offer separate stabilization plans or other *ad hoc* assistance for hogs, nor may the federal government offer compensation to swine producers in a province not a party to an agreement. The scheme must operate at a level that limits losses but does not stimulate over-production. Payments are restricted to the number of hogs corresponding to the domestic production used for domestic consumption and the agreements must specify the method of determining that number.

The Tripartite Agreements provide for a five-year phase-in period to adjust for differences between the Tripartite Program and the provincial programs still in effect. Existing provincial stabilization plans are to be completely phased out by 1991. During the periods of review, eight provincial stabilization programs remained in effect (see provincial programs).

Hogs eligible for stabilization payments under the Tripartite Agreements must index 80 or above. Sows and boars are not eligible for benefits because they are not indexed. Stabilization payments are made when the market price falls below the support price. Support prices for hogs are calculated quarterly based on a guaranteed margin over production costs. The support price equals the cash costs of production in the current period plus 95 percent of the average margin in the same period for the preceding five years. The margin for any period is equal to the national average market price for the period minus the national average cash costs in that period. The difference between the support price and the average market price is the amount of the stabilization payment.

The Omnibus Trade and Competiveness Act of 1988 amended section 771(5)(B) of the Tariff Act to provide that "the administering authority, in each investigation, shall determine whether the bounty, grant, or subsidy in law or in fact is provided to a specific enterprise or industry, or group of enterprises or industries. Nominal general availability, under the terms of the law, regulation, program or rule establishing a bounty, grant, or subsidy, of the benefits thereunder is not a basis for determining that the bounty, grant, or subsidy is not, or has not been, in fact provided to a specific enterprise or industry, or group thereof." Therefore, to determine whether a program is limited to a specific enterprise or industry or group of enterprises or industries, we consider: (1) Whether the law of the foreign government acts to limit the availability of a program; (2) the number of industries or groups thereof that actually use a program; (3) whether there are dominant users of a program, or whether certain industries or groups thereof receive disproportionately large benefits under a program; and (4) the extent to which a government exercises discretion in conferring benefits under a program.

The Tripartite Agreements Program does not act in law to limit the number of commodities that may be covered under agreements. However, the program was limited in fact to only four commodities during FY 1986/87, and eight commodities during FY 1987/88. Hog producers were the dominant users of the program acounting for 57 percent of the total payouts from the program in FY 1986/87 and for 60 percent in FY 1987/88. Furthermore, there are no explicit or standard procedures or criteria for evaluating Tripartite Agreement requests. For the foregoing reasons, in accordance with section 771(5)(B), we preliminarily determine that the Tripartite Agreements Program is countervailable because it is limited to a specific enterprise or industry or group of enterprises or industries.

During the periods of review, no payouts for hogs were made under the Tripartite Agreements. Calculations for the quarter January 1, 1988 through March 31, 1988, triggered a payment for hogs but the payout was made during May and June of 1988, outside the periods of review. Therefore, we preliminarily determine that there was no benefit from the Tripartite Agreements Program for live swine or sows and boars during the periods of review.

2. Canada/British Columbia Agri-Food Regional Development Subsidiary Agreement (ARDSA)

On July 25, 1985, Canada and British Columbia signed an agreement to continue agricultural development cooperation between the two governments. The agreement was preceded by the ARDSA which existed between July 1977 and July 1983. The objectives of the new agreement are to improve the competitiveness of the agri-food industry in British Columbia, increase economic output and employment opportunities in the industry, and conserve and improve the province's agricultural resources. Programs funded under the new agreement are: (1) Productivity Enhancement—including technology

development, technology transfer, market and new product development, farm and agribusiness education, commodity and program planning, and public information, evaluation and implementation; (2) Resource Development—including regional irrigation and water supply systems, watershed drainage systems for agriculture, soil conservation and improvement; and (3) Commodity Development— including on-farm commodity enhancement, new and expanded market facilities, agricultural support facilities and services.

Under the new agreement, each government is committed to spending up to Can$20,000,000 over five years. Funding for projects under this agreement will be jointly shared by both governments. Because projects under this program are limited to British Columbia, we preliminarily determine that the Federal government's contribution is limited to enterprises or industries located in a specific region of Canada and is therefore countervailable. During the periods of review, no benefits from this program were provided to swine producers. Therefore, we find no countervailable benefit from this program during the periods of review. During the next review, we will review projects funded under this program.

3. Canada/Quebec Subsidiary Agreement on Agri-Food Development

On December 14, 1984, the Government of Canada entered into an Economic and Regional Development Agreement with the Province of Quebec. Programs funded under the agreement are: (1) Research and Development—including contract research and food research; (2) Technological Innovations and New Initiatives—including agricultural production, conservation, processing and marketing; and (3) Soil Conservation and Improvement—including inventory of soil degradation problems, soil and water conservation research, and technology transfer in soil and water conservation.

Funding for projects under this agreement is evenly shared by the Federal and provincial governments. Because projects under this program are limited to Quebec, we preliminarily determine that the Federal government's contribution is limited to enterprises or industries located in a specific region of Canada and is therefore countervailable. During the periods of review, no benefits from this program were provided to swine producers. Therefore, we find no benefit from this program during our periods of review. During the next review, we will review projects funded under this program.

Provincial Price Stabilization Programs

1. Saskatchewan Hog Assured Returns Program (SHARP)

SHARP was established in 1976 pursuant to the Saskatchewan Agricultural Returns Stabilization Act. SHARP provides stabilization payments to hog producers in Saskatchewan at times when market prices fall below a designated "floor price." The program is administered by the Saskatchewan Pork Producers, Marketing Board on behalf of the provincial Department of Agriculture. Participation is voluntary and is open to all hog producers in the province. Coverage is limited to 1,500 indexed hogs per producer each quarter. Under the Saskatchewan Agricultural Returns Act, the provincial government may establish a stabilization plan for any agricultural commodity. However, only hogs and cattle have such plans. In accordance with the Tripartite Agreement, SHARP is being phased out and will be terminated by March 31, 1991. No producers have been allowed to join SHARP since December 31, 1985.

The program is funded by levies on the sale of hogs from participating producers and by matching amounts from the provincial government. After the Tripartite Agreement was implemented on July 1, 1986, SHARP payments were reduced by the amount of Tripartite program payments. Producer levies range from 1.5 to 4.5 percent of market returns on the sale of hogs covered by the program. Whenever the balance in the SHARP account is insufficient to make payments to participants, the provincial government lends the needed funds to the program at terms consistent with commercial considerations. The principal and interest on these loans are repaid by the Board using the producer and provincial contributions.

The support price for this program is calculated quarterly using the total of cash production costs plus 75 percent of noncash costs. Stabilization payments are made when the market price is below the support price. During FY 1986/87, payments were made in two quarters. During FY 1987/88, payments were made in three quarters.

Because payments from this program were provided to indexed hogs and cattle only, we preliminarily determine that the program is limited to a specific enterprise or industry or group of enterprises or industries and is countervailable.

To calculate the benefit, we allocated the province's half of the total stabilization payments over the total weight of live swine (minus sows and boars) produced in Saskatchewan during FY 1986/87. We then weight-averaged the benefit by Saskatchewan's share of total Canadian exports of this merchandise (minus sows and boars) to the United States. We made the same calculation for FY 1987/88. On this basis, we preliminarily determine the benefit to be zero for sows and boars for both periods of review. We preliminarily determine that the benefit for all other swine is Can$0.0001/lb. during FY 1986/87 and Can$0.0001/lb. during FY 1987/88.

2. British Columbia Farm Income Insurance Plan (FIP)

The FIP was established in 1979 in accordance with the Farm Income Insurance Act of 1973 (the Farm Act) in order to assure income for farmers when commodity market prices fluctuate below basic costs of production. The guidelines for the individual commodities receiving benefits are in Schedule B of the Farm Act. Schedule B4 is the guidelines for swine producers.

The program is administered by the provincial Ministry of Agriculture and Food and the British Columbia Federation of Agriculture, and is funded equally by producers and the provincial government. Premiums are paid in all quarters regardless of market results.

FIP payments are calculated quarterly based on the difference between costs of production and market returns. Participating producers receive FIP payments for calendar quarters during which costs of production exceed market returns. The basic costs of production and market returns are calculated quarterly according to a cost of production model described in the Farm Act. The same per unit cost of production model is used for all products receiving benefits. The Farm Act requires that ASA payments to individual producers be added to the market return price. Payments were made to indexed hog producers for two quarters of each of the two review periods.

FIP is available to farmers producing commodities specified in the Schedule B guidelines. Therefore, we preliminarily determine that this program is countervailable because payments were limited to a specific group of enterprises or industries.

To calculate the benefit, we followed the same methodology as described for the Saskatchewan SHARP program (see section 1 under Provincial Price Stabilization Programs). On this basis, we preliminarily determine the benefit

to be zero for sows and boars during both periods of review. We preliminarily determine the benefit for all other swine to be less than Can$0.0001/lb. for FY 1986/87 and less than Can$0.0001/lb. for FY 1987/88.

3. Manitoba Hog Income Stabilization Plan (HISP)

The HISP was created in 1983 pursuant to the Farm Income Assurance Plans Act to provide income support payments to producers of indexed hogs. Sows and boars were not eligible for payouts. The program was terminated on June 28, 1986. It was funded by premiums from participating producers and from the Government of Manitoba. Whenever the balance in the HISP account was insufficient to make payments to participants, the provincial government loaned the needed funds to the program. Because the HISP provided payments only to hog producers, we preliminarily determine that this program was provided to a specific group of enterprises or industries and is therefore countervailable.

Payouts from HISP were made during FY 1986/87 for the first and second calendar year quarters of 1986. The last payout from the program was made in July 1986. Upon termination of the HISP on June 28, 1986, the Province of Manitoba agreed to absorb the accumulated deficit of the plan. Subsequent to the termination, the HISP received funding from the provincial government to cover the second calendar year quarter payouts. Because the province imposed no obligations in return, we consider the absorption of the accumulated deficit and the subsequent funding to be grants. We divided the total grant by the total live weight of swine (minus sows and boars) produced in Manitoba during the period of review. We then weight-averaged the result by Manitoba's share of total Canadian exports of this merchandise (minus sows and boars) to the United States. On this basis, we preliminarily determine the benefit to be zero for sows and boars and Can$0.0040/lb. for all other swine during FY 1986/87, our first period of review. There was no benefit to hog producers during FY 1987/88, our second period of review, because the program was terminated and no payouts were made.

4. New Brunswick Hog Price Stabilization Plan (NBHPSP)

The NBHPSP was established in 1974 to assure hog producers greater income stability during periods of both high and low market prices. The plan is administered jointly by the New Brunswick Department of Agriculture Hog Stabilization Board and the New Brunswick Hog Marketing Board. Participation in the plan is voluntary. Producers who sell through the Marketing Board are eligible to receive payments on a maximum of 7,500 hogs per year. Only hogs indexing 100 or above (sows and boars are not eligible) are eligible for stabilization payments. Because this program provided payments that were limited to a specific industry, we preliminarily determine that it is countervailable.

Because New Brunswick did not export hogs to the United States during either of the periods of review, we preliminarily determine that there were no countervailable benefits from this program during the two periods of review.

5. Newfoundland Hog Price Support Program

The Newfoundland Farm Products Corporation, on behalf of the provincial government, pays hog producers a subsidy on all hogs indexing 80 or above (sows and boars are not eligible) purchased by the corporation. Effective April 1, 1986, the calculation of the payout is made according to a formula based on the Newfoundland Farm Products Corporation price plus 75 percent of the difference between the cost of production and the Newfoundland Farm Products price. The Newfoundland Farm Products Corporation price is the average weekly Ontario price plus two cents a pound. The cost of production is updated quarterly. Producers do not contribute to this program. Hogs are the only agricultural commodity that receive stabilization payments in Newfoundland. Because the program provided payments that were limited to a specific industry, we preliminarily determine that it is countervailable.

To calculate the benefit, we followed the same methodology as described for the Saskatchewan SHARP program (see section 1 under Provincial Price Stabilization Programs). On this basis, we preliminarily determine the benefit for sows and boars to be zero during both periods of review and the benefit for all other swine to be less than Can$0.0001/lb. for FY 1986/87. Because Newfoundland did not export hogs to the United States during 1987/88, we preliminarily determine there was no countervailable benefit during 1987/88.

6. Nova Scotia Pork Price Stabilization Program (NSPPSP)

Pursuant to the Nova Scotia Natural Products Act, the NSPPSP is administered under the Pork Producers Marketing Plan of August 9, 1983. On September 20, 1985, the plan was revised from a grant and loan program to a grant-only stabilization plan. The purpose of the program is to assure price stability for hogs by compensating farmers for fluctuations in hog prices and by assuring that producers recover direct operating costs. Participation is voluntary and is open to all hog producers who sell through the Nova Scotia Pork Price Stabilization Board. Maximum eligibility is established annually according to the producers' current production levels. Indexed hogs (sows and boars are not eligible) were the only agricultural commodity that received stabilization payments during the periods of review. Because this program is limited to a specific industry, we preliminarily determine that it is countervailable.

To calculate the benefit, we followed the same methodology as described for the Saskatchewan SHARP program (see section 1 under Provincial Price Stabilization Programs). On this basis, we preliminarily determine the benefit for sows and boars to be zero during both periods of review and the benefit for all other swine to be less than Can$0.0001/lb. for FY 1986/87. Because Nova Scotia did not export hogs to the United States during 1987/88, we preliminarily determine there was no countervailable benefit during 1987/88.

7. Prince Edward Island (PEI) Price Stabilization Program

The PEI Natural Products Marketing Act established marketing boards for hogs, dairy products, tobacco, pedigreed seed, pulp trees, meat, eggs, and cole crops. In 1974, the PEI Hog Commodity Marketing Board established the PEI Price Stabilization Program. The purpose of the program is to provide income stability to hog producers. Support levels are set by the Stabilization Board at 95 percent of the cost of production. Producers contribute to the fund only when the weekly market price of hogs exceeds the support price by Can$3. Whenever the weekly price of hogs is below the support price, the PEI Hog Commodity Board makes stabilization payments from the fund. Half the payment is contributed by the provincial government, and the other half is drawn from the producers' equity in the fund. In the event that the producers' equity in the fund is exhausted, the provincial government assumes the producers' portion of the stabilization payment in the form of an interest-free loan, which is repaid when the fund is in a surplus position.

Payments are made only on hogs indexing between 67 and 114 (sows and

boars are not eligible). Participation in the program is voluntary, and there are no minimum production requirements. However, producers are only eligible to receive stabilization payments on the number of hogs equal to the average number of hogs marketed in the previous quarter, up to a ceiling of 4,300 hogs per year.

Although marketing boards were established for a variety of commodities, a price stabilization plan existed only for hogs. Therefore, hogs were the only agricultural commodity in PEI that received stabilization payments during the review periods. We preliminarily determine that this program is countervailable because it provided stabilization payments and loans inconsistent with commercial considerations, to a specific enterprise or industry or group of enterprises or industries.

To calculate the benefit, we followed the same methodology as described for the Saskatchewan SHARP program (see section 1 under Provincial Price Stabilization Programs). On this basis, we preliminarily determine the benefit for sows and boars to be zero and less than Can$.0001/lb. for all other swine during both periods of review.

8. Quebec Farm Income Stabilization Insurance Programs (FISI)

This program was established in 1976 under the "Loi sur l'assurance-stabilisation des revenus agricoles" (the FISI). The program is administered by the Regie des Assurances Agricoles du Quebec (the Regie). The purpose of the program is to guarantee a positive net annual income to participants whose income is lower than the stabilized net annual income. The stabilized net annual income is calculated according to a cost of production model that includes an adjustment for the difference between the average wage of farm workers and the average wage of all other workers in Quebec. When the annual average farm worker income is lower than the stabilized net annual income, the Regie makes a payment to the participant at the end of the year.

Two-thirds of the funding for the program is provided by the provincial government and one-third by producer assessments. Participation in a stabilization scheme is voluntary. However, once a producer enrolls in a program, he must make a five-year commitment. The maximum number of feeder hogs eligible to be insured is 5,000, and a maximum of 400 sows may be insured. Whenever the balance in the FISI account is insufficient to make payments to participants, the provincial government lends the needed funds to the program. The principal and interest on these loans are repaid by the Regie using the producer and provincial contributions.

The program covers calves, feeder cattle, potatoes, piglets, feeder hogs, corn, oats, wheat, barley, heavy veal, and sheep. Several major agricultural commodities, such as eggs, dairy products, and poultry, which make up almost half of Quebec's total agricultural production, are not covered under this program. Because this program provides benefits to only 12 commodities, we determine that it is limited to a specific group of enterprises or industries, and is therefore countervailable.

To calculate the benefit, we multiplied the total payments for FY 1986/87 made under both the piglet and feeder hog programs by two-thirds to factor out producer assessments. We then weight-averaged the benefit by Quebec's share of total Canadian exports of this merchandise (minus sows and boars) to the United States. We made the same calculation for FY 1987/88. On this basis, we preliminarily determine the benefit to be zero for sows and boars for both periods of review. We preliminarily determine that the benefit for all other swine is Can$0.0001/lb. during our first period of review and Can$0.0001/lb. during our second period of review.

Other Provincial Programs

1. Alberta Crow Benefit Offset Program

During our periods of review, this program operated from July 1, 1987 to March 31, 1988. The purpose of this program, which is administered by Agriculture Alberta, is to eliminate market distortions in feed grain prices created by the federal government's policy on grain transportation. Assistance is provided on feed grain produced in Alberta, feed grain produced outside Alberta but sold in Alberta, and feed grain produced in Alberta to be fed to livestock on the same farm. The government provides certificates to registered feed grain users and registered feed grain merchants, which can be used as partial payments for grains purchased from grain producers. Feed grain producers who feed their own grain to their own livestock submit a claim directly to the government for payment.

Hog producers receive benefits in one of three ways. Hog producers who do not grow any of their own feed grain receive certificates which are used to cover part of the cost of purchasing grain. Second, hog producers who grow all of their own grain submit a claim to the Government of Alberta for direct payment. Finally, hog producers who grow part of their own grain but also purchase grain receive both certificates and direct payments.

Because this program is limited to feed grain users, we preliminarily determine that it is limited to a specific enterprise or industry, or group of enterprises or industries, and is therefore countervailable.

The payout from this program during our period of review was Can$13 per ton. Because respondent furnished no information on this program, as best information available we used data in the *Fresh, Chilled, and Frozen Pork from Canada* case (54 FR 30774, July 24, 1989) and published in *Agriculture in Alberta,* which states that barley is the primary grain fed to hogs and that hogs consumed 15 percent of the province's barley production. Therefore, to calculate the benefit, we used 15 percent of the total payout to feed grain users in Alberta allocated over the live weight of swine produced in Alberta. We then weight-averaged the benefit by Alberta's share of total Canadian exports of live swine to the United States. On this basis, we preliminarily determine the benefit to be Can$0.0028/lb. for FY 1987/88.

2. New Brunswick Swine Assistance Program

In FY 1981/82, the Farm Adjustment Board, created by the Farm Adjustment Act, provided interest subsidies on medium-term loans to hog producers in order to alleviate high interest charges on the producers' short-term debt for operating credit. In 1985, the name of the Farm Adjustment Act changed to Agricultural Development Act. The program was available only to hog producers who entered production or underwent expansion after 1979. The loans bore a five-year term and interest rates of 10.45 percent during FY 1986/87 and 9.95 percent for FY 1987/88. During the periods of review, the average weighted commercial interest rates on medium-term loans was 11.06 percent in 1986 and 11.07 percent in 1987. Because these loans were provided to a specific industry on terms inconsistent with commercial considerations, we preliminarily determine that they are countervailable.

Because New Brunswick did not export hogs to the United States during the periods of review, we preliminarily determine that there were no countervailable benefits from this program during the periods of review.

3. New Brunswick Livestock Incentives Program

This program, which operates under the New Brunswick Livestock Incentives Act, OC 71–544, provides livestock loans and free loan guarantees to producers for purchasing cattle, sheep, swine, foxes and mink for breeding purposes, and for feeding and finishing livestock for slaughter. During FY 1986–87, 13.93 percent of total loans and loan guarantees went to swine. During FY 1987–88, 11.92 percent went to swine. In addition, a 20-percent refund of the loan principal is granted to farmers upon repayment of the breeder loans. We preliminarily determine that this program is countervailable because it provides loan guarantees and loans on terms inconsistent with commercial considerations to a specific industry.

Because New Brunswick did not export hogs to the United States during of the periods of review, we preliminarily determine that there were no countervailable benefits from this program during the periods of review.

4. New Brunswick Hog Marketing Program

Under this program, a transportation pool funded by the Hog Marketing Board, producers, and packers was established to assist in equalizing transportation costs of moving hogs to market from all areas of New Brunswick. The Livestock Branch of the New Brunswick Department of Agriculture contributed up to Can$0.64 for each hog sold by the New Brunswick Hog Marketing Board during the review periods. We preliminarily determine that this program is not countervailable because benefits under this program accrue only to hogs slaughtered in New Brunswick.

5. New Brunswick Swine Industry Financial Restructuring Program

This program was created by the Farm Adjustment Act (OC 85–98) and became effective April 1, 1985. During the period of review, the Government of New Brunswick granted hog producers indebted to the Board a rebate of the interest on that portion of their total debt, the "residual debt," that, on March 31, 1984, exceeded the "standard debt load." The standard debt load is defined in the program regulations as the amount of debt which a swine producing unit can, in the opinion of the Board, reasonably be expected to service. The residual debt does not begin to accrue interest again until the debt load is no longer "excessive."

We preliminarily determine that this program is countervailable because the government's rebate of interest and interest repayment holiday are loan terms inconsistent with commercial considerations. We consider both the interest rebate and the interest holiday to confer benefits. Because New Brunswick did not export hogs to the United States during the periods of review, we preliminarily determine that there were no countervailable benefits from this program during the periods of review.

6. New Brunswick Swine Assistance Policy on Boars

This program is administered by the New Brunswick Department of Agriculture, Animal Industry Branch, for the purpose of improving the quality of hog production. The program provides grants to swine producers for the purchase of boars. Eligible producers are entitled to receive up to Can$110 for the purchase of a maximum of ten boars during a two-year period.

We preliminarily determine that this program is countervailable because it is limited to a specific industry. Because New Brunswick did not export live swine to the United States during the periods of review, we preliminarily determine that there were no countervailable benefits from this program during the periods of review.

7. Newfoundland Weanling Bonus Incentive Policy

This program is operated by the Agriculture Branch, Department of Rural, Agricultural and Northern Development. A payment of Can$3 is provided for each weanling produced by individuals engaged in swine production. Payments are limited to a maximum of Can$2,000 to each producer in a fiscal year.

Because this program is provided only to weanling producers, we preliminarily determine that it is limited to a specific enterprise or industry and is therefore countervailable.

Because the allegation that this program provided a benefit was untimely submitted for the first period of review, we calculated a benefit for FY 1987/88 only (see Supplementary Information: Background). Because Newfoundland did not export live swine to the United States during FY 1987/88, we preliminarily determine that there was no benefit from this program during that period of review.

8. Nova Scotia (NS) Swine Herd Health Policy

The Nova Scotia Department of Agriculture and Marketing administers a herd health program whereby it reimburses veterinarians for house calls made to producers of commercial and purebred breeding livestock. Breeding livestock is not covered by the order on live swine. Therefore, we preliminarily determine that this program isnot countervailable in these reviews because it is available only for breeding stock.

9. Nova Scotia (NS) Transportation Assistance

The NS Department of Agriculture and Marketing provides grants to the NS Hog Marketing Board, which in turn distributes the funds to producers, in order to equalize the cost of transporting hogs to slaughter facilities. The funds are available only to farmers who produce and slaughter their hogs in Nova Scotia. Because this program does not affect live swine exported to the United States, we preliminarily determine that it is not countervailable.

10. Nova Scotia Improved Sire Policy

This program is administered by the Nova Scotia Department of Agriculture and Marketing, Livestock Services Branch, for the purpose of improving the quality of hog production. The program provides grants to purebred and commercial swine producers for the purchase of boars. Because this program is limited to a specific industry, we preliminarily determine that it is countervailable.

Because the allegation that this program provided a benefit was untimely submitted for the first period of review, we calculated a benefit for FY 1987/88 only (see **SUPPLEMENTARY INFORMATION**: Background). Because Nova Scotia did not export live swine to the United States during FY 1987/88, we preliminarily determine that there was no countervailable benefit from this program during that period of review.

11. Ontario Farm Tax Rebate Program

This program replaced the Ontario Farm Tax Reduction Program. Eligible farmers receive a rebate of 100 percent of property taxes levied on farm properties for municipal and school purposes; levied for local improvements under the Local Improvement Act; levied under the Provincial Land Tax Act or the Local Roads Boards Act; imposed under the Local Services Boards Act; and levied under the Provincial Land Tax Act. Farm property includes farm lands and outbuildings. Eligible properties include farms that produce food, fish, breeding horses and donkeys, pregnant mare's urine, fur-bearing animals, tobacco, flowers, nursery stock, sod or ornamentals.

Any resident of Ontario may receive a rebate if he/she owns and pays taxes on eligible properties. Residents of Southern and Western Ontario must produce farm products with a gross value of at least Can$8,000 and residents of Northern and Eastern Ontario must produce products with a gross value of at least Can$5,000. Because the eligibility criteria vary depending on the region of Ontario in which the farm is located, we preliminarily determine that this program is countervailable.

According to the *1986 Census of Agriculture, Statistics Canada,* 4.7 percent of all Ontario swine farmers have sales valued within theCan$5,000 to $8,000 range. Therefore, we assumed as best information available, that 4.7 percent of farmers in the Northern and Eastern Ontario have sales valued within the Can$5,000 to $8,000 range. We calculated the benefit for FY 1986/87 by allocating 4.7 percent of the total payout to farmers in Eastern and Northern Ontario over the total live swine produced in all of Ontario during the corresponding period. We then weight-averaged the result by Ontario's share of total Canadian exports of this merchandise to the United States during the corresponding period. We did the same calculation for FY 1987/88. On this basis, we preliminarily determine the benefit from this program for all swine to be Can$0.0001/lb. for FY 1986/87 and Can$0.0001/lb. for FY 1987/88.

12. Ontario (Northern) Livestock Improvement and Transportation Assistance Programs

The Northern Livestock Improvement Program reimburses farmers for up to 20 percent of the purchase cost of breeding stock, including dairy cows, heifers, beef bulls, rams, ewes, and boars. A maximum of Can$2,500 may be reimbursed to an individual during a three-year period. Swine producers are reimbursed for a maximum of Can$100 per boar. The Northern Livestock Transportation Assistance Program reimburses producers living in Northern Ontario 50 percent of the costs of transporting high quality breeding stock from Southern and Northern Ontario.

Because these programs provide payments that are limited to livestock producers in Northern Ontario, we preliminarily determine that they are countervailable. To calculate the benefit for each period of review, we divided the total payment to hog producers under these programs by the total live weight of swine produced in Ontario during the corresponding period. We then weight-averaged the result by Ontario's share of Canadian exports of live swine to the United States during the corresponding period of review. On this basis, we preliminarily determine the benefit for all swine to be less than Can$0.0001/lb. for FY 1986/87 and less than Can$0.0001/lb. for FY 1987/88.

13. Ontario Weaner Pig Stabilization Plan

This program was statutorily terminated on March 31, 1985. Financial statements of the Farm Income Stabilization Commission of Ontario show no payouts for this program during the periods of review. Therefore, there was no benefit from this program.

14. Ontario Pork Industry Improvement Plan (OPIIP)

This five-year plan is effective from April 1, 1986 to March 31, 1991. The plan provides grants to Ontario swine producers to enable them to improve their productivity, profitability and competitive position by improving their efficiency. To be eligible for the plan, producers must be residents of Ontario, own or lease facilities in Ontario for swine production and have at least 20 sow equivalents. One sow equivalent is equal to one sow or 15 marketweight hogs marketed annually. During the FY 1987/88 period of review, Ontario swine producers received grants under the following programs: swine production analysis, swine ventilation, productivity and quality improvement, rodent control enterprise analysis, feed analysis, private veterinary herd health, artificial insemination, education, and establishment-maintenance-restocking.

Because the OPIIP provides grants only to swine producers, we preliminarily determine that it is limited to a specific enterprise or industry and is therefore countervailable.

Because the allegation that this program provided a benefit was untimely submitted for the first period of review, we calculated a benefit for FY 1987/88 only (see Supplementary Information: Background). To calculate the benefit, we allocated the total of all grants provided to producers during the FY 1987/88 review period over the total live weight of hogs produced in Ontario during this period of review. We then weight-averaged the result by Ontario's share of total Canadian exports of live swine to the United States during the period of review. On this basis, we preliminarily determine the benefit from this program to be Can$0.0005/lb. for all swine.

15. Prince Edward Island (PEI) Hog Marketing and Transportation Subsidies

The PEI Department of Agriculture and Marketing provides grants to one hog packer in order to defray the cost of processing and transportation. We preliminarily determine that this program is not countervailable under this order because the benefit is provided to a packer of pork products, and the order covers only benefits on the production of live swine.

16. PEI Swine Development Program

The Department of Agriculture and Marketing pays a bonus to breeders who purchase boars or purebred and crossbred gilts. The boars and gilts must meet certain Record of Performance standards and are sold as breeding stock. Breeding stock, bred and sold as breeding stock, is not covered by the order on live swine. Therefore, this program is not countervailable under this order.

17. PEI Interest Payments on Assembly Yard Loan

The PEI government provided a grant to hog producers by assuming the interest on a loan granted to hog producers for the purpose of constructing a hog assembly yard. Because this grant was limited to a specific industry, we preliminarily determine that it is countervailable.

To calculate the benefit, for each period of review we allocated the interest payment assumed by the province, over PEI's total swine production. We then weight averaged the benefit by PEI's share of total Canadian exports of live swine to the United States during the respective periods. On this basis, for both periods of review, we preliminarily determine the benefit to be less than Can$0.000001/lb. for all live swine.

18. PEI Swine Incentive Policy Program

This program was established to provide incentives for the increased and efficient production and management of hogs in order for the industry to be more competitive on a regional, national and international basis. The program is administered by the Livestock Section of the Extension Services Branch of the PEI Department of Agriculture. This program provides incentive payments for increased production; cash advances for new construction based on the additional pigs the facility is expected to produce; direct payments on all hogs sold either through the PEI Hog Commodity Marketing Board or to local butcher shops for slaughter locally; payments for participation in the PEI Swine Productivity Program and recognized Herd Health Program; and a bonus of Can$30 per gilt for purchase of minimal disease status gilts. PEI Department of Agriculture regulations

limit the production incentive and the new construction payments to swine slaughtered in PEI. Because this program is limited to swine producers, we preliminarily determine that it is provided to a specific industry and that it is countervailable.

Because the allegation that this program provided a benefit was untimely submitted for the first period of review, we calculated a benefit for the FY 1987/88 only (see Supplementary Information: Background). To calculate the benefit, we allocated the total payout from the program, less the production incentive, the new construction payouts, and the direct payments on all hogs slaughtered locally, over the live weight of swine produced in PEI. We then weight-averaged the benefit by PEI's share of total Canadian exports of live swine to the United States. On this basis, we preliminarily determine the benefit to be less than Can$0.0001/lb. during the FY 1987/88 period of review.

19. Quebec Productivity Improvement and Consolidation of Livestock Production Program

This program was established in April 1987 to provide financial assistance to livestock producers for the diversification and consolidation of farm operations. The program is limited to producers with small farming operations and is divided into eight subprograms. Swine producers are eligible for only the Farm Building Improvements Subprogram. This subprogram provides grants for changes to existing piggeries in order to consolidate single-purpose operations into farrow-to-finish operations. The grants cover up to 30 percent of the actual cost of the conversion as well as the purchase and installation of special equipment.

To be eligible for assistance, applicants must be recognized farm producers according to the Farm Producers' Act and be registered with the Bureau de Renseignements Agricoles. Producers operating farrowing facilities must maintain between 40 and 80 sows, and finishing farms must maintain between 500 and 1,000 hogs. The maximum assistance is Can$200 per sow and Can$25 per hog, with a maximum of Can$15,000 per farm operation for the duration of the program.

Because this program is limited to livestock producers, we preliminarily determine that it is limited to a specific group of enterprises or industries, and is therefore countervailable.

Because this program was established in April 1987, we calculated a benefit only for the period FY 1987/88. We allocated the total payout to swine producers over the total live weight of hogs produced in Quebec during our second period of review. We then weight-averaged the result by Quebec's share of total Canadian exports of swine to the United States during the period of review. On this basis, we preliminarily determine the benefit to be less than Can$0.0001/lb. for all swine during FY 1987/88.

20. Quebec Regional Development Assistance Program

This program was established in April 1987 to promote regional development in Quebec. The program consists of four subprograms: (1) Soil upgrading; (2) consolidation of cattle and sheep production; (3) assistance for transporting livestock; and (4) marketing assistance. The Livestock Transportation Subprogram is the only one available to hog producers. This subprogram provides financial assistance to eligible producers for transporting animals to a government inspected slaughterhouse or to a public market. Quebec is divided into twelve agricultural regions, only five of which (three full regions and parts of two others) are eligible for aid under the subprogram. For purposes of this program, these five regions are divided into seven zones based on the distance from the Montreal-Quebec triangle. The assistance offered varies according to the zone in which the applicant's operation is located.

Because this subprogram is limited to livestock producers in specific regions of Quebec, we preliminarily determine that it is limited to a specific group of enterprises or industries located in a specific region within the province, and is therefore countervailable.

This program became operational in April 1987; therefore, we calculated a benefit for only FY 1987/88, our second period of review. Because respondent did not provide the percent of assistance provided for transportation to slaughterhouses and to public market, to calculate the benefit, we allocated the total payout to swine producers by the total live weight of hogs produced in Quebec during our second period of review. We then weight-averaged the result by Quebec's share of total Canadian exports of live swine to the United States during the period of review. On this basis, we preliminarily determine the benefit for FY 1987/88 to be less than Can$0.0001/lb. for all swine.

21. Saskatchewan Livestock Investment Tax Credit

Saskatchewan's 1984 Livestock Tax Credit Act provides tax credits to individuals, partnerships, cooperatives and corporations who own and feed livestock in Saskatchewan for slaughter. Claimants must be residents of Saskatchewan and pay Saskatchewan income taxes. Eligible claimants receive credits of Can$25 for each bull, steer or heifer, Can$2 for each lamb and Can$3 for each hog. The tax credits may be carried forward for seven years. Each year in which the credit is used, there is a Can$100 deduction from the total credits earned. The credits must be included as taxable income the year after receipt. The credit is available to hogs indexing 80 or higher. We preliminarily determine that this program is available only to livestock producers and therefore countervailable because it is provided only to specific enterprises or industries.

To calculate the benefit, for each year we allocated the aggregate amount of tax credits used by hog producers, minus the Can$100 deduction for each of the estimated number of hog producer claimants, over the total live weight of live swine (minus sows and boars) produced in Saskatchewan. We then weight-averaged the result by Saskatchewan's share of total exports (minus sows and boars) of this merchandise to the United States. On this basis, we preliminarily determine the benefit for live swine to be Can$0.0001/lb. for FY 1986/87 and Can$0.0001/lb. for FY 1987/88. For both periods of review, the benefit is zero for sows and boars.

22. Saskatchewan Livestock Facilities Tax Credit Program

This program was implemented on January 1, 1986 and provides tax credits to livestock producers for investment in livestock production facilities. The credit may only be used to offset provincial taxes. Applications for tax credits must be received by Saskatchewan Agriculture no later than six months after the project is completed.

Livestock covered by this program can be raised for either breeding or slaughter. Eligible livestock include cattle, horses, sheep, swine, goats, poultry, bees, fur-bearing animals raised in captivity, or any other designated animals. Investments covered under the program include new buildings, improvements to existing livestock facilities, and any stationary equipment related to livestock facilities.

The program pays 15 percent of 95 percent of project costs, or 14.25 percent of total costs, in order not to overlap the Business Investment Tax Credit Program, a federal program. Participants may carry forward any unused credit for up to seven years. Because this program is limited to livestock producers, we determine that it is limited to a specific group of enterprises or industries and is therefore countervailable.

To calculate the benefit, we allocated the tax credits used by hog producers during each period of review, over the total live weight of swine produced in Saskatchewan during the corresponding period. We then weight-averaged the result by Saskatchewan's share of total exports of this merchandise to the United States during the periods of review. On this basis, we preliminarily determine the benefit for all live swine to be less than Can$0.0001/lb. during FY 1986/87 and less than Can$0.0001/lb. during FY 1987/88.

Preliminary Results of Review

As a result of our reviews, we preliminarily determine the net subsidy for the period April 1, 1986 through March 31, 1987 to be *de minimis* for sows and boars and Can$0.0061/lb. for all other swine. Further, we preliminarily determine the net subsidy for the period April 1, 1987 through March 31, 1988 to be Can$0.0068/lb. for sows and boars and Can$0.0071/lb. for all other swine.

The Department intends to instruct the Customs Service to liquidate and to assess no countervailing duties on shipments of sows and boars and Can$0.0061/lb. on all other live swine for all shipments exported on or after April 1, 1986 and exported on or before March 31, 1987. It also intends to instruct the Customs Service to liquidate and to assess countervailing duties of Can$0.0068/lb. on shipments of sows and boars and Can$0.0071 on all other live swine for all shipments exported on or after April 1, 1987 and on or before March 31, 1988.

As provided by section 751(a)(1) of the Tariff Act, the Department also intends to instruct the Customs Service to collect cash deposits of estimated countervailing duties of Can$0.0068/lb. on shipments of sows and boars, and Can$0.0071/lb. for all other swine entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. This deposit requirement will remain in effect until publication of the final results of the next administrative review.

Parties to the proceeding may request disclosure of the calculations methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with section 355.38(e) of the Department regulations.

Any request for disclosure under an administrative protective order must be made no later than five days after the date of publication.

The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any case or rebuttal briefs or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and § 355.22 of the Department's regulations.

Dated: May 11, 1990.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 90-11648 Filed 5-18-90; 8:45 am]

BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Proposed Boundary Expansion for the Hudson River (New York) National Estuarine Research Reserve

AGENCY: Marine and Estuarine Management Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Proposed boundary expansion.

SUMMARY: Notice is hereby given that the Marine and Estuarine Management Division, Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, is considering the State of New York's request to expand the boundary of the Stockport component of the Hudson River National Estuarine Research Reserve.

The Hudson River National Estuarine Research Reserve (Reserve) was designated in 1982 pursuant to section 315 of the Coastal Zone Management Act of 1972, as amended. The Reserve includes four sites, Piermont Marsh, Iona Island, Tivoli Bays, and Stockport Flats, along 100 miles of the tidal Hudson.

The State of New York recently requested NOAA approval to amend the Reserve's boundary to include Nutten Hook, a 271-acre parcel of tidal wetlands and upland contiguous to the north boundary of the Stockport component. The purpose of this boundary expansion is to provide increased public access for education and interpretation at this Reserve component.

The tidal wetlands at Nutten Hook include emergent marsh, mudflat, vegetated sand flats, and vegetated shallows. These areas harbor a number of unusual species, and excellent examples of several freshwater tidal communities. They are designated under the New York Coastal Management Program as Significant Coastal Fish and Wildlife Habitats, and are included in the New York Natural Areas Registry.

The State of New York recently acquired 131 acres at the north end of Nutten Hook (within the proposed expanded boundary), and plans to acquire the remaining 140 acres with funds from the 1990 New York State Environmental Quality Bond Act.

Any person wishing to comment on the proposed boundary expansion may forward written comments to Mr. Joseph A. Uravitch, Chief, Marine and Estuarine Management Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, 1825 Connecticut Avenue, NW., suite 714, Washington, DC 20235. Comments must be submitted no later than thirty calendar days from issuance of this notice.

Federal Assistance Catalog Number 11.420 Coastal Zone Management Estuarine Sanctuaries

Virginia K. Tippie,

Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 90-11678 Filed 5-18-90; 8:45 am]

BILLING CODE 3510-08-M

[Modification No. 1 to Permit No. 698]

Marine Mammals; Permit Modification; West Coast Whale Research Foundation (P349)

Notice is hereby given that pursuant to the provisions of § 216.33(d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216) and § 220.24 of the regulations on endangered species (50 CFR parts 217–222), Scientific Research Permit No. 698 issued to the West Coast Whale Research Foundation, c/o Elizabeth A. Mathews and Daniel McSweeney, Applied Sciences 273, Center for Marine Studies, on February 16, 1990 (55 FR 9481) as modified on October 4, 1985 (50 FR 41550), March 6, 1987 (52 FR 7007), and July 31, 1987 (52 FR 6815) is further modified as follows:

Section B.9 which reads "The Holder shall submit photographs/film taken under the authority of this Permit to the National Marine Mammal Laboratory (NMML) for inclusion in the centralized computer photo-identification and retrieval system. Submission of photographs/film should be within 180 days of the completion of each year's research. Refer to Section D.9 for specific requirements for submission of photographs/film" is hereby deleted.

This modification becomes effective upon publication in the **Federal Register**.

Documents pertaining to the Permit and all modifications are available for review in the following Offices:

Office of Protected Resources, National Marine Fisheries Service, 1335 East West Hwy., room 7324, Silver Spring, Maryland 20910.

Director, Southwest Region, National Marine Fisheries Service, 800 South Ferry Street, Terminal Island, California 90731-7415.

Director, Alaska Region, National Marine Fisheries Service, 709 West 9th Street, Federal Bldg., Juneau, Alaska 99802

Dated: March 14, 1990.

Nancy Foster,

Director, Office of Protected Resources and Habitat Programs, National Marine Fisheries Service.

[FR Doc. 90–11675 Filed 5–18–90; 8:45 am]

BILLING CODE 3510-22-M

National Technical Information Service

Government Owned Inventions Available for Licensing

The inventions listed below are owned by the U.S. Government, as represented by the National Institute for Standards and Technology, and are available for licensing in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally funded research and development.

Patent Application S.N.7–410,387, "High Current, Very Wide Band Transconductance Amplifier", relates to transconductance amplifiers that are stable over a very wide bandwidth. The invention includes a differential voltage to current converter and a plurality of complementary unipolar current mirror cells. The differential voltage to current converter isolates the input voltage terminal from the common side of the output load current terminal. A plurality of positive current mirror cells are connected in parallel and a plurality of negative current mirror cells are connected in parallel to avoid the need for a single low resistance current sensing resistor and the fabrication problems inherent in such resistors.

Patent Application S.N.7–414,213, "Digitally Synthesized Audio Frequency Voltage Source", relates to voltage waveform generation systems and more particularly to the digital generation of synthetic alternating current voltage waveforms in the audio frequency range. First and second digital to analog converters are connected to the read only memory through latches. The outputs of the first and second converters are alternatively switched between the inverting input and the non-inverting input of an operational amplifier such that one of the first and second converters is connected to the inverting input while the other is connected to the non-inverting input. The output of the operational amplifier is connected to the inverting input through a variable capacitance, the feedback being determined by the one of the first and second converter connected to the inverting input. A clock is used to control the connection of the first and second converter to the inverting input and to control the determination of the feedback.

Technical and licensing information on these inventions may be obtained by writing to: Douglas J. Campion, Center for the Utilization of Federal Technology, P.O. Box 1423, Springfield, VA 22554.

Douglas J. Campion,

Patent Licensing Specialist, Center for Utilization of Federal Technology, National Technical Information Service, U.S. Department of Commerce.

[FR Doc. 90–11643 Filed 5–18–90; 8:45 am]

BILLING CODE 3510-04-M

Patent and Trademark Office

Trademark Affairs Public Advisory Committee;

AGENCY: Patent and Trademark Office.

ACTION: Notice.

SUMMARY: In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the open meeting of the Public Advisory Committee for Trademark Affairs.

Date: The Public Advisory Committee for Trademark Affairs will meet from 10 a.m. until 4 p.m. on June 19, 1990.

Place: U.S. Patent and Trademark Office, 2121 Crystal Drive, Crystal Park 2, Room 912, Arlington, Virginia.

Status: The meeting wil be open to public observation; seating will be available for the public on a first-come-first-served basis. Members of the public will be permitted to make oral comments of three (3) minutes each. Written comments and suggestions will be accepted before or after the meeting on any of the matters discussed. Copies of the minutes will be available upon request.

Matters to be Considered: The agenda for the meeting is as follows:

(1) Finance
(2) Automation
(3) Strategic Planning
(4) Current Trademark Office Practice Issues

Contact Person for More Information: For further information, contact Lynne Beresford, Office of the Assistant Commissioner for Trademarks, room CPK2–910, Patent and Trademark Office, Washington, DC 20231. Telephone: (703) 557–7464.

Harry F. Manbeck, Jr.,

Assistant Secretary and Commissioner of Patents and Trademarks.

[FR Doc. 90–11718 Filed 5–18–90; 8:45 am]

BILLING CODE 3510-16-M

DEPARTMENT OF DEFENSE

Department of the Army

Availability of a Draft Environmental Impact Statement for the Fort Sheridan Base Closure

AGENCY: DOD, U.S. Army.

SUMMARY: Fort Sheridan was recommended for closure by the Defense Secretary's Commission on Base Realignment and Closure. The Commission specifically recommended the relocation of Headquarters, Fourth Army, and Headquarters, U.S. Army Recruiting Command to Fort Benjamin Harrison, IN; and the U.S. Army Recruiting Battalion, Chicago and the U.S. Army Recruiting Brigade, Midwest to leased space in Chicago. This

document focuses upon the environmental and socioeconomic impacts and mitigations associated with the planned closure of Fort Sheridan and realignment activities at Fort Benjamin Harrison and Fort McCoy, WI.

No long-term adverse environmental effects at Fort Sheridan are expected as a result of realignment and closure implementation. The Department of Defense Office of Economic Adjustment is working with the local community to develop reuse alternatives to lessen the socioeconomic impacts. No adverse environmental or socioeconomic impacts are anticipated at either Fort Benjamin Harrison or Fort McCoy.

The public is encouraged to comment on the Draft EIS. Public notices requesting input and comments will be issued, and public hearings will be held in communities adjacent to Fort Sheridan, Fort Benjamin Harrison and Fort McCoy in about one month. A copy of the Draft EIS may be obtained by contacting Mr. Ray Haynes, (502) 582–5693, or writing to: Commander, U.S. Army Engineer District, Louisville, P.O. Box 59, Louisville, Kentucky 40201–0059. Comments and suggestions should be received not later than July 2, 1990.

Dated: May 11, 1990.

Lewis D. Walker,

Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health) OASA (I, L&E).

[FR Doc. 90–11686 Filed 5–18–90; 8:45 am]

BILLING CODE 3710–08–M

Department of the Navy

Naval Research Advisory Committee; Closed Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App. 2), notice is hereby given that the Naval Research Advisory Committee Panel on Suppression of Enemy Fighter Defense Over Land in the Year 2000 and Beyond will meet on June 7–8, 1990. The meeting is scheduled for June 7–8, 1990 at the Center for Naval Analyses, 4401 Ford Avenue, Alexandria, Virginia. The meeting will commence at 8:00 A.M. and terminate at 4:30 P.M. on June 7–8, 1990. All sessions of the meeting will be closed to the public.

The purpose of the meeting is to provide briefings for the panel members related to the ability of U.S. naval forces to suppress enemy fighter defenses over land in support of strike operations, or ground operations in the year 2000 and beyond. The agenda will include briefings and discussions on technology updates, industry perspective, tactics and deficiencies. These briefings and discussions will contain classified information that is specifically authorized under criteria established by Executive Order to be kept secret in the interest of national defense and is in fact properly classified pursuant to such Executive Order. The classified and non-classified matters to be discussed are so inextricably intertwined as to preclude opening any portion of the meeting. Accordingly, the Secreary of the Navy has determined in writing that the public interest requires that all sessions of the meeting be closed to the public because they will be concerned with matters listed in section 552b(c)(1) of title 5, United States Code.

For further information concerning this meeting contact:

Dated: May 10, 1990.

Commander John Hrenko,

U.S. Navy, Office of Naval Research, 800 North Quincy Street, Arlington, VA 22217–5000, Telephone Number: (202) 696–4488.

Sandra M. Kay,

Departemnt of the Navy, Alternate Federal, Register, Liaison Officer.

[FR Doc. 90–11719 Filed 5–18–90; 8:45 am]

BILLING CODE 3810–AE–M

Navy Resale System Advisory Committee; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (5 U.S.C. App 2), notice is given that the Navy Resale System Advisory Committee will meet June 15, 1990 in Pearl Harbor, Hawaii. Sessions of the meeting will commence at 12:30 p.m. and 1:30 p.m. The 1:30 p.m. to 4 p.m. session will be closed to the public.

The purpose of the meeting is to elicit the advice of the committee concerning internal agency personnel rules and practices; privileged commercial or financial information; and information which, if disclosed prematurely, would be likely to significantly frustrate implementation of a proposed agency action. The Secretary of the Navy has therefore determined in writing that the public interest requires the 1:30 p.m. to 4 p.m. session of the meeting to be closed to the public because it will be concerned with matters listed in section 552b(c) (2), (4), and (9)(B) of title 5, United States Code.

For further information concerning this meeting contact: Commander W.T. Kaloupek, SC, USN, Naval Supply Systems Command, NAVSUP 09B, Room 606, Crystal Mall, Building No. 3, Arlington, VA 22202, Telephone Number: (202) 695–5457.

Dated: May 16, 1990.

Jane M. Virga,

Lieutenant, JAGC, U.S. Navy Reserve, Alternate Federal Register, Liaison Officer.

[FR Doc. 90–11720 Filed 5–18–90; 8:45 am]

BILLING CODE 3810–AE–M

DEPARTMENT OF EDUCATION

Proposed Information Collection Requests

AGENCY: Department of Education.

ACTION: Notice of proposed information collection requests.

SUMMARY: The Director, Office of Information Resources Management, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1980.

DATES: Interested persons are invited to submit comments on or before June 20, 1990.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Jim Houser, Desk Officer, Department of Education, Office of Management and Budget, 726 Jackson Place, NW., room 3208, New Executive Office Building, Washington, DC 20503.

Requests for copies of the proposed information collection requests should be addressed to George P. Sotos, Department of Education, 400 Maryland Avenue SW., room 5624, Regional Office Building 3, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: George P. Sotos (202) 732–2174.

SUPPLEMENTARY INFORMATION: Section 3517 of the Paperwork Reduction Act of 1980 (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 Acting Director, Office of Information Resources Management, publishes this notice containing proposed information collection requests prior to submission of these request 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) Frequency of collection; (4) The affected public; (5) Reporting burden; and/or (6) Recordkeeping burden; and (7) Abstract. OMB invites public comment at the address specified above. Copies of the requests are available from George Sotos at the address specified above.

Dated: May 15, 1990.

George P. Sotos,

Acting Director for Office of Information Resources Management.

Office of Educational Research and Improvement

Type of Review: Revision.
Title: Application for Grants Under the College Library Technology and Cooperation Grants Program.
Frequency: Annually.
Affected Public: Non-profit institutions.
Reporting Burden:
Responses: 400.
Burden Hours: 14,400.
Recordkeeping Burden:
Recordkeeper: 0.
Burden Hours: 0.
Abstract: This form is needed for institutions of higher education or non-profit organizations to apply for federal funds under the College Library Technology and Cooperation Grants Program, Title II–D of the Higher Education Act, as amended. The Department uses this information to make grant awards.

Office of Special Education and Rehabilitative Services

Type of Review: Extension.
Title: Telecaption 4000 Rebate Offer.
Frequency: One time.
Affected Public: Individuals or households.
Reporting Burden:
Responses: 37,500.
Burden Hours: 1,238.
Recordkeeping Burden:
Recordkeepers 0.
Burden Hours: 0.
Abstract: This form will be used by consumers to receive a rebate offer for purchasing the telecaption decoder. The National Captioning Institute, (NMCI) funded by the Department will use the information to verify purchase of the decorder in order to mail the rebate to the consumer.

[FR Doc. 90–11685 Filed 5–18–90; 8:45 am]
BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Morgantown Energy Technology Center Grant; Financial Assistance Award to Ohio State University Research Foundation

AGENCY: Morgantown Energy Technology Center Grant, Department of Energy (DOE).

ACTION: Notice of acceptance of a non-competitive financial assistance application for a grant award.

SUMMARY: Based upon a determination made pursuant to 10 CFR 600.7(b)(2) the DOE, Morgantown Energy Technology Center gives notice of its plans to award a 24-month grant to The Ohio State University Research Foundation, 1314 Kinnear Road, Columbus, Ohio 43212, in the amount of approximately $120,000, including cost-sharing of $80,000 by Ohio State University and other industrial participants. DOE's contribution of approximately $40,000 will enhance the research efforts of the University in the development of an improved method for recovering gas from low-permeability reservoirs.

FOR FURTHER INFORMATION CONTACT: Beverly J. Harness, I–07, U.S. Department of Energy, Morgantown Energy Technology Center, P.O. Box 880, Morgantown, West Virginia 26507–0880, Telephone: (304) 291–4089, Procurement Request No. 21–90MC27351.000.

SUPPLEMENTARY INFORMATION: The pending award is based on an unsolicited application for a research project to develop a new methodology for design, control, and optimization of the hydraulic fracturing process. By the development of this process, cost of natural gas extraction from reservoirs will be reduced and well operators will be able to more efficiently produce natural gas by choosing the optional stimulation treatment volume. In view of the expertise of the personnel at Ohio State to be dedicated to this effort and the enhanced benefits to be received by the public because of DOE's financial support, it has been determined that it is appropriate to award this grant to Ohio State University on a noncompetitive basis.

Louie L. Calaway,

Director, Acquisition and Assistance Division, Morgantown Energy Technology Center.

[FR Doc. 90–11735 Filed 5–18–90; 8:45 am]
BILLING CODE 6450–01–M

Issuance of Decisions and Orders by the Office of Hearings and Appeals

Week of February 5 through February 9, 1990.

During the week of February 5 through February 9, 1990, the decisions and orders summarized below were issued with respect to applications for refund or other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Copies of the full text of these decisions and orders are available in the Public Reference room of the Office of Hearings and Appeals, room 1E–234, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, Monday through Friday, between the hours of 1 p.m. and 5 p.m., except federal holidays. They are also available in *Energy Management: Federal Energy Guidelines*, a commercially published loose leaf reporter system.

Dated: May 15, 1990.

George B. Breznay,

Director, Office of Hearings and Appeals.

Refund Applications

AT&T CSO real estate, 02/09/90, RF272–4754

The DOE issued a Decision and Order granting a refund from crude oil overcharge funds to AT&T CSO Real Estate (AT&T) based on its purchases of refined petroleum products during the period August 19, 1973 through January 27, 1981. AT&T used the petroleum products in the course of its normal business activities as a provider of communications services. AT&T was an end-user of refined petroleum products, and was therefore presumed injured by the DOE. A consortium of 30 states and 2 territories (the States) filed objections to AT&T's Application. In its submission, the States attempted to rebut the end-user presumption of injury. The DOE determined that the presumption was applicable to AT&T, and that a refund of $140,805 should be granted.

Atlantic Richfield Company/Northern Illinois Gas Company, 02/08/90, RF304–4255

The DOE issued a Decision and Order concerning an Application for Refund filed by Northern Illinois Gas Company in the Atlantic Richfield Company special refund proceeding. The applicant, a public utility, documented its purchases of 225,542,950 gallons of ARCO napthas. In addition, the

applicant certified that it would pass the entire refund through to its customers and notify the appropriate regulatory commission of the refund received. The DOE determined that the applicant had satisfied all of the necessary requirements for a public utility to receive a refund in the ARCO proceeding. Accordingly, the DOE granted a refund of $165,744 in principal and $58,585 in interest.

Atlantic Richfield Company/Townsend Enterprises, Inc., 02/05/90, RF304–6172

The DOE issued a Decision and order concerning an Application for Refund filed by Robert Townsend on behalf of Townsend Enterprises, Inc., (TEI) in the Atlantic Richfield Company special refund proceeding. In January 1981, the ownership of TEI was transferred from Mr. Townsend to Swearingen-Howard, Inc. However, Mr. Townsend's refund claim is based upon provisions in the"Stock Purchase Agreement" which was executed in conjunction with the sale of Mr. Townsend's TEI stock to Swearingen-Howard. These provisions stated that Mr. Townsend retained the right to any refunds for overpayments prior to the closing date. Mr. Howard, the purchaser of TEI and a signer of the "Stock Purchase Agreement", sent us a letter in which he, in essence, concurred with Mr. Townsend's interpretation of the "Stock Purchase Agreement". Mr. Howard also stated that any ARCO refund for TEI should be paid to Robert Townsend. The DOE concluded that Mr. Townsend should receive a refund totalling $5,065, representing $43,742 in principal and $1,323 in accrued interest.

Borough of Giarardville, 02/08/90, RF272–48353

The DOE issued a Decision and Order granting a refund of $32 to the Borough of Girardville, an end-user of refined petroleum products, in the subpart V crude oil proceeding. The Borough had no records of the gallons of gasoline, diesel fuel, and heating oil it had purchased during the price control period, but it provided the dollar amounts it had paid for these products. The DOE calculated the gallonage by multiplying the dollar values by dollar-per-gallon ratios approved in earlier Decisions: $0.459 per gallon for diesel, $0.703 per gallon for gasoline, $0.80 per gallon for heating oil in 1979, and $1.05 per gallon for heating oil in 1980.

Door County Cooperative, 02/06/90, RF272–49263

The DOE issued a Decision and Order granting a refund from crude oil overcharge funds to Door County Cooperative, an agricultural cooperative, based on its purchases of refined petroleum products during the period August 19, 1973 through January 27, 1981. The applicant demonstrated the volume of its claim by using a reasonable estimate of its purchases. Generally, the DOE grants refunds to a cooperative based on volumes resold to its members, on the condition that the cooperative certify that it will pass through any refund received to those members. As Door had furnished such certification, it was granted a refund of $10,914.

Exxon Corporation/ITT Rayonier, Inc., 02/08/90, RF307–3237

The DOE issued a Decision and Order concerning an Application for Refund filed by ITT Rayonier, Inc. in the Exxon Corporation special refund proceeding. ITT Rayonier, an end-user, purchased products directly and indirectly from Exxon, and was found to be eligible to receive a refund equal to its full allocable share. Accordingly, the DOE granted a refund of $29,722, representing $23,374 in principal and $6,348 in accrued interest.

Exxon Corporation/UCO Oil Company (Landsea Oil Co.) UCO Oil Company, 02/05/90 RF307–8841, RF307–9310

The DOE issued a Decision and Order concerning two Applications for Refund filed in the Exxon Corporation special refund proceeding. The Applications for Refund were filed by two unrelated parties, UCO Oil Co. (Case No. RF307–9310) and Landsea Oil Co. (Case No. RF307–8841), based on purchases of Exxon products made by UCO Oil Co. In March 1981, Landsea Oil Co. purchased all of the capital stock on UCO Oil Co. from UCO, Inc. UCO, Inc. retained ownership of the name "UCO Oil Co." and formed a new corporation under this name after the sale. Both applicants claimed a refund based on the purchases of Exxon products made by the UCO Oil Co. that existed during the consent order period. The DOE determined that Landsea Oil Co. was the proper recipient of the refund in this proceeding because it acquired UCO Oil Co. through a complete stock purchase. Accordingly, Landsea was granted a refund of $2,167, representing $1,717 in principal and $450 in accrued interest. The Application for Refund submitted by UCO Oil Co. (Case No. RF307–9310) was denied.

Exxon Corporation/Witco Chemical Corporation, 02/05/90, RF307–5917

The DOE issued a Decision and Order concerning an Application for Refund filed by Witco Chemical Corp. (Witco) in the Exxon Corporation special refund proceeding. The firm was a reseller and end-user that purchased directly from Exxon. In the Exxon proceeding a reseller applicant whose allocable share exceeds $5,000 may elect to receive as its refund the larger of $5,000 or 40 percent of the portion of its allocable share attributable to volumes purchased for resale plus 100 percent of any portion of its allocable share attributable to end-use. In the present case, Witco received 100 percent of its end-use allocable share ($7,356) plus 40 percent of its $2,573 reseller allocable share ($1,029). Accordingly, the total refund granted in this Decision was $10,580, representing $8,385 in principal and $2,195 in accrued interest.

Farmers Oil Company, 02/09/90, RF272–43303

The DOE issued a Decision and Order concerning an Application for Refund filed in the crude oil refund proceeding. The applicant was an agricultural cooperative which sold 16,766,359 gallons of petroleum products to its members. The applicants certified that it would pass through any refund received to those members. Accordingly, the applicant was granted a refund of $13,413.

Gulf Oil Corporation, Barker's Gulf, et al., 02/09/90, RE300–6279, et al.

The DOE issued a Decision and Order concerning six Applications for Refund submitted in the Gulf Oil Corporation special refund proceeding. Each applicant established that it purchased products indirectly from Gulf jobbers. P.A.D., Inc. had originally filed four of these Applications, but subsequently was barred from representing refund applicants. Fuel Refunds, Inc. and Akin Energy attempted to have themselves inserted as applicants' representatives. The DOE specified why such insertion would not be permitted. Accordingly, all corespondence, including the refund checks, was sent directly to the applicants. Each application was approved using a presumption of injury. The sum of the refunds granted in this Decision was $17,184.

Gulf Oil Corporation/Evezich Oil Company, 02/08/90, RE300–10958

The DOE issued a Decision and Order concerning an Application for Refund filed by Evezich Oil Company (Evezich), in the Gulf Oil Corporation special refund proceeding. The DOE rescinded the refund granted to Evezich in Case No. RF300–9050, *Plaza Gulf, et al.*, Case Nos. RF300–8814 (January 3, 1990). The refund was rescinded because it was based upon a duplicate application. Evezich had already been granted a

refund in the Gulf II proceeding in Case No. RF300-5084, *Dale Bower, et al.*, 18 DOE ¶ 85,171 (1988). The amount of the refund rescinded was $3,786.

Gulf Oil Corporation/Griffin Oil, 02/09/90, RE300-172

The DOE issued a Decision and Order concerning an Application for Refund submitted in the Gulf Oil Corporation special refund proceeding on behalf of Griffin Oil. Griffin Oil submitted reconstructed cost banks and a competitive disadvantage analysis in an attempt to demonstrate injury. The DOE determined that Griffin Oil's injury showing was inadequate. Griffin Oil's claim was approved using a presumption of injury. The total refund granted in this Decision, including accrued interest, was $3,983.

Gulf Oil Corporation/Naylor's Gulf Servicenter, 02/07/90, RF300-8677

The DOE issued a Decision and Order concerning an Application for Refund submitted in the Gulf Oil Corporation special refund proceeding by the former owners of Naylor's Gulf Servicenter (Naylor's), a New Jersey corporation. The DOE determined that since the former owners sold their Naylor's stock in 1980, they were not entitled to a refund. Accordingly, the DOE denied their Application.

Gulf Oil Products, Et Al., 02/08/90, RF272-69184, et al.

The DOE issued a Decision and Order, denying six Applications for Refund filed in the subpart V crude oil refund proceedings. Each applicant was either a reseller or a retailer during the period August 19, 1973 through January 27, 1981. Because none of the applicants demonstrated that they were injured due to the crude oil overcharges, they were ineligible for a crude oil refund.

Kodiak Electric Association, Inc., 02/06/90, RF272-31585

The DOE issued a Decision and Order granting a refund from crude oil overcharges funds to Kodiak Electric Association, Inc. in the subpart V crude oil refund proceeding. During the period from August 19, 1973 through January 27, 1981, Kodiak operated an electric generation and transmission cooperative. The DOE found that Kodiak submitted sufficient documentation to support its claim. Additionally, Kodiak certified that it would pass through any refund granted. In reaching its determination, the DOE rejected the comments submitted by a group of States in opposition to the granting of this refund. Specifically, the DOE found that the States had not demonstrated that Kodiak was ineligible to receive a refund as a utility. Accordingly, the DOE approved a refund of $23,484 to Kodiak.

Mooney's, Incorporated, 02/05/90, RF272-17493, RD272-17493

The DOE issued a Decision and Order granting a refund from crude oil overcharge funds to Mooney's, Incorporated, a construction company, principally involved in asphalt production and road construction/paving. In reaching its determination, the DOE rejected the Objection to the applicant's claim submitted by a group of States and denied the States' Motion for Discovery. The DOE held that industry-wide data, with no particular reference to the applicant, is insufficient to rebut the presumption of injury for end-users outside of the petroleum industry. The DOE also stated that the mere contention that an industry had the ability to pass through overcharges is not convincing evidence that particular claimants were likely in fact to have passed through overcharges. The refund granted to Mooney's, Incorporated was $42,261.

Murphy Oil Corporation/Mel's Spur, 02/05/90, RF309-458

The DOE issued a Decision and Order granting an Application for Refund in the Murphy Oil Corporation (Murphy) special refund proceeding. The applicant (Mel's Spur) acted as a reseller and as a commissioned dealer of Murphy petroleum products during the consent order period. Mel's Spur overcame the consignee (or commission dealer) presumption of non-injury for its commissioned sales by demonstrating that its commissioned sales volume decreased in relation to the sales volume of its competitors in certain years. Mel's Spur was granted a refund based only on its lost volume of commissioned sales in those years in which its sales volume displayed a decrease relative to its competitors. Mel's Spur was also granted a refund for its purchase volume as a reseller under the small claims injury presumption, as described in Murphy Oil Corporation, 17 DOE ¶85,872, (1988). The total volume approved in this Decision was 1,279,659 gallons and the total refund granted to Mel's Spur was $1,294, representing $1,045 in principal and $249 in accrued interest.

Oceana County Road Commission, 02/05/90, RR272-45

The DOE issued a Decision and Order granting a Motion for Modification filed by Oceana County Road Commission (Oceana) in the Subpart V crude oil refund proceeding. Oceana claimed that it was entitled to receive a refund based on purchases of 1,344,375 gallons of refined products which were not included in its initial filing. The amount of the refund granted was $1,876.

Ohmer Bassford, 02/07/90, RC272-76

The DOE issued a Supplemental Order rescinding a crude oil refund granted in Case No. RF272-51040 to Ohmer Bassford. *See Briley Construction Co.*, 19 DOE ¶ 85,672 (1989). The DOE found that Bassford's Application for Refund contained intentional misrepresentations of material facts.

Placid Oil Company/Berwick Bay Oil Company Inc., et al., 02/08/90, FR314-3, et al.

The DOE issued a Decision and Order concerning four Applications for Refund submitted in the Placid Oil Company special refund proceeding by resellers of Placid products. The applications were approved using a presumption of injury. The sum of the refunds granted was $12,056.

Shell Oil Company/Williamson Oil Co., Inc., et al., 02/07/90, RF315-4132, et al.

The DOE issued a Decision and Order granting eight Applications for Refund filed in the Shell Oil Company special refund proceeding. Each of the applicants purchased over 55,264 gallons of petroleum products directly from Shell. Accordingly, each applicant was granted a refund equal to 40% of its full allocable share plus a proportionate share of the interest that has accrued on the Shell escrow account. The sum of the refunds granted in the Decision was $90,230, representing $73,483 in principal and $16,747 in accrued interest.

Ulland Brothers, Inc., 02/07/90, RF272-18069, RD272-18069

The DOE issued a Decision and Order granting a refund from crude oil overcharge funds to Ulland Brothers, Inc., a construction company, principally involved in asphalt production and road construction/paving. In reaching its determination, the DOE rejected the Objection to the applicant's claim submitted by a group of States and denied the States' Motion for Discovery. The DOE held that industry-wide data, with no particular reference to the applicant, is insufficient to rebut the presumption of injury for end-users outside of the petroleum industry. The DOE also stated that the mere contention that an industry had the ability to pass through overcharges is not convincing evidence that particular claimants were likely in fact to have passed through overcharges. The refund

granted to Ulland Brothers, Inc. was $31,635.

Refund Applications

The Office of Hearings and Appeals granted refunds to refund applicants in the following Decisions and Orders:

Name	Case No.	Date
Atlantic Richfield Co./Jack Rutledge ARCO #1 *et al.*	RF304-8432	02/06/90
Atlantic Richfield Co./Lee & Jack Faulkenberry ARCO *et al.*	RF304-8399	02/09/90
Atlantic Richfield Co./Netherton ARCO *et al.*	RF304-7426	02/05/90
Atlantic Richfield Co./Sanitary Control Service Co. *et al.*	RF304-5700	02/06/90
Atlantic Richfield Co./Warex Petroleum Corp. *et al.*	RF304-6506	02/08/90
Comstock Foods	RF272-11933	02/08/90
Exxon Corp./Bradford Exxon *et al.*	RF307-10	02/08/90
Exxon Corp./Buster's Exxon *et al.*	RF307-10086	02/05/90
Exxon Corp./Powell's Exxon	RF307-10086	02/05/90
Gulf Oil Corp./Consolidated Rail Corp.	RF300-6641	02/06/90
Gulf Oil Corp./Francis X. Monaghan & Haverford, Bryn Mawr Ave. Gulf, Inc., Francis X. Monaghan, Plymouth Meeting Gulf, Inc., Haverford Ave. Gulf, Inc..	RF300-7397, RF300-7398, RF300-7405, RF300-7410, RF300-7412	02/06/90
Gulf Oil Corp./Houston Oil Co.	RF300-10827	02/05/90
Gulf Oil Corp./Larry, Gulf *et al.*	RF300-10030	02/06/90
Gulf Oil Corp./Maxwell Oil Co., Inc., C.P. House Gas Co., Inc.	RF300-7473, RF300-7511	02/05/90
Gulf Oil Corp./Osborne Gulf, Gasland	RF300-10516, RF300-10520	02/06/90
Gulf Oil Corp./Register Gas Co., Reid Street Gulf, Keystone heights Gulf Service, Register Oil Co., Inc.	RF300-7447, RF300-8427, RF300-8963, RF300-10244, RF300-10245	02/05/90
Gulf Oil Corp./Roy J. Hale, Hale Oil Co.	RF300-7474, RF300-7475, RF300-7476	02/05/90
Northeast Petroleum Industries/Exxon Co., U.S.A.	RF214-1	02/08/90
Placid Oil Co./Barrow Oil Co., Inc.	RF314-29	02/09/90
Shell Oil Co./Enterprise Oil Co. *et al.*	RF315-4175	02/05/90
Total Petroleum/Wells Oil Co. *et al.*	RF310-259	02/05/90
Wappingers Central School District *et al.*	RF272-28012	02/06/90

Dismissals

The following submissions were dismissed:

Name	Case No.
A&A Arco	RF304-78
ANR Freight System, Inc.	RF310-283
B&B Arco	RF304-8925
Baker's Hayden Bridge Arco	RF304-10546
Booth's Arco	RF304-8034
Charles Bussey, Jr.	RF307-5700
Chuck Warner's Arco	RF304-8006, RF304-8007
Combined Oil Co., Inc.	RF310-284
Cone Mills Corporation	RF272-23843
CRST INC.	RF310-279
Doug Butler's Exxon	RF307-9829
Fritzen-Halcyon LIJN, Inc.	RF300-10816
E-Z Go	RF310-267
Hardware Charlie	RF272-42776
Hathaway Shell	RF315-2597
Hofer, Inc.	RF310-315
Hutchens Oil Co., Inc.	RF310-271
Jim's Arco	RF304-9495
Joe Dolfi's Arco	RF304-3558
Jurek's Arco	RF304-4075
Mason Oil Company	RF304-5782
McCullough Grocery	RF307-5647
National Welders Supply Company	RF307-7059
Newlon's Transfer, Inc.	RF272-55451
Olson Fuel Co., Inc.	RF304-5157, RF304-5175
Phillips Oil Co.	RF310-3
Post Fuel, Inc.	RF304-5160
Scott's Gulf Service	RF300-9357
Shaw Oil Co.	RF310-78
South Oil Co.	RF310-264
Sport Chalet, Inc.	RF304-10754
Thomas F. Over	RF304-7925
Tom Barnett Gulf	RF300-7252
Triboro Gulf Service	RF300-10174
Umthum Trucking Company	RF307-7057
Vince's Arco #4	RF304-9651
W.G. Holloway	RF307-6712
Wheeling Pipeline, Inc.	RF307-7058
Woods Shell	RF315-1630
Zankey's Arco	RF304-8040

[FR Doc. 90-11739 Filed 5-18-90; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Project No. 3258-002, California]

Pine Creek Project; Availability of Environmental Assessment

May 14, 1990.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for major license for the proposed Pine Creek Hydroelectric Project located on Pine Creek in Inyo County, near Bishop, California, and has prepared an Environmental Assessment (EA) for the proposed project. In the EA, the Commission's staff has analyzed the potential environmental impacts of the proposed project and the no action alternative, and recommends the no action alternative. We conclude that denying a license for the proposed project would not constitute a major federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, Room HR-A, of the Commission's offices at 825 North Capitol Street NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 90-11672 Filed 5-18-90; 8:45 am]

BILLING CODE 6717-01-M

[Project Nos. 516–080 et al.]

Hydroelectric Applications (South Carolina Electric & Gas Co., et al.); Applications Filed With the Commission

Take notice that the following hydroelectric applications have been filed with the Commission and are available for public inspection:

1 a. *Type of Application:* Application to Amend Shoreline Management Plan and the Exhibit R.

b. *Project No:* 516–080.

c. *Date Filed:* January 2, 1990.

d. *Applicant:* South Carolina Electric and Gas Company.

e. *Name of Project:* Saluda Project.

f. *Location:* Lake Murray.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Randolph R. Mahan, Esquire, South Carolina Electric and Gas Company, Legal Dept. 106, Columbia, SC 29218, (803) 748–3538.

i. *FERC Contact:* Brian Romanek, (202) 357–0660.

j. *Comment Date:* June 13, 1990.

k. *Description of Project:* South Carolina Electric and Gas Company proposes to amend its license by revising certain aspects of the Commission approved Shoreline Management Plan and Exhibit R (Recreation Plan) for the Saluda River Project. In summary, the revisions would result in: (1) the addition of seven recreational sites totaling 136.41 acres; (2) reclassification of about 155 acres of shoreline from Future Development to Forest Management; (3) reclassification of about 18.17 acres of shoreline from recreational lands to future private development; (4) significant changes to policies regarding permitting of docks and other shoreline structures and activities around the reservoir; and (5) to increase the collection of environmental data related to cumulative impacts that may be occurring from permitted activities. The purpose for these revisions is primarily to increase SCE&G's control over shoreline activities and reduce the potential for adverse environmental impacts from these activities.

1. *This notice also consists of the following standard paragraphs:* B, C, and D2.

2 a. *Type of Application:* Request for Authorization to Sell Project Land.

b. *Project No:* 2370–024.

c. *Date Filed:* February 26, 1990.

d. *Applicant:* Pennsylvania Electric Company

e. *Name of Project:* Deep Creek Project

f. *Location:* Garrett County, Maryland.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Mr. Timothy N. Atherton, Esquire, Pennsylvania Electric Company, 1001 Broad Street, Johnston, PA 15907, (814) 533–8397.

i. *FERC Contact:* Brian Romanek, (202) 357–0660.

j. *Comment Date:* June 13, 1990.

k. *Description of Project:* Pennsylvania Electric Company (PENELEC) has requested authorization to sell 30.39 acres from the project boundary for the Deep Creek Project. There would be a total of 19 land parcels to be sold, ranging in size from 0.03 acre to 7.54 acres. Of these parcels 9 would be less than 1 acre in size, 6 would be between 1 and 2 acres, and 4 would be greater than 2 acres.

The land would be sold to landowners adjoining the subject parcels and would be used for proposed or existing residential and commercial development. The land is located upland of elevation 2446 mean sea level (MSL).

1. This notice also consists of the following standard paragraphs: B, C, and D2.

3 a. *Type of Application:* Transfer of License.

b. *Project No.:* 2419–006.

c. *Date filed:* March 19, 1990.

d. *Applicant:* Alpena Power Company and Thunder Bay Power Company.

e. *Name of Project:* Hillman Dam Project.

f. *Location:* On the Thunder Bay River in Montgomery County, Michigan.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contract:*

Mr. Stephen Fletcher, Alpena Power Company, 310 North 2nd Avenue, Alpena, MI 49707, (517) 356–2293

Mr. Roger Steed, Thunder Bay Power Company, 109 E. Front Street, #315, Traverse City, MI 49684, (616) 941–5255.

i. *FERC Contact:* Robert Bell, (202) 357–0806.

j. *Comment Date:* June 7, 1990.

k. *Description of Project:* On March 9, 1965, a license was issued to Alpena Power Company (licensee), to operate and maintain the Hillman Dam Project No. 2419. The licensee intends to transfer the license to Thunder Bay Power Company (transferee), to facilitate the continued operation and maintence of the project. The transferee intends to purchase the project and agrees to accept the terms and conditions as if it were the original licensee.

l. This notice also consists of the following standard paragraphs: B and C.

4 a. *Type of Application:* Minor License.

b. *Project No.:* 2622–002.

c. *Date Filed:* January 26, 1990.

d. *Applicant:* Strathmore Paper Company.

e. *Name of Project:* Turner Falls.

f. *Location:* On the Turner Falls Canal off of the Connecticut River in Franklin County, Massachusetts.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Robert Mck. Hunziker, International Paper Company, 2 Manhattanville Road, Purchase, NY 10577, (914) 397–1540.

i. *FERC Comment Date:* Ed Lee, (tag), (202) 357–0809.

j. *Comment Date:* June 17, 1990.

k. *Description of Project:* The existing operating project was issued an initial license in 1969 which will expire on February 28, 1991. The licensee has filed for a new license for the continued operation of the project with no new consturction proposed. The existing project consists of: (1) intake facilities consisting of two rack-and-pinion operated gates; (2) a steel, 8.5-foot-diameter by 30-foot-long penstock; (3) a single 937-kW generating unit located in the mill house; (4) a tailrace; and (5) appurtenant facilities. The project generates an average of 1,160 MWh per year. All project works are owned by the Applicant. The existing license originally waived sections 14 and 15 of the Federal Power Act.

1. *Purpose of Project:* Project power would continue to be utilized in the applicant's paper manufacturing system.

m. This notice also consists of the following standard paragraphs: B, C, and D1.

5 a. *Type of Application:* Non-Project Use of Project Lands.

b. *Project No:* 2742–012.

c. *Date Filed:* March 1, 1990.

d. *Applicant:* Alaska Energy Authority.

e. *Name of Project:* Solomon Gulch Hydroelectric Project.

f. *Location:* Solomon Gulch Reservoir near the City of Valdez, Alaska.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Donald L. Shira, Director of Program Development and Facilities Operations, Alaska Energy Authority, 701 East Tudor Road, P.O. Box 190869, Anchorage, AK 99519–0869, (907) 561–7877.

i. *FERC Contact:* John Estep, (202) 357–0654.

j. *Comment Date:* June 13, 1990.

k. *Description of Project:* The applicant proposes to amend its license to allow private vehicular use within the project boundary of Granby Road, a Revised Statute 2477 public right-of-

way, or alternate access where Granby Road is not longer accessible.

1. This notice also consists of the following standard paragraphs: B, C, and D2.

6 a. *Type of Application:* Request for Extension of Time to Commence and Complete Project Construction.

b. *Project No:* 2833–022.

c. *Date Filed:* March 26, 1990.

d. *Licensee:* Public Utilities District No. 1.

e. *Name of Project:* Cowlitz Falls Hydroelectric Project.

f. *Location:* Located on the Cowlitz River in Lewis County, Washington.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. § 791(a)–825(r) and Public Law No. 101–155, 103 Stat. 935 (1989).

h. *Applicant Contact:* Ritts, Brickfield & Kaufman, Attn: Michael N. McCarty, Watergate 600 Building, Suite 915, Washington, DC 20037, (202) 342–0800.

i. *FERC Contact:* Ms. Regina Saizan, (202) 357–0673.

j. *Comment Date:* June 4, 1990.

k. *Description of the Request:* The licensee for the subject project has requested that the deadlines for commencement and completion of construction be extended for an additional two-year period pursuant to Public Law No. 101–155, 103 stat. 935 (1989). The licensee states that it has been hindered in its efforts to proceed with project financing and construction by factors outside its control, particularly by delays in receiving necessary permits and other regulatory approvals. Further, the licensee maintains that the Northwest Power Planning Council has determined that the project's benefit to the Pacific Northwest Region will be optimized by an on-line date after 1993.

l. This notice also consists of the following standard paragraphs: B, C, and D2.

7 a. *Type of Applications:* Requests for Extension of Time to Commence and Complete Project Construction.

b. *Project Nos.:* 4586–012 and 4587–026.

c. *Date Filed:* March 30, 1990.

d. *Licensee:* City of Tacoma.

e. *Name of Project:* 4586–012—Swamp Creek Project; 4587–026—Ruth Creek Project.

f. *Location:*

4586–012—Swamp Creek Project, located on Swamp Creek in Whatcom County, Washington.

4587–026—Ruth Creek Project, located on Ruth Creek in Whatcom County, Washington.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)–825(r) and Public Law No. 101–155, 103 Stat. 935 (1989).

h. *Applicant Contact:* Tacoma Public Utilities, Light Division, Attn: Gary E. Johnson, 3628 South 35th Street, P.O. Box 11007, Tacoma, WA 98411, (206) 383–2471.

i. *FERC Contact:* Ms. Regina Saizan, (202) 357–0673.

j. *Comment Date:* June 4, 1990.

k. *Description of the Request:* The licensee for the subject projects has requested that the deadlines for commencement of construction at FERC Project Nos. 4586 and 4587 be extended for an additional two-year period pursuant to Public Law No. 101–155, 103 Stat. 935 (1989). The licensee shall develop the subject projects in conjunction with two other projects (Project Nos. 4738 and 4628) in order to coordinate the planning, design, and construction schedules for all four projects. The licensee states that coordinating the four projects would have significant financial and environmental advantage.

l. This notice also consists of the following standard paragraphs: B, C, and D2.

8 a. *Type of Application:* Minor License.

b. *Project No.:* 10812–000.

c. *Date filed:* July 27, 1989.

d. *Applicant:* Daniel Nelson Evans, Jr.

e. *Name of Project:* Henrietta Mills.

f. *Location:* On the Second Broad River in the Town of Henrietta, Rutherford County, North Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* Barbara Wallace Evans, Route #2, Box 419–A, Kings Mountain, NC 28086, (704) 739–9710.

i. *FERC Contact:* Charles T. Raabe (dmt) (202) 357–0811.

j. *Comment Date:* June 16, 1990.

k. *Description of Project:* The proposed run-of-river project would consist of: (1) an existing 20-foot-high, 250-foot-long stone and masonry overflow-type dam having a new 54-inch-diameter steel siphon pipe containing a new 115-kW submersible generating unit operated at a 20-foot-head and at a flow of 85 cfs, and having a new 20-inch-diameter steel siphon pipe; (2) a reservoir having a surface area of about 8-acres and having negligible storage; (3) an existing 30-foot-wide, 350-foot-long power canal having a 50-foot-long overflow-type side-spillway; (4) an existing 7.75-foot-diameter, 174-foot-long steel penstock; (5) an existing powerhouse containing a refurbished 700-kW generating unit operated at a 32-foot-head and at a flow of 250 CFS; (6) an existing 60-foot-wide, 350-foot-long tailrace; (7) a new 600-foot-long, 12.5-kV overhead transmission line; and (8) appurtenant facilities. Applicant would replace the vertical slide gates in the dam, permanently seal the existing 8.75-foot-diameter, 120-foot-long penstock, and install a new trashrack at the siphon and at the penstock. Applicant estimates that the average annual generation would be 2,638,944-kWh. Project power would be sold to the Duke Power Company. The dam is owned by P.K. Ventures, Inc.

1. This notice also consists of the following standard paragraphs: A3, A9, B, C & D1.

9 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10870–000.

c. *Date filed:* January 19, 1990.

d. *Applicant:* Robert A. Davis, III and Michael P. O'Brien.

e. *Name of Project:* Caruther's Mill Site.

f. *Location:* On the Apalachee River in Walton County, Georgia.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:*

Robert A. Davis, III, 390 Timber Laurel Lane, Lawrenceville, GA 30243, (404) 995–0891

Michael P. O'Brien, 3910 Angora Place, Duluth, GA 30136, (404) 246–9015.

i. *FERC Contact:* Mary Golato (dmt) (202) 357–0804.

j. *Comment Date:* June 14, 1990.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) an existing concrete dam approximately 10 feet high; (2) an existing reservoir less than 5 acres in surface area with a surface elevation of approximately 875 feet mean sea level; (3) a proposed powerhouse with one turbine generator having an installed capacity of 147 kilowatts; (4) a proposed 1.7-mile, 3-phase transmission line; and (5) appurtenant facilities. The average annual generation would be 1,147,306 kilowatthours and the cost of the studies would be $2,000,000. The dam is owned by Dr. Hugh A. Caruthers.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

10 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10873–000.

c. *Date filed:* January 19, 1990.

d. *Applicant:* Robert A. Davis, III and Michael P. O'Brien.

e. *Name of Project:* Cullasaja River Site Project.

f. *Location:* On the Cullasaja River, in Macon County, North Carolina.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:*

Robert A. Davis, III, 390 Timber Laurel Lane, Lawrenceville, GA 30243, (404) 995–0891

Michael P. O'Brien, 3910 Angora Place, Duluth, GA 30136, (404) 246–9015.

i. *FERC Contact:* Mary Golato (dmt) (202) 357–0804.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) an existing concrete dam approximately 25 feet high; (2) an existing reservoir 55 acres in surface area with a storage capacity of 1,500 acre-feet at a surface elevation of approximately 3,620 feet mean sea level; (3) an existing 24-inch-diameter penstock approximately 2,500 feet long; (4) an existing powerhouse with a turbine generator having an installed capacity of 750 kilowatts (the powerhouse may be reconstructed); and (5)—appurtenant facilities. The dam is owned by the City of Highlands, North Carolina. The average annual generation would be 5,853,600 kilowatthours and the cost of the studies under permit would be $2,000.00.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

11 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10878–000.

c. *Date Filed:* January 25, 1990.

d. *Applicant:* Howard Energy Company, Inc.

e. *Name of Project:* Bellaire Hydro Project.

f. *Location:* On the Cedar River near Bellaire, Antrim County, Michigan.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Herbert Steed, 109 E. Front St., Suite 315, Traverse City, MI 49684, (616) 941–5255.

i. *FERC Contact:* Ed Lee (202) 357–0809.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed project would consist of: (1) the existing 1,115-foot-long and 15-foot-high earth dam; (2) existing 400-acre Blair Lake reservoir; (3) a proposed intake structure; (4) a new concrete powerhouse housing one 200-kW generating unit; (5) a proposed tailrace; (6) a new 115-kV or equivalent transmission line; and (7) appurtenant facilities. The Applicant estimates that the average annual generation would be 300 MWh. The cost of the work and studies to be performed under the permit would be $200,000. The site is owned by the Village of Bellaire, Michigan. The Applicant proposes that all power generated will be sold to a local utility company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

12 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* P–10883–000.

c. *Date Filed:* February 7, 1990.

d. *Applicant:* Kane Falls Associates.

e. *Name of Project:* Kane Falls Hydroelectric Project.

f. *Location:* On Halfway Creek near Fort Ann, in Washington County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Neal Dunlevy, 185 Genesee Street, Utica, N.Y. 13501, (315) 793–0366.

i. *FERC Contact:* Michael Dees (dmt), (202) 357–0807.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed project would consist of: (1) replacing a diversion structure; (2) reconstruction of an intake structure; (3) a penstock 66 inches in diameter and 300 feet long; (4) a powerhouse 30 feet by 30 feet housing two 500-kW generating units; (5) a tailrace; (6) a 13.8-kV transmission line 200 feet long; and (7) appurtenant facilities. The applicant estimates that the annual energy generation would be 5,000 MWH and that the cost of the studies to be performed under the permit would be $30,000. The dam is owned by Niagara Mohawk Power Corporation.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

13 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* P–10884–000.

c. *Date Filed:* February 7, 1990.

d. *Applicant:* Rossie Mills Associates.

e. *Name of Project:* Rossie Mills Hydroelectric Project.

f. *Location:* On Indian River near Rossie, in St. Lawrence County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Neal Dunlevy, 185 Genesee Street, Utica, N.Y. 13501, (315) 793–0366.

i. *FERC Contact:* Michael Dees, (202) 357–0807.

j. *Comment Date:* June 1, 1990.

k. *Description of Project:* The proposed project would consist of: (1) replacing a concrete and stone dam 80 feet long and nine feet high, and installing crest gates or flashboards three feet high; (2) a 35-acre reservoir; (3) reconstruction of an intake structure; (4) reconstruction of a canal or penstock; (5) a powerhouse housing one 1,000-kW hydropower unit; (6) a tailrace; (7) a transmission line; (8) and appurtenant facilities. The applicant estimates that the annual energy generation would be 5,000 MWH and that the cost of the studies to be performed under the permit would be $30,000. The dam is owned by Niagara Mohawk Power Corporation.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

14 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10886–000.

c. *Date Filed:* February 7, 1990.

d. *Applicant:* Mill Pond Associates.

e. *Name of Project:* Mill Pond Hydroelectric Project.

f. *Location:* On Mill Brook near Port Henry, in Essex County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Neal Dunlevy, 185 Genesee Street, Utica, NY 13501, (315) 793–0366.

i. *FERC Contact:* Michael Dees (tag) (202) 357–0807.

j. *Comment Date:* June 14, 1990.

k. *Description of Project:* The proposed project would consist of: (1) an existing dam 100 feet long and 30 feet high and flashboards; (2) a 13-acre reservoir; (3) a penstock 5,000 feet long; (4) a powerhouse housing a single or multiple hydropower units between 2 MW and 10 MW total capacity; (5) a tailrace; (6) a 13.8–kV transmission line 200 feet long; (7) and appurtenant facilities. The applicant proposes to study the project for operation as run-of-river, peaking, or pumped storage. The applicant estimates that the annual energy generation would be 5,000 MWh and that the cost of the studies to be performed under the permit would be $30,000. The dam is owned by Niagara Mohawk Power Company.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

m. This notice supersedes the notice issued on March 15, 1990.

15 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10889–000.

c. *Date filed:* February 12, 1990

d. *Applicant:* Vineyard Road Associates.

e. *Name of Project: Vineyard Road Project.*

f. *Location:* On the Grant Brook in Essex County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Neal F. Dunlevy, Vineyard Road Associates, 185 Genesee Street, Utica, NY 13501, (315) 793–0366.

i. *FERC Contact:* Robert Bell (202) 357–0806.

j. *Comment date:* June 1, 1990.

k. *Description of Project:* The proposed pumped storage project would consist of a closed loop system using two pools: (1) a proposed lower pool having a storage capacity of 1000 acre-feet made from an excavated quarry to be initially filled with pumped water from Lake Ontario; (2) a pump to a second proposed excavated upper pond having a surface area of 50 acres with a storage capacity of 1000 acre-feet; (3) a proposed intake stucture; (4) 3 proposed 2600-foot-long steel penstock; (5) a proposed powerhouse containing 3 generating units with a total installed capacity between 50 mw and 75 mw; (6) a proposed 4000-foot-long, 115–kV transmission line; and (7) appurtenant facilities.

The applicant estimates the average annual generation would be 180,000 MWH. All energy generated would be sold to a local utility. The cost of the studies to be done under this permit are $100,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

16 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10890–000.

c. *Date filed:* February 13, 1990.

d. *Applicant:*LB Industries, Inc.

e. *Name of Project:* Cochiti Dam.

f. *Location:* At the Corps of Engineers Conchiti Dam, in Sandoval County, New Mexico. Township 16 N Range 6 E.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Mr. Carl L. Myers, Myers Engineering Company, 750 Warm Springs Avenue, Boise, ID 83301, (208) 336–1425.

i. *FERC Contact:* Michael Spencer at (202) 357–0846.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed project would utilize the existing U.S. Corps of Engineers' Cochiti Dam and consist of: (1) two new penstocks utilizing the existing outlet works; (2) a powerhouse containing one generating unit with a capacity of 5,000 kW and an estimated average annual generation of 40 GWh; and (3) a 2,500-foot-long transmission line.

No new access road will be needed to conduct the studies. The applicant estimates that the cost of the studies to be conducted under the preliminary permit would be $120,000.

l. *Purpose of Project:* Project power would be sold.

m. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

17 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* P–10894–000.

c. *Date Filed:* February 16, 1990.

d. *Applicant:* Branch River Hydropower Company, Inc.

e. *Name of Project:* Stiles Brook Hydroelectric Project.

f. *Location:* On Styles Brook near Keene, in Essex County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:*

Mr. Charles Heimerdinger, Evans Road, P.O. Box 1069, Lake Placid, NY 12964, (518) 523–2345.

i. *FERC Contact:* Michael Dees (202) 357–0807.

j. *Comment Date:* June 1, 1990.

k. *Description of Project:* The proposed project would consist of: (1) a proposed diversion intake structure; (2) a penstock 18 inches in diameter and 2,100 feet long; (3) a powerhouse housing a 200–kW hydropower unit; (4) a 480–V transmission line 200 feet long; and (5) appurtenant facilities. The applicant estimates that the annual energy generation would be 600 MWH and that the cost of the studies to be performed under the permit would be $40,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

18 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10904–000.

c. *Date Filed:* March 14, 1990.

d. *Applicant:* Mohawk Dam 7 Associates.

e. *Name of Project:* Mohawk Dam 7—Lock E–11 Project.

f. *Location:* On the Mohawk River, in Amsterdam, in Montgomery County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:*

Neal F. Dunlevy, P.E., Mohawk Dam 7 Associates, 185 Genesee Street, Utica, NY 13501, (315) 793–0366.

i. *FERC Contact:* Mary C. Golato (202) 357–0804.

j. *Comment Date:* June 14, 1990.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) an existing 12-foot-high, 400-foot-long moveable, steel-gated dam; (2) an existing reservoir with a surface area of 300 acres, a storage capacity of 2,500 acre-feet, and a surface elevation of 268 feet mean sea level; (3) a proposed powerhouse with a single generating unit at a rated capacity of less than 2 megawatts; (4) an existing transmission line approximately 10,000 feet long; and (5) appurtenant facilities. The dam is owned by the New York State Department of Transportation. The average annual generation would be about 10,000 megawatthours. The cost of the studies under permit is estimated to be $30,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

19 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10905–000.

c. *Date Filed:* March 14, 1990.

d. *Applicant:* Mohawk Dam 6 Associates.

e. *Name of Project:* Mohawk Dam 6 Hydroelectric Project.

f. *Location:* On the Mohawk River, in Amsterdam and Florida, in Montgomery County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:*

Neal F. Dunlevy, P.E., Mohawk Dam 6 Associates, 185 Genesee Street, Utica, NY 13501, (315) 793–0366.

i. *FERC Contact:* Mary C. Golato (202) 357–0804.

j. *Comment Date:* June 14, 1990.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) an existing moveable, steel-gated dam 15 feet high and 400 feet long; (2) an existing reservoir with a surface area of 300 acres, a storage capacity of 2,500 acre-feet, and a surface elevation of 256 feet mean sea level; (3) a proposed powerhouse with a single generating unit at a rated capacity of less than 2 megawatts; (4) an existing 115–kV transmission line; and (5) appurtenant facilities. The dam is owned by the New York State Department of Transportation. The average annual generation would be about 10,000 megawatts. The cost of the studies under permit would be estimated to be $30,000.

l. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

20 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10906–000.

c. *Date filed:* March 14, 1990.

d. *Applicant:* Mohawk Dam 5 Associates.

e. *Name of Project:* Mohawk Dam 5—Lock E–9 Project.

f. *Location:* On the Mohawk River, in Rotterdam, in Schenectady County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Neal F. Dunlevy, P.E., Mohawk Dam 7 Associates, 185 Genesee Street, Utica, NY 13501, (315) 793–0366.

i. *FERC Contact:* Mary C. Golato (202) 357–0804.

j. *comment Date:* June 14, 1990.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) an existing 15-foot-high, 400-foot-long moveable, steel-gated dam; (2) an existing reservoir with surface area of 350 acres, a storage capacity of 3,000 acre-feet, and a surface elevation of 239 feet mean sea level; (3) a proposed powerhouse with a single generating unit at a rated capacity of less than 2 megawatts; (4) an existing 115–kV transmission line approximately 3,400 feet long; and (5) appurtenant facilities. The dam is owned by the New York State Department of Transportation. The average annual generation would be 10,000 megawatthours. The cost of the studies would be estimated at $30,000.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

21 a. *Type of Application:* Preliminary Permit.

b. *Project No.:* 10907–000.

c. *Date filed:* March 14, 1990.

d. *Applicant:* Mohawk Dam 4 Associates.

e. *Name of Project:* Mohawk Dam 4—Lock E–8 Project.

f. *Location:* On the Mohawk River, in Glenville, in Schenectady County, New York.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Neal F. Dunlevy, P.E., Mohawk Dam 7 Associates, 185 Genesee Street, Utica, NY 13501, (315) 793–0366.

i. *FERC Contact:* Mary C. Golato (202) 357–0804.

j. *Comment Date:* June 14, 1990.

k. *Description of Project:* The proposed project would consist of the following facilities: (1) an existing 14-foot-high, 400-foot-long moveable, steel-gated dam; (2) an existing reservoir with surface area of 300 acres, a storage capacity of 3,500 acre-feet, and a surface elevation of 224 feet mean sea level; (3) a proposed powerhouse with a single generating unit at a rated capacity of less than 2 megawatts; (4) an existing 115–kV transmission approximately 800 feet long; and (5) appurtenant facilities. The dam is owned by the New York State Department of Transportation. The average annual generation would be 10,000 megawatthours. The cost of the studies is estimated at $30,000.

1. This notice also consists of the following standard paragraphs: A5, A7, A9, A10, B, C, and D2.

22 a. *Type of Application:* Declaration of Intention.

b. *Docket No:* EL90–20.

c. *Date Filed:* March 29, 1990.

d. *Applicant:* Wilton Hydro Electric Company, Inc.

e. *Name of Project:* Wilton Hydro Station.

f. *Location*: Souhegan River, Hillsborough County Wilton, New Hampshire.

g. *Filed Pursuant to:* Section 23(b) of the Federal Power Act, 16 U.S.C. §§ 817(b).

h. *Applicant Contact:* Jason M. Hines, Wilton Hydro Electric Company, Inc., P.O. Box 76, Amherst, NH 03031, (603) 654–2678.

i. *FERC Contact:* Diane M. Scire, (202) 357–0682.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed Wilton Hydro Station Project would consist of: (1) a reservoir with a storage area of 14 acre-feet; (2) a 17-foot-high, 150-foot-long dam; (3) proposed 48-inch flashboards; (4) a powerhouse with an installed capacity of 150 kilowatts; (5) a 175-foot-long transmission line; and (6) appurtenant facilities.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Purpose of Project:* Applicant intends to sell the power produced to Public Service Company of New Hampshire.

m. This notice also consists of the following standard paragraphs: B, C, and D2.

23 a. *Type of Application:* Declaration of Intention.

b. *Docket No:* EL90–21.

c. *Date Filed:* March 26, 1990.

d. *Applicant:* Eaglecrest Ski Area.

e. *Name of Project:* Eaglecrest.

f. *Location*: On the northern end of Douglas Island, within the City and Borough of Juneau, Alaska. Copper River Meridian, T. 41 S., R. 67 E., sec. 31, SE1/4SW1/4 and T. 42 S., R. 67 E., sec. 6, NE1/4NW1/4 (protracted sections).

g. *Filed Pursuant to:* Section 23(b) of the Federal Power Act, 16 U.S.C. 817(b).

h. *Applicant Contact:* Gary Mendivil, Business Manager, Eaglecrest Ski Area, 155 S. Seward Street, Juneau, AK 99801, (907) 586–5284.

i. *FERC Contact:* Diane M. Scire, (202) 357–0682.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed Eaglecrest Project would consist of: (1) a reservoir of undetermined size; (2) an existing dam; (3) a proposed powerhouse with an installed capacity of 50 kilowatts; and (4) appurtenant facilities.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Purpose of Project:* Power generated by the Eaglecrest Project would be directed into the existing Eaglecrest power system to provide electrical needs for the Eaglecrest Day Lodge and Maintenance Shop.

m. This notice also consists of the following standard paragraphs: B, C, and D2.

24 a. *Type of Application:* Declaration of Intention.

b. *Project No.:* EL90–22–000.

c. *Date Filed:* April 10, 1990.

d. *Applicant:* H & H Properties.

e. *Name of Project:* Upper Mayodan Dam (NC).

f. *Location:* Town of Mayodan, Rockingham County, North Carolina.

g. *Filed Pursuant to:* Section 23(b) of the Federal Power Act, 16 U.S.C. 817(b).

h. *Applicant Contact:* Timothy H. Henderson, H & H Properties, 1240 Springwood Church Road, Gibsonville, NC 27249, (919) 449–5054.

i. *FERC Contact:* Hank Ecton, (202) 357–0678.

j. *Comment Date:* June 4, 1990.

k. *Description of Project:* The proposed Upper Mayodan Dam Project, a run-of-river project, would consist of: (1) a reservoir with an area of approximately 11 acres; (2) an existing arch-shaped stone masonry dam 18 feet high and 250 feet long, with a non-overflow section approximately 28 feet high and 75 feet long, containing 8 inlet gates in the headwall; (3) an existing canal, 20–25 feet wide, 10 feet deep, and 2000 feet long; (4) an existing 150-foot-long, 9-foot-diameter conduit leading from the canal to the powerhouse; (5) a powerhouse containing two turbine generators, with a projected total capacity of 423 kilowatts; and (6) appurtenant facilities. The energy produced by the project will be sold to the Duke Power Company.

When a Declaration of Intention is filed with the Federal Energy Regulatory Commission, the Federal Power Act requires the Commission to investigate and determine if the interests of interstate or foreign commerce would be affected by the project. The Commission also determines whether or not the project: (1) would be located on a navigable waterway; (2) would occupy or affect public lands or reservations of the United States; (3) would utilize surplus water or water power from a government dam; or (4) if applicable, has involved or would involve any construction subsequent to 1935 that may have increased or would increase the project's head or generating capacity, or have otherwise significantly modified the project's pre-1935 design or operation.

l. *Purpose of Project:* Applicant intends to sell the energy produced to the Duke Power Company.

m. This notice also consists of the following standard paragraphs: B, C, and D2.

Standard Paragraphs

A3. Development Application—Any qualified development applicant desiring to file a competing application must submit to the Commission, on or before the specified comment date for the particular application, a competing development application, or a notice of intent to file such an application. Submission of a timely notice of intent allows an interested person to file the competing development application no later than 120 days after the specified comment date for the particular application. Applications for preliminary permits will not be accepted in response to this notice.

A5. Preliminary Permit—Anyone desiring to file a competing application for preliminary permit for a proposed project must submit the competing application itself, or a notice of intent to file such an application, to the Commission on or before the specified comment date for the particular application (see 18 CFR 4.36). Submission of a timely notice of intent allows an interested person to file the competing preliminary permit application no later than 30 days after the specified comment date for the particular application. A competing preliminary permit application must conform with 18 CFR 4.30(b) (1) and (9) and 4.36.

A7. Preliminary Permit—Any qualified development applicant desiring to file a competing development application must submit to the Commission, on or before the specified comment date for the particular application, either a competing development application or a notice of intent to file such an application. Submission of a timely notice of intent to file a development application allows an interested person to file the competing application no later than 120 days after the specified comment date for the particular application. A competing license application must conform with 18 CFR 4.30(b) (1) and (9) and 4.36.

A9. Notice of Intent—A notice of intent must specify the exact name, business address, and telephone number of the prospective applicant, include an unequivocal statement of intent to submit, if such an application may be filed, either (1) a preliminary permit application or (2) a development application (specify which type of application), and be served on the applicant(s) named in this public notice.

A10. Proposed Scope of Studies under Permit—A preliminary permit, if issued, does not authorize construction. The term of the proposed preliminary permit would be 36 months. The work proposed under the preliminary permit would include economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on the results of these studies, the Applicant would decide whether to proceed with the preparation of a development application to construct and operate the project.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of the Rules of Practice and Procedure, 18 CFR 385.210, 385.211 385.214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title "COMMENTS" "NOTICE OF INTENT TO FILE COMPETING APPLICATION", "COMPETING APPLICATION", "PROTEST", "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. An additional copy must be sent to Dean Shumway, Director, Division of Project Review, Federal Energy Regulatory Commission, Room 1027 (810 1st), at the above-mentioned address. A copy of any notice of intent, competing application or motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

D1. Agency Comments—States, agencies established pursuant to federal law that have the authority to prepare a comprehensive plan for improving, developing, and conserving a waterway affected by the project, federal and state agencies exercising administration over fish and wildlife, flood control, navigation, irrigation, recreation, cultural or other relevant resources of the state in which the project is located, and affected Indian tribes are requested to provide comments and recommendations for terms and conditions pursuant to the Federal Power Act as amended by the Electric Consumers Protection Act of 1986, the Fish and Wildlife Coordination Act, the Endangered Species Act, the National Historic Preservation Act, the Historical and Archeological Preservation Act, the National Environmental Policy Act, Pub. L. No. 88–29, and other applicable statutes. Recommended terms and conditions must be based on supporting technical data filed with the Commission along with the recommendations, in order to comply with the requirement in section 313(b) of the Federal Power Act, 16 U.S.C. Section 8251(b), that Commission findings as to facts must be supported by substantial evidence.

All other federal, state, and local agencies that receive this notice through direct mailing from the Commission are requested to provide comments pursuant to the statutes listed above. No other formal requests will be made. Responses should be confined to substantive issues relevant to the issuance of a license. A copy of the application may be obtained directly from the applicant. If an agency does not respond to the Commission within the time set for filing, it will be presumed to have no comments. One copy of an agency's response must also be sent to the Applicant's representatives.

D2. Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Dated: May 15, 1990, Washington, DC.

Lois D. Cashell,

Secretary.

[FR Doc. 90–11673 Filed 5–18–90; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. MT88–7–002]

Natural Gas Pipeline Filings; Sabine Pipe Line Company, et al.

May 14, 1990.

Take notice that the following filings have been made with the Commission:

1. Sabine Pipe Line Company

[Docket No. MT88–7–002]

Take notice that on May 7, 1990, Sabine Pipe Line Company (Sabine) tendered the following tariff sheets for filing in the captioned docket pursuant to Order No. 497–A and section 250.16 of the Commission's Regulations as part of its FERC Gas Tariff, First Revised Volume No. 1:

First Revised Sheet No. 205B
First Revised Sheet No. 205C
Second Revised Sheet No. 229
First Revised Sheet No. 231
First Revised Sheet No. 232
First Revised Sheet No. 233

Comment date: May 29, 1990, in accordance with Standard Paragraph K at the end of this notice.

2. Mississippi River Transmission Corporation

[Docket No. MT90–8–001]

Take notice that on May 2, 1990, Mississippi River Transmission Corporation, (Mississippi) tendered the following tariff sheets for filing in the captioned docket pursuant to Order No. 497–A and section 250.16 of the Commission's Regulations as part of its FERC Gas Tariff, Original Volume No. 1–A:

Third Revised Sheet No. 72

Comment date: May 29, 1990, in accordance with Standard Paragraph K at the end of this notice.

Standard Paragraphs

K. Any person desiring to be heard or to protest the subject filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR §§ 385.214 and 385.211. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90–11674 Filed 5–18–90; 8:45 am]

BILLING CODE 6717–01–M

Office of Fossil Energy

[FE Docket No. 90–19–NG

Coastal Gas Marketing Co. Application for Blanket Authorization to Import and Export Natural Gas and Liquefied Natural Gas

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of application for blanket authorization to import and export natural gas and liquefied natural gas.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt on March 21, 1990, of an application filed by Coastal Gas Marketing Company (CGM) for a single new import and export authorization that would supersede its current separate blanket authorizations to import and export natural gas. In this application, CGM requests authorization to import a total of up to 600 Bcf of natural gas and liquefied natural gas (LNG) and to export a total of up to 150 Bcf of natural gas and LNG. CGM requests that the new authorization be approved for spot and short-term sales from and to Canada, Mexico, and other countries over a two-year term beginning on the date of the first delivery of imported or exported natural gas or LNG.

CGM intends to use existing pipeline and LNG facilities for the processing and transportation of the volumes to be imported or exported and to submit quarterly reports detailing each transaction.

The application is filed under section 3 of the Natural Gas Act and DOE Delegation Order Nos. 0204–111 and 0204–127. Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures and written comments are to be filed at the address listed below no later than 4:30 p.m., e.d.t., June 20, 1990.

ADDRESSES: Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, FE–50, 1000 Independence Avenue, SW., Washington, DC 20585.

FOR FURTHER INFORMATION:

Larine A. Moore, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, room 3F–056, FE–53, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–9478.

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, room 6E–042, GC–32, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: CGM, (formerly ANR Gathering Company) a Delaware corporation with its principal place of business located in Houston, Texas, currently holds a two-year blanket authorization granted by the Economic Regulatory Administration (ERA) in DOE/ERA Opinion and Order No. 178 (1 ERA 70,708), issued June 29, 1987, and filed in ERA Docket No. 87–20–NG, to import up to 100 Bcf of natural gas from Canada. Under this authorization, which will expire on October 1, 1990, CGM has imported 1,858 MMcf of Canadian natural gas as of December 31, 1989. CGM also holds a two-year blanket authorization granted by FE in DOE/FE Opinion and Order No. 304, (1 FE 70,207) ERA Docket No. 88–75–NG issued on March 29, 1989, to export up to 105 Bcf of natural gas from the U.S. to Mexico over a term of two years beginning on the date of first export. There have been no deliveries under this authorization. FE, in striving for consistency and in keeping with past practice in other proceedings involving requests for an applicant for similar actions in separate dockets at the same

time, is issuing this notice in a new consolidating docket in an effort to reduce potential confusion of multiple import and export authorizations in separate dockets and maintain its policy of permitting an importer or exporter to hold only one such authorization for a two-year term.

Under the requested authority, CGM proposes to export domestically produced natural gas on a short term basis, for sale to purchasers in other countries, including commercial and industrial end-users, and local distribution companies. CGM proposes to continue importing natural gas from various foreign producers for resale in the U.S. at competitive prices on a short term basis.

CGM currently is negotiating arrangements to export natural gas to Canada and Mexico, but is requesting flexibility to enter into future arrangement both for its own account or for the account of others for the import and export of natural gas and LNG with Canada and Mexico as well as other countries. The specific terms of each import and export arrangement would be negotiated on an individual basis, including price and volume. CGM maintains that the proposed export, given the current domestic supply of gas, would provide new markets for these supplies and would enhance competition in the marketplace.

The decision on the application for import authority will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). In reviewing natural gas export applications, the domestic need for the gas to be exported is considered, and any other issues determined to be appropriate in a particular case, including whether the arrangement is consistent with the DOE policy of promoting competition in the natural gas marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that the proposed imports will make competitively priced gas available to U.S. markets while the short-term nature of the transactions will minimize the potential for undue long-term dependence on foreign sources of energy. CGM also asserts that the proposed export volumes would result in a reduction of the current excess domestic natural gas supply, generate income and tax revenues, and reduce the U.S. trade deficit. Parties opposing the arrangement bear the burden of overcoming these assertions.

NEPA Compliance

The National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), requires DOE to give appropriate consideration to the environmental effects of its proposed actions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR part 590. Protests, motions to intervene, notices of intervention, requests for additional procedures, and written comments should be filed with the Office of Fuels Programs at the above address.

It is intended that a decisional record will be developed on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of CGM's application is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F–056 at the above address. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. Issued in Washington, D.C., May 14, 1990.

Clifford P. Tomaszewski,

Acting Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 90–11736 Filed 5–18–90; 8:45 am]

BILLING CODE 6450–01–M

[FE Docket No. 88–30–NG]

Union Gas Limited; Intended Use of New Border Point to Export Natural Gas to Canada

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of intended use of new border point to import/export natural gas from and to Canada.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) is taking notice of the completion of a new facility that will connect U.S. and Canadian natural gas pipeline systems at the international border. Union Gas Limited (Union) has notified DOE that it intends to use this new interconnection under its existing blanket export and import for re-export authorization.

FOR FURTHER INFORMATION CONTACT:

John S. Boyd, Office of Fuels Programs, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F–056, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–4523.

Diane J. Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: On December 20, 1989, Union filed a report in accordance with 10 CFR 590.407 of the program's administrative procedures

notifying FE of changed circumstances. Union intends to use the new border facilities which, according to its filing, are now complete and stand ready to commence service. The facility, known as the "Belle River-Bickford" pipeline, will be used in addition and as an alternative to the existing point of interconnection between Great Lakes Transmission Company (Great Lakes) and TransCanada Pipelines Limited authorized by DOE Opinion and Order No. 283 (Order 283) in this docket. Order 283, issued November 22, 1988, granted Union blanket authority to export up to 250 Bcf and to import for re-export back to Canada up to 100 Bcf over a two-year term at any point on the international border where existing facilities are located over existing pipeline systems operated by Great Lakes and Michigan Consolidated Gas Company (MichCon). In a September 13, 1989, order, the Federal Energy Regulatory Commission approved with conditions the new international border point located near St. Clair, Michigan, and issued a Presidential permit for the facility, which will connect the pipeline systems of MichCon and Union Gas Distribution Company.

A copy of Union's informational filing is available for inspection and copying in the Office of Fuels Programs Docket Room, Fossil Energy, U.S. Department of Energy, Forrestal Building, Room 3F–056, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, May 14, 1990.

Clifford P. Tomaszewski,

Acting Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 90–11737 Filed 5–18–90; 8:45 am]

BILLING CODE 6450–01–M

[Docket No. FE C&E 90–10; Certification Notice—58]

Filing Certification of Compliance: Coal Capability of New Electric Powerplant Pursuant to Provisions of the Powerplant and Industrial Fuel Use Act, as Amended

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of filing.

SUMMARY: Title II of the Powerplant and Industrial Fuel Use Act of 1978, as amended, ("FUA" or "the Act") (42 U.S.C. 8301 *et seq.*) provides that no new electric powerplant may be constructed or operated as a base load powerplant without the capability to use coal or another alternate fuel as a primary energy source (section 201(a), 42 U.S.C. 8311(a), Supp. V. 1987). In order to meet the requirement of coal capability, the owner or operator of any new electric powerplant to be operated as a base load powerplant proposing to use natural gas or petroleum as its primay energy source may certify, pursuant to section 201(d), to the Secretary of Energy prior to construction, or prior to operation as a base load powerplant, that such powerplant has the capability to use coal or another alternate fuel. Such certificaton establishes compliance with section 201(a) as of the date it is filed with the Secretary. The Secretary is required to publish in the **Federal Register** a notice reciting that the certification has been filed. Four owners and operators of proposed new electric base load powerplants have filed self certifications in accordance with section 201(d). Further information is provided in the **SUPPLEMENTARY INFORMATION** section below.

SUPPLEMENTARY INFORMATION: The following companies have filed self certifications:

Name	Date received	Type of facility	Megawatt capacity	Location
Doswell Limited Partnership, Los Angeles, CA	4–30–90	Combined cycle	650	Hanover County, VA.
Indeck Energy Sevices of Kirkwood, Inc., Wheeling, IL	5–03–90	Combined cycle	55.3	Kirkwood, NY.
Mid-County Cogeneration, L.P., Melville, NY	5–03–90	Combined cycle	77	Smithtown, NY.
Country Club Energy Partners, L.P., Melville, NY	5–03–90	Combined cycle	300	Islip, NY.

Amendments to the FUA on May 21, 1987 (Pub. L. 100–42), altered the general prohibitions to include only new electric base load powerplants and to provide for the self certification procedure.

Copies of this self certification may be reviewed in the Office of Fuels Programs, Fossil Energy, Room 3F–056, FE–52, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, phone number (202) 586–6769.

Issued in Washington, DC, on May 15, 1990.

Anthony J. Como,

Director, Office of Coal & Electricity, Office of Fuels Programs, Fossil Energy.

[FR Doc. 90–11738 Filed 5–18–90; 8:45 am]

BILLING CODE 6450–01–M

Office of Hearings and Appeals

Proposed Refund Procedures

AGENCY: Office of Hearings and Appeals, Department of Energy.

ACTION: Notice of Proposed Implementation of special refund procedures.

SUMMARY: The Office of Hearings and Appeals (OHA) of the Department of Energy (DOE) announces the proposed procedures for the disbursement of $450,000, plus accrued interest, obtained by the DOE under the terms of a consent order entered into with the Quantum Chemical Corporation (formerly National Distillers and Chemical Corporation). The subsidiaries of Quantum Chemical Corporation involved in this proceeding include National Hydrocarbons, Inc. and U.S. Industrial Chemicals Company. The OHA has tentatively determined that the funds will be distributed in accordance with the DOE's special refund procedures, 10 CFR part 205, subpart V.

DATE AND ADDRESS: Comments must be filed in duplicate within 30 days of publication of this notice in the **Federal Register** and should be addressed to the Office of Hearings and Appeals, Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585. All comments should display a reference to case number LEF–0011.

FOR FURTHER INFORMATION CONTACT: Thomas L. Wieker, Deputy Director, Office of Hearings and Appeals, Department of Energy, 1000 Independence Ave., SW., Washington, DC 20585, (202) 586–2390.

SUPPLEMENTARY INFORMATION: In accordance with § 205.282(b) of the procedural regulations of the Department of Energy (DOE), 10 CFR

205.282(b), notice is hereby given of the issuance of the Proposed Decision and Order set out below. The Proposed Decision and Order sets forth the procedures that the DOE has tentatively formulated to distribute $450,000 that has been remitted by Quantum Chemical Corporation (formerly National Distillers and Chemical Corporation) to the DOE to settle possible pricing violations with respect to its sales of natural gasoline during the period August 1, 1973 through January 27, 1981. National Hydrocarbons, Inc. and U.S. Industrial Chemicals Company are subsidiaries of Quantum Chemical Corporation involved in this proceeding. The DOE is currently holding the funds in an interest bearing account pending distribution.

Applications for refund should not be filed at this time. Appropriate public notice will be given when the submission of claims is authorized. Any member of the public may submit written comments regarding the proposed refund procedures. Commenting parties are requested to submit two copies of their comments. Comments should be submitted within 30 days of the publication in the **Federal Register** and should be sent to the address set forth at the beginning of this notice. All comments received will be available for public inspection between the hours of 1 p.m. through 5 p.m., Monday through Friday, except federal holidays, in the Public Reference Room of the Office of Hearings and Appeals, located in room 1E–234, 1000 Independence Avenue, SW., Washington, DC 20585. If commentors express sufficient interest in presenting their views orally, the DOE will convene a public hearing. In the event we determine to hold a hearing, notice will be given in the **Federal Register.**

Dated: May 11, 1990.

George B. Breznay,

Director, Office of Hearings and Appeals.

Proposed Decision and Order of the Department of Energy; Implementation of Special Refund Procedures

Name of Firm: Quantum Chemical Corporation.
Date of Filing: February 8, 1990.
Case Number: LEF–0011.

In accordance with the procedural regulations of the Department of Energy (DOE), 10 CFR part 205, subpart V, the Economic Regulatory Administration (ERA) of the DOE filed a Petition for the Implementation of Special Refund Procedures with the Office of Hearings and Appeals (OHA) on February 8, 1990. In its Petition, the ERA requests that the OHA formulate and implement procedures for the distribution of funds received pursuant to a consent order between the DOE and Quantum Chemical Corporation, formerly National Distillers and Chemical Corporation (referred to herein as Quantum).

I. Background

Since the early 1950's, Quantum has owned and operated an integrated petrochemical facility at Tuscola, Illinois. Specifically, this facility has been owned by National Hydrocarbons, Inc. (NHI), a wholly-owned subsidiary of Quantum, and has been operated by U.S. Industrial Chemicals Company (USIC), Quantum's chemical division. The facility is adjacent to the main natural gas pipeline system of the Panhandle Eastern Pipeline Company (Panhandle). At this plant, Quantum produced from Panhandle's gas stream a mixed natural gas liquid (NGL) stream which was then further fractionated into its component products, including natural gasoline. Panhandle was paid for the volume of natural gas "shrinkage" of its gas stream and the balance of that stream was returned to Panhandle. According to the ERA, virtually all of the NGL products produced by Quantum at the Tuscola plant were sold to the Phillips Petroleum Company (Phillips) under a series of long term contracts. The natural gasoline produced at the Tuscola plant was sold to Phillips on a cents-per-gallon basis.

On the basis of an audit of Quantum's pricing practices, the ERA issued a Proposed Remedial Order (PRO) alleging that Quantum overcharged its purchasers of NGL products, including natural gasoline, by $65,565,237 during the period September 1973 through August 1978. On January 27, 1987, DOE issued a Remedial Order to Quantum, upholding the allegations contained in the PRO. *National Distillers and Chemical Corporation,* 15 DOE ¶ 83,015 (1987). On March 25, 1988, Quantum and the DOE entered into a Consent Order to resolve all matters relating to Quantum's compliance with the regulations concerning its sales of natural gasoline during the period August 1, 1973 through January 27, 1981. Quantum's sales of other NGL products were not covered by the terms of the Consent Order.[1] Pursuant to the Consent Order, the DOE received a payment of $450,000 from Quantum on April 25, 1988. These funds have been placed in an interest-bearing escrow account maintained by the Department of the Treasury for ultimate distribution by the DOE through subpart V.

II. Jurisdiction and Authority

The procedural regulations of the DOE set forth general guidelines by which the OHA may formulate and implement a plan of distribution for funds received as a result of an enforcement proceeding. 10 CFR part 205, Subpart V. It is the DOE policy to use the subpart V process to distribute such funds. For a more detailed discussion of subpart V and the authority of the OHA to fashion procedures to distribute refunds obtained as part of settlement agreements, *see Office of Enforcement,* 9 DOE ¶ 82,553 (1982); *Office of Enforcement,* 8 DOE ¶ 82,597 (1981).

We have considered the ERA's petition that we implement a Subpart V proceeding with respect to the Quantum consent order fund and have determined that such a proceeding is appropriate. This Proposed Decision and Order sets forth the OHA's tentative plan for distributing these funds to qualified purchasers of Quantum's natural gasoline. Because the procedures set forth in this Decision are in proposed form, no applications should be filed at this time. A final determination will be issued at a later date announcing that the filing of Quantum refund applications is authorized. Comments are solicited on these proposed procedures.

III. Proposed Refund Procedures

A. Eligibility for Refunds

The settlement amount of $450,000, plus accrued interest, will be available for distribution to purchasers of Quantum natural gasoline who can show that they were injured by Quantum's pricing practices during the Consent Order period.

B. Calculation of Refund Amount

We propose adopting a volumetric method to apportion the Quantum escrow account. We will derive the volumetric figure by dividing the $450,000 received from Quantum by our estimate of the total volume of natural

[1] With respect to NGL products other than natural gasoline, Quantum continued to pursue its appeal of the DOE's Remedial Order before the Federal Energy Regulatory Commission (FERC). In an order dated April 8, 1988, the FERC found that the theory upon which these alleged violations were based was incorrect, and the Remedial Order was remanded to the DOE. *National Distillers and Chemical Corporation,* 43 FERC ¶ 61,060 (1988). Consistent with this decision, the ERA now has concluded that there are no further overcharges related to natural gas products and that the Consent Order concerned natural gasoline sales resolved and settled all disputes between Quantum and the DOE.

gasoline sold by Quantum during the Consent Order period.

As the basis for our estimate of Quantum's total volume of sales of natural gasoline, we are making certain presumptions concerning these sales. The Consent Order between Quantum and the DOE refers to only one petrochemical facility, the Tuscola plant, owned and operated by Quantum through its subsidiaries USI and USIC. The Consent Order also states that Quantum sold "virtually all of the NGL products produced at the Tuscola plant to Phillips * * * under a series of long term contracts in effect since 1951." Consent Order at 4. A review of the PRO audit file indicates that while some NGL products were sold to Amoco as well as to Phillips, all of the natural gasoline produced at the Tuscola plant was sold to Phillips. *See* "NGL Audit Report: National Distillers—Phase II" at p. 2 (January 19, 1979). Accordingly, we presume that Quantum produced natural gasoline only at its Tuscola plant and that all of this natural gasoline was sold to Phillips during the PRO audit period.

The PRO audit period, September 1973 through August 1978, covers exactly two-thirds of the ninety-month period included in the Consent Order. During the PRO audit period, Quantum sold 50,120,682 gallons of natural gasoline to Phillips. When this figure is extrapolated to the entire period covered by the Consent Order, Quantum appears to have sold Phillips approximately 75,181,050 gallons of natural gasoline during the period of the Consent Order. This estimate of total gallonage yields a volumetric refund amount of $.00599 per gallon, exclusive of interest.

This volumetric method is based upon the presumption that the alleged overcharges were spread equally over all gallons of covered products sold by Quantum during the months when the alleged overcharges occurred. Under the volumetric approach, an eligible claimant will receive a refund equal to the number of gallons of natural gasoline purchased from Quantum and its subsidiaries during the Consent Order period. In addition, each successful claimant will receive a pro rata portion of the interest that has accrued on the Quantum funds since the date of remittance.

As in previous cases, we will establish a minimum amount of $15 for refund claims. We have found through our experience in prior refund cases that the cost of processing claims of $15 or less outweighs the benefits of restitution in those situations. *See Uban Oil Co.*, 9 DOE ¶ 82,541 at 85,225 (1982) (*Uban*).

1. Showing of Injury

We propose that each claimant will be required to document its purchases of Quantum's natural gasoline during the Consent Order period, when Quantum's alleged overcharges may have occurred. In addition, we propose to require an applicant to demonstrate that it was injured by the alleged overcharges. In order to demonstrate that it did not subsequently raise its prices and thereby recover the increased costs associated with Quantum's alleged overcharges, a claimant will have to show that it maintained banks of unrecovered product costs. We realize that some applicants may be unable to provide actual cost bank records for the period covered by this proceeding. We are therefore willing to accept information establishing with reasonable likelihood that a claimant had banks. *See Seminole Refining Inc.*, 12 DOE ¶ 85,197 (1985); *Bayou State Oil Corp.*, 12 DOE ¶ 85,197 (1985). The maintenance of banks does not establish injury. *See Tenneco Oil Co./Chevron U.S.A., Inc.*, 10 DOE ¶ 85,014 (1982). In order to demonstrate injury a claimant must show that market conditions would not permit it to pass through those increased costs to its customers. *See American Pacific International*, 14 DOE ¶ 85,158 at 88,295 (1986). Such a showing might be made through a demonstration of a competitive disadvantage, lowered profit margin, decreased market share or depressed sales volumes during the period of purchases of Quantum natural gasoline. *See Gulf Oil Corporation*, 16 DOE ¶ 85,381 at 88,740 (1987).

2. Small Claims Presumption

We also propose to adopt a presumption, as we have in many cases, that purchasers seeking refunds of $5,000 or less were injured by Quantum's pricing practices. *See Uban*, 9 DOE at 85,223–24. We recognize that the cost to the applicant of gathering evidence of injury to support a refund claim of $5,000 or less could exceed the expected refund. Consequently, without simplified procedures, some injured parties would be denied an opportunity to obtain a refund. For example, some firms may have limited accounting and data-retrieval capabilities, and may therefore be unable to produce the records necessary to prove either the existence of banks of unrecovered costs, or that they did not pass the alleged overcharges on to their own customers. We also seek to insure that the cost to the applicant and to the government of compiling and analyzing information sufficient to establish a claim does not exceed the amount of the refund. *See Marion Corp.*, 12 DOE ¶ 85,014 (1984) (*Marion*). Under the small claims presumption, an applicant seeking total refunds of $5,000 or less will not be required to make a detailed demonstration of injury. Such an applicant need only document its purchase volume of Quantum natural gasoline during the months of the Consent Order period.

3. End-Users

We propose to adopt the presumption that end-users, *i.e.*, ultimate consumers, whose businesses are unrelated to the petroleum industry, were injured by Quantum's alleged overcharges. Unlike regulated firms in the petroleum industry, end-users were generally not subject to price controls during the period covered by this proceeding, and were not required to keep records that justified selling price increases by reference to cost increases. For these reasons, an analysis of the impact of the alleged overcharges on the final prices of non-petroleum goods and services would be beyond the scope of a special refund proceeding. *See Marion*, 12 DOE at 88,030; *see also Thornton Oil Corp.*; 12 DOE ¶ 85,112 (1984). We therefore propose that end-users of Quantum natural gasoline need only document their purchase volumes during the Consent Order period to make a sufficient showing of injury.

4. Regulated Firms and Cooperatives

We propose that claimants whose prices for goods and services are regulated by a government agency (such as a public utility), or by the terms of a cooperative agreement, will be presumed to have absorbed the alleged overcharges. Accordingly, such claimants need only document the volume of covered products purchased by them, during the months when the alleged overcharges occurred, in order to receive a full volumetric refund. These firms would have routinely passed price increases through to their customers, and will now pass on the benefits of the refund to their customers. Accordingly, these firms will not be required to make a detailed demonstration of injury. However, regulated firms and cooperatives will be required to certify that they will pass any refund on to their customers or member-customers, provide us with a full explanation of how they plan to accomplish the restitution, and certify that they will notify the appropriate regulatory body or membership group of their receipt of the refund. *See Marathon Petroleum Co.*, 14 DOE ¶ 85,269 at 88,514 (1986); *Office of Special Counsel*, 9 DOE

¶ 82,538 at 85,203 (1982). We will not require a public utility seeking a refund of $5,000 or less to submit the above reference certifications and explanation. Sales of covered products by cooperatives to non-members will be treated in the same manner as sales by other resellers or retailers.

5. Indirect Purchasers

We propose that firms which made indirect purchases of Quantum natural gasoline during the Consent Order period may also apply for refunds. If an applicant did not purchase directly from Quantum or its subsidiaries, but believes that natural gasoline it purchased from Phillips or some other firm was originally purchased from Quantum during the Consent Order period, the applicant must establish its basis for that belief and identify the reseller from whom the products were purchased. Indirect purchasers who either fall within a class of applicant whose injury is presumed, or who can prove injury, may be eligible for a refund if the reseller of Quantum natural gasoline passed through Quantum's alleged overcharges to its own customers. *See Dorchester Gas Corp.*, 14 DOE ¶ 85,240 at 88,451 (1986).

6. Spot Purchasers

We propose to adopt the rebuttable presumption that a claimant who made only spot purchases from Quantum or its subsidiaries was not injured as a result of those purchases. A claimant is a spot purchaser if it made only sporadic purchases of significant volumes of Quantum natural gasoline. This proposal is based on our determination that spot purchasers tend to have considerable discretion as to the timing of purchases and the market in which to make purchases. Accordingly, they generally would not have made spot purchases from Quantum at increased prices unless they were able to pass through the full amount of any price increases to their own customers. *See Office of Enforcement*, 8 DOE ¶ 82,597 at 85, 396-97 (1981).

Accordingly, a spot purchaser claimant must submit specific and detailed evidence to rebut the spot purchaser presumption and to establish the extent to which it was injured as a result of its spot purchases from Quantum.

IV. Distribution of Refunds Remaining After Consideration of All Refund Applications

In the event that money remains after all meritorious refund applications have been processed, the funds in the Quantum escrow account will be disbursed in accordance with the provisions of the Petroleum Overcharge and Distribution Act of 1986 (PODRA), 15 U.S.C.A. 4501–4507 (West Supp. 1989).

It is therefore ordered that:

The refund amount remitted to the Department of Energy by Quantum Chemical Corporation (formerly National Distillers and Chemical Corporation) pursuant to the Consent Order executed on March 24, 1988 will be distributed in accordance with the foregoing Decision.

[FR Doc. 90–11740 Filed 5–18–90; 8:45 am]
BILLING CODE 6450–01–M

Office of Minority Economic Impact Objective Merit Review System

AGENCY: Department of Energy, Office of Minority Economic Impact.

ACTION: Program notice.

SUMMARY: The Department of Energy, Office of Minority Economic Impact is publishing its Merit Review System for discretionary financial assistance applications in accordance with the requirements set forth in the Department of Energy Financial Assistance Rules, 10 CFR 600.16.

EFFECTIVE DATE: May 21, 1990.

FOR FURTHER INFORMATION CONTACT: Isiah O. Sewell, Office of Minority Economic Impact, U.S. Department of Energy, 1000 Independence Avenue SW., room 5B–110, Washington, DC 20585, (202) 586–1593.

SUPPLEMENTARY INFORMATION: .

I. Purpose and Scope
II. Responsible Official
III. Deviation
IV. Application Evaluation

I. Purpose and Scope

A. This announcement sets forth the procedures applicable to the merit review and evaluation of discretionary financial assistance applications by the Department of Energy (DOE) Office of Minority Economic Impact (MI) for the following listed areas: Data Development and Minority Energy Assessment Model; Policy Assessments and Analysis; Technical Market Analysis and Information; Technical Support to Minority Educational Institutions; Minority Energy Information Clearinghouse; Minority Business and Community Development and Minority Undergraduate Training for Energy-Related Careers.

B. The MI activities are primarily performed through the following Procurement Offices: Oak Ridge Operations Office, Oak Ridge, Tennessee; San Francisco Operations Office, Oakland, California; Chicago Operations Office, Argonne, Illinois.

However, activities may be implemented through any DOE Procurement Office or through any other means authorized by law.

II. Responsible Official

The Director of MI is responsible for this system of objective merit review and evaluation of discretionary financial assistance applications funded by MI.

III. Deviation

Single-case deviations from the following procedures may be authorized in writing by the Director MI upon the written request by a staff member. Whenever a proposed deviation from this system of review would be a deviation from 10 CFR part 600, the deviation must also be authorized in accordance with the procedures prescribed in that part.

IV. Application Evaluation

A. *Unsolicited Applications:* Unsolicited applications should be addressed to the U.S. Department of Energy, Office of Minority Economic Impact, 1000 Independence Avenue, SW., Washington, DC 20585, *Attention:* Administrative Officer, room 5B–110. The applications will be evaluated for funding generally within 6 months but, in any event, no later than 12 months from the date of receipt by DOE. The terms of the original application may be required to be revalidated by the applicant at the request of DOE if the application is held beyond a 6-month period.

1. *Qualifier Review:* All applications are initially reviewed by a Program Official with the MI to verify that the applications have the appropriate information (e.g., company address, signature, etc.), and that the proposed effort adequately addresses one or more specific objectives of the mission of MI. Those applications which do not support the mission of the office or do not contain the information required by 10 CFR 600.14 or by a Notice of Program Interest, will be returned to the sender.

2. *Comprehensive Review:* A comprehensive review will be performed on all relevant unsolicited applications through the review process described below.

a. A Senior Program Official within the appropriate MI program shall perform an initial technical evaluation of all applications to ensure that the proposed effort is technically sound and feasible, and that the effort is consistent with current program funding priorities.

b. For applications which pass the initial evaluation, MI shall objectively evaluate each proposal received against the criteria set forth in 10 CFR part 600.14. Field Offices and other Headquarters Program Offices may supplement internal staff review resources when there are not sufficient reviewers in MI, with the objective of having the technical/scientific evaluation conducted by the most qualified individuals available. At times, external reviewers (non-DOE) may be utilized to supplement internal review. All review groups shall consist of at least three members, who will be chosen by the Director.

c. MI selects evaluators on the basis of their professional qualifications and expertise in the field of activity proposed in the application. Outside evaluators are required to comply with 10 CFR 600.16(c), 10 CFR 600.17, and any other applicable DOE rules or directives concerning the use of outside evaluators.

d. After the completion of all technical reviews, the evaluations are forwarded to the appropriate Senior Program official within the MI for a final accept/reject recommendation to the Director. The Director of MI decides to either accept or reject the unsolicited application in accordance with 10 CFR 600.14. If the decision is to reject the application, the Senior Program Official prepares a justification for the decision and summarizes the results of the reviewer's comments. Notification is provided to the applicant of the decision to reject the application. If the decision is to accept the application, the Senior Program official initiates the procurement process to make an award. Notification of acceptance of the application will be made by the Contracting Officer upon approval of the procurement request by MI. Upon written request by the applicant, MI will provide a written summary of the evaluation results.

B. *Applications in Response to Specific Solicitations by the Office of Minority Economic Impact:* MI has two areas for which financial assistance applications were requested i.e., Minority Educational Institution Assistance and Minority Honors Training and Industrial Assistance. Additional programs may be developed where solicitations for applications will be issued. The merit review procedures for these programs will be issued in the solicitations.

Issued in Washington, DC on May 16, 1990.

Melva G. Wray,

Director, Office of Minority Economic Impact.

[FR Doc. 90-11734 Filed 5-18-90; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL 3780-6]

Clarification of Scope of Chemicals Sources Covered and Open Meetings of the Negotiated Rulemaking Advisory Committee—Fugitive Emissions From Equipment Leaks Rule

As required by section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), we are giving notice of open meetings of the Advisory Committee to negotiate a rule to control fugitive emissions of toxic volatile organic compounds (VOCs) from chemical equipment leaks.

The next meeting will be held on June 6 from 10 a.m. to 5 p.m., and on June 7, 1990, from 9 a.m. to 5 p.m., at the Compri Hotel 4620 S. Miami Blvd., Morrisville, NC (919) 941-6066. The Compri Hotel is at Exit 281 on I-40 just two exits from the Raleigh-Durham Airport.

The Federal Advisory Committee Act Charter for this Committee was originally set to terminate April 30, 1990. The Charter has been extended until September 1990. However, EPA expects that the Committee will reach agreement on the rule before that date.

The Committee has been meeting since September 1989. Issues and options for monitoring and reducing fugitive emissions from equipment leaks have been greatly narrowed. The purpose of this meeting is to attempt to reach agreement on a conceptual framework for reducing fugitive emissions from valves, pumps and flanges. The conceptual framework will address issues such as: leak definition, percentage leakers permissable, emission factors and approaches to assessing the cost of the standard.

The scope of this and other rules that are planned for adoption within the first two years after passage of Clean Air Act (CAA) revisions will now include all categories of SOCMI sources that produce, and possibly all that use (as raw materials or intermediates) chemicals in the CAA list (e.g., the current list of 191). Although organic chemical processes (e.g., benzene/toluene/xylene units) located in refineries or on refinery property would be affected, the Agency does not plan at this time, to include pertroleum refinery processes among the source categories affected by this initial phase of rules.

The Committee has set July 17 and 18 as its July meeting date. That meeting will be held in the Washington, DC, area at a location to be announced.

The meetings are open to the public without advance registration. Persons needing further information on substantive aspects of the rule should call Robert Ajax, Office of Air Quality Planning and Standards, U.S. EPA, (919) 541-5579. Person needing further information on committee arrangements or procedures should contact the Committee's facilitator, Philip Harter, (202) 887-1033.

Dated: May 15, 1990.

Paul Lapsley,

Director, Regulatory Management Division, Office of Policy, Planning and Evaluation.

[FR Doc. 90-11722 Filed 5-18-90; 8:45 am]

BILLING CODE 6560-50-M

[OPTS-51748; FRL 3765-9]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Statutory requirements for section 5(a)(1) premanufacture notices are discussed in the final rule published in the **Federal Register** of May 13,1983 (48 FR 21722). This notice announces receipt of 182 such PMNs and provides a summary of each.

DATES: Close of Review Periods:

P 90-558, 90-559, 90-560, 90-561, June 9, 1990.

P 90-562, June 6, 1990.

P 90-563, 90-564, June 9, 1990.

P 90-565, 90-566, 90-567, 90-568, June 10, 1990.

P 90-569, 90-570, 90-571, June 11, 1990.

P 90-572, June 17, 1990.

P 90-573, June 12, 1990.

P 90-574, 90-575, June 16, 1990.

P 90-576, 90-577, June 17, 1990.

P 90-578, June 18, 1990.

P 90-579, 90-580, June 17, 1990.

P 90-581, 90-582, June 18, 1990.

P 90-583, 90-585, 90-586, June 19, 1990.

P 90-587, 90-588, 90-589, 90-590, 90-591, June 20, 1990.

P 90-592, 90-593, 90-594, 90-595, 90-596, June 23, 1990.

P 90-597, 90-598, 90-599, June 25, 1990.

P 90-600, June 26, 1990.

P 90-601, 90-602, 90-603, 90-604, June 25, 1990.

P 90–605, June 27, 1990.
P 90–606, 90–607, 90–608, 90–609, 90–610, June 25, 1990.
P 90–611, June 27, 1990.
P 90–612, 90–613, June 26, 1990.
P 90–614, June 30, 1990.
P 90–615, June 26, 1990.
P 90–616, 90–617, 90–618, 90–619, 90–620, 90–621, 90–622, 90–623, June 27, 1990.
P 90–624, 90–625, July 1, 1990.
P 90–626, June 27, 1990.
P 90–627, 90–629, 90–630, 90–631, 90–632, 90–633, July 1, 1990.
P 90–634, 90–635, 90–636, July 2, 1990.
P 90–637, 90–638, 90–639, 90–640, 90–641, 90–642, July 3, 1990.
P 90–643, 90–644, 90–645, 90–646, 90–647, 90–648, 90–649, 90–650, July 4, 1990.
P 90–651, 90–653, July 7, 1990.
P 90–654, 90–655, 90–656, 90–657, July 8, 1990.
P 90–658, July 9, 1990.
P 90–659, July 4, 1990.
P 90–660, 90–661, 90–662, 90–663, 90–664, 90–665, 90–666, 90–667, 90–668, 90–669, July 10, 1990.
P 90–670, 90–671, 90–672, 90–673, July 11, 1990.
P 90–674, 90–675, 90–676, July 15, 1990.
P 90–677, July 10, 1990.
P 90–678, 90–679, 90–680, 90–681, 90–682, 90–683, 90–684, 90–685, 90–686, 90–687, 90–688, 90–689, 90–690, July 15, 1990.
P 90–698, July 16, 1990.
P 90–699, 90–700, 90–701, July 15, 1990.
P 90–702, 90–703, July 16, 1990.
P 90–704, 90–705, 90–706, 90–707, July 17, 1990.
P 90–708, 90–709, 90–710, 90–711, 90–712, 90–713, 90–714, 90–715, 90–716, July 18, 1990.
P 90–717, July 21, 1990.
P 90–718, 90–719, 90–720, 90–721, 90–722, 90–723, 90–724, 90–725, 90–726, 90–727, 90–728, 90–729, 90–730, 90–731, 90–732, 90–733, 90–734, 90–735, 90–736, 90–737, 90–738, 90–739, 90–740, 90–741, 90–742, 90–743, 90–744, 90–745, 90–746, 90–747, 90–748, 90–749, June 23, 1990.

Written comments by:

P 90–558, 90–559, 90–560, 90–561, May 10, 1990.
P 90–562, May 7, 1990.
P 90–563, 90–564, May 10, 1990.
P 90–565, 90–566, 90–567, 90–568, May 11, 1990.
P 90–569, 90–570, 90–571, May 12, 1990.
P 90–572, May 18, 1990.
P 90–573, May 13, 1990.
P 90–574, 90–575, May 17, 1990.
P 90–576, 90–577, May 18, 1990.
P 90–578, May 19, 1990.
P 90–579, 90–580, May 18, 1990.
P 90–581, 90–582, May 19, 1990.
P 90–583, 90–585, 90–586, May 20, 1990.
P 90–587, 90–588, 90–589, 90–590, 90–591, May 21, 1990.
P 90–592, 90–593, 90–594, 90–595, 90–596, May 24, 1990.
P 90–597, 90–598, 90–599, May 26, 1990.
P 90–600, May 27, 1990.
P 90–601, 90–602, 90–603, 90–604, May 26, 1990.
P 90–605, May 28, 1990.
P 90–606, 90–607, 90–608, 90–609, 90–610, May 26, 1990.
P 90–611, May 28, 1990.
P 90–612, 90–613, May 27, 1990.
P 90–614, May 31, 1990.
P 90–615, May 27, 1990.
P 90–616, 90–617, 90–618, 90–619, 90–620, 90–621, 90–622, 90–623, May 28, 1990.
P 90–624, 90–625, June 1, 1990.
P 90–626, May 28, 1990.
P 90–627, 90–629, 90–630, 90–631, 90–632, 90–633, June 1, 1990.
P 90–634, 90–635, 90–636, June 2, 1990.
P 90–637, 90–638, 90–639, 90–640, 90–641, 90–642, June 3, 1990.
P 90–643, 90–644, 90–645, 90–646, 90–647, 90–648, 90–649, 90–650, June 4, 1990.
P 90–651, 90–653, June 7, 1990.
P 90–654, 90–655, 90–656, 90–657, June 8, 1990.
P 90–658, June 9, 1990.
P 90–659, June 4, 1990.
P 90–660, 90–661, 90–662, 90–663, 90–664, 90–665, 90–666, 90–667, 90–668, 90–669, June 10, 1990.
P 90–670, 90–671, 90–672, 90–673, June 11, 1990.
P 90–674, 90–675, 90–676, June 15, 1990.
P 90–677, June 10, 1990.
P 90–678, 90–679, 90–680, 90–681, 90–682, 90–683, 90–684, 90–685, 90–686, 90–687, 90–688, 90–689, 90–690, June 15, 1990.
P 90–698, June 16, 1990.
P 90–699, 90–700, 90–701, June 15, 1990.
P 90–702, 90–703, June 16, 1990.
P 90–704, 90–705, 90–706, 90–707, June 17, 1990.
P 90–708, 90–709, 90–710, 90–711, 90–712, 90–713, 90–714, 90–715, 90–716, June 18, 1990.
P 90–717, June 21, 1990.
P 90–718, 90–719, 90–720, 90–721, 90–722, 90–723, 90–724, 90–725, 90–726, 90–727, 90–728, 90–729, 90–730, 90–731, 90–732, 90–733, 90–734, 90–735, 90–736, 90–737, 90–738, 90–739, 90–740, 90–741, 90–742, 90–743, 90–744, 90–745, 90–746, 90–747, 90–748, 90–749, May 24, 1990.

ADDRESS: Written comments, identified by the document control number "(OPTS–51748)" and the specific PMN number should be sent to: Document Processing Center (TS–790), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Room L–100, Washington, DC, 20460, (202) 382–3532.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS–799), Office of Toxic Substances, Environmental Protection Agency, Room EB–44, 401 M Street, SW., Washington, DC 20460 (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer on the PMNs received by EPA. The complete nonconfidential document is available in the Public Reading Room NE–G004 at the above address between 8 a.m. and 4 p.m., Monday through Friday, excluding legal holidays.

P 90–558

Manufacturer. Eastman Kodak Company.

Chemical. (G) (4-(1-Methylbutoxy)phenyl)hydrazine monohydrochloride.

Use/Production. (G) Chemical intermediate. Prod. range: 2,000–3,500 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 544 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: strong species (Rabbit). Skin irritation: slight species (Rabbit). Skin sensitization: negative species (Guinea Pig).

P 90–559

Manufacturer. Confidential.

Chemical. (S) 1-(1-methylbutoxy)-4-benzenamine hydrochloride.

Use/Production. (G) Chemical intermediate. Prod. range: 3,000–5,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 335 mg/kg species (Rat). Eye irritation: moderate species (Rabbit).

P 90–560

Manufacturer. Eastman Kodak Company.

Chemical. (G) 1-(1-methylbutoxy)-4-nitrobenzene.

Use/Production. (G) Chemical intermediate. Prod. range: 3,500–6,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 1166 mk/kg species (Rat). Acute dermal toxicity: LD50 > 20 ml/kg

species (Rabbit). Eye irritation: slight species (Rabbit).Skin irritation: slight species (Rabbit). Skin sensitization: negative species (Guinea Pig).

P 90-561

Manufacturer. Eastman Kodak Company.

Chemical. (S) 4-Methylbenzenesulfonate 2-pentanol.

Use/Production. (G) Chemical intermediate. Prod. range: 7,000–12,000 kg/yr.

Toxicity Data. Eye irritation: slight species (Rabbit).

P 90-562

Manufacturer. Confidential.

Chemical. (G) 2-Ethylhexyl phosphoric acid oleylamine salt.

Use/Production. (G) Lubricating oil additive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: moderate species (Rabbit). Skin irritation: moderate species (Rabbit). Mutagenicity: negative.

P 90-563

Manufacturer. E. I. Du Pont De Nemours & Co. Inc.

Chemical. (G) Polyurethane.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 90-564

Manufacturer. Confidential.

Chemical. (G) Imidozoethione.

Use/Production. (G) Open, nondispersive uses. Prod. range: Confidential.

P 90-565

Manufacturer. Aldrich Chemical Company.

Chemical. (G) Alkyl heterocyclic thiol derivative.

Use/Production. (G) Contained use. Prod. range: Confidential.

P 90-566

Manufacturer. Confidential.

Chemical. (G) A difunctional epoxy, polyether prepolymer.

Use/Production. (G) Resin & sealant modifier. Prod. range: Confidential.

P 90-567

Importer. Ciba-Geigy Corporation.

Chemical. (S) 1-Butanona, 2-Ddimethylamino)-1-(4-(4-morpholiny) phenyl)-2-(phenylmethyl)-.

Use/Import. (S) Photoinitiator. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: none species (Rabbit). Mutagenicity: positive. Static acute toxicity: time LC50 96H0.46 mg/l species (Zebra Fish). Skin irritation: negligible species (Rabbit). Skin sensitization: negative species (Guinea Pig).

P 90-568

Manufacturer. Confidential.

Chemical. (S) N-butyl alcohol; maleic anhydride; polytetra methylene ether-glycol; hexane diol dicarylate; trimethylene diamine.

Use/Production. (S) To be used in a coating for aircrafts. Prod. range: 500–20,000 kg/yr.

Toxicity Data. Static acute toxicity: time LC50 48H16.9 mg/l species (Daphnia Magna).

P 90-569

Manufacturer. Confidential.

Chemical. (G) Methacrylate acrylic copolymer.

Use/Production. (G) Component of a coating with an open, nondispersive use. Prod. range: 19,000–35,000 kg/yr.

P 90-570

Manufacturer. Confidential.

Chemical. (G) Polyester polyurethane resin.

Use/Production. (S) Coatings. Prod. range: Confidential.

P 90-571

Manufacturer. Confidential.

Chemical. (G) Polyester resin.

Use/Production. (S) Coatings. Prod. range: Confidential.

P 90-572

Manufacturer. Confidential.

Chemical. (G) Polyester polyurethane resin.

Use/Production. (S) Coatings. Prod. range: Confidential.

P 90-573

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Acrylic polymer.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 90-574

Manufacturer. Confidential.

Chemical. (G) Mixed salts of modified rosin.

Use/Production. (G) Printing ink resin. Prod. range: Confidential.

P 90-575

Manufacturer. Confidential.

Chemical. (G) Groups and hydroxy terminated polyisocyanate.

Use/Production. (S) Graphic arts printing plate. Prod. range: Confidential.

P 90-576

Importer. Harvey E. Giss & Associates.

Chemical. (G) Terpene acetal.

Use/Import. (S) Perfume. Import range: 1,000–3,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 3,600 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea Pig).

P 90-577

Manufacturer. Rhone Poulenc Surfactants & Speciality.

Chemical. (G) Polyamide.

Use/Production. (G) Processing aid for nylon type fibers. Prod. range: Confidential.

P 90-578

Importer. Nicca U.S.A., Inc.

Chemical. (G) Reaction product of oxurane, methyl - polymer with oxirane, ether(1,2-ethanedlydintrilo)tetrakis; hexane, 1,6-diisocyanto; and sodium hydrogensulfite.

Use/Import. (S) Finishing agent for cotton, nylon, and poly cotton. Import range: Confidential.

P 90-579

Manufacturer. The Dow Chemical Company.

Chemical. (G) Modified styrene acrylate polymer.

Use/Production. (G) Polymeric stabilizer or additive for manufacturing. Prod. range: Confidential.

P 90-580

Manufacturer. The Dow Chemical Company.

Chemical. (G) Anionic polymeric surfactant.

Use/Production. (G) Polymeric stabilizer or additive for manufacturing. Prod. range: Confidential.

P 90-581

Manufacturer. Atochem North America.

Chemical. (G) Brominated phthalate ester.

Use/Production. (S) Flame retardant. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: none species (Rabbit). Mutagenicity: negative. Skin irritation: negligible species (Rabbit). Skin sensitization: negative species (Guinea Pig).

P 90-582

Importer. Confidential.

Chemical. (G) Grafted EVA copolymer.

Use/Import. (S) Binder in coextruded plastic packaging and additive for thermoplastic powder coating. Import range: Confidential.

P 90-583

Manufacturer. Confidential.

Chemical. (G) Tin and titanium alkylate, acrylic mixture.

Use/Production. (G) Electrical encapsulant. Prod. range: Confidential.

P 90-585

Manufacturer. Estron Chemical, Inc.

Chemical. (G) Polyether.

Use/Production. (S) Used to improve characteristics of resins. Prod. range: Confidential.

P 90-586

Manufacturer. Ciba-Geigy Corporation.

Chemical. (S) Acetic acid, hydroxyphosphono-, trisodium salt.

Use/Production. (S) Corrosion inhibitor. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 1,383 mg/kg species (Rat). Static acute toxicity: time LC50 46H> 820 mg/l species (Zebra Fish). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: positive species (Guinea Pig).

P 90-587

Importer. Confidential.

Chemical. (G) Polyfluorosulfonic acid salt.

Use/Import. (G) Fluorosurfactant used in floor polish. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Eye irritation: slight species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-588

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Disubstituted naphthalene sulfonic acid salt.

Use/Production. (S) Fiber reactive dye for cellulose and nylon. Prod. range: 2,500–7,500 kg/yr.

Toxicity Data. Eye irritation: moderate species (Rabbit). Skin irritation: slight species (Rabbit).

P 90-589

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Disubstituted naphthalene sulfonic acid salt.

Use/Production. (S) Fiber reactive dye for cellulose and nylon. Prod. range: 2,500–7,500 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: moderate species (Rabbit). Skin irritation: slight species (Rabbit).

P 90-590

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Disubstituted naphthalene sulfonic acid salt.

Use/Production. (S) Fiber reactive dye for cellulose and nylon. Prod. range: 2,500–7,500 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: moderate species (Rabbit). Skin irritation: slight species (Rabbit).

P 90-591

Manufacturer. Confidential.

Chemical. (G) Carbonic acid, bis(alkenyl)acid.

Use/Production. (S) Site–limited intermediate. Prod. range: Confidential.

P 90-592

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Polybisphenol-A Phthalate.

Use/Production. (S) Polymer is a thermoplastic engineering plastic resinused in applications. Prod. range: Confidential.

P 90-593

Importer. Mitsubishi Gas Chemical America, Inc.

Chemical. (S) Hexanedioic acid, compound with 1-3-benzene dimethanamine (1:).

Use/Import. (S) Raw material of polyamides. Import range: 200,000–1,000,000 kg/yr.

P 90-594

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Substituted hydrazine.

Use/Production. (G) Intermediate in nucleating agent manufacturing. Prod. range: Confidential.

P 90-595

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Substituted aromatic amine salt.

Use/Production. (G) Raw material. Prod. range: Confidential.

P 90-596

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Substituted pyridine.

Use/Production. (G) Intermediate in nucleating agent manufacturing. Prod. range: Confidential.

P 90-597

Manufacturer. Monsanto Company.

Chemical. (S) L-Aspartic acid, mono ammonium salt.

Use/Production. (S) Isolated intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 5,000 mg/kg species (Rabbit). Eye irritation: none species (Rat). Skin irritation: negligible species (Rabbit).

P 90-598

Manufacturer. Confidential.

Chemical. (G) Modified acrylic copolymer.

Use/Production. (G) Open nondispersive use. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5 g/kg species (Rat). Acute dermal toxicity: LD50 > 2 g/kg species (Rabbit). Eye irritation: none species (Rabbit). Skin irritation: slight species (Rabbit).

P 90-599

Manufacturer. Confidential.

Chemical. (G) Modified acrylic latex.

Use/Production. (G) Open, nondispersive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5 g/kg species (Rat). Acute dermal toxicity: LD50 > 2 g/kg species (Rabbit). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-600

Importer. Confidential.

Chemical. (S) 1,5-Dintro-2,3,4-trichloro benzene.

Use/Import. (S) Chemical intermediate. Import range: Confidential.

P 90-601

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Acrylic polymer.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 90-602

Manufacturer. Confidential.

Chemical. (G) Carboxylic acid modified vegetable oil.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 90-603

Importer. Confidential.

Chemical. (G) Trisubstituted-s-triazine.

Use/Import. (G) Flame retardant additive for polymer. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5 g/kg species (Rat). Eye

irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative.

P 90-604

Manufacturer. Century Adhesives Corporation.

Chemical. (G) Polyurethane polyalkylene ether.

Use/Production. (S) As an adhesive for non food packaging. Prod. range: Confidential.

P 90-605

Importer. Basf Corporation.

Chemical. (G) Perylene derivative.

Use/Import. (S) Colorant for paint. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (RAbbit). Mutagenicity: negative.

P 90-606

Importer. Basf Corporation.

Chemical. (G) Sulfonated trisubstituted amine salt.

Use/Import. (S) Reducing agent and discharging agent. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-607

Manufacturer. Basf Corporation.

Chemical. (G) ((Dialkylcarbomomocyclic)amino)xanthylium salt, methylheteromonocyclic, phenylheteromonomocyclic formal polymer, alkanoic acid salt.

Use/Production. (S) Paper dyestuff. Prod. range: Confidential.

P 90-608

Importer. Sherex Chemical Company, Inc.

Chemical. (G) Amidomethylammonium methyl sulfate.

Use/Import. (G) Ingredient for auto maintenance products. Import range: Confidential.

P 90-609

Manufacturer. Sherex Chemical Company, Inc.

Chemical. (G) Aluminum alkyl.

Use/Production. (G) Contained use. Prod. range: Confidential.

P 90-610

Manufacturer. Essex Specialty Products.

Chemical. (G) Alkoxysilane-isocyanate terminated polyether based urethane prepolymer.

Use/Production. (S) Polymer used in sealant manufacture. Prod. range: Confidential.

P 90-611

Manufacturer. Monsanto Company.

Chemical. (S) Butenedioic acid (E), diammonium salt.

Use/Production. (S) Chemical intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-612

Manufacturer. Confidential.

Chemical. (G) Aromatic aliphatic polyester.

Use/Production. (G) Ingredient in a dispersively used coating. Prod. range: 410,000 kg/yr.

P 90-613

Manufacturer. H.B. Fuller Company.

Chemical. (G) Dimerized C18 unsaturated fatty acid hexamethylenediamine caprolactam acid functional hydrocarbon copolymer.

Use/Production. (G) Adhesive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 750 mg/kg species (Rat).

P 90-614

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Aromatic sulfone.

Use/Production. (S) Organic intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 3750 mg/kg species (Rat). Eye irritation: strong species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative.

P 90-615

Importer. Confidential.

Chemical. (G) Urethane alkyd.

Use/Import. (G) Protective coating. Import range: Confidential.

P 90-616

Importer. Confidential.

Chemical. (G) Halogenated hydrocarbon.

Use/Import. (G) Solvent. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Mutagenicity: negative.

P 90-617

Importer. Confidential.

Chemical. (G) Halogenated hydrocarbon.

Use/Import. (G) Solvent. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Mutagenicity: negative.

P 90-618

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Homopolymer of p-Ethylphenol acetate plus initiator fragment plus chain transfer fragments.

Use/Production. (S) Intermediate. Prod. range: Confidential.

P 90-619

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Homopolymer of p-ethenylphenol acetate plus initi-ator fragment plus chain transfer fragments.

Use/Production. (S) Intermediate. Prod. range: Confidential.

P 90-620

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Homonopolymer of p-ethenylphenol acetate plus initiatee fragment plus chain transfer fragments.

Use/Production. (S) Intermediate. Prod. range: Confidential.

P 90-621

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Homopolymer of 4-ethenylphenol plus initiator end groups/fragments plus chain transfer end groups/fragments.

Use/Production. (S) Photorexist binder for microelectronics. Prod. range: Confidential.

P 90-622

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Homopolymer of 4-ethylphenol plus initiator end groups/fragments plus chain transfer end groups/fragments.

Use/Production. (S) Photorexist binder for microelectronics. Prod. range: Confidential.

P 90-623

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Homopolymer of 4-ethenylphenol plus initiator end groups/fragments plus chain transfer end groups/fragments.

Use/Production. (S) Photorexist for microelectronics. Prod. range: Confidential.

P 90-624

Manufacturer. America Cyanamid Company.

Chemical. (G) Substituted heterocycle.

Use/Production. (G) Chemical intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: slight species (Rabbit). Skin irritation: negligible species (Rabbit).

Mutagenicity: negative. Skin sensitization: negative species (Guinea pig).

P 90-625

Manufacturer. American Cyanamid Company.

Chemical. (G) Substituted heterocycle.

Use/Production. (G) Chemical intermediate. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 species (Rat). Eye irritation: slight species (Rabbit). Mutagenicity: negative. Skin irritation: negligible species (Rabbit).

P 90-626

Manufacturer. American Cyanamid Company.

Chemical. (G) Compounds A and B substituted heterocycle.

Use/Production. (G) Polymer additive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: slight species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea Pig).

P 90-627

Manufacturer. American Cyanamid Company.

Chemical. (G) Compounds A and B: substituted heterocycle.

Use/Production. (G) Polymer additive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: slight species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea Pig).

P 90-629

Manufacturer. Confidential.

Chemical. (G) Polyalkylamine of chloromethylated, cross-linked polystyrene.

Use/Production. (G) Ion exchange resin for treatment of water. Prod. range: Confidential.

P 90-630

Importer. Metal Coatings.

Chemical. (G) Alkyl acrylate graft polymer.

Use/Import. (G) Open, nondispersive use. Import range: Confidential.

P 90-631

Manufacturer. Reichhold Chemicals, Inc.

Chemical. (G) Unsaturated polyester resin.

Use/Production. (S) Cultured marble reisin. Prod. range: Confidential.

P 90-632

Manufacturer. Eastman Chemical Company.

Chemical. (G) Modified choroinated polyolefin.

Use/Production. (S) Paint additive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rat). Eye irritation: moderate species (Rabbit). Skin irritation: negligible species (Guinea Pig). Skin sensitization: negative species (Guinea Pig).

P 90-633

Importer. Confidential.

Chemical. (G) Adhesion promoter.

Use/Import. (G) Paint additive. Import range: Confidential.

P 90-634

Manufacturer. Callaway Chemical Company.

Chemical. (G) AMPs anionic polymer.

Use/Production. (S) High temperature drilling fluid additive. Prod. range: Confidential.

Toxicity Data. Static acute toxicity: time LC50 5404ppmmysid shrimp.

P 90-635

Manufacturer. Freeman Chemical Corporation.

Chemical. (G) Medium oil chain-stopped alkyd resin.

Use/Production. (S) Transportation coatings. Prod. range: 42,000–77,000 kg/yr.

P 90-636

Manufacturer. Reichhold Chemicals, Inc.

Chemical. (G) Polyurethane.

Use/Production. (G) Hot melt adhesive. Prod. range: Confidential.

P 90-637

Manufacturer. Cello Corporation.

Chemical. (G) Acrylic copolymer, ammonium salt.

Use/Production. (S) Resins for water based ink. Prod. range: Confidential.

P 90-638

Manufacturer. Cello Corporation.

Chemical. (G) Acrylic copolymer, monoethanolamine ammonium salt.

Use/Production. (S) Resins for water based ink. Prod. range: Confidential.

P 90-639

Manufacturer. Cello Corporation.

Chemical. (G) Acrylic copolymer, sodium salt.

Use/Production. (S) Resins for water based ink. Prod. range: Confidential.

P 90-640

Manufacturer. Cello Corporation.

Chemical. (G) Acrylic copolymer, 2-amino-2-methyl-1-propanol salt.

Use/Production. (S) Resins for water based ink. Prod. range: Confidential.

P 90-641

Manufacturer. Confidential.

Chemical. (G) Alkyd resin.

Use/Production. (G) Baking enamel. Prod. range: Confidential.

P 90-642

Importer. Confidential.

Chemical. (G) Halogen substitution-modified methacrylate polymer.

Use/Import. (G) Coating resin and clad material. Import range: Confidential.

P 90-643

Manufacturer. Confidential.

Chemical. (G) Alkyl ammonium oxide.

Use/Production. (G) Fuel additive. Prod. range: Confidential.

P 90-644

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-645

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-646

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-647

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-648

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-649

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-650

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Blocked aromatic isocyanate.

Use/Production. (G) Coating. Prod. range: Confidential.

P 90-651

Importer. Confidential.

Chemical. (G) Substituted aryl nitrothiophene.

Use/Import. (G) Dye. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit). Eye irritation: slight species (Rabbit). Static acute toxicity: time LC50 96H>320 mg/l species (Rainbow trout). Skin irritation: negligible species (Rabbit). Mutagenicity: positive.

P 90-653

Manufacturer. Sika Corporation.

Chemical. (G) IPDI reaction product with polymeric diol and triol.

Use/Production. (G) Adhesive component in sealant formulations for industrial and automotive applications. Prod. range: 3,500 kg/yr.

P 90-654

Importer. International Paint Powder Coatings,Inc.

Chemical. (G) Polyester resin IP1200.

Use/Import. (G) Resin for surface coatings. Import range: Confidential.

P 90-655

Importer. Confidential.

Chemical. (S) 10H-phenothiazine, 3,7,-dicotyl-10(2-propenyl).

Use/Import. (G) Turbine lubricant antioxidant. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 5 g/kg species (Rat). Acute dermal toxicity: LD50 > 2 g/kg species (Rabbit). Eye irritation: none species (Rabbit). Mutagenicity: negative. Skin irritation: negligible species (Rabbit).

P 90-656

Manufacturer. Confidential.

Chemical. (G) Rosin, phenolic modified alkyd.

Use/Production. (G) Resin for coatings (protective). Prod. range: Confidential.

P 90-657

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Acrylic copolymer.

Use/Production. (G) Highly dispersive use. Prod. range: Confidential.

P 90-658

Importer. Confidential.

Chemical. (G) Polyacrylate.

Use/Import. (S) Maintenance coatings (bridges/steel structures) automotive coatings (OEM primers). Import range: 120,000–250,000 kg/yr.

P 90-659

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (S)

Use/Production. (G) Dispersively applied coating. Prod. range: 80,000–165,000 kg/yr.

P 90-660

Importer. Roure, Inc.

Chemical. (S) Ammi visnaga.

Use/Import. (S) Ingredient in multi-component fragrance compounds. Import range: 100 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Eye irritation: slight species (Rabbit). Skin irritation: slight species (Rabbit). Mutagenicity: negative.

P 90-661

Manufacturer. Basf Corporation.

Chemical. (G) Ester of disubstituted monocarboxycycle.

Use/Production. (S) Intermediate for production of dyestuff. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 1,990 mg/kg species (Rat). Inhalation toxicity: LC50 46-100 mg/l species (Golden orfe). Mutagenicity: negative.

P 90-662

Manufacturer. 3(M).

Chemical. (G) Substituted epoxy resin.

Use/Production. (G) Polymeric coating. Prod. range: Confidential.

P 90-663

Manufacturer. Sika Corporation.

Chemical. (G) Complex epoxy resin/amine adducts and thereof.

Use/Production. (S) Crosslinking agent for epoxy-type coatings for floors. Prod. range: 2,000–3,000 kg/yr.

P 90-664

Manufacturer. Confidential.

Chemical. (G) Metal salts of alkyl succinic acid and substituted phosphoric acid esters.

Use/Production. (G) Petroleum additive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 2.0 mg/kg species (Rat). Eye irritation: slight species (Rabbit). Skin irritation: slight species (Rabbit).

P 90-665

Manufacturer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Substituted squarylium dye.

Use/Production. (G) Photosensitive film additive. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 >11,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-666

Manufacturer. Confidential.

Chemical. (G) Cycloalkenol disubstituted alkyl ether.

Use/Production. (G) Fragrance component. Prod. range: Confidential.

Toxicity Data. Skin irritation: negligible species (Rabbit). Skin sensitization: negative species (Guinea Pig).

P 90-667

Manufacturer. Confidential.

Chemical. (S) Reaction products of epoxy phenolic novolac resin, tetrabromo-bis-phenol A, methacrylic acid.

Use/Production. (G) Resin used in fiber reinforced laminates. Prod. range: Confidential.

P 90-668

Manufacturer. Confidential.

Chemical. (S) Reaction products of epoxy phenolic novolac resin, tetrabromo-bis-phenol A, carboxyl-terminated butadiene/acrylonitrile copolymer, methacrylic acid.

Use/Production. (G) Resin used in fiber reinforced laminates. Prod. range: Confidential.

P 90-669

Importer. Huls America Inc.

Chemical. (S) 12-Aminododecanoic acid.

Use/Import. (G) Additive for polymers. Import range: 50,000–20,000 kg/yr.

Toxicity Data. Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-670

Importer. Confidential.

Chemical. (G) Modified diphenylmethane diisocyanate.

Use/Import. (G) Polyurethane coatings and adhesives. Import range: Confidential.

P 90-671

Importer. Idemitsu Apollo Corporation.
Chemical. (G) Polyalkylene glycol.
Use/Import. (G) Lubricating oil. Import range: Confidential.

P 90-672

Importer. Idemitsu Apollo Corporation.
Chemical. (G) Polyalkylene glycol.
Use/Import. (G) Lubricating aid. Import range: Confidential.

P 90-673

Importer. Confidential.
Chemical. (G) Polyester grafted copolymer.
Use/Import. (G) Binder of pigment. Import range: Confidential.

P 90-674

Importer. Uniroyal Chemical Co., Inc.
Chemical. (G) Modified hydrocarbon polymer.
Use/Import. (G) Sealant. Import range: Confidential.

P 90-675

Manufacturer. Alpha Resins Corporation.
Chemical. (G) Unsaturated polyester polymer.
Use/Production. (G) Category A - polyester resin system component. Prod. range: Confidential.

P 90-676

Manufacturer. The C. P. Hall Company.
Chemical. (S) Fatty acids, C14-18 unsaturated, esters with C11-14 iso C13 rich alcohols.
Use/Production. (G) Lubricant for fibers. Prod. range: Confidential.

P 90-677

Importer. Confidential.
Chemical. (G) Vinyl chloride-vinyl isobutyl ether copolymer.
Use/Import. (S) Copolymer. Import range: Confidential.

P 90-678

Importer. Confidential.
Chemical. (G) Sodium phosphate.
Use/Import. (G) Nucleating use in thermoplastic resin. Import range: Confidential.

P 90-679

Manufacturer. Confidential.
Chemical. (G) Salts of arcylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-680

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-681

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-682

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-683

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-684

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-685

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-686

Manufacturer. Confidential.
Chemical. (G) Salts of acrylate-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-687

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-688

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-689

Manufacturer. Confidential.
Chemical. (G) Salts of arcylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (rabbit).

P 90-690

Manufacturer. Confidential.
Chemical. (G) Salts of acrylic-aromatic polymers.
Use/Production. (G) Polymeric component of ink or coating. Prod. range: Confidential.
Toxicity Data. Acute oral toxicity: LD50 2,050 mg/kg species (Rat). Acute dermal toxicity: LD50 1,000 mg/kg species (Rabbit).

P 90-698

Manufacturer. Synethetic Products Co.

Chemical. (S) Yttrium stearate.

Use/Production. (S) Ceramics additive. Prod. range: 5,000-20,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 5 g/kg species (Rat).

P 90-699

Importer. Confidential.

Chemical. (G) Acrylic copolymer latex.

Use/Import. (G) Nongelatin photographic binder. Import range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 >10 ml/kg species (Rast). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit).

P 90-700

Manufacturer. Confidential.

Chemical. (G) Silyl acrylate monomer.

Use/Production. (G) Polymer intermediate. Prod. range: Confidential.

P 90-701

Manufacturer. Confidential.

Chemical. (G) Silyl acrylate polymer.

Use/Production. (G) Inert ingredient for pesticide application. Prod. range: Confidential.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Acute dermal toxicity: LD50 > 2,000 mg/kg species (Rabbit).

P 90-702

Manufacturer. Eastman Kodak Company.

Chemical. (G) Nitroacyloxy alkanoic acid derivative.

Use/Production. (G) Chemical intermediate. Prod. range: 40,000–75,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 3,536 mg/kg species (Rat). Eye irritation: strong species (rabbit). Skin irritation: strong species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea Pig).

P 90-703

Importer. Shin-Etsu Silicones of America, Inc.

Chemical. (G) Organopolysiloxane.

Use/Import. (S) Adhesive promoter for silicone rubber compounds cross-linking agent for silicone rubber compounds. Import range: 1,000-3,000 kg/yr.

P 90-704

Importer. Confidential.

Chemical. (G) Polyfluoroalkyl polyester.

Use/Import. (G) Additive for electomers and plastics. Import range: Confidential.

P 90-705

Importer. Confidential.

Chemical. (G) Polyhalogenated acrylate.

Use/Import. (G) Textile coating. Import range: 50,000–200,000 kg/yr.

Toxicity Data. Acute oral toxicity: LD50 > 2,000 mg/kg species (Rat). Eye irritation: none species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative.

P 90-706

Manufacturer. Confidential.

Chemical. (G) Dialkyl phosphonate, polymers with alkyl alkanolamine, borate.

Use/Production. (G) Industrial lubricating oils and greases. Prod. range: 450,000–900,000 kg/yr.

P 90-707

Manufacturer. SCM Glidco Organics.

Chemical. (G) Alkenyl substituted ester of acetic anhydride.

Use/Production. (G) Highly dispersive use. Prod. range: Confidential.

P 90-708

Importer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Epoxy urethane polymer.

Use/Import. (G) Open, nondispersive use. Import range: Confidential.

P 90-709

Importer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Epoxy acrylic polymer.

Use/Import. (G) Open, nondispersive use. Import range: Confidential.

P 90-710

Importer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Diurea molecule.

Use/Import. (G) Open, nondispersive use. Import range: Confidential.

P 90-711

Importer. E. I. Du Pont De Nemours & Co., Inc.

Chemical. (G) Acrylic anhydride copolymer.

Use/Import. (G) Destructive and open nondispersive use. Import range: Confidential.

P 90-712

Manufacturer. Hoechst Celanese Corporation.

Chemical. (G) Sulfonated copper phthalocyanine salt.

Use/Production. (S) Fiber reactive dyestuff for cellulose dyeing. Prod. range: Confidential.

Toxicity Data. Eye irritation: moderate species (Rabbit). Skin irritation: moderate species (Rabbit).

P 90-713

Manufacturer. Confidential.

Chemical. (G) Acrylated fatty acid alkyd.

Use/Production. (S) Coating for general metal. Prod. range: Confidential.

P 90-714

Manufacturer. Sherex Chemical Company, Inc.

Chemical. (G) Epoxy curing agent.

Use/Production. (G) Open, nondispersive use. Prod. range: Confidential.

P 90-715

Importer. MTC American, Inc.

Chemical. (G) Block urethane modified epoxy resin.

Use/Import. (S) Anti-corrosion primer coating. Import range: Confidential.

P 90-716

Manufacturer. Davidson Technology Center Textron.

Chemical. (G) Fleible polyesterurthane resin.

Use/Production. (S) Polymer for use in resin used to make coatings that are used to vacuum metalize plastic auto parts. Prod. range: Confidential.

P 90-717

Manufacturer. Arco Chemical Company.

Chemical. (G) Olefin/alkyl carboxylate copolymer, inorganic salt.

Use/Production. (S) Absorbent fiber. Prod. range: Confidential.

P 90-718

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-719

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-720

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-721

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers acrylic salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-722

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-723

Manufacturer. S.C Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymer salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-724

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acr ylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-725

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-726

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymer and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-727

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-728

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-729

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-730

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-731

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-732

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-733

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-734

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-735

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-736

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-737

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Conidential.

P 90-738

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-739

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-740

Manufacturer. S.C. Johnson & Son, Inc.
Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.
Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-741

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-742

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-743

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-744

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-745

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-746

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidentrial.

P 90-747

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-748

Manufacturer. S.C. Johnson & Son, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

P 90-749

Manufacturer. S.C. Johnson & Sons, Inc.

Chemical. (G) Acrylic copolymers and salts thereof: styrene/acrylic copolymers and salts thereof.

Use/Production. (G) Aqueous emulsion copolymer. Prod. range: Confidential.

Dated: May 14, 1990.

Steven Newburg-Rinn,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 90-11616, Filed 5-18-90; 8:45 am]

BILLING CODE 6560-50-D

FEDERAL COMMUNICATIONS COMMISSION

Applications, Hearings, Determinations, etc.: Radio Representatives, Inc., et al.

1. The Commission has before it the following mutually exclusive applications for 4 new FM stations:

I.

Applicant, city and state	File No.	MM docket No.
A. Radio Representatives, Inc.; Orcutt, CA.	BPH-880620MB	90-207
B. Rodolfo & Associates, Inc.; Orcutt, CA.	BPH-880622MK	
C. Trapper/Cole Radio, Inc.; Orcutt, CA.	BPH-880623ML	
D. Caballero Spanish Media, Inc.; Orcutt, CA.	BPH-880623MM	
E. Nelson Broadcasting Limited Partnership; Orcutt, CA.	BPH-880623MN	
F. Irene Escalante; Orcutt, CA.	BPH-880623MO	

Issue Heading and Applicants

1. Financial Qualifications, F
2. Air Hazard, A,C,D,F
3. See Appendix, B
4. See Appendix, B
5. See Appendix, B
6. Environmental, D
7. Comparative, A-F
8. Ultimate, A-F

II.

Applicant and city, and state	File No.	MM Docket No.
A. Irene Bustos and COMUN, Inc., d/b/a Los Lunas Project; Los Lunas, NM.	BPH-880519NQ	90-209
B. Patricia Benns Komorowski; Los Lunas, NM.	BPH-880519OA	

Issue Heading and Applicants

1. Air Hazard, A
2. Comparative, A11
3. Ultimate, A11

III.

Applicant, city, and state	File No.	MM docket No.
A. Engineer Broadcasting; Irvine, KY.	BPH-880322MA	90-208
B. Estill County Broadcasting, Inc.; Irvine, KY.	BPH-880323ML	
C. Kentucky River Broadcasting, Co.; Irvine, KY.	BPH-880324ME	

Issue Heading and Applicants

1. Air Hazard, B, C
2. Comparative, A, B, C
3. Ultimate, A, B, C

IV.

Applicant and city, and state	File No.	MM Docket No.
A. Shenandoah Broadcasting of Texas, Inc.; Cleveland, TX.	BPH-880428ME	90-206
B. Multicom Broadcasting, Inc.; Cleveland, TX.	BPH-880428MF	
C. Sam Houston National Broadcasting, Inc.; Cleveland, TX.	BPH-880428MG	
D. San Jacinto Communications Company; Cleveland, TX.	BPH-880428MJ	
E. Cleveland Broadcasting Company; Cleveland, TX.	BPH-880428MK	
F. Texas Classical Radio, Inc.; Cleveland, TX.	BPH-880428MM	
G. Southeast Texas Communications, Inc.; Cleveland, TX.	BPH-880428MO	
H. Advent Broadcasters, Inc.; Cleveland, TX.	BPH-880428MP	
I. McDuffie Service Corporation; Cleveland, TX.	BPH-880428MQ	

Applicant and city, and state	File No.	MM Docket No.
J. Gerald J. Lofton; Cleveland, TX.	BPH-880428MH (Dismissed herein)	
K. Cleveland Associates; Cleveland, TX.	BPH-880428MS (Previously Dismissed)	

Issue Heading and Applicants

1. Financial Qualifications, E
2. Comparative, A,B,C,D,E,F,G,H,I
3. Ultimate, A,B,C,D,E,F,G,H,I

2. Pursuant to section 309(e) of the Communications Act of 1934, as amended, the above applications have been designated for hearing in a consolidated proceeding upon the issues whose headings are set forth below. The text of each of these issues has been standardized and is set foth in 1986. The letter shown before each applicant's name above, is used, below to signify whether the issue in question applies to that particular applicant.

3. If there are any non-standardized issues in this proceeding, the full text of the issue and the applicants to which it applies are set forth in an appendix to this Notice. A copy of the complete HDO in this proceeding is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington DC. The complete text may also be purchased from the Commission's duplicating contractor, International Transcription Services, Inc., 2100 M Street, NW., Washington 20037. (Telephone (202) 857-3800).

W. Jan Gay, Assistant Chief, Audio Services Division, Mass Media Bureau.

Appendix Orcutt, Californa

1. To determine whether Sonrise Management Services, Inc. is an undisclosed party to the application of B (Rodolfo)

2. To determine whether B's (Rodolfo) organization struture is a sham.

3. To determine from the evidence adduced pursuant to Issues 3 through 4 above, whether B (Rodolfo) possess the basis qualifications to be a licensee of the facilities sought herein

[FR Doc. 90-11706 Filed 5-18-90; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Agreement(s) Filed

The Federal Maritime Commission hereby gives notice of the filing of the following agreement(s) pursuant to section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, DC Office of the Federal Maritime Commission, 1100 L Street NW., room 10325. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments are found in § 572.603 of title 46 of the Code of Federal Regulations. Interested persons should consult this section before communicating with the Commission regarding a pending agreement.

Agreement No.: 207-011280.

Title: Star West Joint Service Agreement.

Parties:

The Blue Star Line, Ltd.,
Overseas Freezer Operations GmbH.

Synopsis: The proposed Agreement would provide for the joint marketing, chartering, scheduling, bunkering and related cargo operations of up to a total of five reefer vessels to be contributed to the service by the parties. It would also provide for the pooling of revenues and expenses and the division of profits by the parties. The joint service will operate from ports and points in Western Europe to ports and points on the U.S. East Coast. The parties have requested a shortened review period.

By Order of the Federal Maritime Commission.

Dated: May 16, 1990.

Joseph C. Polking,

Secretary.

[FR Doc. 90-11745 Filed 5-18-90; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Arvest Bank Group, Inc.; Application to Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in effeciency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 8, 1990.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President), 411 Locust Street, St. Louis, Missouri 63166:

1. *Arvest Bank Group, Inc.* (formerly Heartland Bank Group, Inc.), Bentonville, Arkansas; to engage *de novo* through its subsidiary, Arvest Trust Company, National Association, Rogers, Arkansas, in all bank trust department functions and related investment advisory activities pursuant to § 225.25 (b)(3) and (b)(4) of the Board's Regulation Y. These activities will be limited to the four counties of Benton, Carroll, Madison, and Washington located in northwest Arkansas.

Board of Governors of the Federal Reserve System, May 15, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-11699 Filed 5-18-90; 8:45 am]

BILLING CODE 6210-01-M

FB&T Corp.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation

Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweight possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 8, 1990.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. *FB&T Corporation,* Hanover, Pennsylvania; to acquire Monumental Savings Bank, FSB, Baltimore, Maryland, and thereby own, control and operate a savings association pursuant to § 225.25(b)(9) of the Board's Regulation Y. This activity will be conducted in Maryland.

Board of Governors of the Federal Reserve System, May 15, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90–11700 Filed 5–18–90; 8:45 am]

BILLING CODE 6210–01–M

First Midwest Corp. of Delaware; Formation of, Acquisiton by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.24) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than June 8, 1990.

A. Federal Reserve Bank of Chicago (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *First Midwest Corporation of Delaware,* Elmwood Park, Illinois; to acquire 100 percent of the voting shares of Midwest Bank and Trust Company of Dupage County, East St. Louis, Illinois, which will relocate to Hinsdale, Illinois, after consummation.

Board of Governors of the Federal Reserve System, May 15, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90–11701 Filed 5–18–90; 8:45 am]

BILLING CODE 6210–01–M

Michael R. Harvey; Change in Bank Control Notice Acquisition of Shares of Banks or Bank Holding Companies

The notificant listed below has applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notice is available for immediate inspection at the Federal Reserve Bank indicated. Once the notice has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for the notice or to the offices of the Board of Governors. Comments must be received not later than June 4, 1990.

A. Federal Reserve Bank of San Francisco (Harry W. Green, Vice President), 101 Market Street, San Francisco, California 94105:

1. *Michael R. Harvey,* to retain 11.65 percent of the voting shares of Burlingame Bancorp, Burlingame, California, and thereby indirectly acquire Burlingame Bank & Trust Co., Burlingame, California.

Board of Governors of the Federal Reserve System, May 15, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90–11702 Filed 5–18–90; 8:45 am]

BILLING CODE 6210–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

[Program Announcement Number 032]

Availability of Fiscal Year 1990 Funds for Breast and Cervical Cancer Prevention and Control Program

Introduction

The Centers for Disease Control (CDC) announces the availability of funds in Fiscal Year 1990 for new and competing cooperative agreements to (A) enhance an existing breast and cervical cancer control program coordinated by the State health agency, and (B) initiate planning for the development of comprehensive breast and cervical cancer control programs.

Authority

This program is authorized by $ection 301(a) [42 U.S.C. 241a] and Section 317(k)(3) [42 U.S.C. 247b(k)(3)] of the Public Health Service Act, as amended.

Eligible Applicants

Eligible applicants are official State public health agencies, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, American Samoa, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

Availability of Funds

Approximately $1,000,000 will be available in Fiscal Year 1990 for funding two elements of this program: (A) The enhancement of an existing breast and cervical cancer control program, and (B) the planning and development of four comprehensive breast and cervical cancer control programs. Please specify

if you are applying for program A or B (you may not apply for both). These awards are expected to begin on or about August 15, 1990, for a 12-month budget period within a 1- to 5-year project period. Funding estimates may vary and are subject to change. Continuation awards within the approved project period will be made on the basis of satisfactory performance and the availability of funds.

Requests for direct assistance (i.e. "in lieu of cash") for personnel, for organizing and conducting the project described in this announcement, are encouraged.

A. Enchancement of existing breast and cervical cancer control program applications.

Approximately $400,000 will be available in Fiscal Year 1990 for enhancing one existing breast and cervical cancer control program. Applicants will be required to address specific elements as noted in "Recipient Activities".

State health agencies requesting funds for supplementing the existing breast and cervical cancer control program (A) are not eligible to apply for funds for planning the development of a comprehensive breast and cervical cancer screening and follow-up program (B).

B. Planning the development of comprehensive breast and cervical control program applications.

Approximately $600,000 will be available in Fiscal Year 1990 for funding four programs for planning the development of comprehensive breast and cervical cancer control. Applicants will be required to address specific elements as noted in "Recipient Activities". Awards will average $150,000.

State health agencies requesting funds for planning the development of a comprehensive breast and cervical cancer control program (B) are not eligible to apply for funds for the existing breast and cervical cancer control program (A).

Use of Funds

Cooperative agreement funds shall not be used for treatment or treatment services, or for screening tests.

Recipient Financial Participation

This program has no statutory formula. No specific matching funds are required; however, the application should include specifics on the applicant's contribution to the overall program cost and reflect a commitment to long-term progressive support on the part of non-federal funding sources.

Program Goals

The goal of this program is to reduce morbidity and mortality among women at risk for developing breast and cervical cancer. Applicants approved to receive assistance under this cooperative agreement program will be expected to demonstrate that: (A) an existing breast and cervical cancer control program can be measurably enhanced; or (B) a plan for the development of a comprehensive breast and cervical cancer control program can be institutionalized.

Purpose

The purpose of this cooperative agreement is to support State health agencies in their efforts to enhance or develop the capability to assure that effective, comprehensive breast and cervical cancer control programs are available and accessible to women at risk.

Cooperative Activities

The nature and extent of the project activities are described below:

I. Recipient Activities

A. Enhancement of an existing breast and cervical cancer control program.

The recipient shall enhance an existing breast and cervical cancer control program and evaluate that program, in a target area based on the following seven elements.

1. *Surveillance and Evaluation:* Monitoring both the distribution and the determinants of breast and cervical cancer morbidity and mortality is necessary to establish and evaluate a comprehensive prevention program. To do this, a surveillance system should encompass:

a. Information on incidence, staging, and mortality from breast and cervical cancer.

b. Identification of segments of the population at higher risk, for effective allocation of program resources.

c. Definition of factors contributing to the disease burden, such as behavioral risk factors, underutilization of technology known to be effective, and limited or inequitable access to preventive services.

d. Measurement of screening activity.

e. Establishment of an ongoing monitoring mechanism to assess progress towards objectives.

f. Case studies and other epidemiologic investigations to determine factors associated with preventable morbidity and avoidable mortality.

2. *State Health Agency Capacity and Plan:* This element is manifested by a viable State-level breast and cervical cancer prevention and control plan which strategically incorporates the following elements: (a) Establishment of a State-level cancer control coalition which includes representation from key private, voluntary (e.g. American Cancer Society), and public cancer organizations, (b) a description of the incidence and trends of breast and cervical cancer within the State, (c) a description of the cancer burden among subpopulations in the State, (d) a copy of the plan including goals and objectives to address the breast and cervical cancer problem, (e) proposed strategies to meet those objectives, and (f) an assessment of both existing and needed resources to implement a comprehensive breast and cervical cancer program.

3. *Screening:* A comprehensive breast and cervical cancer control program includes the Pap test for cervical cancer and the clinical breast examination and mammography for breast cancer. The program should target those women identified in nationally approved guidelines. The screaning program should be accessible to all women, including the uninsured, underinsured, and medically indigent. To accomplish timely screening of the population, a system should be in place that includes linkages between the public, private, and voluntary sectors.

4. *Follow-up:* Providing follow-up and continuity of care is an essential component of any comprehensive breast and cervical cancer control program. A system should be in place to assure that women whose screening tests are suspicious or abnormal receive appropriate, adequate, and timely follow-up, and treatment as necessary.

5. *Public education:* Public education includes the systematic design and sustained delivery of a combination of theoretically sound and effective methods which will favorably influence priority behaviors and their determinants related to the primary, secondary, and tertiary prevention of avoidable cancer mortality, morbidity, and disability among women. Successful public education programs are those that favorably influence important and modifiable behavioral determinants and behaviors leading to changes in the health status of the target population.

6. *Professional education:* Health care professionals play a central role in assuring that women are screened at appropriate intervals, that the screening tests are parformed optimally, and that women with abnormal test results receive appropriate diagnostic follow-up and treatment. A provider education/information program that effectively

transmits state-of-the art information on the efficacy and appropriate use of screening procedures must not only inform the breadth of providers, but also demonstrate an influence on practice. Such a program should result in an increase in the appropriate referral and performance of cancer screening procedures by primary care providers, as well as an improved level of test interpretation, diagnostic and therapeutic follow-up for abnormal results.

7. *Quality assurance:* Quality assurance is necessary to assure that screening tests are performed optimally and to maintain that level of performance.

Breast: At a minimum, quality mammography includes the following:

a. Properly trained and experienced personnel.

b. Proper use of appropriate, well maintained, dedicated equipment.

c. Periodic performance evaluation tests of the imaging system following guidelines recommended by the American College of Radiology.

Cervical: At a minimum, quality assurance of cervical cytology should include the following:

a. Properly trained and accredited/certified personnel.

b. Licensed or accredited laboratories which maintain an ongoing quality assurance program.

c. Appropriate reporting and communication of results.

To be eligible for the enhancement of an existing breast and cervical cancer control program (A), State health agencies must be able to demonstrate that the following elements, as described in Recipient Activities are already in place: (1) A breast and cervical cancar surveillance system as described, (2) a strategic plan to control breast and cervical cancer, (3) available breast and cervical cancer screening sites and services, and (4) staff and organization within the State health agency to support the proposed enhancement program.

CDC and other CDC grantees will collaborate with the successful applicant in developing the Public Education component of their cancer control program. Applicants should address Provider Education, Follow-up and Quality Assurance by providing a narrative description of how these components will be developed or enhanced.

B. Planning for development of comprehensive breast and cervical cancer control programs.

Recipients will be required to complete five tasks during the initial 2 years of funding:

1. *Year 01:* Identify and place an appropriate individual who is responsible for the management of breast and cervical cancer issues.

2. *Year 01:* Establish a State-wide task force or advisory group to provide advice and guidance to the State as it plans for a comprehensive program. Task force membership should include, but is not limited to, public health experts; practicing oncologists, radiologists, and pathologists; primary care practitioners; representatives of appropriate voluntary agencies including the American Cancer Society and professional groups; and consumers.

3. *Year 01:* Identify existing data that can be used as the foundation of a surveillance system to monitor and evaluate the effectiveness and efficiency of a comprehensive program. Develop and implement strategies to use these data for monitoring, evaluating, and reporting progress.

4. *Years 01 and 02:* Conduct two assessments of existing resources. The first assessment will determine how and where women receive screening, follow-up, treatment, information, and other services related to breast and cervical cancer. The second assessment will be a survey of professional attitudes and practices. These investigations will be used to identify needs and gaps that must be addressed in developing a comprehensive program.

5. *Year 02:* Using the data gathered relating to existing services and needs, the advice and input from the advisory group, the staff's experience and knowledge of the State system, and technical assistance from CDC, develop a comprehensive breast and cervical cancer program based on the seven elements described in Recipient Activities.

In the third and subsequent years, pending the availability of funds, a comprehensive breast and cervical cancer screening and follow-up program will be implemented.

II. Centers for Disease Control Activities

A. Convene awardees for regular information sharing and training.

B. Disseminate to State health agencies relevant state-of-the-art research findings and public health recommendations related to early detection, diagnosis, and treatment for breast and cervical cancer.

C. Collaborate in the planning, operation, and evaluation of program activities and coordinate the project's participation in all components of the total Woman's Cancer Program.

D. Collaborate in the development of surveillance and data systems and in the State's analysis and evaluation of data.

E. Collaborate in the development of public and professional education components.

F. Collaborate in the dissemination of outcome indicators and their integration into program operation.

G. Collaborate in the development and establishment of specific morbidity reduction objectives.

H. Collaborate in the development of quality assurance procedures for mammography and cervical cytology.

I. Collaborate in the evaluation efforts.

Projects funded through a cooperative agreement that involve collection of information from 10 or more individuals will be subject to review under the Paperwork Reduction Act.

Application Review and Evaluation Criteria

A. Enhancement of existing breast and cervical cancer prevention and control program.

Absolute Criteria

As described in the Recipient Activities Section for the enhancement of an existing breast and cervical cancer control program (A), the applicant must be able to demonstrate that the following elements are already in place: (1) A strategic plan to address breast and cervical cancer; (2) staff and organizational location within the State health agency to support the proposed enhancement program; (3) available breast and cancer screening sites and services; (4) a breast and cervical cancer surveillance system; and (5) evidence of a long-term commitment to nonfederal support for which the amount of support increases over time.

Weighted Criteria

The initial application for the project period for the proposal to enhance an existing breast and cervical cancer control program (A) will be reviewed and evaluated based upon the following criteria:

1. The extent to which the application reflects community, voluntary agency, and professional support for the program and ensures the integration of breast and cervical cancer program elements into the health care delivery system for women at risk. (20 points)

2. The extent to which the applicant describes the breast and cervical cancer program needs of the target population and justifies the focus on that population, and the assurance of appropriate screening and follow-up services. (20 points)

3. The consistency of the specific and time-related measurable objectives with the stated purpose of the cooperative agreement and the ability to monitor and document the effects of the program both in terms of health outcomes and the impact upon the existing system of cancer control. (10 points)

4. The indication that community provider groups are willing to participate in appropriate aspects of the program. (10 points)

5. The qualifications and appropriateness of proposal personnel. (10 points)

6. Evidence of the applicant's long-term commitment to maintain the capacity to carry out a comprehensive cancer control program. (10 points)

7. The quality of surveillance data, demonstrated ability to utilize it, and evidence of the future continued existence of the data sources. (10 points)

8. The documentation and appropriateness of the existing cancer plan and the role of the coalition in proposed activities. (10 points)

9. The extent to which the budget is reasonable and consistent with the intended use of cooperative agreement funds. (Not weighted)

B. The initial application for the proposal for planning for the development of a comprehensive breast and cervical cancer control program (B) will be reviewed on the evaluation criteria listed below. In addition, special consideration will be given in the review process to applications from State health departments that are at the elementary levels in the planning of statewide approaches to breast and cervical cancer screening and are not otherwise funded to undertake that planning process.

1. The extent of the State health agencies commitment to carrying out the planning, intervention, and evaluation process and the overall plan to accomplish the process. (20 points)

2. The ability of the applicant to identify appropriate staff for the program who are available and trained to carry out the required tasks. (20 points)

3. The consistency of the specific and time-related measurable objectives with the stated purpose of the cooperative agreement and the ability to achieve the objectives, activities and milestones of the program within the specified period. (15 points)

4. Evidence of the applicant's commitment to develop and maintain a surveillance system. (15 points)

5. The extent to which the applicant's plan reflects integration of breast and cervical cancer program elements into the health care delivery system through the formation of program linkages and the development of a cancer program advisory group/task force. (15 points)

6. The extent of the applicant's ability to assure community and professional support and involvement, to utilize available resources, and to ensure that the coalition assumes a major role in the program. (15 points)

7. The extent to which the budget is reasonable and consistent with the intended use of cooperative agreement funds. (Not weighted)

C. Continuation awards within the project period will be made on the basis of the following criteria:

1. Availability of funds.

2. The extent to which the accomplishments of the current budget period show that the applicant is achieving its objectives.

3. The consistency of the specific and time-related measurable objectives for the new budget period with purpose of the cooperative agreement and the extent to which they are realistic, specific, and measurable.

4. The extent to which the methods described will clearly lead to achievement of these objectives.

5. The quality of the evaluation plan proposed to be used in monitoring the efficacy of the methods to be used.

6. The extent to which the budget request is justified, reasonable, and consistent with the intended use of cooperative agreement funds.

7. Evidence of a long-term commitment to nonfederal support for which the amount of support increases over time.

Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order 12372.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance number is 13.283.

Application Submission and Deadline

The original and two copies of the application (PHS Form 5161-1) must be submitted to Candice Nowicki, Grants Management Officer, Grants Management Branch, Mailstop E-14, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., room 321, Atlanta, Georgia 30305, on or before June 15, 1990.

A. *Deadline:* Applications will be considered to meet the deadline if they are either:

1. Received at the above address on or before the deadline date, or

2. Sent on or before June 15, 1990, and received in time for submission to the independent review group. (Applicant should request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks will not be accepted as proof of timely mailing.)

B. Late Applications: Applications which do not meet the above criteria in A.1. or 2. are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description, information on application procedures and an application package may be obtained from Linda Long, Grants Management Specialist, Grants Management Branch, Mailstop E-14, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Rd, NE., Atlanta, GA 30305, telephone (404) 842-6511 or FTS 236-6511.

Please refer to Announcement Number 032 when requesting information and submitting any application on the Request for Assistance.

Technical assistance may be obtained from Duke Bell, Cancer Prevention and Control Branch, Division of Chronic Disease Control and Community Intervention, Mailstop F-11, Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control, Atlanta, GA 30333, telephone (404) 488-4391 or FTS 236-4391.

Dated: May 15, 1990.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 90-11714 Filed 5-18-90; 8:45 am]

BILLING CODE 4160-18-M

Injury Research Grant Review Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control (CDC) announces the following Committee meeting.

Name: Injury Research Grant Review Committee.

Time and Date: 7 p.m.-8:30 p.m., June 10, 1990; 8 a.m.-8 p.m., June 11, 1990; 8 a.m.-6 p.m., June 12, 1990; 8 a.m.-3 p.m., June 13, 1990.

Place: Atlanta Airport Hilton, 1031 Virginia Avenue, Atlanta, Georgia 30354.

Status: Open 7 p.m.-8:30 p.m., June 10, 1990. Closed June 11-13, 1990.

Purpose: This Committee is charged with advising the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the scientific merit and technical feasibility of grant applications relating to the support of injury control research and demonstration projects and injury prevention research centers.

Matters to be Discussed: Agenda items for the meeting will include announcements, discussion of review procedures, future meeting dates, and review of grant applications. Beginning at 8 a.m., June 11, through 3 p.m., June 13, the Committee will conduct its review of grant applications. This portion of the meeting will be closed to the public in accordance with provisions set forth in section 552b(c) (4) and (6), title 5 U.S.C., and the Determination of the Director, CDC, pursuant to Public Law 92–463.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Thomas Bartenfeld, Grants Manager, Division of Injury Control, Center for Environmental Health and Injury Control, CDC, 1600 Clifton Road NE., Mailstop F36, Atlanta, Georgia 30333, telephone 404/488–4265, (FTS) 236–4265.

Dated: May 15, 1990.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 90–11716 Filed 5–18–90; 8:45 am]

BILLING CODE 4160–18–M

Vessel Sanitation Program—Water Systems; Meeting

The Center for Environmental Health and Injury Control (CEHIC) of the Centers for Disease Control (CDC) announces the following meeting.

Name: Vessel Sanitation Program—Water Systems.

Place: Conference Room, Building 32, CEHIC, CDC, 4770 Buford Highway, Chamblee, GA 30341.

Time and Date: 8:30 a.m.–5 p.m., Thursday, June 21, 1990; 8:30 a.m.–12:30 p.m., Friday, June 22, 1990.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 30 people.

Matters To Be Discussed: All passenger cruise ships, which carry at least 13 passengers, with foreign itineraries arriving at U.S. ports are subject to vessel sanitation inspections twice a year to insure compliance by the cruise ship industry with CDC sanitation standards. Recently, there has been concern expressed about the application of CDC sanitation standards to passenger cruise vessels of less than 3,000 tons.

The major point of concern is the application of CDC standards for chlorinating and monitoring water systems on board these smaller passenger cruise ships (less than 3,000 tons). CDC will convene representatives of the companies which own or operate the smaller ships along with a group of individual sanitation consultants and representatives of involved State health departments. The purpose of the meeting is to provide an opportunity for the small ship owners/operators and others to express their concerns.

Contact Person for More Information: Additional information concerning the meeting may be obtained from Thomas Hunt, Chief, Vessel Sanitation Program, CEHIC, CDC, 1015 North America Way, room 107, Miami, Florida 33132. Telephones: FTS 350–4307; Commercial (305) 536–4307.

Dated: May 15, 1990.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 90–11717 Filed 5–18–90; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

[Docket No. 88F–0028]

Shell Oil Co.; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice to a future filing of a petition proposing that the food additive regulations be amended to provide for the safe use of cerium stearate as a stabilizer in olefin polymers intended for use in contact with food. The petition was withdrawn by Shell Oil Co.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the Federal Register of March 1, 1988 (53 FR 6203), FDA published a notice that it had filed a petition (FAP 8B4059) from Shell Oil Co., P.O. Box 4320, One Shell Plaza, Houston, TX 77210, that proposed to amend the food additive regulations to provide for the safe use of cerium stearate as a stabilizer in olefin polymers intended for use in contact with food. Shell Oil Co. has now withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: May 1, 1990.

Douglas L. Archer,

Acting Deputy Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90–11633 Filed 5–18–90; 8:45 am]

BILLING CODE 4160–01–M

National Institutes of Health

National Heart, Lung, and Blood Institute; Meeting

Notice is hereby given of the meeting of the National Cholesterol Education Program Coordinating Committee, sponsored by the National Heart, Lung, and Blood Institute on Tuesday, June 12, 1990, from 9 a.m. to 3 p.m., at the Quality Hotel, 8727 Colesville Road, Silver Spring, Maryland 20910, (301) 589–5200.

The entire meeting is open to the public. The Coordinating Committee is meeting to define the priorities, activities, and needs of the participating groups in the National Cholesterol Education Program. Attendance by the public will be limited to space available.

For the detailed program information, agenda, list of participants, and meeting summary, contact: Dr. James I. Cleeman, Coordinator, National Cholesterol Education Program, Office of Prevention, Education and Control, National Heart, Lung, and Blood Institute, National Institutes of Health, Building 31, room 4A05, Bethesda, Maryland 20892, (301) 496–0554.

Dated: May 14, 1990.

William F. Raub,

Acting Director, NIH.

[FR Doc. 90–11741 Filed 5–18–90; 8:45 am]

BILLING CODE 4140–1–M

Meeting of the Advisory Committee to the Director

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Advisory Committee to the Director, NIH, on June 1, 1990, at the National Institutes of Health, Bethesda, Maryland 20892, from 8:30 a.m. to 5 p.m., in Building 31, Conference Room 10, C Wing. The meeting will be open to the public.

The meeting will be devoted to discussion of a "Review of the National Institutes of Health Biomedical Research Training Programs."

The Executive Secretary, Jay Moskowitz, Ph.D., National Institutes of Health, Shannon Building, room 103, Bethesda, Maryland 20892, (301) 496–3152, will furnish the meeting agenda, rosters of Committee members and consultants, and substantive program information upon request.

Dated: May 14, 1990.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 90–11639 Filed 5–18–90; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Dental Research; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Advisory Dental Research Council, National Institute of Dental Research, May 30–31, 1990, Building 31, Conference Room 6, National Institutes of Health, which was published in the Federal Register on April 12, (55 FR 13849).

As stated in the previous notice and in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Pub. L. 92–463, the Council meeting will be closed to the public on May 30 from 8:30 a.m. to 9:30 a.m.; open on May 30 from 9:30 a.m. to recess; and closed on May 31 from 9 a.m. to adjournment for the review, discussion and evaluation of individual grant applications.

In addition, the National Advisory Dental Research Council plans to use a portion of the closed session on May 31 under provisions set forth in section 552b(c)9(B), for discussion and preparation of comments the Council wishes to submit to the Director, NIH, for inclusion in the biennial report that will be forwarded to the Congress and the President.

Dated: May 10, 1990.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 90–11638 Filed 5–18–90; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council and its subcommittees, National Institute of Diabetes and Digestive and Kidney Diseases, on May 30–31, 1990, Conference Room 10, Building 31, National Institutes of Health, Bethesda, Maryland. The meeting will be open to the public May 30, from 8:30 a.m. to 12 noon and again on May 31 from 10:30 a.m. to adjournment to discuss administrative details relating to Council business and special reports. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the subcommittee and full Council meeting will be closed to the public for the review, discussion and evaluation of individual grant applications. The following subcommittees will be closed to the public on May 30 from 1 p.m. to recess: Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney, Urologic and Hematologic Diseases. The full Council meeting will be closed on May 31 from 8:30 a.m. to 10:30 a.m.

These deliberations could reveal confidential trade secrets or commercial property, such as patentable materials, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Further information concerning the Council meeting may be obtained from Dr. Walter Stolz, Executive Secretary, National Diabetes and Digestive and Kidney Diseases Advisory Council, NIDDK, Westwood Building, Room 657, Bethesda, Maryland 20892, (301) 496–7277.

A summary of the meeting and roster of the members may be obtained from the Committee Management Office, NIDDK, Building 31, Room 9A19, National Institutes of Health, Bethesda, Maryland 20892, (301) 496–6917.

(Catalog of Federal Domestic Assistance Program No. 13.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: May 8, 1990.

Betty J. Beveridge,

Committee Management Officer, NIH.

[FR Doc. 90–11637 Filed 5–18–90; 8:45 am]

BILLING CODE 4140–01–M

Public Health Service

Expanded Availability of Investigational New Drugs Through a Parallel Track Mechanism for People With AIDS and HIV-Related Disease

AGENCY: Public Health Service, HHS.

ACTION: Notice; proposed policy statement.

SUMMARY: The Public Health Service (PHS) is announcing and seeking public comment on a proposed policy to make promising investigational drugs for AIDS and HIV-related diseases more widely available under "parallel track" protocols while assuring that the controlled clinical trials essential to establish the safety and effectiveness of new drugs are carried out. The "parallel track" initiative would be designed to expand the availability of promising investigational agents and to make these agents more widely available to people with AIDS and HIV-disease who have no therapeutic alternatives and who cannot participate in the controlled clinical trials. Even though a combination of safeguards has been built into this proposed policy (including careful product selection, informed consent, patient and physician education, national human subjects protection review panel and community involvement and oversight), allowing increased availability of drugs prior to definitive evidence of either safety or efficacy carries very serious potential risks for the participants.

Although persons with other life-threatening diseases might also wish to have investigational drugs available through a parallel track mechanism, the policy at this time will be limited to individuals with AIDS or HIV-related diseases. Several factors have contributed to this criterion: (1) The HIV epidemic has resulted in an estimated one million HIV-infected persons in the United States for whom there are no wholly satisfactory therapies; (2) this initiative is a pilot effort, therefore it is preferable to work out the procedures and to evaluate its operation, and; (3) based on the interactions with patient advocacy groups (e.g., National Association of People with AIDS, The AIDS Coalition to Unleash Power and Project Inform) and physicians specializing in the care of HIV-infected individuals, there exists willingness among HIV-infected persons to participate in clinical studies as well as an expanded availability program. Therefore it is prudent to implement this system initially as a pilot process with a single disease for which there are not yet satisfactory alternative therapies and for which there is high probability that both patient and health care provider populations will be willing to participate. However, comments are requested especially on whether this policy of expanded availability should be extended beyond AIDS-related therapies to those therapies for other life-threatening diseases.

While comments are being received and evaluated, this proposed policy statement will not represent an FDA advisory opinion which the Agency would be obligated to follow.

DATES: Comments by July 20, 1990.

ADDRESSES: Written comments to: Parallel Track Policy, National AIDS Program Office, 200 Independence Avenue SW., Room 738–G, Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Dr. Valerie Setlow, (202) 472–4248, same address as above.

SUPPLEMENTARY INFORMATION:

Introduction

Through this notice, the Public Health Service is announcing and is seeking comment on a proposed policy under the Food, Drug and Cosmetic Act (the Act). The purpose of this proposed policy is to permit promising investigational agents to be made available to people with AIDS and HIV-related diseases who are not able to take standard therapy, or for whom standard therapy is no longer effective, and who are not able to participate in ongoing controlled clinical trials. Through this proposed policy, promising new drugs would be made available through studies without concurrent control groups to monitor drug safety that are conducted in parallel with the principal controlled clinical investigations (hence the name "parallel track").

This proposed policy, developed by the Public Health Service with significant input from community advocates, industry representatives, the research community, and other interested members of the public, would represent a further step in expanding availability of promising investigational drugs under the Act to those persons with AIDS and HIV-related diseases who are without satisfactory alternative therapy and who cannot participate in the controlled clinical trials. Because some investigational drugs for these conditions would be more widely available at a very early point in the drug development process, this procedure would recognize the need for participating physicians and their patients to consider what is and is not known about the risks and benefits of a variety of potential therapeutic agents when making clinical decisions.

Patients and physicians must recognize that products available under this procedure would be in the very early stages of product development and would only be made available to provide potential therapeutic options to those people with serious and life-threatening HIV-related disease who have no satisfactory alternative therapy. It must be clearly understood that the earlier availability of experimental treatments on a wide scale exposes larger numbers of patients to greater uncertainty and the risk of unforeseen and serious reactions.

There are many issues and problems related to providing potential therapies to individuals with HIV-related diseases. Although certain problems have been addressed in this document, others, in particular some that are not within the purview of the Public Health Service still require attention, but will not be discussed in this publication. For example, this proposal does not deal with aspects of the health care system that can affect the availability and affordability of parallel track mechanisms to underserved groups. It also does not address the role of third-party payers in covering the costs of medical services associated with the use of parallel track drugs. While the Public Health Service recognizes the importance of these issues, and will attempt to facilitate a broader consideration of them, they are beyond the scope of this proposed policy.

In the development of this proposed policy, it was recognized that well conducted clinical trials are crucial to the development of new treatments. While the goal of making promising investigational agents more widely available to persons with HIV infection and no therapeutic alternatives is an important one, controlled clinical trials that yield definitive information on the safety and effectiveness of investigational new drugs must continue. It is extremely important, therefore, that this proposed policy include sufficient safeguards and oversight to ensure that it neither delays nor compromises the controlled clinical trials.

Background

Normally, the development of a new experimental therapy proceeds through a systematic series of clinical trials that yield data growing from an initial understanding of appropriate dosing, side effects, and initial hints of efficacy, to a substantial body of definitive evidence of safety and effectiveness sufficient to support product marketing. This often lengthy approach is based upon well substantiated and widely accepted scientific and ethical principles and a mandate from society that protection of individuals from the risks of experimental therapy is extremely important.

Although the AIDS epidemic has heightened interest in expanded access to investigational drugs, the issue is not new. Persons with life-threatening diseases for which no satisfactory alternative therapy is available have at times requested an investigational new drug prior to the drug's approval by the Food and Drug Administration (FDA). The issue has been dealt with by FDA in the past in both formal and informal ways. In the 1970's a number of large protocols were developed in which physicians, generally at academic referral centers, had access to investigational drugs for persons with serious or life threatening conditions who were without satisfactory alternative therapy. The drugs in these protocols were usually under active development in controlled trials and some of these protocols involved large numbers of patients. A similar mechanism was developed to provide investigational drugs to persons with cancer. The FDA and National Cancer Institute (NCI) have described a special category of investigational drugs, "Group C" drugs, which may be provided by oncologists to appropriately chosen patients through protocols outside the controlled clinical trials prior to the drug's approval.

In 1987 FDA incorporated into a final regulation the treatment investigational new drug application (Treatment IND). Under a Treatment IND protocol, eligible patients have access to investigational drugs intended to treat serious or life-threatening diseases. A Treatment IND may be granted after sufficient data have been collected to show that the drug "may be effective" and does not have unreasonable risks, but before marketing approval has been granted. Treatment IND status has been granted for 18 investigational new drugs, 6 of these for AIDS-related conditions.

Under this proposed policy, expanded availability protocols might be approved for promising investigational drugs when the evidence for effectiveness is less than that generally required for a Treatment IND. The expanded availability protocol may include one or more studies without concurrent control groups and may be accompanied by a Treatment IND protocol. All drugs distributed under the parallel track mechanism will be under a study protocol. Data, particularly pertaining to side effects and safely will be collected under these studies. However, most of the data essential for market approval will come from the controlled clinical trials.

As is the case for all investigational uses of drugs, FDA has authority for approving and monitoring the study protocols that are developed under this expanded availability policy. A proposed regulation detailing the FDA's authority to terminate these studies is published elsewhere in this issue of the Federal Register.

Selection of Investigational Therapeutic Agents for Expanded Availability Through Parallel Track

FDA ecourages potential sponsors (21 CFR 312.3(b)) to seek advice and information from FDA and other

scientists outside the agency as early, and as frequently as possible, during the preapplication process.

The FDA has authority for the final decisions regarding which investigational agents will be placed in a program for expanded availability. Applications for experimental therapies to be considered for expanded access (parallel track) would be submitted to FDA as amendments to existing INDs.

(1) FDA would refer all parallel track proposals to the AIDS Research Advisory Committee (ARAC), a committee chartered by the National Institute of Allergy and Infectious Diseases (NIAID) unless the sponsor indicates otherwise. This committee, composed of outside scientists and physicians experienced with AIDS, persons with HIV-related diseases, and others, will review the available data and make a recommendation to the Director of NIAID. After review, the Director of the NIAID will forward a recommendation, through the Director of the NIH, to the Commissioner of the FDA. In all cases, requests to be presented to the ARAC will be screened and scheduled by NIAID Committee Management Staff.

(2) If the sponsor prefers, the formal parallel track proposal can be submitted to the FDA for review without being forwarded to the ARAC.

Review Criteria

Ordinarily in reviewing a proposal to make an investigational drug available through a parallel track proposal, the ARAC Committee and FDA would consider whether there was:

1. Sufficient information showing:

a. Promising evidence of efficacy based on an assessment of all laboratory and clinical data;

b. Evidence that the investigational drug is reasonably safe, taking into consideration the intended use of the drug and the patient propulation for which this drug is intended; and

c. Sufficient data to recommend an appropriate starting dose.

2. Preliminary pharmacokinetic and dose-response data and, ideally, data about interactions with other drugs commonly used in the intended patient population.

3. Evidence of a lack of satisfactory alternative therapy for defined patient populations. In general, the investigational drug should meet a serious unfulfilled health need such that the potential benefits justify the considerable risks of very early expansion of use.

4. A description of the patient population to receive the drug under expanded access. Patient priority categories based on clinical condition should be determined if the drug may not be available in sufficient quantities to supply all of those who satisfy the basic eligibility criteria.

5. Assurance that the manufacturer is willing and able to produce sufficient amounts of the drug product for both the controlled clinical trials and the proposed expanded availability study.

6. A statement on the status of the controlled clinical trial protocols. Phase 2 controlled clinical trial protocols are to be approved by the FDA and patient enrollment initiated prior to or simultaneously with release of drugs for expanded availability under the parallel track protocol.

7. An asessment of the impact that the parallel track study may have on patient enrollment for the controlled clinical trials and a proposed plan for monitoring progress of the controlled trials.

8. Information describing the educational efforts that will be undertaken to ensure that participating physicians and potential recipients have sufficient knowledge of the potential risks and benefits of the investigational agent being studied in the parallel track process.

In general, deliberations about the advisability of expanded availability for a specific drug can be accomplished best during the review of a relatively detailed protocol for expanded availability in conjunction with the review of the protocols for the controlled clinical trials. While a detailed protocol would not be required during the initial discussion stage, an outline of the proposed parallel track study should be provided.

Review and approval of a formal IND protocol would be carried out by FDA, which may elect to involve one or more advisory committees in the review process. The FDA, through its existing regulations and procedures, may also discuss proposed protocols with appropriate consultants to the Agency.

A decision not to allow expanded availability of an investigational drug would not imply a judgement about a drug's ultimate safety or efficacy nor preclude additional controlled trials.

Protocol Development and Approval

The protocol for distribution and monitoring of an investigational drug under parallel track (expanded access protocol) would be developed by the manufacturer or other sponsor. The FDA has regulatory authority for approval of the protocol and, in most cases, would interact with the sponsor during its development.

Elements to be contained in the expanded access protocol would be the same as those for other protocols of investigational agents in clinical trials (21 CFR 312.23 (a)(6)). Normally, a protocol submission for a parallel track study would include information about: the administration of the protocol; the sponsor's responsibilities under the protocol; patient selection criteria; phasing in of expanded use; physician selection for participation; dosage level and frequency; data reporting requirements and data collection forms; data monitoring procedures by the sponsor; physician and patient educational materials; patient consent documents; and criteria for terminating the protocol.

Eligibility Criteria for Patients To Receive Investigational New Drugs Through Parallel Track

Criteria for patient eligibility would be included in each protocol for expanded availability. General principles for determining patient eligibility are described below. They are intended to provide flexibility as the specific criteria may vary for different agents and different clinical situations.

The determinants of patient eligibility include all of the following:

1. The patient has clinically significant HIV-related illness or is at imminent health risk due to HIV-related immunodeficiency.

2. The patient cannot participate in the controlled clinical trials because:

(a) The patient does not meet the entry criteria for the controlled clinical trials, or

(b) The patient is too ill to participate, or

(c) Participation in controlled clinical trials is likely to cause undue hardship (e.g. travel time) as defined by the protocol.

(d) The controlled clinical trials are fully enrolled.

3. The patient cannot take standard treatment (i.e. a drug approved for marketing or available under a treatment IND for the same clinical condition for which the investigational drug is being studied) because it is contraindicated, cannot be tolerated, or is no longer effective. (The terms "cannot be tolerated" and "no longer effective" should be defined in each protocol. Generally these definitions will include a description of the standard therapy including dosages and the minimum duration of treatment to assess clinical utility, the range and severity of adverse reactions that constitute intolerance, and the clinical conditions or laboratory markets that

constitute evidence that the therapy is no longer effective). If the basis for enrollment in the parallel track study is that standard treatment is no longer effective, the patient's physician or physician group would be required under the protocol to certify that the patient is failing clinically despite reasonable efforts to optimize therapy with the standard treatment.

The protocol should establish patient priority categories if a sufficient quantity of the investigational drug is not likely to be available to all those who would satisfy the basic criteria for eligibility.

Because the primary objective of the IND phase of drug development is to establish the safety and efficacy of the drug through controlled clinical trials, it would be critical that the sponsor work with participating physicians to assure that reasonable efforts are made to encourage persons to enter controlled clinical trials for which they are eligible. The protocol should specify a process for determining if a person for whom the investigational drug is being requested under the parallel track protocol is eligible for a controlled clinical trial of the drug, and methods for contacting clinical trial directors for possible inclusion.

The expanded availability protocol should not exclude certain patient populations based on age, sex or medical status unless there is adequate justification. Protocols should also consider and address potential problems associated with use of the drug in such special populations. The regulations for human subjects protections are discussed later in this document.

Criteria for Physician Participation In Parallel Track

As specified in FDA's IND regulations (21 CFR part 312) physicians administering investigational drugs under parallel track protocols become clinical investigators subjet to all the obligations and responsibilities of investigators. The protocol would specify the minimum qualifications for participating physicians and the process by which a physician may be accepted by the sponsor as a clinical investigator under the expanded availability protocol. Physicians would be required to certify that the patients meet the requirements of the protocol and that all efforts have been made to optimize standard therapy prior to enrollment in parallel track protocols. Becaue investigational drugs will be made available through parallel track protocols when relatively little is known about the drug, physicians must be familiar with potential adverse effects, willing to instruct patients in the early recognition of these effects and willing to monitor their patients closely. Participation by all physicians, including those serving rural, inner-city, medically indigent, and racial and ethnic minority populations should be encouraged.

Collection of Patient Data in Parallel Track Protocols

The data to be collected by the participating physicians and reported to the sponsor would be specified in each parallel track protocol. All participating physicians would be required to report safety data, while the nature and extent of efficacy data collection may vary in different clinical settings. The frequency of reporting would be specified in the protocol. Because of the early stage at which investigational drugs are to be made available under a parallel track protocol, and the relative lack of information about risk that is likely to exist, it is critical that participating physicians comply with data reporting requirements to provide important information on the risk of the drug and to assure patient safety.

The data collection forms should be designed to be easy to use and as concise as possible. Appropriate data collection and reporting by the administering physician would be a prerequisite for continued drug supply.

Monitoring the Protocols

The sponsor of a parallel track protocol should monitor the study closely through a specific monitoring mechanism described in the protocol. The sponsor should establish a Data and Safety Monitoring Board (DSMB) or its equivalent with responsibility for monitoring the parallel track studies and gathering information from all protocols testing the investigational drug. The DSMB or its equivalent may recommend to FDA, the Sponsor, ARAC and other appropriate bodies taht the parallel track and/or clinical trial protocols be terminated. (See Terminating Protocols).

The description and mechanism of operation of the DSMB (or other monitoring system) and its precise relationship to the sponsor and other oversight bodies would be specified in the expanded availability protocols.

The sponsor would be responsible for submitting reports to the FDA as required in the IND regulations (21 CFR part 312), except where a waiver has been specially granted.

Education

An extremely important accompaniment to a parallel track protocol will be a program for the education of physicians, patients, IRBs, community-based health institutions, community and migrant health centers, the general public, and affected communities to ensure that participating physicians and potential recipients have sufficient knowledge of the potential risks and benefits of the parallel track drug as well as the risks and benefits of other treatment options. These programs, as noted in the "Review criteria" section above, should reflect the joint efforts of the PHS, the medical community, industry, academic communities and AIDS-related organizations. Sponsors should specify how their particular education program will be carried out as well as how new information will be collected, analyzed, and publicly circulated.

Economic Considerations

Existing IND regulations permit sponsors to request the recovery of costs for certain investigational drugs in clinical studies, in the unusual circumstance in which the trial could not otherwise continue (21 CFR 312.7 (d) (1)). FDA approval of a request to charge must be obtained.

Sponsors should specify the extent of economic support they would be willing to provide to pursue the expanded access of the investigational agent through the parallel track. They should also specify the degree of support, if any, they would provide for the administration of the drug for the conduct of necessary laboratory and clinical testing to determine product safety and the monitoring, collection, and distribution of drug-specific information through their education programs.

Human Subjects Protection

There are two sets of relevant federal regulations for the protection of human subjects which include requirements for local institutional review board (IRB) review and informed consent: the FDA regulations (21 CFR parts 50 and 56) that apply to all investigational drug studies, and HHS regulations (45 CFR part 46) which pertain to institutions that receive HHS support for research involving human subjects.

(a) HHS Regulations

Certain requirements of the current HHS regulations cannot reasonably be met for drugs released under the parallel track program. These regulations require local IRB review and approval of each protocol and written Assurance of Compliance from each organization or individual practitioner involved in the research and not affiliated with an assured institution. This may not be

practical for many reasons: (1) local IRB review could slow the dissemination of drugs under parallel track policies and procedures; (2) local review could be made by IRBs without sufficient information on which to base a recommendation; (3) local review could result in some physicians forming their own IRBs; (4) local review might place IRBs in a situation in which they are expected to monitor activities of physicians for whom they are not otherwise responsible. Consequently, the HHS regulatory provisions would be waived. Other mechanisms, in lieu of local IRB review, to provide for review of the protocol according to established ethical principles and to develop informed consent procedures appropriate to the parallel track program are described below. The Secretary of HHS will waive provisions of 45 CFR part 46 as appropriate.

(b) FDA Regulations

The Commissioner of Food and Drugs will permit review by the human subjects panel under 21 CFR part 56 on a case by case basis as appropriate.

(c) Human Subjects Panel

While local IRBs would always have the option of reviewing expanded availability protocols, a national human subjects protections review panel (human subjects panel) with a broadly-based membership would be established. This panel will provide for patient protections, including approval of consent procedures and documentation and provide for continuing ethical oversight of each parallel track protocol. It will be particularly important for this body to review the proposed informed consent process of each protocol and review an initial "model" informed consent document, and to review the process to update the procedures and the document as knowledge about the investigational drug becomes available. The human subjects panel will also ascertain that for each parallel track protocol the sponsor has established an appropriate procedure for data and safety monitoring.

The ARAC will establish an ad hoc subcommittee to carry out the duties of the human subjects review panel until a permanent body is established. Outside consultants representing the relevant specialties and constituencies will be called on as needed to advise this body. PHS will take steps necessary to create a chartered national human subjects protections review panel with a broadly-based membership.

IRBs would continue to review drugs on the controlled clinical trial side of the "parallel track." In addition, individual institutions *have the option* to require that their IRBs review the expanded availability protocols when such a study is conducted by the institution or its affiliated investigators.

The PHS specifically invites comment upon the advisability of granting the waiver of provisions of 45 CFR part 46 and requests comment upon what specific mechanisms should be employed to safeguard patients.

Informed Consent

It is important that potential participants in the parallel track have as much information as is available in order to make informed decisions. The informed consent process must make clear the risks involved in taking a drug about which relatively little is known. The proposal for agents in the parallel track must describe a detailed process for informed consent, including specific information about patient and physician education. An informed consent document would be required to be included with the protocol. There should also be a description of how the informed consent document will be updated and how physicians and patients and the human subjects panel will be notified of new information (e.g. toxicity, adverse reaction reports) after the initial informed consent document has been put into use.

Terminating Protocols

Because the parallel track program would allow early, widespread distribution of investigational agents prior to full marketing approval, it is necessary to develop criteria to terminate or curtail a parallel track program. In general, these should include the following:

(1) Evidence that subjects are being exposed to unreasonable and significant risks,

(2) Evidence that the parallel track study is interfering with the successful enrollment in, and completion of, adequate and well-controlled studies of this or other investigational drugs,

(3) Evidence that the sponsor is not in active pursuit of marketing approval,

(4) The product has been studied in an adequately controlled clinical trial that strongly suggests lack of effectiveness,

(5) Another product approved or under investigation for the same indication in the same population demonstrates a better potential balance of risks and benefits,

(6) The drug receives marketing approval for the same indication in the same patient population,

(7) Insufficient product exists to conduct both the parallel track protocols and the controlled clinical trials,

(8) The Commissioner of Food and Drugs determines that, in the interest of the public health, the parallel track study should not be continued.

A principal purpose of the Data and Safety Monitoring Board, or its equivalent, would be to examine data to determine if the parallel track and/or clinical trials should be stopped and to make recommendations to the sponsor, FDA, ARAC, and other oversight bodies. A proposed regulation detailing the FDA's authority to terminate these studies is published concurrently with this proposed policy statement.

Periodic Review

A periodic review of the implementation and progress of expanded availability of all investigational drugs being distributed by a parallel track study would be conducted by the Public Health Service (PHS). The objective of this periodic review would be to help ensure the continued rapid development and evaluation of therapeutic agents for treatment or prevention of HIV infection and HIV-associated diseases, as well as the safety of participants in these trials.

Dated: April 2, 1990.

James O. Mason,

Assistant Secretary for Health and Acting Surgeon General.

James S. Benson,

Acting Commissioner, Food and Drug Administration.

William F. Raub,

Acting Director, National Institutes of Health.

[FR Doc. 90-11822 Filed 5-18-90; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-050-4351-10]

Temporary Closure Order of Public Lands

AGENCY: Bureau of Land Management (BLM) Interior.

ACTION: Temporary closure order of public lands.

SUMMARY: Notice is hereby given related to the temporary closure of Bureau of Land Management (BLM) administered lands to all public use in accordance with regulations contained in 43 CFR 8364.1 and known as the Cache Creek Management Area in Lake and Yolo county. The area will be temporarily

closed to all public use effective with date of publication and continuing through June 30th.

DATES: This closure order is effective upon date of publication.

SUPPLEMENTARY INFORMATION: The purpose of this temporary closure is to protect resource values within the Cache Creek Management Area which has become a favorite destination for many outdoor enthusiasts, and may be causing a problem for the tule elk. One of the most critical and sensitive times for tule elk is the calving season which begins around April 1st and extends to about June 15th. A preferred calving area is in and around Wilson Valley which is also the favorite destination of a large number of people that utilize the Cache Creek Management Area. In an attempt to maintain Wilson Valley as elk habitat and minimize the disturbances during the critical calving season the California Department of Fish and Game in cooperation with the Bureau of Land Management is implementing a temporary closure of the Wilson Valley area to all public uses. The closed area involves all public lands located south of the main fork of Cache Creek and south of Stample Creek. Maps showing the area closed to public use are available at the Clear Lake Resource Area Office, 555 Leslie Street, Ukiah, CA 95482.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Ukiah Office at (707) 462–3873 or Department of Fish and Game, Yountville Office at (707) 944–5500.

Catherine Robertson,

Clear Lake Resource Area Manager.

[FR Doc. 90–11704 Filed 5–18–90; 8:45 am]

BILLING CODE 4310–40–M

[NV–050–00–4210–02]

Las Vegas District Advisory Council Meeting

AGENCY: Bureau of Land Management, Department of Interior Notice is hereby given in accordance with Public Law 920463 that a meeting of the Bureau of Land Management, Las Vegas District Advisory Council will be held June 11, 1990, at 10 a.m., 3 p.m. and 7 p.m.–9 p.m. in the State Industrial Insurance System building, 1700 W. Charleston, Las Vegas, Nevada.

The meeting agenda will include: 1. Disposition of BLM public land within the Las Vegas Valley planning Sub-Unit.

2. District Sanitary Landfill Program.

3. FWS perspective of the Endangered Species Act.

4. Stateline Resource Management Plan—Status Report.

5. Decatur Cadastral Survey—Status Report.

6. District Prescribed Burning Program—Status Report.

7. Public Comment.

8. District Sand and Gravel Program.

Advisory Council meetings are open to the public. Persons wishing to make oral statements to the Council must notify the District Manager, Bureau of Land Management, Las Vegas District, P.O. Box 26569, Las Vegas, Nevada 89125, prior to May 18, 1990.

Minutes of the meeting will be available, upon request, at the Las Vegas District Office on July 11, 1990.

Dated: May 14, 1990

Ben F. Collins,

District Manager, Las Vegas, Nevada.

[FR Doc. 90–11715 Filed 5–18–90; 8:45 am]

BILLING CODE 4310–HC–M

[NV–930–4212–11; N–7301B]

Termination of Classification and Opening Order

May 10, 1990.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This notice terminates Recreation and Public Purposes Classification N–7301B and opens the lands to the operation of the public land laws, including location under the mining laws.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Ben Collins, District Manager, Bureau of Land Management, Las Vegas District Office, P.O. Box 26569, Las Vegas, NV 89126, (702) 647–5000.

SUPPLEMENTARY INFORMATION: Pursuant to 43 CFR 2091.7–1(b)(1), the segregative effect on the following described lands will terminate on June 20, 1990.

Mount Diablo Meridian, Nevada

T. 21 S., R. 60 E.,
Sec. 13, W½SE¼NE¼SW¼.

On July 1, 1981, the subject lands were classified as suitable for lease or sale pursuant to the Recreation and Public Purposes Act of June 14, 1926, as amended (43 U.S.C. 869—869–4) and at that time the lands became segregated from all forms of appropriation under the public land laws and location under the mining laws. A lease was subsequently issued to the Clark County School District. Said lease has recently been relinquished and the case closed.

At 10 a.m. on June 20, 1990, the land will be open to the operation of the public land laws, subject to valid existing rights. All valid applications received prior to 10 a.m. on June 20, 1990, will be considered as simultaneously filed. All other applications received will be considered in the order of filing.

At 10 a.m. on June 20, 1990, the land will also be open to location under the mining laws. Appropriation of lands under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determination in local courts.

The land remains open to the mineral leasing laws, the material disposal laws, and the Geothermal Steam Act.

Fred Wolf,

Acting State Director, Nevada.

[FR Doc. 90–11645 Filed 5–18–90; 8:45 am]

BILLING CODE 4310–HC–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research Act of 1984—Open Software Foundation, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Open Software Foundation, Inc. ("OSF") on April 19, 1990, has filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The additional notification was filed for the purpose of extending the protections of section 4 of the Act limiting recovery of antitrust plaintiffs to actual damages under specific circumstances.

On August 8, 1988, OSF filed its original notification pursuant to section 6(a) of the Act. The Department of Justice (the "Department") published a notice in the **Federal Register** pursuant to section 6(b) of the Act on September 7, 1988 (53 FR 34594). On November 4, 1988, February 2, 1989, May 3, 1989, July 28, 1989, October 26, 1989, and January 22, 1990, OSF filed additional written notifications. The Department published notices in the **Federal Register** in

response to these additional notifications on November 25, 1988 (53 FR 47773), February 23, 1989 (54 FR 7893), August 25, 1989 (54 FR 35407), August 25, 1989 (54 FR 35408), November 29, 1989 (54 FR 49123), and April 18, 1990 (55 FR 14493), respectively.

The identities of the new, non-voting members of OSF are as follows:

Member	Date
IRIT, Universite Paul Sabatier	1/16/90
Hughes Aircraft Company–Displays Lab	1/18/90
Mead Data Central	1/25/90
Superconducting Super Collider Lab	1/29/90
Exxon Production Research Company	2/22/90
Nielsen Advanced Information Tech Center	2/28/90
British Telecommunication Public Ltd. Co.	3/21/90
University of Newcastle upon Tyne	3/21/90
NKK Corporation	3/22/90
University of Cambridge, Computer Lab	3/22/90
RUS-Rechenzentrum Univ. Stuttgart	3/23/90
University of Tokyo	4/05/90
University of Waterloo	4/09/90

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 90–11640 Filed 5–18–90; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984—Unix International, Inc.

Notice is hereby given that, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), UNIX International, Inc. ("UNIX") on May 1, 1990, filed an additional written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The additional written notification was filed for the purpose of extending the protections of section 4 of the Act, limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

On January 30, 1989, UNIX filed its original notification pursuant to section 6(a) of the Act. The Department of Justice (the "Department") published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 1, 1989 (54 FR 8608). On May 4, 1989, August 1, 1989, October 31, 1989, and February 1, 1990, UNIX filed additional written notifications. The Department published notices in the **Federal Register** in response to the additional notifications on June 22, 1989 (54 FR 26266), August 17, 1989 (54 FR 33985), November 29, 1989 (54 FR 49124), and March 14, 1990 (55 FR 9517), respectively.

As of April 30, 1990, the following have become members of UNIX International, Inc.:

BankAmerica
Commodore International
Cray Computer
Dublin City University
Elea
Epoch Systems
Facom Center
Facom Software
Ingres Corp.
Norsk Data
Pick Systems
Rechenzentrum University
Simula
SPARC International
Swedish Telecom
System Strategies
Tietohtedas
U.H. Corp.
UniRel
University of Genoa
University of Erlangen
University of Bergen

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 90–11641 Filed 5–18–90; 8:45 am]

BILLING CODE 4410–01–M

Notice Pursuant to the National Cooperative Research Act of 1984—the Development of a Computer-Aided Armor Design/Analysis System Southwest Research Institute

Notice is hereby given that, on April 19, 1990, pursuant to section 6(a) of the National Cooperative Research Act of 1984, 15 U.S.C. 4301 *et seq.* ("the Act"), Southwest Research Institute ("SwRI") filed a written notification simultaneously with the Attorney General and the Federal Trade Commission disclosing the addition of a party to its group research project regarding "The Development of a Computer-Aided Armor Design/Analysis System." The notification was filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, SwRI advised that British Aerospace PLC (effective March 5, 1990) has become a party to the group research project.

No other changes have been made in either the membership or planned activity of the group research project.

On June 26, 1989, SwRI filed its original notification pursuant to section 6(a) of the Act. The Department of Justice (the "Department") published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 20, 1989, 54 FR 30481. On August 7, 1989, SwRI filed an additional written notification. The Department published a notice in the **Federal Register** in response to the additional notification on August 31, 1989, 54 FR 36066. On November 1, 1989, SwRI filed an additional written notification. The Department published a notice in the **Federal Register** in response to the additional notification on November 30, 1989, 54 FR 49368.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 90–11642 Filed 5–18–90; 8:45 am]

BILLING CODE 4410–01–M

Drug Enforcement Administration

Controlled Substances; Proposed Revised 1990 Aggregate Production Quotas

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed revised 1990 aggregate production quotas.

SUMMARY: This notice proposes revised 1990 aggregate production quotas for controlled substances in Schedule II of the Controlled Substances Act. Since the establishment of the 1990 aggregate production quotas on December 26, 1989 (54 FR 53012), DEA has reviewed data submitted by the registered manufacturers concerning 1989 dispositions and year-end inventories and has determined that revisions of some of the previously established quotas are necessary.

DATES: Comments or objections should be received on or before June 20, 1990.

ADDRESSES: Send comments or objections to the Acting Administrator, Drug Enforcement Administration, Washington, DC 20537, Attn: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, Telephone: (202 307–7183.

SUPPLEMENTARY INFORMATION: Section 306 of the Controlled Substances Act (21 U.S.C. 826) requires the Attorney General to establish aggregate production quotas for all controlled substances in Schedules I and II each year. This responsibility has been delegated to the Acting Administrator of the DEA pursuant to § 0.100 of title 28 of the Code of Federal Regulations.

On December 26, 1989, a notice of the 1990 established aggregate production quotas was published in the **Federal Register** (54 FR 53012). The notice stipulated that the Acting Administrator of the DEA would adjust the quotas in

early 1990, as provided for in title 21, Code of Federal Regulations, § 1303.23(c). These aggregate production quotas represent those amounts of controlled substances that may be produced in the United States in 1990 and do not include amounts which may be imported for use in industrial processes.

Based on a review of 1989 year-end inventories, 1989 disposition data submitted by quota applicants, estimates of the medical needs of the United States submitted to the DEA by the Food and Drug Administration, and the other information available to DEA, the Acting Administrator of the DEA, under the authority vested in the Attorney General by section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826) and delegated to the Acting Administrator by § 0.100 of title 28 of the Code of Federal Regulations, hereby proposes the following changes in the 1990 aggregate production quotas for the listed controlled substances, expressed in grams of anhydrous acid or base.

Schedule II	Previously established 1990 aggregate production quota	Proposed revised 1990 aggregate production quota
Alfentanil	5,000	3,000
Amobarbital	596,000	459,000
Amphetamine	279,000	417,000
Cocaine	600,000	663,000
Codeine (for conversion)	5,093,000	6,570,000
Desoxyephedrine	1,252,000	1,581,000
Levodesoxyephedrine	1,252,000	1,581,000
Methamphetamine	0	0
Dextropropoxyphene	79,955,000	85,409,000
Dihydrocodeine	435,000	201,000
Diphenoxylate	882,000	441,000
Hydrocodone	3,026,000	4,473,000
Hydromorphone	223,000	229,000
Levorphanol	10,700	8,200
Meperidine	10,019,000	9,426,000
Methadone	1,441,000	2,069,000
Methadone Intermediate (4-Cyano-2-dimethylamino-4, 4-diphenylbutane)	1,802,000	2,586,000
Methylphenidate	2,262,000	1,768,000
Morphine (for sale)	3,841,000	4,707,000
Morphine (for conversion)	59,243,000	61,774,000
Opium (tinctures, extracts, etc., expressed in terms of USP powdered opium)	1,337,000	1,237,000
Oxycodone (for sale)	2,427,000	2,884,000
Pentobarbital	11,296,000	16,665,000
Phenylacetone	684,000	1,612,000
Secobarbital	583,000	370,000
Sufentanil	400	440

All interested persons are invited to submit their comments and objections in writing regarding this proposal. A person may object to or comment on the proposal relating to any of the above mentioned substances without filing comments or objections regarding the others. If a person believes that one or more of these issues warrant a hearing, the individual should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Acting Administrator finds warrant a hearing, the Acting Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

Pursuant to section 3(c)(3) and 3(e)(2)(C) of Executive Order 12291, the Director of the Office of Management and Budget has been consulted with respect to these proceedings.

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The Acting Administrator hereby certifies that this matter will have no significant impact upon small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq. The establishment of annual aggregate production quotas for Schedule I and II controlled substances is mandated by law and by the international commitments of the United States. Such quotas impact predominantly upon major manufacturers of the affected controlled substances.

Dated: April 11, 1990.

Terrence M. Burke,

Acting Administrator, Drug Enforcement Administration.

[FR Doc. 90–11729 Filed 5–18–90; 8:45 am]

BILLING CODE 4410–09–M

Manufacturer of Controlled Substances; Registration

By Notice dated June 13, 1989, and published in the **Federal Register** on June 20, 1989, (54 FR 25916), Sterling Drug, Inc., 33 Riverside Avenue, Rensselear, New York 12144, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of (pethidine) (9230), a basic class of controlled substance listed in Schedule II.

No comments or objections have been received. Therefore, pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 and title 21, Code of Federal Regulations, section 1301.54(e), the Deputy Assistant Administrator hereby orders that the application submitted by the above firm for registration as a bulk manufacturer

of the basic class of controlled substance listed above is granted.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration.

Dated: May 10, 1990.

[FR Doc. 90-11732 Filed 5-18-90; 8:45 am]

BILLING CODE 4410-09-M

Office of Justice Programs

Discretionary Grant Program Awarded by Office for Victims of Crime

AGENCY: Office for Victims of Crime.

ACTION: Public announcement of availability of funds under the Discretionary Grant Program of the Edward Byrne Memorial State and Local Law Enforcement Assistance Program, authorized under the Anti-Drug Abuse Act of 1988 (Pub. L. 100-690).

SUMMARY: The Office for Victims of Crime is publishing this notice to announce the availability of funds under five new program initiatives entitled: (1) Law Enforcement Training and Technical Assistance to Improve Treatment of Crime Victims; (2) Technical Assistance and Training Project for Victims of Drug Related Crime; (3) Corrections-based Victims Assistance Project; (4) Offender Supervision and Victim Restitution Project; and (5) Legal Remedies for Crime Victims Against Perpetrators—Basic Principles.

DATES: The deadlines for receipt of applications are listed in section II "Program Descriptions."

ADDRESSES: OVC, 633 Indiana Avenue, NW., Washington, DC 20531.

FOR FURTHER INFORMATION, CONTACT: Special Projects Division, (202) 272-6500, OVC, 633 Indiana Avenue, NW., Washington, DC 20531.

SUPPLEMENTARY INFORMATION:

I. Introduction
II. Program Descriptions
III. Eligibility Requirements
IV. Application Requirements
V. Procedures and Criteria for Selection
VI. Submission Requirements
VII. Civil Rights Requirements

I. Introduction

The Office for Victims of Crime (OVC) is awarding funds in FY 90 for a wide array of programs intended to address often neglected victim priorities related to drug control, including areas of victim assistance through law enforcement training, other enhanced criminal justice system victim services and the safeguarding of victim rights. These programs are designed to lessen the adverse impact of the criminal justice system on crime victims, provide greater victim satisfaction with the criminal justice system, promote compensating crime victims for losses suffered as a result of criminal activity, and provide restitution. Victims of drug related crime will be emphasized and their needs described and addressed.

The Office for Victims of Crime is announcing these programs in collaboration with the Bureau of Justice Assistance (BJA) as part of the Discretionary Grant Program of the Edward Byrne Memorial State and Local Law Enforcement Assistance Program, authorized under the Anti-Drug Abuse Act of 1988 (Public Law 100-690). These projects reflect a growing recognition of the relationship between substance abuse and increased criminal activity producing greater numbers of victims in need of assistance. They also reflect enhanced coordination and greater efficiency in addressing substance abuse issues vital to the health of the nation, in accordance with the President's priorities and those of the National Drug Control Strategy.

II. Program Descriptions

Law Enforcement Training and Technical Assistance to Improve Treatment of Crime Victims

The goal of this program is to improve the quality of instruction available to law enforcement officials so that they may be better skilled at serving and communicating with crime victims.

The President's Task Force on Victims of Crime in 1982 recommended that "Police departments should develop and implement training programs to ensure that police officers are: (a) Sensitive to the needs of victims; and (b) informed, knowledgeable, and supportive of the existing local services and programs for victims." Police officers frequently see victims and their families immediately after the crime, when they are most in need of help. The officers' response to these persons often has a major effect on the victim's recovery. Police officers who respond quickly after the report is made, who listen attentively, who show understanding and compassion, and who take appropriate action will greatly assist the victim to overcome fear, injury and other harms. The purpose of this program is to implement the Task Force recommendations for improved law enforcement training and other related reforms which will result in better treatment of crime victims.

The grantee will collect and analyze the best law enforcement training information related to improving the treatment of crime victims for purposes of developing a training curriculum to be adopted by state and local law enforcement training academies. A national seminar may be conducted to introduce the curriculum and focus on how to most effectively train law enforcement officials on topics including victims' response to violent crime and how to improve victim cooperation with criminal justice officials. It is anticipated that the project will consult with, or use, the Law Enforcement Training Network, a television network that offers training to law enforcement agencies and develops training videos that focus on police responses to crime victims. Videos that might be developed include methods of responding to victims concerns during the course of investigation of various violent crimes, including rape, assault, homicide, robbery and burglary. This program will be funded for a 12-month duration. One grant of up to $200,000 will be awarded. Applications submitted in response to this announcement will be due 60 days from the date of publication.

Technical Assistance and Training Project for Victims of Drug Related Crime

The goal of this program is to enhance the capability of victim service organizations to treat victims of drug related crime.

One of the great tragic consequences of widespread drug abuse in the nation today is the impact on victims of drug related crime. As emphasized in the President's National Drug Control Strategy, drug dealers harass, intimidate, and assault law-abiding citizens. They entice and coerce children to join their ranks. Crack houses promote the deterioration of neighborhoods. Parks and public spaces have become havens for illicit activity. In such neighborhoods, drugs are sold freely and openly and buyers too often escape criminal sanction. Residents feel they are left alone with the task of protecting their lives and property, while trying to keep their children away from a life of drug use. The purpose of this program activity is to enhance the ability of victim service organizations to assist victims of drug related crime and thereby improve the lives of those living in high drug crime neighborhoods.

The grantee will develop a training and technical assistance program for use by victim assistance organizations in the delivery of services to victims of drug related crimes. The project will require the development of a training manual. The manual will be developed with the participation of law enforcement and victim assistance

organizations with special interests and expertise in this area. The manual will promote increased cooperation between law enforcement, victims service providers and community leaders in order to better respond to the needs of victims of drug related crime. The manual will be tested in at least two sites which have significant drug related crime problems. One grant of up to $80,000 will be awarded for a 12-month project. Applications for this program announcement are due 45 days from the date of publication of this announcement.

Corrections-based Victims Assistance Project

The goal of this program is to improve the correctional system's response to the needs and rights of crime victims.

The 1982 report of the President's Task Force on Victims of Crime recognized that the treatment of crime victims should be improved at all points in the criminal justice process, even after conviction, sentencing, and incarceration. Victim notification and participation in parole hearings are recognized as important and positive steps that affect the way victims feel about, and are served by, the criminal justice system. The American Correctional Association (ACA) Task Force on Crime Victims has made 15 recommendations for the improvement of the treatment of crime victims from a corrections perspective. The recommendations include four major areas: (1) Recommendations that involve direct services to victims; (2) recommendations that call for the development of victim assistance programs for correctional staff; (3) recommendations that involve training; and (4) recommendations that involve offender-directed programs. The purpose of this program is to implement the President's and the ACA's Task Force recommendations and related reforms for improving the treatment of crime victims by the correctional system.

The grantee will develop a protocol for establishing and operating corrections-based victim assistance programs. It will address release notification information and release processes, recommend procedures to assist crime victims in recovering court-ordered restitution, and initiate activities to implement recommendations of the ACA Task Force on Crime Victims and the President's Task Force on Victims of Crime. A training curriculum on victims issues will be developed and tested that instructs correctional programs on how to provide needed protection and information to crime victims. This protocol and curriculum will be used to provide training and technical assistance to state correctional systems. Applications are invited from public and private agencies and organizations which have particular expertise with corrections operations and an understanding of state-of-the-art victims services in corrections. Up to $150,000 will be awarded for a project of 12 months duration. Applications for this program are due 45 days from the date of publication of this announcement.

Offender Supervision and Victim Restitution Project

The goal of this program is to improve the response of probation and parole personnel to the needs of crime victims with emphasis upon the management of restitution.

Crime exacts a tremendous economic cost. In the vast majority of cases it is the victim, not the offender, who eventually shoulders the burden. This is unjust. The concept of personal accountability for the consequences of one's conduct, and the allied notion that the person who causes the damage should bear the cost, are important elements of an effective restitution project. For these reasons this program's purpose is to train probation and parole personnel to better serve crime victims, placing emphasis upon assessing the impact of crime upon victims and the management of restitution.

The present project will require examining probation and parole supervision practices related to protecting victims and providing victim services (particularly restitution) for purposes of developing a model curriculum and incorporating it into actual case management systems through training. Probation and parole officials are in a unique position to: (1) Assess the psychological, physical, and economic impact of crime upon victims and provide this information to the courts; (2) recommend requirements for release to the community (e.g. drug testing); (3) monitor and supervise offender compliance with restitution requirements; and (4) notify victims of changes in offender status. The promotion of restitution as part of a criminal sanction, the enforcement of notification requirements, and the provision of viable enforcement mechanisms will enhance the image and operations of probation and parole practices, while serving the needs of victims.

Applications are invited from public and private agencies and organizations with expertise in the operation of parole and probation programs and knowledge of current impediments to effective implementation of restitution and other victim services. Up to $150,000 will be available for a project of 12-months duration. Applications for this program are due 45 days from the date of publication of this announcement.

Legal Remedies for Crime Victims Against Perpetrators—Basic Principals

The goal of this program is to train non-lawyer victim service providers and practitioners to assist victims of violent crime in: (1) Understanding their legal rights and remedies against perpetrators; and (2) determining how and when to obtain qualified legal assistance in appropriate cases.

The commission of a crime detrimental to an individual is generally sufficient cause of action against the perpetrator; and a criminal conviction is usually sufficient to support the success of a civil action brought to court on behalf of a crime victim. Additionally, civil litigation is often a means by which justice is achieved and compensation for loss of property or the cost of medical treatment is obtained by the victim. This program will provide a clear explanation of the civil litigation process to crime victims and help place civil litigation options within their grasp.

The project will provide accurate, up-to-date information to victims about their legal remedies emphasizing appellate case law on this topic; inform victims that civil litigation may be an effective remedy in certain circumstances; and guide victims in determining how and when to obtain legal representation. A manual will be drafted which will describe in non-technical, easy-to-comprehend language the basic legal principles involved in victim versus perpetrator cases with major emphasis on: (1) How victims can collect from perpetrators; (2) when a valid case warrants consulting an attorney; (3) what legal principles and case law apply and what remedies should be sought; and (4) highlights and pitfalls in potential cases.

Applicants must demonstrate that they have ready access to the growing body of relevant case law (especially recent appellate decisions), experience with crime victim issues and can publish professional works dealing with civil litigation. The award will be for a 12-month period. Up to $80,000 will be awarded. Applications for this program are due 30 days after the publication date of this announcement.

III. Eligibility Requirements

In addition to any special eligibility requirements listed within the individual program descriptions (section II above),

the following apply: Applications are invited from public and private agencies and organizations. Applications will be accepted from for-profit agencies as long as they agree to waive their profit fee and accept only actual allowable costs.

Applicants must demonstrate that they have ample expertise and/or prior experience in the design and conduct of project of a nature similar to that for which they are applying.

Applicants must also demonstrate that they have the management capability, fiscal integrity and financial responsibility, including, but not limited to, an acceptable accounting system and internal controls, and compliance with grant fiscal requirements. Applicants who fail to demonstrate that they have the capability to manage the program will be ineligible for funding consideration.

IV. Application Requirements

All applicants must submit a completed Application for Federal Assistance (Standard Form 424), including a program narrative, a detailed budget, and budget narrative. All applications must include the information outlined in this section of the solicitation (Section IV. Application Requirements) in Part IV, Program Narrative of the application (SF–424). The program narrative of the application should not exceed 35 double-spaced pages in length.

In accordance with Executive Order No. 12549, 28 CFR 67.510, applicants must also provide certification that they have not been debarred (voluntarily or involuntarily) from the receipt of Federal funds. Form 4061/2, which will be supplied with the application package, must be submitted with the application.

Other certifications required with the application include: (1) Drug-Free Workplace, OJP Form 4061/3, (2) Lobbying Certification and disclosure form SF LLL (if appropriate). Applications that include non-competitive contracts for the provision of specific services must include a sole source justification for any procurement in excess of $10,000.

The following information must be included in the application (SF–424) Part IV Program Narrative:

A. Organizational Capability—Applicants must demonstrate that they are eligible to compete for this grant on the basis of the eligibility criteria established in section III of this solicitation. Applicants must concisely describe their organizational experience with respect to the eligibility criteria specified in each program description listed above. Applicants must demonstrate how their organizational experience and capabilities will enable them to achieve the goals and objectives of this initiative. Applicants are invited to append examples of prior work products of a similar nature to their application.

Applicants must demonstrate that their organization has or can establish fiscal controls and accounting procedures that assure Federal funds available under this agreement are disbursed and accounted for properly. Applicants who have not previously received Federal funds will be asked to submit a copy of the Office of Justice Assistance, Research and Statistics (OJARS) Accounting System and Financial Capability Questionnaire (OJARS Form 7120/1). Copies of the form will be provided in the application kit and must be prepared and submitted along with the application. Other applicants may be requested to submit this form. All questions are to be answered regardless of instructions (Section C.I.B. note). The CPA certification is required only of those applicants who have not previously received Federal funding.

B. Program Goals and Objectives—A succinct statement of your understanding of the goals and objectives of the program should be included. The application should also include a problem statement and a discussion of the potential contribution of this program to the field.

C. Program Strategy—Applicants should describe the proposed approach for achieving the goals and objectives of each program. A detailed discussion of how the activities and products of each program would be accomplished should be included.

D. Program Implementation Plan—Applicants should prepare a plan that outlines the major activities involved in implementing the program, describe how they will allocate available resources to implement the project, and also describe how the program will be managed.

The plan must also include an organizational chart depicting the roles and describing the responsibilities of key organizational and functional components and a list of key personnel responsible for managing and implementing the major stages of the project. Applicants must present detailed position descriptions, qualifications, and selection criteria for each position. This documentation and individual résumés may be submitted as appendices to the application.

E. Time-Task Plan—Applicants must develop a time-task plan for the duration of the project periods, clearly identifying major milestones and products. This must include designation of organizational responsibility and a schedule for the completion of the activities and products. Applicants should also indicate the anticipated cost schedule per month for the entire project period.

F. Products—Applicants must concisely describe the interim and final products of each stage of the program.

G. Program Budget—Budgets must be accompanied by a detailed justification for all costs, including the basis for computation of these costs. Applications containing contract(s) must include detailed budgets for each organization's expenses.

H. Evaluation—Each funded project will be required to submit formal findings from an assessment or evaluation, within 60 days of the completion of each year's activities and within 90 days of project completion. Each application must provide a plan for assessing or evaluating the project.

V. Procedures and Criteria for Selection

All applications will be evaluated and rated based on the extent to which they meet the following weighted criteria. In general, all applications received will be reviewed in terms of their responsiveness to the minimum program application requirements set forth in section IV. Applications will be evaluated by a peer review panel according to the OVC Competition and Peer Review Guidance. The selection criteria and their point values (weights) are as follows:

A. The problem to be addressed by the project is clearly stated. This criterion includes a concise, well-justified statement of the problem. (5 points)

B. The goals and objectives of the proposed project are clearly defined. This criterion includes a succinct statement of the goals and objectives of the project as well as an understanding of project requirements and definitions of key terms. (10 points)

C. The project design is sound and contains program elements directly linked to the achievement of project objectives. This criterion includes appropriateness and technical adequacy of the approach to the activities and products of each stage of the program for meeting the goals and objectives. (25 points)

D. The project management structure is adequate to the successful conduct of the project. (Total 25 points) This criterion includes:

1. Adequacy and appropriateness of the project management structure and the feasibility of the time-task plan. (10 points)

2. The qualifications of staff identified to manage and implement the program, including staff to be hired through contracts (if any). This criterion includes the clarity and appropriateness of position descriptions, required qualifications and selection criteria relative to the specific functions set out in the Implementation Plan. (15 points)

E. Organizational capability is demonstrated at a level sufficient to successfully support the project. This criterion includes the extent and quality of organizational experience in the development, delivery and coordination of programs of similar nature. (25 points)

F. Budgeted costs are reasonable, allowable, and cost-effective for the activities to be undertaken. This criterion includes completeness and appropriateness of the proposed costs in relation to the proposed strategy and tasks to be accomplished. (10 points)

Applications will be evaluated by a peer review panel. The results of the peer review will be a relative aggregate ranking of applications in the form of "Summary of Ratings." These will ordinarily be based on numerical values assigned by individual peer reviewers. Peer review recommendations, in conjunction with the results of internal review and any necessary supplementary reviews, will assist OVC in considering competing applications and in selection of the application for funding. The final award decision will be made by the OVC Director.

VI. Submission Requirements

All applicants responding to this solicitation are subject to the following requirements:

1. Upon request to OVC, the necessary forms for application will be provided, along with Department of Justice certification information.

2. Applicants must submit the original signed application (Standard Form 424) and three copies to OVC, including the certification that the organization has not been debarred (Form 4061/2). Additionally, applicants must also provide with the application a Certification Regarding Drug-Free Workplace Requirements which meets the requirements of the Drug-Free Workplace Act of 1988 (Public Law 100–690, title V, subtitle D). Form 4061/3, which will be supplied with the application information package; and a Certification Regarding Lobbying and, if appropriate a completed Disclosure of Lobbying Activities form (SF LLL) in accordance with 31 U.S.C. 1352 which will also be supplied with the application information package.

3. All applications must be received by mail or hand delivered to OVC by 5 p.m. EST on the assigned deadline. Those applications sent by mail should be addressed to: OVC, U.S. Department of Justice, 633 Indiana Avenue, NW., Washington, DC 20531. Hand delivered applications must be taken to OVC, 633 Indiana Avenue, NW, Washington, DC between the hours of 8 a.m. and 5 p.m. except Saturdays, Sundays or Federal holidays.

OVC will notify applicants in writing of the receipt of their application. Subsequently, applicants will be notified by letter as to the decision made regarding whether or not their submission will be recommended for funding. Applications will be reviewed as Peer Review Panels can be convened. Every effort will be made to review applications in a timely manner.

VII. Civil Rights Compliance

A. All recipients of OVC assistance including any contractors, must comply with the non-discrimination requirements of the Victims of Crime Act of 1984, as amended; title VI of the Civil Rights Act of 1964; Section 504 of the Rehabilitation Act of 1973, as amended; title IX of the Education Amendments of 1972; the Age Discrimination Act of 1975; and the Department of Justice Non-Discrimination Regulations (28 CFR part 42, subparts C, D, E, and G).

B. In the event a Federal or State court or Federal or State administrative agency makes a finding of discrimination after a due process hearing on the grounds of race, color, religion, national origin or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office for Civil Rights (OCR) of the Office of Justice Programs.

Jane Nady Burnley,

Director, Office for Victims of Crime.

T. March Bell,

Acting General Counsel, Office of General Counsel.

[FR Doc. 90–11676 Filed 5–18–90; 8:45 am]

BILLING CODE 4410–18–M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

[Application No. D–8176 et al.]

Proposed Exemptions; Dyncorp Pension Trust, et al.

AGENCY: Pension and Welfare Benefits Administration, Labor.

ACTION: Notice of Proposed Exemptions.

SUMMARY: This document contains notices of pendency before the Department of Labor (the Department) of proposed exemptions from certain of the prohibited transaction restriction of the Employee Retirement Income Security Act of 1974 (the Act) and/or the Internal Revenue Code of 1986 (the Code).

Written Comments and Hearing Requests

All interested persons are invited to submit written comments or request for a hearing on the pending exemptions, unless otherwise stated in the Notice of Pendency, within 45 days from the date of publication of this **Federal Register** Notice. Comments and request for a hearing should state the reasons for the writer's interest in pending exemption.

ADDRESSES: All written comments and request for a hearing (at least three copies) should be sent to the Pension and Welfare Benefits Administration, Office of Exemption Determinations, room N–5671, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. *Attention:* Application No. stated in each Notice of Pendency. The applications for exemption and the comments received will be available for public inspection in the Public Documents room of Pension and Welfare Benefits Administration, U.S. Department of Labor, room N–5507, 200 Constitution Avenue, NW., Washington, DC 20210.

Notice to Interested Persons

Notice of the proposed exemptions will be provided to all interested persons in the manner agreed upon by the applicant and the Department within 15 days of the date of publication in the **Federal Register**. Such notice shall include a copy of the notice of pendency of the exemption as published in the **Federal Register** and shall inform interested persons of their right to comment and to request a hearing (where appropriate).

SUPPLEMENTARY INFORMATION: The proposed exemptions were requested in applications filed pursuant to section 408(a) of the Act and/or section 4975(c)(2) of the Code, and in accordance with procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). Effective December 31, 1978, section 102 of Reorganization Plan No. 4 of 1978 (43 FR 47713, October 17, 1978) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Therefore, these notices of pendency are issued solely by the Department.

The applications contain representations with regard to the proposed exemptions which are summarized below. Interested persons are referred to the applications on file with the Department for a complete statement of the facts and representations.

Dyncorp Pension Trust (the Trust) Located in Reston, Virginia

[Exemption Application No. D–8176]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of section 406(a), 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed cash sale by the Trust of a parcel of improved real property located in Fort Worth, Texas (the Property) to Dyncorp (the Employer), a party in interest with respect to the Trust; provided that the price paid is the greater of $765,000 or the fair market value of the Property on the date of such sale.

Summary of Facts and Representations

1. The Employer is a Delaware private corporation, previously known as Dynalectron Corporation, engaged in the provision of technical services for government and aviation. The Employer sponsors a defined benefit pension plan designated as the Pension Plan for Employees of Dyncorp and Associated Companies (the Plan), the assets of which are the corpus of the Trust. The trustee of the Trust are T. Eugene Blanchard, Richard A. Hutchinson and John Schelling (the Trustees), each of whom is an employee and officer of the Employer.

The Plan was terminated in November, 1988. The Trustees have applied to the Internal Revenue Service for a favorable determination with respect to the Plan termination. At the time of the Plan termination there were 6,213 participants in the Plan.

2. The Tristees represent that full and complete distributions of all benefits and interests in the Plan have been made to all Plan participants except those who appear to have been overlooked because of administrative error and those who are entitled to a share of excess Plan funding in accordance with regulations under the Act. In order to enable final distribution of Plan assets, the Trustees desire to complete the process of Plan asset liquidation which has been ongoing since the Plan termination. The sole remaining assets in the Plan are the Property and a limited partnership interest, each of which the Trustees represent to have sought actively to sell. Because the Employer has offered to purchase the Property at a price higher than any offer resulting from the Trustees' efforts to sell the Property to an unrelated party, the Trustees propose to sell the Property to the Employer. The Trustees are requesting an exemption to permit the Employer's purchase of the Property from the Plan under the terms and conditions described herein.

3. The Property consists of a three-story commercial office building situated on a 48,750 square-foot parcel of land located at 6801 Calmont Street in Fort Worth, Texas. The Trust acquired the Property on behalf of the Plan in 1973 for a purchase price of $500,000 and has leased it continuously since acquisition to the Employer. The Trustees represent that the Employer's lease of the Property from the Plan (the Lease) is exempt from the prohibitions of section 406 of the Act by virtue of an individual administrative exemption, Prohibited Transaction Exemption 84–181 (PTE 84–181, 49 FR 49736, December 21, 1984), which was issued by the Department. The Plan's interests under the Lease are represented by an independent fiduciary, TeamBank of Fort Worth, Texas (the Bank), formerly known as the Texas American Bank. The Bank represents that the Employer has complied with all terms and conditions of PTE 84–181 and the Lease for its duration. As of February 5, 1990, the Property had a fair market value of $760,000, according to Kenneth L. Huffman, MAI (Huffman), a professional real estate appraiser in Fort Worth, Texas. Huffman states in his appraisal that the Property's current fair market value represents a decline from its fair market value of $900,000 in 1983 due to a severe excess in commercial office construction in the area of the Property from 1983 through 1986. Huffman also represents that his appraisal has taken into consideration any special value which the Property may have to the Employer as a purchaser which it may not have to an unrelated third party purchaser.

The Trustees represent that soon after the Plan termination they commenced efforts to sell the Property by listing the Property under an exclusive arrangement with a professional real estate broker. The three purchase offers which the Trustees received from unrelated parties during this exclusive listing were not acceptable to the Trustees and the exclusive listing expired. Thereafter, the Trustees continued negotiations with unrelated parties in efforts to sell the Property at an acceptable price but no acceptable purchase offer was obtained by the Trustees.

4. In consideration of the Trustees' unsuccessful sale efforts, their desire to obtain a price of no less than the Property's fair market value and the Property's utility to the Employer, the Employer made a purchase offer which the Trustees have determined to be acceptable. The Employer proposes to purchase the Property from the Trust for cash in the amount of no less than $765,000, with no brokerage fees or commissions to be paid. The Employer will bear any and all costs and expenses related to the transaction.

5. The Bank states that it approves of the Plan's proposed sale of the Property to the Employer pursuant to the Employer's offer. The Trustees represent that the proposed transaction will enable the continuing liquidation of the Trust's assets by facilitating a sale of the Property, without cost to the Plan, at a price which is at least the Property's fair market value and which is greater than that offered by any potential purchasers during the Trustees' efforts to sell the Property to unrelated parties.

6. In summary, the applicants represent that the criteria of section 408(a) of the Act are satisfied in the proposed transaction for the following reasons: (1) The Plan will receive cash for the Property in the amount of no less than the Property's fair market value to the Employer and in no event less than $765,000; (2) The transaction will enable the continuing liquidation of the assets of the Plan, which is terminated, in order to facilitate complete asset distribution; and (3) The proposed transaction accomplishes a sale of the Property on terms which are more favorable to the Plan than any offers made in response to the Trustees' efforts to sell the Property to an unrelated party.

FOR FURTHER INFORMATION CONTACT: Ronald Willett of the Department, telephone (202) 523–8881. (This is not a toll-free number.)

BancTEXAS Group Inc. and Subsidiaries Employees Retirement Plan (the Plan) Located in Dallas, Texas

[Exemption Application No. D–8222]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in

accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to: (1) The sale on October 26, 1989 by the Plan of a certain parcel of improved real property (the Property) to BancTEXAS Group, Inc. (the Holding Company), a party in interest with respect to the Plan, provided that the sale price was not less than the fair market value of the Property on the date of the sale; and (2) the payment to the Plan by BancTEXAS Dallas, N.A. (the Bank), a party in interest with respect to the Plan, of $295,553 pursuant to a guaranty agreement between the Bank and the Plan, provided that the terms of the transaction were at least as favorable to the Plan as a similar transaction between unrelated parties.

EFFECTIVE DATE: If the proposed exemption is granted, the exemption will be effective October 26, 1989.

Summary of Facts and Representations

1. The Plan is a defined benefit plan established to provide retirement, disability and death benefits for qualified employees of the Holding Company and its subsidiaries. As of January 1, 1989, there were approximately 533 participants in the Plan and total assets of approximately $7,001,516. The Bank is the trustee of the Plan (the Trustee) and an employer of employees covered by the Plan.

The Plan is administered by a four-person committee (the Committee) appointed by the Board of Directors of the Holding Company. The Committee is the decision-maker for Plan investments. The members of the Committee are Daniel S. Pigott, Marvin J. Jaynes, Robert B. Kidder, and Dan E. Wright, all of whom are officers of the Holding Company.

2. The Property is a 70,718 square foot parcel of real property (the Land) and improvements located at 2150 Lone Star Drive in Dallas, Texas. The improvements consist of a 14,520 square foot, one-story office/warehouse building (the Building).

The Plan acquired the Property on June 11, 1982 from the Bank, which at the time was named the National Bank of Commerce of Dallas, Texas. Immediately following the Plan's purchase of the Property, the Plan leased the Property back to the Bank under a commercial lease agreement (the Lease) which allowed the Bank to use the Building as a storage facility. Both the purchase of the Property by the Plan and the Lease were exempted from the prohibited transaction provisions of the Act by Prohibited Transaction Exemption (PTE) 82–88, which was published in the Federal Register on May 21, 1982.[1]

3. The applicant states that the amount the Plan paid for the Property (i.e. $598,553.26) represents the total cost to the Bank for the acquisition of the Land and the construction of the Building. The Property was appraised on May 14, 1982 by Kathleen W. Price, M.A.I., a qualified, independent appraiser in Dallas, Texas, as having a fair market value of $600,000. Therefore, the applicant represents that the price paid for the Property by the Plan was slightly less than the fair market value of the Property at the time of the transaction. In addition, the Plan did not pay any commissions or other expenses in connection with the transaction. The applicant states further that only approximately 15.8% of the Plan's assets were invested in the Property at the time of the transactions, based on the fair market value of the Property.

The Lease was a triple net lease with an initial term of ten years and a option to renew for another ten years. The monthly rentals under the Lease were based on the fair market rental value of the Property as established by an independent, qualified appraiser. The monthly rentals were subject to a mandatory adjustment every five years, based on the current fair market value of the Property. However, the Lease required that the rental adjustments were subject to a minimum rate of $6,000 per month, which was the initial monthly rate. The Lease also required a security deposit of $36,000, which equalled six months rent under the initial rental rate.

4. The Bank appointed Mr. Lovell M. Turner, a real estate broker in Dallas, Texas, as an ancillary trustee (the Ancillary Trustee) to act as an independent fiduciary for the Property on behalf of the Plan. The Ancillary Trustee had full authority over the acquisition, ownership, management, and disposition of the Property. The Ancillary Trustee examined the terms of the purchase of the Property, the most current appraisal of the Property, and the terms of the Lease, prior to the Plan entering into the transactions. The Ancillary Trustee determined that the transactions were protective and in the best interests of the Plan. The Ancillary Trustee also determined that the terms of the transactions were at least as favorable to the Plan as the terms the Plan could have obtained in similar transactions involving an unrelated party. In addition, the Ancillary Trustee monitored the Lease to safeguard the interests of the Plan. The Ancillary Trustee represents that all specified rents under the Lease were received by the Plan and that the rental rate was reviewed after five years to assure that it reflected the fair market rental value of the Property. The Ancillary Trustee represents that all other provisions of the Lease were adhered to by the parties.

5. In accordance with the representations made by the applicant in PTE 82–88, a guaranty agreement (the Guaranty Agreement) was executed between the Bank and the Ancillary Trustee on June 11, 1982. The Guaranty Agreement provided that if, within thirty-five years of the date of the sale of the Property to the Plan, the Property were sold, exchanged or otherwise disposed of at a loss, the Bank would reimburse the Plan for the loss. Under the Guaranty Agreement, a "loss" was defined to mean anything less than $598,553.26, the amount the Plan paid the Bank for the Property (the Guaranteed Amount).

6. The applicant states that the Property depreciated significantly in value between June 1982 and October 1989. In addition, the Bank was having financial difficulties in 1989 and the Committee was concerned about the Bank's ability to honor the Guaranty Agreement in the future. In this regard, the Holding Company offered to purchase the Property in October, 1989, for cash at a price established by an independent, qualified appraiser. The Committee recommended that the Plan sell the Property to the Holding Company and the Ancillary Trustee reviewed the terms of the transaction and the Guaranty Agreement and concluded that the transaction would be in the best interests of the Plan and its participants and beneficiaries.

7. The Property was appraised by Thomas J. Morey, M.A.I. (Mr. Morey), an independent real estate appraiser and consultant in Dallas, Taxas, as having a fair market value of $303,000, as of October 26, 1989, and the Plan sold the Property to the Holding Company on this date for $303,000. The Plan did not pay any commissions or other expenses with respect to the sale. Pursuant to the Guaranty Agreement, the Bank paid an additional $295,553 to the Plan at closing, an amount which equalled the difference between the purchase price paid by the Holding Company and the

[1] See 47 FR 22242 (1982).

Guaranteed Amount. The applicant states that the Plan did not incur any expenses with respect to the holding of the Property because all such expenses were paid by the Bank. Therefore, the applicant states that the sale of the Property to the Holding Company and the payment of the additional $295,553 to the Plan by the Bank made the Plan financially "whole" with respect to its investment in the Property.

8. The applicant states that on January 26, 1990, the Bank was declared insolvent and the Federal Deposit Insurance Corporation (FDIC) was appointed receiver of the Bank. Pursuant to a purchase and assumption agreement dated January 26, 1990, the FDIC as receiver sold and assigned to Hibernia National Bank in Texas (Hibernia) all the right, title, and interest of the receiver in all assets belonging to the Bank. Hibernia assumed some, but not all, of the debts of the Bank. The Bank still exists as a legal entity under FDIC receivership. The applicant states that no attempt has been made by the FDIC to rescind the transaction under which the Bank paid its obligation under the Guaranty Agreement. In addition, the Holding Company is solvent and the sale of the Property by the Plan to the Holding Company was based on the Property's fair market value, as appraised by an independent appraiser.[2] The applicant states that the satisfaction of the Guaranteed Amount by the Bank prior to insolvency was in the best interest of the Plan and its participants and beneficiaries.

9. In summary, the applicant represents that the transaction met the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because: (a) The sale was a one-time transaction for cash; (b) the Plan received an amount which made the Plan "whole" and which was considerably greater than the fair market value of the Property, as established by an independent, qualified appraiser, pursuant to the Guaranty Agreement which required the Bank to reimburse the Plan for any loss on its investment in the Property; (c) the Plan did not pay any commissions or other expenses in connection with the transaction; and (d) the Ancillary Trustee and the Committee determined that a sale of the Property to the Holding Company would be in the best interests of the Plan and its participants and beneficiaries.

Tax Consequences of Transaction

The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or affiliate thereof) results in the plan either paying less than or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer to the plan and therefore must be examined under applicable provisions of the Code, including sections 401(a)(4), 404 and 415.

For Further Information Contact: Mr. E.F. Williams of the Department, telephone (202) 523-8883. (This is not a toll-free number.)

Huselton & Morgan Self-Employed Retirement Plan (the Plan) Located in Richardson, Texas

[Application No. D-8259]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975). If the exemption is granted the restrictions of sections 406(a) and 406 (b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to (1) The proposed loan (the Loan) of $35,000 for a term of 5 years by the self-directed account within the Plan of Gary D. Huselton (Mr. Huselton) to Mr. Huselton, a party in interest with respect to the Plan; and (2) Mr. Huselton's personal guarantee with respect to the Loan; provided the terms of the Loan are at least as favorable as the Plan could obtain in an arm's-length transaction with an unrelated party.

Summary of Facts and Representations

1. Huselton & Morgan (the Partnership) is a general partnership engaged in supplying services as certified public accountants. Mr. Huselton is an approximate 40 percent owner of the Partnership and co-trustee of the Plan. The Plan is a profit-sharing Keogh plan with elective salary deferral provisions under section 401(k) of the Code. The Plan has approximately 15 participants with individually directed accounts. The funds of such accounts are kept separate and maintained separately for each participant. As of October 31, 1989, Mr. Huselton's separate self-directed account had assets of approximately $149,000.

2. The Plan proposes to make a loan of $35,000 to Mr. Huselton from his account. The Loan will account for less than 25 percent of the assets in Mr. Huselton's account in the Plan.

The Loan will be amortized over a period of 5 years and will provide for equal monthly payments of principal and interest. The interest rate on the Loan will be a fixed rate of 12 percent per annum. The Plan obtained a letter dated January 24, 1990, from Cornerstone Bank (the Bank), an unrelated commercial lender located in Dallas, Texas. The letter stated that the Bank would consider a loan based on the terms the same as those described in the application commercially feasible in the current market.

The Loan will provide that the Plan will receive a perfected first security interest in Mr. Huselton's 40 percent interest in the Partnership's accounts receivable (the Accounts Receivable). In addition, Mr. Huselton will personally guarantee the repayment of the Loan to the Plan.

3. The applicant obtained an appraisal on the Accounts Receivable from Hoover, Violett & Associates (Hoover, Violett), an independent Certified Public Accounting firm located in Dallas, Texas. Using generally accepted auditing standards, Hoover, Violett estimated the average fair market value of the Accounts Receivable during the 12 month period ending December 31, 1989, to be $475,721. Mr. Huselton's approximate 40 percent share of this value is in excess of 200 percent of the amount of the proposed loan.

4. In summary, the applicant represents that the proposed transaction will satisfy the statutory criteria of section 408(a) of the Act because: (1) The Loan involves less than 25 percent of the assets of Mr. Huselton's account; (2) the interest rate was negotiated at arm's-length and represents a prevailing rate, as verified by an unrelated commercial lender; and (3) the Loan will be secured by property with a fair market value, as determined by a qualified independent appraiser, in excess of 200 percent of the amount of the Loan.

Notice to Interested Persons: Since the only Plan assets involved in the proposed transaction are those in Mr. Huselton's account under the Plan and he is the only participant affected by the proposed transaction, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and hearing requests on the

[2] The Department is not providing any exemptive relief in this proposed exemption for transactions which may result from a possible rescission of the subject transactions by either the FDIC, as receiver of the Bank, or a court-appointed trustee in bankruptcy, as a receiver of the Holding Company, in the event the Holding Company is declared insolvent.

proposed exemption are due 30 days after the date of publication of this notice in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Ms. Kay Madsen of the Department, telephone (202) 523–8194. (This is not a toll-free number).

Potts and Callahan, Inc. Profit Sharing Plan (the Plan) Located in Baltimore, Maryland

[Application No. D–8276]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code shall not apply to: (1) The proposed sale by the Plan of certain improved real property (the Property) to Potts and Callahan, Inc. (the Employer), a party in interest with respect to the Plan; and (2) the proposed extension of credit by the Plan to the Employer in connection with the sale of such Property, provided the terms of the transactions are at least as favorable to the Plan as those obtainable in arm's length transactions with an unrelated party.

Summary of Facts and Representations

1. The Plan is a profit sharing plan with total assets having a fair market value of $3,329,273 as of December 31, 1989. As of April 17, 1990, the Plan had 56 participants. The trustees of the Plan (the Trustees) are Messrs. Charles M. Holub and Ronald D. Bender. The Plan is administered by a seven member committee (the Committee) of employee participants that includes the Trustees. Investment decisions for the Plan are made by the Committee. The Employer, which maintains its business premises at 500 West 29th Street, Baltimore, Maryland, is engaged in excavation, paving, demolition, grading and heavy equipment rental.

2. On October 12, 1988, the Plan executed a contract of sale (the Contract) with an unrelated party, the Mobil Oil Corporation (Mobil) of Fairfax, Virginia, for the purchase of Mobil's right, title and interest in certain real property and improvements located at 5101 Pulaski Highway, Baltimore, Maryland. The Property consists of .839 acres of land on which is situated a vacant, former Mobil gas station containing approximately 1,591 square feet. The Property is contiguous to other real property owned by the Employer and on which the Employer conducts a large portion of its operations. Pursuant to the Contract, on December 30, 1988, the Plan purchased the Property from Mobil for cash for a discounted value of $224,371. At the time of the acquisition, the Property had a fair market value of $250,000. At present, the Property is not encumbered by a mortgage. In addition, since the acquisition by the Plan, the Property has never been used by or leased to anyone, including parties in interest. Besides paying the acquisition price, the Plan has not incurred any other expenses in connection with its ownership of the Property.[3]

3. The Property was appraised by Messrs. Karl R. Rubach, Associate, and Daniel V. Urquhart, M.A.I., S.R.P.A. (Messrs. Rubach and Urquhart), independent appraisers affiliated with Donald V. Urquhart and Associates, Limited of Kensington, Maryland. In an appraisal report dated February 15, 1989, Messrs. Rubach and Urquhart placed the fair market value of the Property at $250,000 as of February 8, 1989. In an updated appraisal report of October 24, 1989, Messrs. Rubach and Urquhart determined that the Property had a fair market value of $292,000 as of October 13, 1989. Messrs. Rubach and Urquhart also concluded that the Property would have no special or unique value to the Employer by reason of its proximity to other real property owned by the Employer.

4. To facilitate the repair and refueling of its vehicles, the Employer proposes to purchase the Property from the Plan for an amount in excess of the fair market value of the Property. The proposed sales price for the Property will be $301,500. The Employer will execute a promissory note (the Note) with the Plan in the amount of $301,500. The Note will carry a floating interest rate that is equal to the prime rate of interest as published in the "Money Rates" section of The Wall Street Journal plus 1.25 percent. The Note will require the Employer to pay a loan origination fee of ½ point as well as monthly principal installments of $5,025 and interest over a five year period. The interest rate will be adjusted every 30 days by Mr. Francis T. Burch, Jr. (Mr. Burch), who will serve as the independent fiduciary for the Plan with respect to the proposed transaction. Installments under the Note may be prepaid in whole or in part by the Employer at any time. In addition, the Plan will not be required to pay any real estate fees or commissions that are associated with the proposed sale of the Property or loan servicing fees that may be charged in connection with the administration of the Note.[4]

As further security for the Note, an unrelated party, the Bank of Baltimore (the Bank) of 120 East Baltimore Street, Baltimore, Maryland, issued an irrevocable letter of credit (the Letter of Credit) to the Employer on March 28, 1990. The Letter of Credit is for a one year duration and is in the amount of $200,000. The Letter of Credit will be renewed annually by the Employer over the term of the Note. It will cover accrued interest on the Note and any interest which may accrue during any one year period it is in effect. In the event that the Bank gives Mr. Burch written notice at least 30 days prior to any renewal date that it will not re-extend the Letter of Credit, Mr. Burch will call the loan and draw upon the Letter of Credit before it lapses. In addition, in the event the Note remains unpaid by the Employer for 30 days, Mr. Burch will present the Letter of Credit to the Bank for payment. Payment will be made by the Bank within 24 hours of presentment.

At all times, throughout the duration of the Note, the value of the Property and the Letter of Credit will represent at least 150 percent of the outstanding balance of the Note. If the collateral to loan ratio should ever fall below the 150 percent level, Mr. Burch will require that the Employer pledge additional collateral.

6. The Employer has discussed with the Bank potential financing arrangements the Bank would extend to the Employer in connection with the purchase of the Property. By letter dated March 26, 1990, the Bank indicated that it would make a comparable loan to the Employer on the same terms and conditions, including the interest rate and loan origination fee, as those described in the Note.

[3] The applicant does, however, represent that the Committee, whose members are employees to the Employer, undertook the tasks of cleaning-up and repainting the Property on its own initiative and at no cost to the Plan. Although the applicant believes that the provision of such services to the Plan on the part of the Committee is covered by the statutory exemptive relief that is available under section 408(b)(2) of the Act, the Department expresses no opinion herein on whether the provisions of section 408(b)(2) of the Act have been satisfied. Similarly, in this proposed exemption, the Department expresses no opinion on whether the acquisition and holding of the Property by the Plan has violated any of the provisions of Part 4 of Title I of the Act.

[4] The applicant represents that the amount by which the sales price for the Property exceeds its fair market value, if treated as an Employer contribution to the Plan, when added to the balance of the annual additions to such Plan, will not exceed the limitation prescribed by section 415 of the Code.

7. As stated above, Mr. Burch will serve on behalf of the Plan as the independent fiduciary for the proposed installment sale. Mr. Burch is a Certified Public Accountant who has been licensed in the State of Maryland since 1967. He is a principal in the firm of Burch and Company, Certified Public Accountants of Towson, Maryland. Approximately 25 percent of Mr. Burch's practice relates to the provision of auditing services to multiemployer pension, annuity, health, vacation and apprenticeship training plans for various trades and construction-related entities. Mr. Burch is completely unrelated to the Plan and the Employer and he explains that he does not provide services to either organization. Mr. Burch represents that he has discussed at length the proposed transaction with legal counsel to the Plan who is familiar with the provisions of the Act. On the basis of these discussions, Mr. Burch asserts that he understands and accepts the duties, responsibilities and liabilities that will be placed upon him as the independent fiduciary.

Mr. Burch believes the proposed transaction is in the best interest of the Plan and its participants and beneficiaries. Mr. Burch states that his review of various documents which have been provided to him indicates that the proposed transaction conforms to that which would be encountered in a similar transaction between unrelated parties dealing at arm's length. He asserts that the addition of the Letter of Credit further secures the interest of the Plan and that the interest rate and terms of the Note are comparable to what would be encountered in the market place and represent fair market value terms.

With respect to the impact of the proposed installment sale on the overall investment portfolio of the Plan, Mr. Burch observes that the Plan will realize a profit of over $75,000 and that the rate of interest specified in the Note will exceed the return on other Plan investments for a similar period of time. Additionally, Mr. Burch asserts that the substitution of the Note for the Property in the Plan's investment portfolio will not significantly alter the Plan's investment mix. Further, Mr. Burch represents that the substitution of the Note for the Property will not impair the liquidity requirements of the Plan.

As the independent fiduciary, Mr. Burch states that, in addition to the duties noted above, he will review all documents relating to the sale and inform the appropriate parties of any exceptions. During the term of the Note, Mr. Burch represents that he will ensure that all installments are being made in accordance with the conditions of the Note, verify that the collateral to loan ratio will at all times represent 150 percent of the outstanding balance of the Note, and take all actions that are necessary and proper to enforce the rights of the Plan and protect the participants and beneficiaries of the Plan.

8. In summary, it is represented that the proposed transaction will satisfy the statutory criteria for an exemption under section 408(a) of the Act because: (a) Mr. Burch, who will monitor the terms and conditions of the installment sale on behalf of the Plan, approves of the transaction and believes that the invesment is an appropriate one for the Plan and is in the best interests of the Plan's participants and beneficiaries; (b) the Property has been appraised by Messrs. Urquhart and Rubach who are qualified, independent appraisers; (c) the Employer's obligation to the Plan under the terms of the Note represent less than 25 percent of the assets of the Plan; (d) the Note will be secured by a first deed of trust on the Property and by an irrevocable Letter of Credit; (e) the value of the Property and Letter of Credit will, at all times, represent at least 150 percent of the outstanding balance of the Note; (f) additional collateral for the Note will be pledged by the Employer if the fair market value of the Property falls below 150 percent of the outstanding loan balance; (g) the terms of the Note are based upon terms that are the same as those required by the Bank; and (h) the Plan will not be required to pay any real estate fees or commissions in connection with the proposed sale of the Property or loan servicing fees in connection with the administration of the Note.

Tax Consequences of Transaction

The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or affiliate thereof) results in the plan either paying less than or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer to the plan and therefore must be examined under applicable provisions of the Code, including sections 401(a)(4), 404 and 415.

FOR FURTHER INFORMATION CONTACT: Ms. Jan D. Broady of the Department, telephone (202) 523–8881. (This is not a toll-free number.)

Pathology Associates, Ltd. Restated Money Purchase Pension Plan (the Plan) Located in Phoenix, Arizona

[Application No. D–8286]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale of a certain parcel of unimproved real property (the Property) by the individually directed account (the Account) of William D. Anderson, M.D. (Dr. Anderson) in the Plan to Dr. Anderson, provided that the sales price is the greater of either (1) The original purchase price paid by the Account for the Property, plus all additional expenses incurred by the Account in holding the Property, or (2) the fair market value of the Property on the date of sale.

Summary of Facts and Representations

1. The Plan is a defined contribution plan with approximately 11 participants. As of June 30, 1988, the Plan had total assets of $5,869,159. The Plan is sponsored by Pathology Associates, Ltd. (the Employer), an Arizona professional corporation located at 555 W. Catalina Drive, Phoenix, Arizona. The trustees of the Plan (the Trustees) are Richard W. Trepeta, M.D., Peter C. Johnson, M.D., Melvyn C. Rothman, M.D., E. Smith Collum, M.D., Robert A. Brooks, M.D., Ned A. Kuivinen, M.D., Roy I. Davis, M.D., Charles E. Evans, M.D. and Dr. Anderson. The Trustees are all affiliated with the Employer. The Plan allows participants to direct investments for their own indivdual accounts. As of June 30, 1988, the Account had assets of approximately $80,000.

2. The Property is a 53.33 acre parcel of unimproved real property located in Corwin Township, Ida County, Iowa. The Property was acquired as an investment for the Account on June 30, 1988. The Account purchased the Property from Mr. Clifford Wissink, an unrelated party, for $25,332. The Property had been used previously for farming. The applicant states that the Property has not been cultivated since the Account acquired the Property and is part of a conservation reserve

program administered by the U.S. Department of Agriculture.

The Property is adjacent to another parcel of unimproved real property (the Adjacent Property) owned by Dr. Anderson's wife, Jeanne Marie Anderson (Ms. Anderson). However, the applicant states that the Property has not been leased to, or used by, a party in interest with respect to the Plan.

3. The applicant represents that the Property has declined in value and cannot be sold by the Account on the open market without incurring a loss. Dr. Anderson proposes to purchase the Property from the Account for cash. Dr. Anderson states that the sale price will be the greater of either the Account's original purchase price, plus all additional expenses incurred by the Account in holding the Property, or the fair market value of the Property, as established by an independent, qualified appraiser, on the date of sale.

4. The Property was appraised on February 27, 1990 by James J. McGuire (Mr. McGuire) of the McGuire Auction Company, Inc., an independent, qualified appraiser in Holstein, Iowa, as having a fair market value of $22,665. Mr. McGuire is a member of the American Society of Farm Managers and Rural Appraisers and a member of the National Association of Real Estate Appraisers.

Mr. McGuire states that consideration has been given in the appraisal to the possible special value of the Property to Dr. Anderson as a result of the ownership of the Adjacent Property by Ms. Anderson. However, Mr. McGuire states that the Property would have not additional value if the Property and the Adjacent Property were combined under a common ownership. Therefore, Mr. McGuire does not believe that any adjustment to the Property's fair market value, as a result of the ownership of the Adjacent Property by Ms. Anderson, is necessary.

5. The applicant states that the proposed transaction is in the best interests of the Account. The sale of the Property to Dr. Anderson for cash will allow the Account to divest itself of the Property and reinvest the proceeds in other investments which yield greater returns. Since the sale price will be the greater of either the Account's total expenditures in the acquisition and holding of the Properety or the fair market value of the Property on the date of dale, the proposed transaction will guarantee that the Account is at least made "whole" with respect to its investment in the Property. The applicant states that the Account will not pay any sales commission or other expenses in connection with the transaction. Finally, the applicant states that the appraisal of the Property will be updated as of the date of sale.

6. In summary, the applicant represents that the proposed transaction will satisfy the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because: (a) The sale will be a one-time transaction for cash; (b) the Account will receive the greater of either the fair market value of the Property as determined by an independent, qualified appraiser, or the original purchase price paid by the Account for the Property, plus all additional expenses incurred by the Account in connection with the holding of the Property; (c) the Account will not pay any sales commission or other expenses with respect to the sale; and (d) the sale of the Property will allow the Account to divest itself of the Property and reinvest the proceeds in other investments which yield greater returns.

Notice to Interested Persons: Because Dr. Anderson is the only participant in the Plan to be affected by the proposed transaction, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a public hearing are due 30 days from the date of publication of this proposed exemption in the **Federal Register.**

Tax Consequences of Transaction

The Department of the Treasury has determined that if a transaction between a qualified employee benefit plan and its sponsoring employer (or affiliate thereof) results in the plan either paying less than or receiving more than fair market value, such excess may be considered to be a contribution by the sponsoring employer to the plan, and therefore must be examined under the applicable provisions of the Internal Revenue Code, including sections 401(a)(4), 404 and 415.

FOR FURTHER INFORMATION CONTACT: Mr. E.F. Williams of the Department, telephone (202) 523–8883. (This is not a toll-free number).

Malcolm M. McHenry, M.D., Inc. Defined Benefit Pension Trust (the Plan) Located in Sacramento, California

[Application No. D–8288]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1) (A) through (E) of the Code, shall not apply to the proposed sale by the Plan of thirty-four Indian miniature paintings (the Paintings), fourteen Japanese Netsuke items of wood and ivory (the Netsuke), two diamond rings (the Rings) and one silk gum rug (the Rug; collectively, the Collectibles) to Malcolm M. McHenry, M.D. (Dr. McHenry) and Anna B. McHenry (together, the McHenrys), disqualified persons with respect to the Plan; provided that the price paid is the greater of $167,475 or the fair market value of the Collectibles on the date of sale.

Summary of Facts and Representations

1. The Plan is a defined benefit plan sponsored by Malcolm M. McHenry, M.D., Inc. (the Employer), a California private professional corporation engaged in the practice of medicine in Sacramento, California. The Employer is wholly owned by the McHenrys, who are the sole participants in the Plan.[5] Dr. McHenry also serves as Plan trustee. As of June 30, 1989, the total value of all Plan assets was $972,977.25.

2. The Collectibles were purchased on behalf of the Plan by Dr. McHenry at various times between December 12, 1976 and October 31, 1981. Dr. McHenry represents that the Collectibles were purchased from unrelated parties in arm's-length cash transactions for purchase prices totalling $148,024. Dr. McHenry further represents that the Collectibles were purchased solely for their appreciation values and potential as Plan investments and have not been personally used by or displayed by the McHenrys. The McHenrys represent that the Collectibles have been stored, protected and maintained in the following manners: The Rings and the Natsuke have been stored in safe deposit boxes since their acquisition and are currently stored in a safe deposit box in the Wells Fargo Bank in Sacramento, California. The Paintings have been stored in a special protective cabinet and the Rug has been stored in a special protective wrapping, each at the residence of the McHenrys in Sacramento, California.

3. The McHenrys represent that the Collectibles have not appreciated in value as greatly as expected and that they constitute costly and unproductive

[5] Since the McHenrys are the sole shareholders of the Plan's sponsor and the only participants in the Plan, there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3–3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

Plan assets which the McHenrys choose to replace with more liquid or income-producing assets. The McHenrys are intending to liquidate all assets of the Plan, including the Collectibles, as they proceed to terminate the Plan, distribute the liquidated assets to themselves and roll over the distributed assets into individual retirement accounts (the IRAs) which they intend to establish in their names. It is anticipated that liquidation of the Collectibles in particular is essential to enable a roll over of Plan assets into the IRAs because the custodian of the IRAs would not accept the Collectibles as IRA assets. The McHenrys represent that they are seeking to maximize the preservation of Plan assets in the liquidation of the Collectibles by avoiding, if possible, the payment of sales commissions, advertising costs and other selling expenses which they maintain are generally involved with open market sales of fine art collectibles. For these reasons the McHenrys are proposing to purchase the Collectibles from the Plan under the terms and conditions described herein.

4. The McHenrys propose to pay the Plan cash for the Collectibles in the total amount of their fair market values at the time of the sale as determined by independent appraisers (the Appraisers) who are specially qualified as appraisers of fine art collectibles. The Appraisers are identified as follows: The Appraiser with respect to the Paintings will be Raymond E. Lewis, a professional dealer and appraiser of miniature paintings who is located in Larkspur Landing, California and who represents himself to be independent of and unrelated to the McHenrys. The Appraiser with respect to the Rug will be Mohanned H. Shakoori, American Society of Appraisers Senior Member, located in Sacramento, California who represents that he is not affiliated with or related to the McHenrys. The Appraiser with respect to the Rings will be R. D. Grebitus, a Certified Gemologist-Appraiser located in Sacramento, California who represents that he is unrelated to and independent of the McHenrys. The Appraiser with respect to the Netsuke will be Paul Moss, member of the British Antique Dealers Association and the Oriental art dealing firm of Sidney L. Moss in London, England. Paul Moss represents that he is not affiliated with or related to the McHenrys. According to appraisals conducted by the Appraisers between December 22, 1988 and September 6, 1989, the Collectibles had a collective fair market value totalling $167,475 as of December 19, 1989. The McHenrys represent that the total purchase price to be paid for the Collectibles will be determined by the Appraisers and will be the total fair market value of the Collectibles as of the sale date. In no event will the McHenrys pay a total purchase price of less than $167,475. The McHenrys will pay all costs and expenses related to the proposed sale transaction, including all costs related to determination of fair market values by the Appraisers.

5. In summary, the applicants represent that the proposed transaction satisfies the criteria of section 4975(c)(2) of the Code for the following reasons: (1) The Plan will receive cash for the Collectibles in an amount no less than their total fair market value and in no event less than $167,475, which exceeds the amount paid by the Plan for the Collectibles; (2) The Plan will not pay any costs or expenses related to the transaction, which will enable the avoidance of selling expenses generally related to the liquidation of fine art collectibles on the open market; (3) The transaction will enable the liquidation of collectible assets which the participants would have been unable to roll over to the IRAs upon termination of the Plan; and (4) The transaction will affect only the McHenrys, who desire that the transaction be consummated.

Notice to Interested Persons: Because the McHenrys are the sole shareholders of the Plan sponsor and the only participants in the Plan, the Department has determined that there is no need to distribute the notice of pendency to interest persons. Comments and requests for a hearing must be received by the Department within 30 days of the date of publication of this notice of proposed exemption.

FOR FURTHER INFORMATION CONTACT: Ronald Willett of the Department (202) 523–8881. (This is not a toll-free number.)

L. Henry Lackner, M.D., P.A. Profit Sharing Plan (the Plan) Located in Albuquerque, New Mexico

[Application No. D–8293]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code in accordance with the procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted, the restrictions of section 406(a), 406(b)(1) and (b)(2) of the Act and the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the past sale on January 11, 1989 of a certain automobile by the Plan to L. Henry Lackner, M.D., P.A. (the Employer), the sponsor of the Plan and as such a party in interest with respect to the Plan, provided that the sales price was not less than the fair market value of the automobile on the date of sale.

EFFECTIVE DATE: If the proposed exemption is granted, the exemption will be effective as of January 11, 1989.

Summary of Facts and Representations

1. The Plan is a defined contribution plan which, as of October 31, 1988, had two participants and total assets of approximately $344,647. The trustee of the Plan, and the decision-maker for Plan investments, is L. Henry Lackner, M.D. (Dr. Lackner).

2. The Employer is a New Mexico professional association which is located at 711 Encino Place, NE., Granada Medical Plaza, Albuquerque, New Mexico.

3. The applicant requests an exemption for the sale on January 11, 1989 of a 1964 Mustang Convertible (the Car) by the Plan to the Employer for $12,000 in cash. The Plan had purchased the Car on May 5, 1983 from Mr. Leon Hagelgantz (Mr. Hagelgantz) of Clovis, New Mexico, for a total purchase price of $7,000. Mr. Hagelgantz was unrelated to Dr. Lackner and was not a party in interest with respect to the Plan. The applicant represents that the Plan purchased the Car as a investment and held the Car for appreciation.[6] The Car was registered in the name of Dr. Lackner, as trustee of the Plan. The applicant states that the Car was never leased to a party in interest with respect to the Plan during the Plan's ownership of the Car. In addition, the applicant states that the Car was never used by Dr. Lackner, or any other party in interest with respect to the Plan, for personal purposes. The Plan incurred expenses of approximately $1,978 in connection with its ownership of the Car, including storage and maintenance.

4. The Car was appraised on January 5, 1989, by Paul G. McLaughlin (Mr. McLaughlin) of the Mustang Owners Club, Int., an independent, qualified appraiser in Albuquerque, New Mexico, as having a fair market value of $12,000. Mr. McLaughlin's appraisal took into consideration the year, make and model of the Car, the Car's overall condition, and the added value of the Car's optional equipment and features. Mr.

[6] The Department is expressing no opinion as to whether the acquisition of the Car by the Plan violated any provision of Part 4 of Title I of the Act.

McLaughlin states that he has been involved with Mustang automobiles as a collector, appraiser and Mustang club sponsor for over 25 years.

5. The applicant represents that the transaction was in the best interests of the Plan and its participants and beneficiaries. The sale of the Car to the Employer enabled the Plan to divest itself of a non-income producing asset which was not expected to appreciate significantly in value at the time it was sold. The Plan received an amount in cash which equalled the fair market value of the Car at the time of the transaction, as established by an independent appraisal. The Plan did not pay any commissions or other expenses in connection with the transaction.

6. In summary, the applicant represents that the transaction met the statutory criteria of section 408(a) of the Act and section 4975(c)(2) of the Code because: (a) the sale was a one-time transaction for cash; (b) the Plan received an amount which equalled the fair market value of the Car at the time of the transaction, as established by a qualified, independent appraiser; and (c) the Plan did not pay any commissions or other expenses in connection with the sale.

FOR FURTHER INFORMATION CONTACT: Mr. E.F. Williams of the Department at (202) 523–8883. (This is not a toll-free number).

Ed Cave & Sons, Inc. Profit Sharing Plan (the Plan) Located in Roseville, Minnesota

[Application No. D–8307]

Proposed Exemption

The Department is considering granting an exemption under the authority of section 4975(c)(2) of the Code and in accordance with procedures set forth in ERISA Procedure 75–1 (40 FR 18471, April 28, 1975). If the exemption is granted the sanctions resulting from the application of section 4975 of the Code, by reason of section 4975(c)(1)(A) through (E) of the Code, shall not apply to the proposed sale by the Plan of certain land (the Property) to Ed Cave and Sons, Inc., (the Employer), the Plan sponsor and as such a disqualified person with respect to the Plan, provided the Plan receives the greater of $105,000 or the fair market value of the Property at the time of the sale.[7]

[7] Because Samuel Cave is the only participant in the Plan and the Employer is wholly owned by Samuel Cave, there is no jurisdiction under Title I of the Act pursuant to 29 CFR 2510.3–3(b). However, there is jurisdiction under Title II of the Act pursuant to section 4975 of the Code.

Summary of Facts and Representations

1. The Plan is a profit sharing plan which was established on April 1, 1977. The Plan has only one participant, Samuel Cave (Mr. Cave). As of March 31, 1988, the Plan had $172,514 in total assets. The current trustees of the Plan are Mr. Cave and Mrs. Diane C. Cave who are the president and the secretary of the Employer, respectively. The Employer is a Minnesota corporation which is in the general contracting business.

2. The Property was purchased for investment purposes by the Plan in 1986 for $55,000 in cash from an independent third party. The Property consists of 8.79 acres of undeveloped land. The Property, which is located in Maplewood, Minnesota, has recently received plat approval for 14 residential building sites from the City of Maplewood. The Property is also adjacent to property which has been recently purchased by the Employer. However, the applicant maintains that the Property has not been used by any parties in interest since its acquisition by the Plan.

3. The applicant proposes to sell the Property to the Employer in a one-time cash sale with no expenses related to the transaction to be paid by the Plan. An appraisal of the Property (the Appraisal) was prepared on September 15, 1989, by Dwight Dahlen, MAI, SREA (Mr. Dahlen), an independent, qualified real estate appraiser with Dahlen & Dwyer, Inc. In conducting the Appraisal, Mr. Dahlen relied on the comparable sales appraisal method and determined that as of that date, the fair market value of the Property was $105,000. Accordingly, the price of $105,000 reflects a value of $16,000 per acre for the 6.49 acres of the Property which are buildable and a zero value for the remaining 2.3 acres. Mr. Dahlen stated that the adjacency of the Property to the property which is owned by the Employer does not affect the original valuation of the Property.

4. The applicant represents that the transaction is desirable for the Plan because the sale will increase the liquidity of the Plan's investment portfolio. The transaction is protective of the Plan because the fair market value of the Property has been determined by an independent, qualified appraiser. The applicant represents that it has unsuccessfully attempted to sell the Property for the asking price of $95,000 to independent third parties by placing ads in local newspapers and by contacting builders in Maplewood. The applicant also maintains that economic hardship will be sustained by the Plan if the transaction is denied as the Plan will forego an opportunity to invest in other instruments and to diversify its investment portfolio.

5. In summary, the applicant represents that the transaction satisfies the statutory criteria of section 4975(c)(2) of the Code because:

(a) The proposed sale will be a one-time cash transaction;

(b) The price paid to the Plan will be the greater of $105,000 or the fair market value of the Property at the time of the sale as determined by a qualified, independent appraiser;

(c) The Plan will pay no expenses associated with the transaction;

(d) The sale will allow the Plan to diversity its investment portfolio; and

(e) Mr. Cave as the sole participant of the Plan would be the only individual affected by the transaction.

Notice To Interested Persons

Because Mr. Cave is the sole participant of the Plan, it has been determined that there is no need to distribute the notice of proposed exemption to interested persons. Comments and requests for a hearing are due 30 days from the date of publication of this notice in the Federal Register.

FOR FURTHER INFORMATION CONTACT: Ekaterina A. Uzlyan of the Department, telephone (202) 523–8194. (This is not a toll-free number.)

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under section 408(a) of the Act and/or section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest of disqualified person from certain other provisions of the Act and/or the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act, which among other things require a fiduciary to discharge his duties respecting the plan solely in the interest of the participants and beneficiaries of the plan and in a prudent fashion in accordance with section 404(a)(1)(b) of the act; nor does it affect the requirement of section 401(a) of the Code that the plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries;

(2) Before an exemption may be granted under section 408(a) of the Act and/or section 4975(c)(2) of the Code, the Department must find that the

exemption is administratively feasible, in the interests of the plan and of its participants and beneficiaries and protective of the rights of participants and beneficiaries of the plan; and

(3) The proposed exemptions, if granted, will be supplemental to, and not in derogation of, any other provisions of the Act and/or the Code, including statutory, or

(4) The proposed exemption, if granted, will be subject to the express condition that the material facts and representations contained in each application are true and complete, and that each application accurately describes all material terms of the transaction which is the subject of the exemption.

Signed at Washington, DC, this 16th day of May 1990.

Ivan Strasfeld,

Director of Exemption Determinations, Pension and Welfare Benefits Administration, U.S. Department of Labor.

[FR Doc. 90-11710 Filed 5-18-90; 8:45 am]

BILLING CODE 4510-29-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 90-33]

NASA Wage Committee; Renewal

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of renewal.

SUMMARY: Pursuant to section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), and after consultation with the Committee Management Secretariat, General Services Administration, NASA has determined that the Renewal of the NASA Wage Committee is in the public interest in connection with the performance of duties imposed upon NASA by law.

FOR FURTHER INFORMATION CONTACT: Mr. John N. Remissong, National Aeronautics and Space Administration, Code NPM, Washington, DC 20546 (202/453-2593).

SUPPLEMENTARY INFORMATION: The function of this Committee is to provide recommendations to NASA relating to a survey of wages and the establishment of wage schedules for trades and labor employees in the Cleveland, Ohio, Wage area. NASA has been designated as the "lead agency" for that area under Federal Personnel Manual Supplement 532-1.

Dated: May 15, 1990.

John W. Gaff,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 90-11730 Filed 5-18-90; 8:45 am]

BILLING CODE 7510-01-M

[Notice (90-34)]

NASA Advisory Council (NAC), Space Science and Applications Advisory Committee (SSAAC), Life Sciences Subcommittee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92-463, as amended, the National Aeronautics and Space Administration announces a forthcoming meeting of the NASA Advisory Council, Space Science and Applications Advisory Committee, Life Sciences Subcommittee.

DATES: June 5, 1990, 8:30 a.m. to 5:30 p.m. and June 6, 1990, 8:30 a.m. to 1:15 p.m.

ADDRESSES: National Aeronautics and Space Administration, room 226A, 600 Independence Avenue SW., Washington, DC 20546.

FOR FURTHER INFORMATION CONTACT: Dr. Ronald J. White, Code EB, National Aeronautics and Space Administration, Washington, DC 20546 (202/453-1525).

SUPPLEMENTARY INFORMATION: The Space Science and Applications Advisory Committee consults with and advises the NASA Office of Space Science and Applications (OSSA) on long range plans for, work in progress on, and accomplishments of NASA's Space Science and Applications programs. The Life Sciences Subcommittee provides advice to the Life Sciences Division concerning all of its programs in the space life sciences. The Subcommittee will meet to discuss Life Sciences status and issues, activities of the Office of Space Science and Applications, and receive reports on Life Sciences activities. The Subcommittee is chaired by Dr. Francis J. Haddy and is composed of 22 members. The meeting will be closed on June 6, from 12:15 p.m. to 1:15 p.m. to discuss and evaluate qualifications of candidates being considered for membership on the Subcommittee. Such discussions would invade the privacy of the individuals involved. Since this session will be concerned with matters listed in 5 U.S.C. 552(C)(6), it has been determined that the meeting will be closed to the public for this period of time. The remainder of the meeting will be open to the public up to the capacity of the room (approximately 45 including Subcommittee members). It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the participants.

TYPE OF MEETING: Open—except for a closed session as noted in the agenda below.

Agenda

Tuesday, June 5
- 8:30 a.m.—Introduction and Chairman's remarks.
- 8:45 a.m.—Office of Space Science and Applications Status.
- 9:30 a.m.—Life sciences status.
- 10:45 a.m.—Reports on activities of other advisory committees.
- 11:15 a.m.—Summary of life sciences activities.
- 1:30 p.m.—NASA Activities related to cell biology: Microgravity science and applications and Office of Commercial Programs.
- 5:30 p.m.—Adjourn.

Wednesday, June 6
- 8:30 a.m.—Candidates for NASA Specialized Centers of Research and Training (NSCORT).
- 10 a.m.—NASA/National Institutes of Health (NIH) cooperative activity.
- 11 a.m.—Committee strategy and actions.
- 12:15 p.m.—Closed session.
- 1:15 p.m.—Adjourn.

Dated: May 15, 1990.

John W. Gaff,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 90-11731 Filed 5-18-90; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE (NCLIS)

White House Conference Advisory Committee; Meeting

Date and Time: June 7, 1990, Thursday, 9 a.m. to 8 p.m. June 8, 1990, Friday, 9 a.m. to 4 p.m.

Place: Governor's House Holiday Inn, Rhode Island Avenue at 17th St., NW., Washington, DC 20036, Phone (202) 296-2100.

Subcommittee Meetings in Board rooms 1 and 2; Advisory Committee Meeting in Cabinet Room.

Status: All meetings are open.

Matters To Be Discussed: White House Conference on Library and Information Services Advisory Committee.

Subcommittee meetings:

June 7, 1990

—9:00–9:30 a.m.
—Meeting of Subcommittee Chairs.
—9:30–10:45 a.m.
—Resource Development.
—10:45–Noon
—Fiscal Oversight.
—Public Relations and Awareness.
—Noon–3 p.m.
—National Conference Program Planning.

White House Conference on Library and Information Services Advisory Committee

June 7, 1990, Thursday

3:15–3:30 p.m.
—Introduction of Committee Members, Official Observers and Staff.
—Approval of Agenda
—Approval of Minutes of April 5–6, 1990 Meeting.
—Remarks of WHCAC Acting Chair/ NCLIS Chair.
3:30–3:45 p.m.
—Nominations from the Floor for WHCAC Chair.
—Election of WHCAC Chair.
3:45–4 p.m.
—Remarks of the WHCAC Chair.
4–5 p.m.
—Report on ALA Activities in Support of White House Conference.
5–6 p.m.
—Executive Director's Report.
—Presentation of Budget.
6:30–8 p.m.
—Advisory Committee Members' working dinner and Discussion of State Activities.

June 8, 1990, Friday

9–10:15 a.m.
—Resource Development Subcommittee Report.
—Public Relations and Awareness Subcommittee Report.
—National Conference Program Planning Subcommittee Report.
10:30–Noon
—Discussion of National Conference Program and Format for Issues.
Noon–1:30 p.m.
—Advisory Committee Members' working lunch—Discussion continued.
1:30–3 p.m.
—Continued Discussion of National Conference Program and Format for Issues.
3–3:30 p.m.
—Public Comments.
3:30–4 p.m.
—Old and New Business.
4 p.m.
—Adjourn.

Persons appearing before, or submitting only written statements to the Advisory Committee, are asked to hand over to the Committee prior to presenting testimony, 80 copies of their prepared statement. This will ensure that ample copies are available for the members of the Advisory Committee, the attending press, and the observers.

Special provisions will be made for handicapped individuals by contacting John W.A. Parsons 1–202–254–5100, no later than one week in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Mary Alice Hedge Reszetar, NCLIS Associate Executive Director, Designated Federal Official, 1111 18th Street NW., suite 310, Washington, DC 20036, 1–202–254–3100.

Mary Alice Hedge Reszetar,

NCLIS Associate Executive Director, Designated Federal Official.

[FR Doc. 90–11682 Filed 5–18–90; 8:45 am]

BILLING CODE 3165–01–M

NUCLEAR REGULATORY COMMISSION

Draft Regulatory Guide; Issuance, Availability

The Nuclear Regulatory Commission has issued for public comment a draft of a proposed revision to a guide in its Regulatory Guide Series. This series has been developed to describe and make available to the public such information as methods acceptable to the NRC staff for implementing specific parts of the Commission's regulations, techniques used by the staff in evaluating specific problems or postulated accidents, and data needed by the staff in its review of applications for permits and licenses.

The proposed Revision 1 to Regulatory Guide 3.58, "Criticality Safety for Handling, Storing, and Transporting LWR Fuel at Fuels and Materials Facilities," is temporarily identified by its task number, DG–3004. This revision is being developed to provide guidance acceptable to the NRC staff on procedures for preventing criticality accidents in operations involving light-water-reactor fuel outside reactors. This revision will endorse the reaffirmed ANSI/ANS–8.17–1984 (R1989), "Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors."

This draft guide is being issued to involve the public in the early stages of the development of a regulatory position in this area. It has not received complete staff review and does not represent an official NRC staff position.

Public comments are being solicited on the guide, including any on the implementation schedule. Comments should be accompanied by supporting data. Written comments may be submitted to the Regulatory Publications Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW., Washington, DC. Comments will be most helpful if received by July 13, 1990.

Although a time limit is given for comments on these drafts, comments and suggestions are encouraged at any time, especially items for inclusion in guides currently being developed or improvements in all published guides.

Regulatory guides are available for inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC. Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Information Support Services. Telephone requests cannot be accommodated. Regulatory guides are not copyrighted, and Commission approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland, this 9th day of May 1990.

For the Nuclear Regulatory Commission.

Frank A. Costanzi,

Deputy Director, Division of Regulatory Applications, Office of Nuclear Regulatory Research.

[FR Doc. 90–11711 Filed 5–18–90; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–213]

Connecticut Yankee Atomic Power Co.; Consideration of Issuance of Amendment to Facility Operating License and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR–61, issued to Connecticut Yankee Atomic Power Company (CYAPCO), (the Licensee), for operation of the Haddam Neck Plant located in Middlesex County, Connecticut.

The amendment would revise the Technical Specifications by removing Table 4.4–5, "Reactor Vessel Surveillance Material Withdraw Schedule," and the direct reference to this Table in Surveillance Requirement 4.4.9.1.2. In addition, the applicability for Figures 3.4–3, 4, and 5 heatup and cooldown curves will be revised from 22 equivalent full power (EFPYs) to 18 EFPYs to reflect the effects of the removal of the thermal shield.

Prior to issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

By June 20 1990, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714 which is available at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC 20555 and at the Local Public Document Room located at the Russell Library, 123 Broad Street, Middletown, Connecticut 06457. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the result of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC, by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at 1–(800) 325–6000 (in Missouri 1–(800) 342–6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to John F. Stolz: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Gerald Garfield, Esquire, Day, Berry & Howard, Counselors at Law, City Place, Hartford, Connecticut 06103–3499, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

If a request for a hearing is received, the Commission's staff may issue the amendment after it completes its technical review and prior to the completion of any required hearing if it publishes a further notice for public comment of its proposed finding of no significant hazards consideration in accordance with 10 CFR 50.91 and 50.92.

For further details with respect to this action, see the application for amendment dated February 16, 1990, which is available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street NW., Washington, DC 20555, and at the Local Public Document Room, Russell Library, 123 Broad Street, Middletown, Connecticut 06457.

Dated at Rockville, Maryland, this 15th day of May 1990.

For the Nuclear Regulatory Commission.

John F. Stolz,

Project Directorate I–4, Division of Reactor Projects–I/II Office of Nuclear Reactor Regulation.

[FR Doc. 90–11712 Filed 5–18–90; 8:45 am]

BILLING CODE 7590–01–M

[Dockets Nos. 50-269, 50-270, 50-287]

Duke Power Co.; Issuance of Amendments to Facility Operating Licenses

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendments Nos. 184, 184, and 181 to Facility Operating Licenses Nos. DPR-38, DPR-47, and DPR-55 issued to Duke Power Company (the licensee), which revised the Technical Specifications for operation of the Oconee Nuclear Station, Units 1, 2, and 3 (the facility) located in Oconee County, South Carolina. The amendments were effective as of the date of issuance.

The amendments revise the Technical Specifications to allow an increase in the linear heat rate at the 2-foot core elevation level for Oconee Units 1, 2 and 3.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendments.

Notices of Consideration of Issuance of Amendments and Opportunity for Hearing in connection with this action were published in the **Federal Register** June 2, 1988 (53 FR 20196) and January 26, 1990 (55 FR 2720). No request for a hearing or petition for leave to intervene was filed following the notices.

The Commission has prepared an Environmental Assessment related to the action and has determined not to prepare an environmental impact statement. Based upon the environmental assessment, the Commission has concluded that the issuance of these amendments will not have a significant effect on the quality of the human environment (55 FR 18991).

For further details with respect to the action see (1) the application for amendments dated January 22, 1988, as supplemented October 9, 1989, (2) Amendments Nos. 184, 184, and 181 to Licenses Nos. DPR-38, DPR-47, DPR-55 and (3) the Commission's related Safety Evaluation and Environmental Assessment. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the Oconee County Library, 501 West South Broad Street, Walhalla, South Carolina 29691. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects I/II.

Dated at Rockville, Maryland this 10th day of May 1990.

For the Nuclear Regulatory Commission.

Leonard A. Wiens,

Project Manager, Project Directorate II-3, Division of Reactor Projects—I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 90-11713 Filed 5-18-90; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-28012; File No. SR-CBOE-90-04]

Self-Regulatory Organizations; Chicago Board Options Exchange, Inc.; Order Approving Proposed Rule Change Relating to Evaluation of Trading Crowd Performance

On February 14, 1990, the Chicago Board Options Exchange, Incorporated ("CBOE" or "Exchange") submitted to the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b-4 thereunder,[2] a proposed rule change seeking permanent approval for its pilot program providing for the evaluation of trading crowd performance by the CBOE's Market Performance Committee ("MPC").

The proposed rule change was published in Securities Exchange Act Release No. 27797 (March 13, 1990), 55 FR 10336. No comments were received on the proposed rule change.

In January 1987 the Commission approved on a pilot basis a CBOE proposal to establish a program for the evaluation of its trading crowds.[3] Under the program, the MPC evaluates members, individually and collectively as trading crowds, to determine whether members have met performance standards relating to quality of markets, competition among market-makers, observance of ethical standards, and administrative factors. In making an evaluation the MPC may consider any relevant information, including information provided in trading crowd evaluation questionnaires.

If the MPC finds that a market-maker has failed to meet minimum performance standards, one or more of the following actions may be taken: The market-maker's registration or appointment to one or more options classes may be suspended, terminated or restricted, or his appointment to additional option classes may be suspended; option classes may be relocated; and the member may be prohibited from trading at a particular station.

The CBOE has found that its trading crowd evaluation program has helped the Exchange to maintain the quality of its trading crowds.[4] In particular, the crowd evaluation surveys have allowed the Exchange to identify trading crowds which have not fulfilled performance standards. Using the survey results, the MPC has met with approximately 40 low-ranking trading crowds to advise them of the need to improve their performance, has held two hearings with two separate trading crowds, has redistributed option classes to other trading crowds, and has consolidated four weaker trading crowds with four stronger trading crowds in order to strengthen the weaker crowds.[5] The CBOE also believes the crowd evaluation program has been instrumental in increasing the usage of the Exchange's Retail Automatic Execution System, the successful implementation of the Firm Quote Program, and the allocation of new issues to crowds with a history of maintaining higher performance standards. In addition, the CBOE notes that the average scores on the trading crowd evaluation questionnaires have increased, indicating a general improvement in crowd performance.[6]

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6(b)(5) of the Act [7] because it is designed "to remove impediments to and perfect the mechanism of a free and open market * * * and, in general, to protect investors and the public interest * * *." In particular, the Commission finds that the trading crowd evaluation program is consistent with section 6(b)(5) because it helps the Exchange to maintain market

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1989).

[3] *See* Securities Act Release No. 24008 (January 16, 1987), 52 FR 3072 (order approving File No. SR-CBOE-85-44).

[4] The crowd evaluation questionnaires have been distributed nine times since May 1985. Most recently, 240 brokers (86% of all floor brokers eligible to participate) participated in the February 1990 survey.

[5] *See* Memorandum of Daniel Hustad to Robert Ackerman, Vice President, Legal Services, CBOE, dated April 26, 1990.

[6] *Id.* at 2.

[7] 15 U.S.C. 78f (1982).

quality and integrity by providing a means to identify market-makers and trading crowds which fail to meet performance standards. By allowing the Exchange to assess the quality of its trading crowds and market-makers, and to take appropriate remedial measures where necessary, the trading crowd evaluation program helps the Exchange provide a more competitive, efficient, and fair market.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[8] that the proposed rule change (SR–CBOE–90–04) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[9]

Dated: May 14, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–11687 Filed 5–18–90; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–28017; File No. SR–DGOC–90–02]

Self-Regulatory Organizations; Order Approving a Proposed Rule Change by the Delta Government Options Corporation, Relating to Procedures for Narrowing Strike Prices of Certain Securities

May 14, 1990.

On Feburary 15, 1990, the Delta Government Options Corporation ("DGOC") filed with the Securities and Exchange Commission ("Commission") a proposed rule change (File No. SR–DGOC–90–02) under section 19(b)(1) of the Securities Exchange Act of 1934, as amended ("Act").[1] On March 15, 1990, the Commission published notice of the proposal in the **Federal Register.**[2] The Commission did not receive any letters of comments. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Description

The proposal amends the definition of "Exercise price" contained in Article I section 101 of DGOC's procedures to permit exercise prices in halves and quarters depending on the maturity date of the securities underlying the option contract. Under DGOC's procedures, a holder of an option must state the exercise price of the option as a specified percentage of a $1,000,000 principal amount of the underlying securities, which is the unit of trading.[3] Pursuant to the proposed amendments, holders will be able to state the exercise price of option contracts on treasury bonds or treasury notes with a remaining term to maturity of three years or more in whole numbers and halves. In addition, the proposal will allow holders to express the exercise prices of an option contract on treasury bills [4] or treasury notes with a remaining term to maturity of less than three years in whole numbers and quarters.

II. DGOC's Rationale for the Proposed Rule Change

DGOC believes that the proposed rule change will increase the use of options in DGOC's system and have no impact on unexpired option contracts. For this reason, DGOC believes that the proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to DGOC.

III. Discussion

The Commission believes the proposed rule change is consistent with section 17A of the Act, and, in particular, with section 17A(b)(3)(F) of the Act.[5] DGOC's registration as a clearing agency has allowed, for the first time, over-the-counter ("OTC") treasury options to be issued, cleared and settled within an automated clearing facility subject to Commission oversight. Market participants trade these treasury options to hedge against or speculate on changes in treasury security interest rates. In particular, OTC treasury options enable market participants to tailor option terms, such as the exercise price, to their individual needs.[6]

DGOC's proposal to reduce the quotation intervals, will provide a broader range of exercise prices, thus affording participants additional flexibility to adjust option prices in relation to their treasury security portfolios. The proposal, moreover, will enable participants to submit, for processing at DGOC, OTC treasury option trades that, prior to this proposal, could not be submitted because they were stated in intervals other than whole numbers, for bonds or notes with a maturity of more than seven years, or, whole numbers and halves for bills or notes with a maturity of seven years or less.

DGOC's proposal, therefore, will allow for the automated clearance and settlement of securities transactions that, otherwise, would have been cleared via a decentralized, inefficient and labor-intensive process.[7] The Commission believes that by promoting the clearance and settlement of treasury option transactions in DGOC's automated environment, the proposal should reduce transaction costs and provide the efficiencies associated with DGOC's netting system. In particular, DGOC will serve as a third-party intermediary guaranteeing the performance of obligations arising under OTC treasury option contracts. For these reasons, the Commission believes that the proposal is consistent with section 17A(b)(3)(F) of the Act which requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[8] As such, by facilitating treasury option transactions, DGOC's proposal will enhance the protection of investors.[9]

IV. Conclusion

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[10] that the proposed rule change, SR–DGOC–90–02, be, and hereby is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority. 17 CFR 200.30–(12) (1989).

Jonathan G. Katz,

Secretary.

[FR Doc. 90–11688 Filed 5–18–90; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–28014; File No. SR–MSE–90–05]

Self-Regulatory Organizations; Midwest Stock Exchange, Inc.; Filing and Order Granting Accelerated Approval to Proposed Rule Change Relating to Orders Received Over the Midwest Automatic Execution System

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1]

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[8] 15 U.S.C. 78s(b)(2) (1982).

[9] 17 CFR 200.30–3(a)(12) (1989).

[1] 15 U.S.C. 78s(b)(1) (1989).

[2] Securities Exchange Act Release No. 27776 (March 7, 1990), 55 FR 9816 (March 15, 1990).

[3] Thus, for example, if a price is stated as "99," the price for a single option contract on exercise is 99% of $1,000,000, or $990,000.

[4] As previously stated, the purchase or sale price of options must be specified as a percentage of a $1,000,000 principal amount of the underlying securities, which is the unit of trading. In the case of treasury bills, this percentage, however, does not reflect accruing interest because treasury bills are issued at a discount from face value. The price at which treasury bills can be purchased or sold is, therefore, calculated by quoting yield as the percentage amount of the discount on an annualized basis.

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] Securities Exchange Act Release No. 26450 (January 12, 1989), 54 FR 2010, 2013–14 (January 18, 1989).

[7] *See id.* at 2014.

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] *See* 15 U.S.C. 78q–1(a)(1)(A).

[10] 15 U.S.C. 78s(b)(2).

[1] 15 U.S.C. 78s(b)(1) (1982).

and Rule 19b–4 thereunder [2] notice is hereby given that on April 10, 1989, the Midwest Stock Exchange, Inc ("MSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission" or "SEC"), the proposed Rule change as described in Items I, II, and III below, which Items have been prepared for the self-regulatory organization. The proposal provides for a pilot program for six months whereby the guaranteed execution price of small agency market orders received over the Midwest Automatic Execution ("MAX") System will be automatically improved from the consolidated best bid or offer according to certain pre-defined criteria ("SuperMAX"). The Exchange has requested accelerated approval of the proposed rule change pursuant to section 19(b)(2) of the Act [3] because the Exchange has already made the programming changes for SuperMAX and has implemented it on a limited, voluntary pilot basis with successful results. Accelerated effectiveness was requested in order to allow public customers to continue to receive the benefits of improved SuperMAX executions without unnecessary delay.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change provides for a pilot program for six months whereby the guaranteed execution price of small agency market orders received over MAX will be automatically improved from the consolidated best bid or offer according to the SuperMAX pricing parameters and execution procedures. Participation in SuperMAX will be voluntary by specialists and will apply on a stock-by-stock basis. It will apply only to agency market orders of 599 shares or less in Dual Trading Systems issues.[4] The MAX System will immediately execute market orders without any specialist intervention based upon the following criteria:

(1) Both buy and sell orders in markets quoted with a minimum variation (1/8th spread) or orders which do not meet the criteria in 2 or 3 below will be executed based upon consolidated best bid or offer as the case may be.

(2) Buy orders in markets quoted with more than 1/8th spread will be executed at a price 1/8th better (*i.e.*, lower) than the consolidated best offer if (a) an execution at the consolidated best offer would create a double uptick based upon the last sale in the primary market or (b) an execution at the consolidated best offer would result in a greater than 1/8th price change from the last sale in the primary market.

(3) Sell orders in markets quoted with more than 1/8th spread will be executed at a price 1/8th better (*i.e.*, higher) than the consolidated best bid if (a) an execution at the consolidated best bid would create a double down tick based upon the last sale in the primary market or (b) an execution at the consolidated best bid would result in a greater than 1/8th price change from the last sale in the primary market.

For example, the execution price for a market buy order in a 1/4 – 1/2 quoted market is as follows:

Tick/last sale	Execution price
+1/2	1/2
+3/8	3/8
−3/8	1/2
−1/4	3/8
+1/4	3/8 (if in range)

The execution price for a market buy order in a 1/4 – 5/8 quoted market is as follows:

Tick/last sale	Execution price
+5/8	5/8
+1/2	1/2
+3/8	1/2
−1/2	5/8
−3/8	1/2
−1/4	1/2
+1/4	1/2

The execution price for a market sell order in a 1/4 – 1/2 quoted market is as follows:

Tick/last sale	Execution price
−1/4	1/4
−3/8	3/8
+3/8	1/4
+1/2	3/8

Any eligible order in a stock included in a SuperMAX which is manually presented at the specialist post by a floor broker must also be guaranteed an execution by the specilist pursuant to the above listed criteria. In the event that a contra side order which would better a SuperMAX execution is presented at the post, the incoming order which is executed pursuant to the SuperMAX criteria must be adjusted to the better price.

SuperMAX will operate during the trading day from 9 a.m. CST until the close. During volatile periods, individual stocks or all stocks may be removed from SuperMAX with the approval of two members of the Committee on Floor Procedure.

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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item III below. The self-regulatory organization 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 amend the rules governing the use of MAX to allow for small agency market orders to be guaranteed an execution at a price that is better than the consolidated best bid or offer according to the proposed SuperMAX pricing and execution criteria. Currently, MSE Article XX, Rule 37 ("BEST Rule") requires a specialist to guarantee execution on all agency market orders from 100 to 2,099 shares based on the consolidated best bid or offer. The MAX System provides an automated routing and execution facility for orders up to 1,099 shares (or higher if the specialist so chooses) to be executed in accordance with the BEST Rule parameters.

The MAX System currently allows for a 15 second delay before market orders are automatically executed at the consolidated ITS best bid or offer in order to allow the specialist time to better the price if available on the floor. Market orders, however, are executed immediately if the quote spread at the time is ⅛ point because the price cannot be bettered. Virtually all market orders entered over MAX, however, are executed at the consolidated best bid or offer price and are not bettered during the 15 second delay.[5]

[2] 17 CFR 240.19b–4 (1989).

[3] 15 U.S.C. 78s(b)(2) (1982).

[4] The Dual Trading System of the MSE provides for the execution of both round-lot (100 shares) orders and odd-lot (1 to 99 shares) orders in certain issues assigned to specialists on the MSE and either the NYSE or the AMEX. MSE Guide, Explanatory Notes, at 800 (CCH 1990).

[5] *See* Securities Exchange Act, Release No. 27727 (February 22, 1990), 55 FR 7396 (March 1, 1990) (order approving File Nos. SR–MSE–88–09 and SR–PSE–87–12).

SuperMAX will provide a mechanism whereby the execution price of small market orders (599 shares or less) will be improved automatically from the consolidated best bid or offer under certain pre-defined criteria. The automated execution feature of SuperMAX provides a much more efficient means of bettering the execution price on a large volume of machine delivered market orders than manual processing could.

Participation in SuperMAX is voluntary by the specialist on a stock-by-stock basis. Certain stocks, depending upon the specific trading characteristics of the issue, may not be appropriate for SuperMAX, and the Exchange, at this time, believes that the specialist is in the best position to determine SuperMAX eligibility.

The execution criteria under SuperMAX are as follows: On a buy order the price will be bettered by a ⅛ point if an execution at the best offer would result in a double uptick based upon the last sale in the primary market. On a sell order the price will be bettered by a ⅛ point if an execution at the best bid would result in a double down tick, again based upon the last sale in the primary market. Both buy and sell orders will be bettered by a ⅛ point if an execution at the best bid or offer would result in receiving a price more than ⅛ point away from the last sale in the primary market.

The primary market last sale is used because customers assess their quality of executions on the MSE based upon executions in the primary market. The execution critera of SuperMAX also contribute to an orderly market because they help to reduce variations from trade to trade on small volume. The execution criteria of SuperMAX will also be applicable to eligible floor broker orders in SuperMAX issues so that a customer will receive the same execution whether the order was delivered manually or electronically.

The Exchange does not believe that SuperMAX will have any adverse impact upon the MSE systems capacity.[6] Indeed, the Exchange states that the elimination of the 15 second execution delay for eligible orders in SuperMAX issues increases systems capacity because of the elimination of the processing time to monitor the delay. This offsets the added demands on the system for processing the SuperMAX algorithm.

In the unlikely event that a better price than a SuperMAX execution would provide is available at the post, the specialist must adjust the SuperMAX execution to the better price. This should alleviate Commission staff concerns about the effect of the elimination of the 15 second delay upon the quality of executions in SuperMAX issues.[7] The 15 second execution delay will continue to apply for orders and issues not eligible for a SuperMAX execution.

The introduction of SuperMAX directly responds to customer comments concerning the quality of fills on the MSE and the negative impact of making post-trade adjustments. It should contribute to increased order flow to the MSE, thereby making the Exchange and its specialists more competitive without using disproportionate system resources or placing undue burdens upon specialist profitability.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with section 6 of the Act [8] in that it will promote just and equitable principles of trade and will help to perfect the mechanism of a free and open market and a national market system and will foster competition among markets.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believes that any burden will be placed on competition as a result of the proposed rule change.

C. Self-Regulatory Organization's Statements on Comments on the Proposed Rule Change Received from Members, Participants, or Others

Comments on SuperMAX were informally received from members of the Exchange and were unanimously favorable.

III. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. 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, 450 Fifth Street NW., Washington, DC 20549. Copies of such filings will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by June 11, 1990.

IV. Discussion and Conclusion

The Commission has reviewed carefully the MSE's proposed rule change and concludes, for the following reasons, that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange and, in particular, with section 6(b)(5) of the Act.[9]

The Commission continues to recognize that the increased competition that results from permitting regional specialists to attract orders from other markets by providing superior quotations and more efficient order executions generally enhances market-making ability and the quality of customer order executions. The Commission believes the MSE's SuperMAX automated pricing parameters and execution procedures are consistent with enhanced competition by providing an efficient electronic order routing and execution system for smaller sized orders of up to 599 shares from broker-dealers to the Exchange's floor for automatic execution.

The Commission believes the SuperMAX pricing and execution procedures are designed to ensure the fair and efficient execution of customer orders consistent with brokers' fiduciary duty to achieve a best execution for

[6] In this connection, the Exchange has made the following representations regarding the effect of the implementation of the SuperMAX enhancements to the MAX System on MSE systems' capacity: (1) Capacity should continue to be sufficient to handle reasonably anticipated volume on an on-going basis; (2) capacity should continue to be sufficient to handle periodic surges in volume; (3) existing internal safeguards should continue to be sufficient to prevent tampering and ensure adequate system security; and (4) there should not be any adverse effects on the capacity of other MSE systems. *See* letter from J. Craig Long, Vice President and General Counsel, MSE, to George Scargle, Staff Attorney, SEC, Division of Market Regulation, dated May 9, 1990.

[7] *See* Securities Exchange Act Release No. 27727 (February 22, 1990), 55 FR 7396 (March 1, 1990) (order approving File Nos. SR–MSE–86–9 and SR–PSE–87–12, proposals to implement reduced exposure time for orders transmitted through MAX and the Pacific Securities Communication Order Routing and Execution ["SCOREX"] System).

[8] 15 U.S.C. 78f (1982).

[9] 15 U.S.C. 78f(b)(5) (1982).

customer orders. The Commission fully supports the MSE's efforts to develop automated execution procedures that provide for superior execution of public orders and promote competition among exchanges and other competing market centers.

Moreover, because any eligible order in a stock included in SuperMAX which is manually presented at the specialist post by a floor broker also must be guaranteed an execution by the specialist pursuant to the SuperMAX criteria, the benefits of an improved SuperMAX execution also will be available to nonsystematized orders. In addition, in the event that a contra side order which would better a SuperMax execution is presented at the post, the incoming order which is executed pursuant to the SuperMAX criteria must be adjusted to the better price. These two additional features further ensure that both nonsystematized and systematized orders receive the best possible execution.

The Commission has expressed concerns in the past about the possible adverse effects on execution quality of a lack of order exposure.[10] Increased order exposure may provide economic benefits to the securities markets by encouraging enhanced interaction of orders, increased opportunities for best execution of customer orders, and greater intermarket competition for order flow (and, ultimately, increased market efficiencies). On the other hand, increased order exposure may impose certain economic costs in terms of execution delay and interjection of manual processing.

Although orders executed through SuperMAX are not exposed to the market for possible price betterment, the Commission is satisfied that the Exchange's SuperMAX proposal may actually improve the chances that a customer's order will be executed between the bid-ask spread. Because very few MSE executions are improved during the 15 second order exposure period, the SuperMAX algorithm that improves upon the consolidated best bid or offer for issues in markets quoted with more than a ⅛th spread will provide for greater opportunities for price betterment of customers orders. Moreover, in the event that a better price than a SuperMAX execution is available at the post, the specialist must adjust the SuperMAX execution to the better price.

[10] *See, e.g.*, Securities Exchange Act Release No. 20074 (August 12, 1983), 28 SEC Docket 938, 940 (August 30, 1983) (deferral of proposed Commission order exposure rule).

Finally, the Commission believes the enhanced SuperMAX pricing and execution procedures are consistent with the maintenance of fair and orderly auction markets on national securities exchanges. As the examples provided by the Exchange illustrate, the execution criteria of SuperMAX should contribute to an orderly market because they help to reduce variations from trade to trade on small volume. In addition, because individual stocks or all stocks may be removed from SuperMAX with the approval of two members of the MSE's Committee on Floor Procedure during volatile periods, the Exchange is able to increase overall systems capacity for systematized orders routed through MAX, as well as reduce the market risk exposure to specialists who participate in SuperMAX. The Commission believes that both of these aspects of SuperMAX are consistent with the maintenance of fair and orderly auction markets on national securities exchanges and the protection of investors.

For the reasons discussed above, the Commission finds that the MSE's proposal to adopt on a six-month pilot basis the new SuperMAX pricing parameters and execution procedures is consistent with the requirements of sections 6 and 11A of the Act [11] and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds that the proposed rule change is consistent with sections 6(b)(5) and 11A(a) of the Act,[12] in that it is designed to promote just and equitable principles of trade, perfect the mechanisms of a free and open national market system, and, in general, further investor protection and the public interest in fair and orderly auction markets on national securities exchanges, as well as facilitate the linking of qualified markets through appropriate communication systems, facilitate the practicability of brokers executing investors' orders in the best market, and, finally, contribute to the best execution of such order.

The Commission finds good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice thereof in the **Federal Register**. The Commission believes it is appropriate to approve the proposed rule change on an accelerated basis so that the Exchange can enable public customers to receive the benefits of improved SuperMAX executions without delay. In addition, the Commission is approving MSE's SuperMAX proposal only for a six-month pilot period. During that time, the Commission and the MSE will be able to examine whether SuperMAX is successful at providing for the automatic execution of small orders at prices consistent with the maintenance of fair and orderly markets and can determine whether to extend the pilot for a further period or make SuperMAX permanent.[13] The Commission believes, therefore, that granting accelerated approval of the proposed rule change is appropriate and consistent with section 6 of the Act.[14].

It is therefore ordered, pursuant to section 19(b)(2) of the Act [15] that the proposed rule change (SR–MSE–90–05) be, and hereby is, approved for a six-month period ending November 14, 1990.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[16]

Dated: May 14, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–11691 Filed 5–18–90; 8:45 am]

BILLING CODE 8010-01-M

[11] 15 U.S.C. 78f and 78k–1 (1982).

[12] 15 U.S.C. 78f(b)(5) and 78k–1(a) (1982).

[13] The Commission is interested in reviewing data that would support the Exchange's proposal to extend the SuperMAX pilot or make it permanent. For example, the number of specialists and stocks participating in SuperMAX, the number of orders received through SuperMAX, and the number of times an execution is bettered through SuperMAX would all be revelvant to the Commission's subsequent determination(s).

[14] 15 U.S.C. 78f (1982).

[15] 15 U.S.C. 78s(b)(2) (1982).

[16] *See* 17 CFR 200.30–3 (1989).

[Release No. 34–28016; File No. SR–NASD–90–23]

Self-Regulatory Organizations; Proposed Rule Change by National Association of Securities Dealers, Inc. Relating to Communications with the Public

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed on April 17, 1990, and amended on April 30, 1990,[1] with the Securities and Exchange Commission ("Commission" or "SEC"), the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the NASD. The Commission is publishing this notice to

[1] Amendment No. 1 reports the results of the NASD membership vote necessary for the approval of the rule change. Eighty-one percent (81%) of the valid ballots received approved the proposal. Copies of the amendment are available for examination in the Commission's public reference room.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The NASD is proposing amendments to Article III, section 35 of the Association's Rules of Fair Practice [2] regarding: (1) Filing requirements and review procedures for advertisements and sales literature concerning public direct participation programs; (2) adjustment of the time period for spot-check review of members' advertising and sales literature; and (3) conformity of members' public communications with all applicable SEC rules.

The following is the full text of the proposed rule changes ot Article III, section 35 of th Rules of Fair Practice of the NASD. Material to be added is italicized, material to be deleted is in brackets.

Section 35. Communications with the Public

(c) Filing Requirements and Review Procedures

(6) In additon to the foregoing requirements, every member's advertising and sales literature shall be subject to a routine spot-check procedure. Upon written request from the Association's Advertising Department, each member shall promptly submit the material requested. Members will not be required to submit material under this procedure which has been previously submitted pursuant to one of the foregoing requirements and, except for material related ot municipal securities, *direct participation programs* or investment company securities, the procedure will not be applied to members who have been, within the *NASD's current examination cycle* [preceding calendar year] subjected to a spot-check by a registered securities exchange or other self-regulatory organization [utilizing comparable] *using* procedures [,] *comaprable to those used by the Association.*

(8) Material which refers to investment company securities [or] options *or direct participation programs* solely as part of a listing of products and/or services offered by the member, is excluded from the requirements of paragraphs (c)(1), [and] (c)(2) *and (c)(3)* of this section.

[2] *NASD Manual*, par. 2001 *et seq.*

(e) [Standards Applicable to Investment Company-Related Communications]

Application of SEC Rules

In addition to the provisions of paragraph (d) of this section, members' public communications [concerning investment company securities] shall conform to all applicable rules of the SEC, as in effect at the time the material is used.

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 NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD 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

Article III, section 35 of the Association's Rules of Fair Practice governs members' communications with the public. The rule contains internal approval and recordkeeping requirements, filing requirements and standards applicable to the content of such communications.

An amendment to Article III, section 35(c)(3) was adopted on July 1, 1987, requiring that advertising and sales literature concerning publicly offered direct participation programs be filed with the NASD for review within 10 days of first use of publication. The Board of Governors has determined that the adoption of Article III, section 35(c)(3) has generated the necessity to make conforming amendments to three other sections of Article III, section 35: Section 35(c)(6), section 35(c)(8), and section 35(e).

Section 35(c)(6) sets forth the procedures for conducting a spot-check of every member's advertising and sales literature. The procedures do not apply to members who have been subjected to a spot-check by a registered securities exchange or other self-regulatory organization utilizing comparable procedures, except for material relating to municipal securities and investment company securities which remain subject to the Association's spot-check procedures regardless of whether there has been a spot-check by an exchange or self-regulatory organization within the preceding calendar year. In order to be consistent with the requirements for other types of securities products, the Board of Governors has determined that Article III, section 35(c)(6) should be amended to require that advertising and sales literature on behalf of public direct participation programs be submitted in response to the Association's spot-check request, regardless of whether the member has been spot-checked by an exchange or self-regulatory organization.

Section 35(c)(6) also states that, except for material related to municipal securities or investment company securities, the spot-check procedure will not be applied to members who have been spot-checked "within the preceding calendar year" by a registered securities exchange or other self-regulatory organization using comparable procedures. When this rule was originally adopted in 1980, the Association conducted annual spot-checks of each member firm. Since then, the volume of filings and complaints has increased to such a degree that the Association cannot effectively spot-check all members within a one year period, and the cycle has been changed to conduct the spot-check biennially. The New York Stock Exchange ("NYSE") also conducts its spot-check of its members' advertising and sales literature on a two-year cycle.

The current language in the rule means that some NASD members may be required to respond fully to an NASD spot-check because they were spot-checked by the NYSE beyond the "preceding calendar year," even though the spot-check was conducted within the same cycle for both the NYSE and NASD. Therefore, the Board of Governors has determined that this section of the rule should be amended to eliminate the fixed time period and to insert a flexible time period that would parallel the time frame used by the NYSE, thus creating a more efficient spot-check process that would avoid duplicative spot-checking of members.[3]

Section 35(c)(8) allows an exclusion from all filing requirements and spot-check procedures for advertising and sales material that refers to investment company securities or options communicated soley in a listing of the member's products or services. The Board of Governors has determined that

[3] The NASD has become aware that the NYSE has filed with the SEC a proposed rule change that would eliminate the NYSE spot-check procedure. At such time as this change becomes effective dual NASD/NYSE members no longer will have this exception available.

section 35(c)(8) should be amended to include direct participation program securities to be excluded from the review and spot-check procedures where the information communicated is merely a listing of the member's products or services.

Section 35(e) sets forth "Standards Applicable to Investment Company-Related Communications." This section provides for the conformation of such communications to applicable SEC rules, in addition to the standards set forth in section 35(d). The Board of Governors has determined that this section should be amended to require that all communications with the public conform to applicable SEC rules. The Board of Governors believes that protection of the public and maintaining public trust in the securities markets is an important priority of the Association. Therefore, the Board of Governors believes that expanding the scope of section 35(e) to require that members' communication with the public conform to applicable SEC rules is consistent with the Association's longstanding policy to ensure that, in conjunction with making informed investment decisions, the investing public receives accurate and complete information from Association members.

The proposed rule change is consistent with section 15A(b)(6) under the Act, as amended , which requires, in pertinent part, that the rules of a national securities association be designed to prevent fradulent and manipulative acts and practices, to promote just and equitable principles of trade, and to protect investors and the public interest by subjecting members' advertising to appropriate spot-check procedures and enforcing compliance with SEC rules related to advertising.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Association believes that these rule changes do not impose any burden on competition 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

Comments were neither solicited nor received with respect to the rule changes contained in this filing.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. 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, with be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by June 11, 1990.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12).

Dated: May 14, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90-11689 Filed 5-18-90; 8:45 am]

BILLING CODE 8010-01-M

Release No. 34-28011; File No. SR-NYSE-90-01]

Self-Regulatory Organizations; New York Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to Basket Trading

I. Introduction

On January 3, 1990, the New York Stock Exchange, Inc. ("NYSE" or "Exchange") submitted to the Securities and Exchange Commission ("Commission" or "SEC"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act") [1] and Rule 19b-4 thereunder,[2] a proposed rule change designed to amend certain of the Exchange's rules that govern trading in Exchange Stock Portfolios ("ESPs" or "Baskets").[3] On May 10, 1990, the Exchange filed Amendment No. 1 to the proposed rule change with the Commission.[4] The proposed rule change would require initiating a discontinuous auction market when certain futures market "circuit breakers" take effect or when there would be a Basket execution significantly away from the value of the underlying index. In addition, the Exchange proposes to cease disseminating component stock "tier" quotations two minutes prior to the close of trading.

Notice of the proposed rule change was provided by the issuance of a Commission release (Securities Exchange Act Release No. 27615, January 12, 1990), and by publication in the **Federal Register** (55 FR 2187, January 22, 1990). The Commission received no comments on the proposed rule change. This order approves the proposed rule change.

II. Description of the Proposal

A. Discontinuous Auction Markets

The proposed rule change coordinates the operation of the Exchange's Basket discontinuous auction market rules with the rules governing the trading of the Basket component stocks and the futures contracts [5] on the same index on which the Basket is based. The proposed rule change amends NYSE Rule 815, which generally establishes the trading procedures governing Basket openings and reopenings,[6] to clarify that the

[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b-4 (1989).

[3] *See* Securities Exchange Act Release No. 27382 (October 26, 1989), 54 FR 45834 (October 26, 1989) (order approving File No. SR-NYSE-89-05, a proposed rule change designed to enable the trading of ESPs, standardized baskets of stock, at an aggregate price in a single execution on the NYSE equity trading floor).

[4] Amendment No. 1 to the proposed rule change made several non-substantive, strictly technical language changes to the Series 800 rules that govern trading in Baskets. The amendment made the following terminology substitutions throughout the Basket rules: (1) The term "Basket Book Dealer" replaces "Basket Book Broker"; (2) the term "discontinuous auction market(s)" replaces "Basket call market(s)" or "call market(s)"; and (3) the term "Index Closing Value" replaces "Index on Close".

[5] The primary futures contract on the Standard & Poor's ("S&P") 500 Index trades on the Chicago Mercantile Exchange ("CME").

[6] NYSE Rule 815 permits the Basket market to open or reopen only at a single price, and only at one which all market orders can be executed. All market orders are matched. If there is an order imbalance, the imbalance will be satisfied with the limit orders on the book at a single price, unless the imbalance is significant enough to warrant entry into a discontinuous auction market.

Exchange has the authority to declare a Basket discontinuous auction market at the opening of Basket trading.[7] The proposal also amends the Basket Guidelines governing discontinuous auction markets to specify that a discontinuous auction market is mandatory if (1) The primary futures contract on Standard & Poor's ("S&P") 500 Index has opened down its price limit, has declined to an interim or daily price limit, or has been halted, or (2) a Basket execution, other than at the opening, would result in a transaction at a price three or more points below the then-current S&P 500 Index value.

By establishing a mandatory Basket discontinuous auction market when the futures market has opened down, or declined to, a price limit, or when the Basket market would be trading at a price significantly below the market for component stocks, the Exchange believes that the Basket will not trade in a destabilizing manner and lead to increased market volatility. While the Exchange's proposal will allow the Basket to continue to trade in the discontinuous auction market mode, all executions must be approved by a Floor Governor,[8] who can evaluate proposed executions in light of then-existing market conditions.

B. Component Stock Quotations

The proposed rule change also provides a mechanism to cease the dissemination of component stock "tier" quotations two minutes prior to the close of trading.[9] NYSE Rule 803(e) currently provides that, whenever all the Basket's component stocks listed on the Exchange are open for trading, the Exchange includes "aggregate Tier 1" and "aggregate Tier 2" quotations as part of the Basket market.[10] These quotations represent the weighted summation of bids and offers furnished by the specialists in the component stocks, as well as quotations for the "mini-basket" of non-Exchange listed stocks.[11]

Currently, if there is an execution of a "tier" trade during the last two minutes of trading, specialists may receive notice of the execution after the close of the trading day. The Exchange is proposing to cease disseminating these "tier" quotations two minutes prior to the close of trading to help ensure that specialists receive notices of "tier" executions prior to the close of trading.

III. Discussion and Conclusion

The Commission has considered carefully the Exchange's proposed rule change, and finds, for the following reasons, that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder and, in particular, the requirements of section 6.[12] The Commission believes the proposal is designed rationally to coordinate trading activity in the NYSE's ESP Basket product with trading in the component stocks, as well as in the trading markets for certain derivative products, such as related stock index futures.

Both the Exchange and other market centers continue to consider varying market mechanisms that are intended to address price volatility in related equity and derivative products in order to help ensure investor confidence in the fairness and orderliness of the nation's securities markets. For example, the Exchange recently submitted amendments to Rule 80A to expand program trading limitations during times of market volatility.[13] The Exchange also proposed additional amendments to Rule 80A that would prohibit covered program trades from being executed on destabilizing ticks,[14] as well as impose comparable stabilization requirements for trading in baskets of stocks.[15]

The Commission believes that the amendments to NYSE Rule 815, which generally establishes the trading procedures governing Basket openings and reopenings, should operate to clarify the Exchange's authority under Rule 816 to declare a Basket discontinuous auction market at the opening of Basket trading when market conditions warrant entry into a discontinuous auction market. As noted above, a Basket discontinuous auction market is conducted through the collection and dissemination of indications of interest and the subsequent execution of matching trading interest at specified time intervals.

The amendments to the Basket Guidelines establish appropriate parameters for initiating a mandatory discontinuous auction market. By requiring Exchange officials to initiate a discontinuous auction market when certain futures market "circuit breakers" take effect or when there would be a Basket execution significantly away from the value of the underlying index, the proposed rule change should operate to diminish the opportunity of Basket market participants to sell the Basket short in a declining market. Accordingly, the proposal should help to curtail order imbalances and downward speculative selling pressures in the Basket market in periods when the underlying stocks and related derivative instruments are experiencing price volatility.[16]

Moreover, the initiation of a Basket discontinuous auction market suspends the obligation of market makers in the Basket to disseminate firm quotations. To the extent that Basket market makers rely on the stock index futures market to hedge their market-making risk, it is logical to initiate a discontinuous auction market when the underlying futures contract is not trading in order to relieve Basket market makers from assuming undue market risk in periods of extraordinary price volatility. In addition, the proposal should reduce those instances in fast-moving markets where specialists otherwise would be required to fill Basket "tier" executions when their quotations in the individual component stocks are not reflective of their current quotations. Nevertheless, subject to Floor Governor approval, public orders in Baskets will still receive executions when there exists matching

[7] NYSE Rule 816 establishes the trading procedures that govern ESP discontinuous auction markets. Under NYSE Rule 816(b), the existence of a discontinuous auction market suspends the obligations of ESP market makers to establish, maintain, and communicate Basket and component stock quotations. (The market structure supporting ESP trading is discussed fully in the order approving File No. SR–NYSE–89–05. *See supra* note 3.) In general, a Basket discontinuous auction market is conducted through the collection and dissemination of indications of interest and the subsequent execution of matching trading interest at specified time intervals.

[8] *See* NYSE Rule 816.

[9] For a further description of the "tier" market, *see* File No. SR–NYSE–89–05, *supra* note 3, at Exhibit D, page I–11.

[10] *See also* NYSE Rule 104.11A.

[11] For purposes of ESP trading, NYSE Rule 800(b)(ix) defines the term "mini-basket" as "a group of stocks that consist of those of a Basket's stocks that are not listed for trading on the Exchange and whose inclusion and relative representation in the group are determined by the inclusion and relative representation of their current market prices in the stock index from which the Basket is derived."

[12] 15 U.S.C. 78f (1982).

[13] *See* Securities Exchange Act Release No. 27588 (January 5, 1990), 55 FR 1127 (January 11, 1990) (notice of filing of File No. SR–NYSE–89–41). The Exchange has incorporated by reference into this filing the purposive statements governing the subject matter of File No. SR–NYSE–89–41.

[14] *See* Securities Exchange Act Release No. 27708 (February 13, 1990), 55 FR 6142 (February 21, 1990) (notice of filing of File No. SR–NYSE–90–05).

[15] *See* Securities Exchange Act Release No. 27812 (March 16, 1990), 55 FR 11284 (March 27, 1990) (notice of filing of File No. SR–NYSE–90–11).

[16] For example, if the Basket's related futures market has closed down, the Basket could begin to trade at prices lower than the component stocks that comprise the "tier" quotations, with the ultimate result of further driving down the prices in the Basket's individual component stocks—as well as the Basket itself.

buying or selling interest. Accordingly, the Commission believes that requiring a Basket discontinuous auction market to be declared when the futures market has opened down, or declined to, a price limit, or when the Basket market would be trading at a price significantly below the market for the component stocks, should mitigate the potential adverse price effects of possibly destabilizing trades on all Basket market participants in times of increased market volatility.

The proposed amendments leave intact the current discontinuous auction market guideline that allows, but does not require, the institution of a discontinuous auction market when the "sidecar" provisions of Rule 80A have been triggered. The Commission believes that this flexibility will continue to allow the Exchange to determine whether a Basket discontinuous auction market would be appropriate based on the market conditions at the time the sidecar procedures took effect (as long as those procedures remain in effect).

Finally, the Commission believes that the amendment to Rule 803(e) that enables the Exchange to cease disseminating Basket "tier" quotations two minutes prior to the close of the trading day should help to ensure that specialists receive timely notices of "tier" executions prior to the close of the trading session. In addition, the amendment should help to protect specialists from filling Basket "tier" executions after the close at prices that are likely to differ from their actual closing quotations. At the same time, the amendment would continue to allow participants in the Basket market to trade with other Basket participants in the crowd and upstairs market makers up to the close of trading on the NYSE.

For the reasons discussed above, the Commission finds that the proposed rule change is consistent with the requirements of section 6 of the Act and the rules and regulations thereunder applicable to a national securities exchange. In particular, the Commission finds that the proposed rule change is consistent with section 6(b)(5) of the Act,[17] in that it is designed to promote just and equitable principles of trade, as well as further investor protection and the public interest in fair and orderly auction markets on national securities exchanges.

It is therefore ordered, pursuant to section 19(b)(2) of the Act,[18] that the proposed rule change (SR–NYSE–90–01) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[19]

Dated: May 11, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–11692 Filed 5–18–90; 8:45 am]

BILLING CODE 8010–01–M

[17] 15 U.S.C. 78f(b)(5) (1982).

[18] 15 U.S.C. 78s(b)(2) (1982).

[19] *See* 17 CFR 200.30–3(a)(12) (1989).

[Release No. 34–28013; File No. SR–PSE–90–14]

Self-Regulatory Organizations; Filing of Proposed Rule Change by the Pacific Stock Exchange, Inc. Relating to the Trading of Options on the PSE's Technology Index.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on April 4, 1990, the Pacific Stock Exchange ("PSE" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The PSE proposes to re-commence the trading of options on the PSE Technology Index ("Index") in the exact manner in which they were traded prior to the delisting of these options in 1987. The PSE also proposes to classify the Index as a broad-based index.

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 self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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

This filing is designed to re-commence the trading of options on the Index on the PSE Options Trading Floor.

The Index was first established, and approved for trading by the Commission, in January 1984.[1] As stated in that filing, the Index consists of one hundred underlying securities, representing a broad spectrum of companies principally engaged in manufacturing or service-related products within the advanced technology fields. The Exchange designed the Index, at least in part, to allow investors holding positions in some or all of the one hundred underlying securities to hedge the risks associated with their portfolios. The Exchange believes that due to the rapidly changing nature of the products and processes of many manufacturing and service companies involved in advanced technology, the degree of investment risk in this field is substantial.

The trading of options on the Index occurred from its inception until October 1987, when the Exchange determined to terminate the trading of these options. In conjunction with this determination, the Commission approved an Exchange proposal to delete from the PSE's rules the one reference to the Index. Specifically, the reference appeared in PSE Rule XXI, section 3(j), which stated, "For the purposes of this Rule, the PSE Technology Index shall be considered a broad based Index."[2]

After extensive research, the Exchange believes that its members and the public have an interest in the re-commencement of the trading of options on the Index, and that there will be substantial trading volume in these options. In addition, the Exchange believes that the implementation of trading may be accomplished without re-adopting the above language deleted in 1987. Since the introduction to Rule XXI states that the provisions of the Rule apply to the trading of index options in general, the Exchange does not believe that it is necessary for the Rule to reference specifically the Index.

[1] Securities Exchange Act Release Nos. 20423 (November 29, 1983) 48 FR 54557 (December 5, 1983) (order approving File No. SR–PSE–83–10) and 20499 (December 16, 1983) 48 FR 56880 (December 23, 1983).

[2] *See* Securities Exchange Act Release No. 25052 (October 21, 1987) (order approving File No. SR–PSE–87–24).

The Exchange proposes to trade options on the Index in the exact manner in which they were traded prior to the termination of their trading in 1987. The Exchange also proposes to classify the Index as a broad-based index.

During the time options on the Index were traded, the underlying securities comprising the Index were periodically revised by the Exchange to maintain the integrity and purpose of the Index, pursuant to section 3(a) of Rule XXI. Any effected revision to the Index involved the replacement of an underlying security with a security from an identical field in the technology industry. Although the trading of options on the Index ceased in October 1987, the Index, itself, has remained active and has continued to be revised by the Exchange in the above manner. For instance, from November 1988 to the present, several replacements of underlying securities have been effected by the Exchange, each for the purpose of maintaining the integrity and purpose of the Index. A comparison of the composition of the present Index to the original index of January 1984 reveals a difference in 38 listed securities.

Finally, the Exchange proposes to institute the same surveillance procedures as were present when options on the Index were being traded. These procedures include complete access to trading activity in the underlying securities.

The PSE believes that the proposed rule change is consistent with the requirements of the Act, and in particular, section 6(b)(5), as the options are designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade, and are not designed to permit unfair discrimination between customers, issuers, brokers or dealers.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will impose no burden on competition.

(C) Self-Regulatory Organization's Statement of Comments on the Proposed Rule Change Received from Members, Participants, or Others

Written comments on the proposed rule change were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self–regulatory organization consents, the Commission will:

(a) By order approve such proposed rule change, or

(b) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, DC 20549. 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, 450 Fifth Street NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by June 11, 1990.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[3]

Dated: May 14, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–11690 Filed 5–18–90; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q During the Week of May 11, 1990

The following applications for certificates of public convenience and foreign air carrier permits were filed under subpart Q of the Department of Transportation's Procedural Regulations (See 14 CFR 302.1701 et seq.). The due date for answers, conforming application, or motion to modify scope are set forth below for each application. Following the answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: 46929.

Date filed: May 9, 1990.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 6, 1990.

Description: Application of Pan American World Airways, Inc. pursuant to section 401 of the Act and subpart Q of the Regulations applies for an amendment to its certificate of public convenience and necessity for Route 565, to provide daily nonstop service between Miami, Florida and Cancun, Mexico.

Docket Number: 46930.

Date filed: May 9, 1990.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 9, 1990.

Description: Application of Aerovias De Mexico, S.A. De C.V., pursuant to section 402 of the Act and subpart Q of the Regulations, applies for a foreign air carrier permit authorizing Aerovias to engage in scheduled and charter foreign air transportation of persons, property and mail between points in Mexico and points in the United States in accordance with the air transport agreement between the United States and the United Mexican States.

Phyllis T. Kaylor,

Chief, Documentary Services Division.

[FR Doc. 90–11681 Filed 5–18–90; 8:45 am]

BILLING CODE 4910–62–M

Federal Aviation Administration

Research, Engineering, and Development Advisory Committee

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. app. I), notice is hereby given of a meeting of the System Capacity Subcommittee of the Federal Aviation Administration Research, Engineering, and Development Advisory Committee to be held Thursday and Friday, June 14–15, 1990. The meeting will take place at 9 a.m. in the MacCracken room, 10th floor, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC.

The agenda for this meeting follows:

[3] 17 CFR 200.30–3(a) (12) (1989).

• Airport Development and Government Roles Working Group Report.
• Noise Working Group Report.
• Finance Working Group Report.
• System Capacity and Technology Working Group Report.
• Review of Recommendations.

Attendance is open to the interested public but limited to space available. With the approval of the Subcommittee chairman, members of the public may present oral statements at the meeting. Persons wishing to present oral statements or obtain information should contact Mr. Edward T. Harris, Director, System Capacity Office, ASC–1, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–8445.

Any member of the public may present a written statement to the Subcommittee at any time.

Issued in Washington, DC, on May 15, 1990.

Martin T. Pozesky,

Associate Administrator for System Engineering and Development.

[FR Doc. 90–11697 Filed 5–18–90; 8:45 am]

BILLING CODE 4910–13–M

Research and Special Programs Administration

International Standards on the Transport of Dangerous Goods; Public Meeting

AGENCY: Research and Special Programs Administration (RSPA), Department of Transportation.

ACTION: Notice of public meeting.

SUMMARY: This notice is to advice interested persons that RSPA, in conjunction with the International Regulations Committee (INTEREC) of the Hazardous Materials Advisory Council (HMAC), will conduct a public meeting to exchange views on proposals submitted to the third session of the United Nation's Sub-Committee of Experts on the Transport of Dangerous Goods.

DATES: June 26, 1990 at 9:30 a.m.

ADDRESSES: Room 4234, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Frits Wybenga, International Standards Coordinator, Office of Hazardous Materials Transportation, Department of Transportation, Washington, DC 20590; (202) 366–0656.

SUPPLEMENTARY INFORMATION: This meeting will be held in preparation for the third session of the Sub-Committee of Experts on the Transportation of Dangerous Goods to be held July 2 to 13, 1990, in Geneva. During this meeting the U.S. position on proposals submitted to the third session of the Sub-Committee will be discussed. Topics to be covered include various issues relating to explosives; classification and grouping criteria for self-reactive substances; application of performance packaging test requirements to minor variations of previously tested combination packages; requirements for infectious substances; revision of the classification and grouping criteria for gases; adoption of a generic classification system for all classes of dangerous goods; classification of specific dangerous goods; and other proposed amendments to the United Nations Recommendations on the Transport of Dangerous Goods.

Documents that will be discussed may be obtained for a nominal fee from HMAC, suite 250, 1110 Vermont Avenue NW., Washington, DC 20005; (202) 728–1460.

Issued in Washington, DC, on May 15, 1990.

Alan I. Roberts,

Director, Office of Hazardous Materials Transportation.

[FR Doc. 90–11680 Filed 5–18–90; 8:45 am]

BILLING CODE 4910–60–M

DEPARTMENT OF THE TREASURY

Office of Thrift Supervision

Appointment of Conservator; The Federal Savings Banc, F.A.

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2) (B) and (H) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Conservator for The Federal Savings Banc, F.A., Arlington, Texas, on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11651 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Appointment of Conservator; First Federal Savings Association of Breaux Bridge

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2) (B) and (H) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Conservator for First Federal Savings Association of Breaux Bridge, Breaux Bridge, Louisiana ("Association") on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11652 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Appointment of Conservator; Great West, a Federal Savings Bank

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(B) and (H) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Conservator for Great West, a Federal Savings Bank, Craig, Colorado ("Association") on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11653 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Santa Barbara Federal Savings and Loan Association; Appointment of Conservator

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2) (B) and (H) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Conservator for Santa Barbara Federal Savings and Loan Association, Santa Barbara, California ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11654 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Appointment of Conservator; United Savings Bank, F.S.B.

Notice is hereby given that, pursuant to the authority contained in section

5(d)(2) (B) and (H) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Conservator for United Savings Bank, F.S.B., Windom, Minnesota, on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11655 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Replacement of Conservator with a Receiver; Ameriway Savings

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Ameriway Savings, Houston, Texas ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11666 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Cabrillo Federal Savings Bank; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(F) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for Cabrillo Federal Savings Bank, San Jose, California ("Savings Bank"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11656 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Cross Roads Savings & Loan Association, F.A.; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(F) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for Cross Roads Savings and Loan Association, F.A., Checotah, Oklahoma ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11657 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Replacement of Conservator With a Receiver; Eunice Federal Savings and Loan Association

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly replaced the Resolution Trust Corporation as Conservator for Eunice Federal Savings and Loan Association, Eunice, Louisiana ("Association"), with the Resolution Trust Corporation as sole receiver for the Association on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11667 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Replacement of Conservator with a Receiver; First Equity Savings Association, F.A.

Notice is hereby given that, pursuant to the authority contained in subdivisision (F) of section 5(d)(2) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for First Equity Savings Association, F.A., Tomball, Texas ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11668 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Appointment of Receiver; First Federal Savings and Loan Association of Breaux Bridge

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(A) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for First Federal Savings and Loan Association of Breaux Bridge, Breaux Bridge, Louisiana ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11658 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Appointment of Receiver; Great West Savings Bank, F.S.B.

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(A) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for Great West Savings Bank, F.S.B. ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11659 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Peoples Federal Savings and Loan Association of Thibodaux; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(F) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust

Corporation as sole Receiver for Peoples Federal Savings and Loan Association of Thibodaux, Thibodaux, Louisiana ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11660 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Platte Valley Savings, A Federal Savings and Loan Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(F) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for Platte Valley Savings, A Federal Savings and Loan Association, Gering, Nebraska ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11661 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Replacement of Conservator With a Receiver; Royal Oak Savings and Loan Association

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Royal Oak Savings and Loan Association, Manteca, California ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11669 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Santa Barbara Savings and Loan Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(C) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for Santa Barbara Savings and Loan Association, Santa Barbara, California ("Association"), on May 11, 1990.

Dated: May 14, 1990,

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11662 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Notice of Appointment of Receiver; The Savings Banc, a Savings and Loan Association

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(C) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for The Savings Banc, a Savings and Loan Association, Arlington, Texas, OTS Docket No. 6439, on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11663 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Replacement of Conservator With a Receiver; Sun Savings Association, F.A.

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owner's Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Sun Savings Association, F.A., Kansas City, Kansas ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11670 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Replacement of Conservator With a Receiver; Topeka Savings, a Federal Savings and Loan Association

Notice is hereby given that, pursuant to the authority contained in subdivision (F) of section 5(d)(2) of the Home Owner's Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision duly replaced the Resolution Trust Corporation as Conservator for Topeka Savings, a Federal Savings and Loan Association, Topeka, Kansas ("Association"), with the Resolution Trust Corporation as sole Receiver for the Association on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11671 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Appointment of Receiver; United Federal Savings Bank

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(A) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery and Enforcement Act of 1989, the Office of Thrift Supervision duly appointed the Resolution Trust Corporation as sole Receiver for United Federal Savings Bank, Windom, Minnesota, Docket No. 3058, on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11665 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

Washington Savings and Loan Association; Appointment of Receiver

Notice is hereby given that, pursuant to the authority contained in section 5(d)(2)(F) of the Home Owners' Loan Act of 1933, as amended by section 301 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, the Office of Thrift Supervision has duly appointed the Resolution Trust Corporation as sole Receiver for Washington Savings and Loan Association, Stockton, California ("Association"), on May 11, 1990.

Dated: May 14, 1990.

By the Office of Thrift Supervision.

Nadine Y. Washington,

Executive Secretary.

[FR Doc. 90–11664 Filed 5–18–90; 8:45 am]

BILLING CODE 6720–01–M

UNITED STATES INSTITUTE OF PEACE

Grants and Cooperative Agreements; Availability, etc.; Jennings, Randolph Program for International Peace Fellowships

AGENCY: United States Institute of Peace.

ACTION: Notice.

SUMMARY: The United States Institute of Peace announces its annual international competition for fellowships to begin in September, 1991. the fellowships enable professionals and scholars to undertake original research and education projects that will increase knowledge and spread awareness on the part of the public and policymakers regarding the nature of violent international conflicts and the full range of ways to deal with them peacefully. Fellowships are awarded in three categories: Distinguished Fellow, Peace Fellow, and Peace Scholar. Distinguished and Peace Fellows are principally one-year awards for work to be done at the Institute. Peace Scholars are out-of-residence doctoral students working on their dissertations. In order to be considered in the current competition, Distinguished Fellow nominations and Peace Fellow applications must arrive at the Institute by October 15, 1990. Peace Scholar applications must arrive at the Institute by November 15, 1990.

DATES: See in summary above.

ADDRESSES: United States Institute of Peace; 1550 M Street NW—Suite 700FR; Washington, DC 2005–1708.

FOR FURTHER INFORMATION CONTACT: Jennings Randolph Program for International Peace at the address given above; telephone (202) 457–1700.

Dated: May 16, 1990.

Bernice Carney,

Director of Administration.

[FR Doc. 90–11733 Filed 5–18–90; 8:45 am]

BILLING CODE 3155–01–M

DEPARTMENT OF VETERANS AFFAIRS

Career Development Committee; Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Department of Veterans Affairs Career Development Committee has been renewed for two years beginning May 4, 1990 through May 4, 1992.

Dated: May 7, 1990.

By direction of the Secretary

Sylvia Chavez Long,

Committee Management Officer.

[FR Doc. 90–11742 Filed 5–18–90; 8:45 am]

BILLING CODE 8320–01–M

Cooperative Studies Evaluation Committee; Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92–463) of October 6, 1972, that the Department of Veterans Affairs Cooperative Studies Evaluation Committee has been renewed for two years beginning May 2, 1990, through May 2, 1992.

Dated: May 7, 1990.

By direction of the Secretary.

Silvia Chavez Long,

Committee Management Officer.

[FR Doc. 90–11743 Filed 5–18–90; 8:45 am]

BILLING CODE 8320–01–M

Advisory Commission on the Future Structure of Veterans Health Care; Meeting

The Department of Veterans Affairs gives notice under the Federal Advisory Committee Act that a meeting of the Commission on the Future Structure of Veterans Health Care will be held at Techworld Plaza, South Lobby, rooms B and C on the fourth floor, 800 K Street, NW., Washington, DC., June 19 and 20, 1990, between 9 a.m. to 4:30 p.m. daily. This is the first meeting of the Commission. The Commission's primary responsibility will be to review the missions and programs of VA's health care facilities to determine whether changes in services, programs, or missions at individual facilities are needed, with a focus on providing care to eligible veterans in the decade 2000–2010. The agenda for this two-day meeting will include an orientation for the commission as well as working sessions to establish processes to govern its study and analysis of VA health care facilities.

The two-day meeting will be open to the public up to the seating capacity of the room. Interested persons may file statements with the commission, or may offer views (for up to five minutes) during a public forum session beginning at 9 a.m. on June 20. Statements, if in written form, may be filed before or within 10 days after the close of the meetings. To assure an opportunity to present a statement before the commission, interested persons should notify Mr. Bob Moran at, Commission on the Future Structure of Veterans Health Care, VACO (00RC), room 650, 810 Vermont Avenue, NW., Washington, DC 20420, or telephone (202) 233–2706 no later than June 12. Persons wanting additional information regarding the meeting may contact Mr. Moran.

Dated: May 14, 1990.

By direction of the Secretary:

Sylvia Chavez Long,

Committee Management Officer.

[FR Doc. 90–11744 Filed 5–18–90; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 55, No. 98
Monday, May 21, 1990

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

SECURITIES AND EXCHANGE COMMISSION

Agency 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 May 21, 1990.

A closed meeting will be held on Tuesday, May 22, 1990, at 2:30 p.m.

The Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c) (4), (8), (9) (A) and (10) and 17 CFR 200.402(a)(4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Lochner, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, May 22, 1990, at 2:30 p.m., will be:

Institution of administrative proceedings of an enforcement nature.
Reject settlement of administrative proceeding of an enforcement nature.
Settlement of injunctive actions.
Institution of injunctive actions.

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: Dan Gray at (202) 272–2300.

Dated: May 16, 1990.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–11814 Filed 5–17–90; 1:29 pm]

BILLING CODE 8010–01–M

Corrections

Federal Register
Vol. 55, No. 98
Monday, May 21, 1990

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.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of an Import Limit for Certain Cotton Textile Products Produced or Manufactured in Indonesia

Correction

In notice document 90-11201 beginning on page 20179 in the issue of Tuesday, May 15, 1990, make the following correction:

On page 20179, in the third column "**SUMMARY:**" should read "**EFFECTIVE DATE:**".

BILLING CODE 1505-01-D

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 200 and 230

[Release No. 33-6862; 34-27928; IC-17452; File No. S7-23-88 Int, Series—121]

RIN 3235-AC65

Resale of Restricted Securities; Changes to Method of Determining Holding Period of Restricted Securities Under Rules 144 and 145

Correction

In rule document 90-9860 beginning on page 17933, in the issue of Monday, April 30, 1990, make the following correction:

On page 17935, in the third column, in footnote 25, after the last sentence, text was missing and should have appeared as follows:

[25] For example, if a $1000 bond is convertible into 25 shares of common, and the bond is issued at par (*i.e.*, the price at issuance is $1000), and the market price of the common is $35 on the day the bond is priced (*i.e.*, the conversion value is $875, the product of $35 multiplied by 25), then the effective conversion premium would be 14.29% ($125 [obtained by subtracting $875 from $1,000] as a percentage of $875).

BILLING CODE 1505-01-D

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 89-NM-217-AD; Amdt. 39-6586]

Airworthiness Directives; Boeing Model 747 Series Airplanes

Correction

In rule document 90-9942 beginning on page 17928 in the issue of Monday, April 30, 1990, make the following correction:

On page 17929, in the first column, in paragraph "B.", in the 12th line "S-37 and S-39" should read "S-37 to S-39".

BILLING CODE 1505-01-D

federal register

Monday
May 21, 1990

Part II

Department of Health and Human Services

Health Care Financing Administration

42 CFR Part 405 et al.

Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88); Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405, 416, 440, 482, 483, 488, and 493

[HSQ-176-P]

RIN 0938-AE47

Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend regulations for laboratories to implement provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Public Law 100-578. The regulations would require that all laboratories in the United States and its territories that examine human specimens meet performance requirements based on test complexity and risk factors related to erroneous test results in order to be certified by HHS.

These provisions would require that the following laboratories or entities that perform test procedures or examinations also meet Federal requirements: Accredited, nonaccredited and Federal hospital laboratories; independent laboratories; physician office laboratories; laboratories located in critical care facilities, including operating rooms; laboratories located in skilled nursing facilities, end-stage renal disease facilities, intermediate care facilities, including intermediate care facilities for the mentally retarded; laboratories associated with tissue banks and tissue repositories; ambulatory surgical centers, and rural health clinics; College of American Pathologist accredited, New York State licensed, and low volume exempt laboratories; industrial laboratories; city, State and county laboratories; laboratories located in Federal clinics and all other laboratories such as laboratories located in Planned Parenthood clinics, and health maintenance organizations (HMO), drug screening laboratories, mobile laboratories and any other facility or entity including pharmacies and health fairs that perform quantitative, qualitative, or screening test procedures or examinations on materials derived from the human body.

DATES: To assure consideration, comments must be submitted to the appropriate address, as provided below, and should be received no later than 5 p.m. on August 20, 1990.

ADDRESSES: Mail comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ-176-P, P.O. Box 26676, Baltimore, Maryland 21207.

Please address a copy of comments on information collection requirements to: Office of Information and Regulatory Affairs, Office of Management and Budget, room 3002, New Executive Office Building, Washington, D.C. 20503, Attention: Allison Herron.

If you prefer, you may deliver your comments to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Ave., SW., Washington, DC, or, room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments. In commenting, please refer to file code HSQ-176-P. Comments received timely will be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, in room 309-G of the Department's, offices at 200 Independence Ave., SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

FOR FURTHER INFORMATION, CONTACT: Rhonda Whalen, (301) 966-6801.

SUPPLEMENTARY INFORMATION:

I. Background

Consolidation of Regulations

On March 14, 1990, HHS published a final rule on requirements for clinical laboratories (55 FR 9536). This was the result of a Departmental effort to update, consolidate, and recodify into 42 CFR part 493 all requirements applicable to clinical laboratories engaged in testing in interstate commerce, which are licensed under the Clinical Laboratories Improvement Act of 1967 (CLIA '67), and laboratories participating in the Medicare and Medicaid programs. Our final rule updates laboratory requirements, deletes obsolete regulations, imposes new quality assurance standards applicable to all such laboratories, and establishes uniform proficiency testing requirements for laboratory assessment. In addition, it establishes personnel standards applicable to clinical cytogenetics technical supervisors in any setting, permits individuals qualified in independent laboratories as a technical supervisor in cytology to function in that capacity in a hospital setting, and implements section 6141 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99-509) which allows a person qualified by State law to direct a laboratory in that State to meet the Medicare requirements for laboratory director.

After the proposed rule, on which the March 14, 1990 final rule was based, was published on August 5, 1988 (53 FR 29590), Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), Public Law 100-578, on October 31, 1988. Since the comment period for the proposed rule ended November 3, 1988, so soon after the enactment of CLIA '88, we determined that the final rule published March 14, 1990 should not contain personnel requirements included in our August 5, 1988 proposed rule so that we could establish personnel standards that are in accordance with testing performed, as mandated by CLIA '88.

II. Legislation

CLIA '88 establishes a new section 353 of the Public Health Service (PHS) Act to replace existing section 353. New section 353 requires the Department of HHS to establish certification requirements for any laboratory performing tests in the United States and its territories that performs tests on human specimens, and certify through issuance of a certificate that those laboratories meet the certificate requirements established by HHS. Also, the legislation contains certificate requirements and specifies circumstances that permit waiver of the certificate. The law also includes requirements for approval of accreditation bodies, inspections, sanctions, judicial review, fees, and disclosure of information to the public.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law 101-239, requires that laboratories participating in the Medicare program comply with CLIA '88 requirements. Only laboratories who have a current unrevoked and unsuspended certificate of waiver, provisional certificate, certificate, or certificate of accreditation will be eligible for reimbursement in the Medicare or Medicaid programs or both.

III. Purposes of the Proposed Rule

This proposed rule would implement the following sections of CLIA '88:

Section 353 (a) Definitions
Section 353 (b) Certificate Requirements
Section 353 (c) Issuance and Renewal of Certificates

Section 353 (d) Requirements for Certificates
Section 353 (f) Standards
Section 353 (g) Inspections

We will implement the following sections through a separate rulemaking which will replace the sections of Subpart O pertaining to adverse actions under CLIA '67:

Section 353 (h) Intermediate sanctions
Section 353 (i) Suspension, Revocation and Limitation
Section 353 (j) Injunctions
Section 353 (k) Judicial Review
Section 353 (l) Sanctions

Another rule will implement procedures for collection of fees in accordance with section 353(m), fees. The standards for collection of fees will be contained in subpart F of part 493. Also, in subpart F, we will establish interim procedures for registration of all laboratories and issuance of certificates to laboratories that were subject to CLIA '67 as of December 31, 1988 and for issuance of provisional certificates to all other laboratories that test human specimens. These interim certification procedures will be implemented as soon as possible after evaluation of comments to the proposed rule and publication of the final rule. The interim certification procedures will be in place until such time as this rule is effective after publication as a final rule.

In a fourth rule, we will implement provisions 353(e), Accreditation, and 353(p), State laws, of CLIA '88 by setting forth the criteria we will use to evaluate and approve State programs and private non-profit organizations as accreditation bodies. When this proposed rule is published in final, the requirements will be located in subpart E.

IV. Proposed Rule

Applicability

The provisions of CLIA '88 have a much broader effect on laboratories than the CLIA '67 provisions. Effective January 1, 1990, all laboratories in the United States that perform tests on human specimens for the purpose of information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings, are subject to the requirements in new section 353 of the PHS Act, with no provision in the law for exemptions.

This rule does not apply to any component or function of a laboratory that has been certified by the National Institute on Drug Abuse for the performance of forensic urine drug testing. We have established an exception for those components or functions of laboratories that maintain a current certification by the National Institute on Drug Abuse (NIDA) in accordance with Executive Order 12564 and section 503 of Public Law 100–71. Components or functions of laboratories that are not certified by NIDA are subject to these rules. Where a laboratory conducts both NIDA certified forensic urine drug testing and other laboratory tests, the laboratory would be subject to both NIDA certification for the forensic urine drug testing and these rules for all other tests, including other urine drug testing performed by the laboratory. This is consistent with past requirements. Any laboratory not certified by NIDA that engaged in interstate commerce, whether or not it performed forensic testing, was required to have a CLIA '67 license. If NIDA certification is removed for any reason, the formerly NIDA certified laboratory will become subject to the applicable CLIA '88 regulations, fees, and penalties.

Previously, certain accredited laboratories, many small laboratories, and those engaged in intrastate testing were exempt from section 353 of the PHS Act. Every laboratory that performs tests on human specimens, regardless of whether it participates in Medicare or Medicaid or engages in testing in interstate commerce, must go through a new administrative procedure by which it applies and is evaluated by HHS for compliance with Federal standards. However, these components or functions of laboratories certified by NIDA would not be subject to CLIA '88 certification requirements as long as the NIDA certification remains in effect. HHS approved laboratories will be issued a certificate in order to engage in the testing or examination of human specimens.

Certificate of Waiver

CLIA '88 provides that laboratory certification requirements must be based on test complexity and risk factors related to erroneous results, rather than on the location of the laboratory. The law also contains a provision for the issuance of certificates of waiver to laboratories that perform only tests that are simple and, as determined by HHS, have an insignificant risk of an erroneous result. The law defines simple laboratory tests as those determined by HHS to have an insignificant risk of an erroneous result. These may include tests that have been approved by the Food and Drug Administration (FDA) for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or that HHS has determined pose no reasonable risk of harm to the patient if performed incorrectly. Laboratories performing only certificate of waiver tests are subject only to application and fee collection procedures for waiver and are not subject to routine biennial inspections or compliance with proficiency testing, patient test management, quality control, personnel, quality assurance, and computer systems requirements of part 493. A certificate of waiver would be valid for a period of no longer than 2 years, during which time the laboratory must apply for renewal of the certificate of waiver.

Provisional Certificate

The effective date for the issuance of CLIA '88 certificates is January 1, 1990, which is also the effective date for the establishment of the Federal standards for certification. However, the effective date for personnel requirements and inspections of laboratories not subject to CLIA '67 on December 31, 1988 is July 1, 1991. Inasmuch as HHS did not have sufficient time to establish the certification standards and procedures for issuance of certificates, we propose to establish a process whereby provisional certificates would be issued initially to all laboratories not eligible for a certificate of waiver and to all laboratories that were not subject to CLIA '67 on December 31, 1988. This provisional certificate would allow laboratories previously not subject to CLIA '67 to continue to operate while HHS is establishing the health and safety standards proposed herein.

After the establishment of these requirements in a final rule, HHS would continue to issue provisional certificates to newly established laboratories to allow these laboratories to conduct testing, thus providing HHS with a sufficient basis for the determination of compliance.

A provisional certificate would generally be valid for a period of 2 years and would not be renewable. However, HHS would reissue a provisional certificate to any laboratory that HHS or its designee has not had an opportunity to evaluate for compliance with the requirements for certification.

The issuance of provisional certificates to "new" laboratories (those laboratories not previously subject to CLIA '67) meets the statutory application provisions of CLIA '88. Certificates cannot be issued to new laboratories because HHS cannot determine compliance through conducting inspections or evaluating personnel qualifications until July 1, 1991, the effective date specified in the legislation. Inasmuch as the new

laboratories would not be subject to personnel standards or inspections until July 1, 1991, the only standards presented under CLIA '88 that HHS has not implemented that could have been applied to "new" laboratories would be participation in proficiency testing. With regard to proficiency testing, the programs seeking HHS approval need sufficient time to make revisions in services offered and grading criteria in order to apply to HHS for approval; and the programs require a minimum of 6–9 months to make these revisions. On the other hand, laboratories licensed under CLIA '67 to test specimens in interstate commerce and those laboratories participating in Medicare or Medicaid will be subject to the revised Federal standards (published March 14, 1990) on September 10, 1990, except for participation in proficiency testing which is effective January 1, 1991.

Also, the proposed rule is written to reflect our plans for the final rule implementation with respect to the issuance of certificates rather than provisional certificates to those laboratories subject to CLIA '67 as of December 31, 1988.

However, in the meantime, we plan to initiate interim procedures for issuing CLIA '88 provisional certificates to those laboratories that, as of December 31, 1988, were subject to CLIA '67. We are instituting provisional certifications for laboratories licensed under CLIA '67 because, for the majority of these laboratories, their CLIA '67 licenses will expire June 30, 1990 and issuance of licenses under CLIA '67 is no longer valid. We are in the process of establishing the interim procedures and will be notifying CLIA '67 laboratories shortly of the procedures to be followed to receive a provisional certificate.

Provisional certificates issued to CLIA '67 laboratories would be valid for a period of not more than 2 years and should allow HHS sufficient time to publish in a separate rule (to become subpart F of part 493 when finalized) the interim procedures for issuance of CLIA '88 certificates to those laboratories that as of December 31, 1988 were licensed under CLIA '67.

Certificate

Section 353(f) of the PHS Act provides authority for HHS to establish standards of laboratory performance and specific certificate requirements for those laboratories not qualifying for a certificate of waiver. These standards would be designed to take into consideration the degree of risk of harm to a patient if the test is performed incorrectly, the type of tests performed by a laboratory, the degree of independent judgment involved in the test, the amount of interpretation required, the difficulty of calculations, the calibration and quality control requirements of the instruments used, the type of training required to operate the instruments, and other factors considered relevant by HHS.

Certificates would be issued to laboratories that perform one or more non-waivered tests. Initially, we are proposing categorizing non-waivered tests either as Level I or Level II based on test complexity. The certificate would reflect the extent of the testing performed by the laboratory including, if applicable, certificate of waiver tests and Level I or Level II tests. Laboratories that perform one or more Level I or Level II tests would be subject to the application procedures for a certificate, fee collection for a certificate, compliance with the applicable requirements of proficiency testing, patient test management, quality control, personnel requirements for Level I or Level II tests, respectively, quality assurance, computer systems and inspections in part 493. A certificate would be valid for a period of no longer than 2 years, during which time the laboratory must apply for renewal of the certificate.

Recognition of Accreditation and State Programs

Under CLIA '67, approximately 1200 laboratories were exempted from Federal regulation because:

- The laboratories had been accredited by the College of American Pathologists (CAP) or approved under the New York State program of laboratory standards enforcement; or
- The laboratories performed fewer than 100 tests in a given category.

CLIA '88 does not provide any exemptions based on the volume of testing performed or approval by an accreditation program such as CAP or a State program such as New York State. This means that no accreditation program or State licensure program is automatically deemed by statute to meet the CLIA '88 standards. However, CLIA '88 authorizes HHS to approve private, non-profit organizations' accreditation programs and State licensure programs provided the accreditation or State licensure programs' standards are equal to or more stringent than HHS' standards under section 353(f) of the PHS Act. In the final rule published March 14, 1990, we specified that HHS would recognize Federal programs, provided that the program requirements are equivalent to the Medicare/Medicaid CLIA '67 proficiency testing standards. We would propose in this rule to recognize Federal programs whose standards for proficiency testing are equivalent to the requirements specified in subpart I.

Section 353(e) of the PHS Act provides that a laboratory may be deemed to meet the Federal requirements if the laboratory meets the standards of an HHS approved accreditation program. Such a laboratory would be eligible to receive a certificate of accreditation provided it complies with the certificate of accreditation requirements. The law also requires that HHS establish criteria and procedures to approve private, nonprofit organizations to be accreditation bodies. The organizations must meet certain standards specified in the law. The organization must use qualified inspectors to evaluate laboratory methods and procedures, and apply standards to accredit laboratories that equal or exceed the standards established by HHS. The accrediting organization must also ensure that the laboratory continues to meet the standards, and if the standards are no longer met, and accreditation is denied, suspended, withdrawn revoked, or otherwise adversely affected, the organization must notify HHS within 30 days of the action. The law also requires a 30 day notice by the organization to HHS before it changes its standards, and if the organization has its approval withdrawn by HHS, it must agree to notify each accredited laboratory within 10 days of the withdrawal.

Section 353(p) of the PHS Act authorizes HHS to exempt from CLIA '88, those laboratories located in States in which the State enacts laws related to laboratory testing of human specimens that are equal to or more stringent than the CLIA '88 standards.

Following establishment of the criteria for HHS to approve accreditation and State programs (to be proposed through a separate rulemaking), accreditation and State programs with standards that are equivalent to or more stringent than CLIA '88 requirements may apply to HHS for approval. HHS will publish in the **Federal Register** the evaluation and its determination of whether an applicant accreditation or State program's standards are equivalent.

We will issue a separate rule to propose the criteria we will use to evaluate and approve accreditation and State programs; these requirements will be located in part 493, subpart E. We plan to issue the final rule containing the requirements for recognition of accreditation and State programs at approximately the same time that this final rule is published. Until we approve an accreditation program or State

program, laboratories will be subject to the final regulations implementing CLIA '88.

To minimize the impact of requiring laboratories to meet potentially new Federal requirements and to allow accreditation, State programs, and HCFA sufficient time to evaluate their standards for equivalency with CLIA '88 requirements, we propose, as previously mentioned, to initially issue provisional certificates to laboratories that were not subject to CLIA '67 on December 31, 1988. While the laboratory has provisional certification, it should establish compliance with applicable CLIA '88 standards. Also, during this two year time period, State and accreditation programs, seeking recognition under CLIA '88, should apply to HHS for approval.

Although we stated in the final rule, published March 14, 1990, our intention to evaluate accreditation programs and State programs currently recognized under CLIA '67 or Medicare, this evaluation, based on the Federal requirements published March 14, 1990, will not suffice for the evaluation required under CLIA '88. The CLIA '88 law supersedes all previous Federal requirements for laboratories. Moreover, standards implementing CLIA '88 will undoubtedly be different from standards published March 14, 1990, which were not based on test complexities.

Penalties

The law provides that any person who intentionally violates any requirement of CLIA '88 or any implementing regulation is subject to 1 year in prison or a fine, or both, for the first violation. Second and subsequent violations are subject to not more than 3 years in prison or fines in accordance with title 18, United States Code, or both. As was the case under CLIA '67, laboratories that fail to meet specific statutory requirements are subject to having their certificates revoked, suspended, or limited; however, under CLIA '88, HHS has additional authority to impose intermediate sanctions in lieu of certificate limitation, suspension, or revocation. As previously mentioned, a separate rule will address the provisions of CLIA '88 dealing with intermediate sanctions, suspension, revocation and limitation, injunctions, judicial review, and sanctions. That rule will replace the section of subpart O of the March 14, 1990 final rule which addresses CLIA '67 adverse actions.

Relationship of CLIA '88 Requirements and Those of Medicare and Medicaid

Under section 1902(a)(9)(C) of the Act, laboratories eligible for payment under the Medicaid program must comply with Medicare requirements. In accordance with section 6141 of OBRA '89, laboratories seeking payment in the Medicare program must meet the CLIA '88 requirements and must possess, therefore, a current unrevoked and unsuspended certificate of waiver, provisional certificate, certificate or certificate of accreditation to be eligible to seek payment in the Medicare or Medicaid program or both.

The uniform requirements applicable to laboratories issued a certificate under CLIA would also apply to laboratories participating in the Medicare-Medicaid programs. This, in effect, would establish a single set of health and safety standards applicable to all laboratories.

Although we intend for the Federal health and safety requirements to be the same for Medicare and CLIA, failure to meet the requirements for part 493 would result in different adverse actions under Medicare, as opposed to CLIA. Under the Social Security Act, laboratories not in compliance with the requirements would be subject to suspensions or denial of Medicare payments and subsequently would be provided an opportunity for a hearing. In accordance with CLIA '88, laboratories that do not comply with the requirements would be notified of the basis of the noncompliance determination and offered an opportunity for a hearing prior to the revocation, suspension, or limitation of their certificates unless HHS determines that the laboratory constitutes an imminent and serious threat to human health. The statutes differ with respect to hearing procedures ostensibly because suspension or termination of Medicare payments would not affect the laboratory's ability to provide services for non-Medicare patients whereas suspension or revocation of a CLIA certificate would preclude a laboratory from the performance and reporting of any tests on human specimens.

Current regulations contain differing personnel requirements based on the laboratory location. We propose to establish personnel requirements based on the levels of complexity of testing performed by a laboratory.

In response to our proposed rule of August 5, 1988, most of the 1600 commenters offered recommendations on proficiency testing and personnel. We received relatively few comments on the quality assurance subpart. We would assume from the small response that the quality assurance section was acceptable to commenters; therefore, the proposed changes were adopted in the final rule of March 14, 1990. This same subpart appears in this proposed rule for CLIA '88. We request review and recommendations from the public, particularly those who were not affected by the final rule of March 14, 1990.

Summary

A number of subparts of existing rules are proposed to apply to all laboratories, not just those participating in Medicare or Medicaid or subject to CLIA '67. The proposed rule contains many current laboratory requirements now in part 493. We propose that compliance with applicable requirements of proficiency testing, patient test management, quality control, personnel, quality assurance and computer systems is essential for assuring that patient testing is accurate. The majority of laboratory testing requires equipment calibration, verification of reactivity of reagents, appropriate facilities including acceptable temperatures and humidity for testing, interpretation and judgment in processing and testing of specimens. All these variables must be checked and verified during the testing activity to assure quality results. The minimum Federal requirements published in the final rule of March 14, 1990, specify the types of activities that a laboratory should perform to assure accurate test results. Laboratories that were previously not subject to these requirements but perform testing that is not simple or low risk should comply with these requirements to assure quality test results, regardless of the site or size of the facility. Exempted from these requirements would be those laboratories that perform only tests that HHS determines qualify as waiver tests. All other laboratories would be subject to the applicable requirements in part 493. Detailed explanation of these requirements adopted from the **Federal Register** of March 14, 1990 is found in the preamble to the final rule. We are soliciting comments on their applicability to those laboratories made subject to regulation by CLIA '88.

Effective Date

Generally, the provisions of CLIA '88 implemented in these regulations are effective January 1, 1990. Section 353(f)(1)(c), which concerns personnel qualifications, and section 353(g)(2), which concerns certain aspects of inspections, are effective July 1, 1991 for those laboratories not subject to CLIA '67 on December 31, 1988. Other provisions including certain inspection requirements; intermediate sanctions; suspension, revocation and limitation; injunctions; judicial review; sanctions; and fees are effective January 1, 1989. In

implementing CLIA '88, we propose to issue to laboratories not subject to CLIA '67, provisional certificates, effective for a period of two years.

V. Provisions of the Regulations

In consolidating laboratory provisions in part 493, we would make numerous technical and conforming changes to parts 405, 416, 440, 482, 483 and 488. We would note that § 405.1128, which concerns laboratory services for skilled nursing facilities, was altered by regulations published February 2, 1989 at 54 FR 5316, Requirements for Long Term Care Facilities. Section 405.1128 is effective until October 1, 1990, the effective date of the February 2 regulations, after which the contents of § 405.1128 will be found in § 483.75 (l) and (m).

Subpart A General Provisions

Section 493.1 Basis and Scope

In existing § 493.1, Basis and scope, we would specify that all laboratories as defined under "laboratory" in § 493.2, Definitions, are now subject to the requirements specified in part 493.

However, this rule would not apply to any laboratory or component or function of a laboratory that maintains a valid certification by the National Institute on Drug Abuse for the performance of forensic urine drug testing. The laboratories subject to CLIA '88 certification provisions on January 1, 1990, include, but are not limited to the following entities that perform test procedures or examinations:

- Accredited hospital-based facilities;
- Nonaccredited hospital-based facilities;
- Federal hospitals, such as military, Veterans Administration and Public Health Service hospitals;
- Independent laboratories;
- Critical care units;
- Physician office laboratories;
- Skilled nursing facilities;
- End stage renal disease facilities;
- Intermediate care facilities, including intermediate care facilities for the mentally retarded;
- Laboratories associated with tissue banks and tissue repositories;
- Ambulatory surgical centers;
- Rural health clinics;
- CAP Accredited, New York State Approved, and low volume exempt laboratories;
- Industrial laboratories that monitor employee health and test for drugs of abuse;
- Insurance company laboratories;
- City, State and county laboratories;
- Federal clinics; and
- All other facilities that perform laboratory tests such as Planned Parenthood clinics, mobile laboratories, drug screening laboratories, and health maintenance organizations and any other facility including pharmacies and health fairs that perform quantitative, qualitative or screening test procedures or examinations.

However, laboratories that perform research testing on human specimens, but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patient are exempt from the CLIA '88 regulations.

Section 493.2 Definitions

We have added a definition for the term "analyte" as it had been used frequently in the final rule of March 14, 1990 and we inadvertently omitted it in that rule.

Also included is the definition of "screening test." This term is used to distinguish waivered tests and some level I tests from more complex procedures.

Section 493.3 Applicability

In § 493.3, Applicability, we would restate the CLIA '88 requirement that any laboratory, as defined in § 493.2, may not perform tests on materials derived from the human body unless the laboratory has a certificate issued by HHS applicable to the category of procedures performed by the laboratory. This is specified in the law under certificate requirements. Under section 6141 of OBRA '89, the Social Security Act was amended to require that Medicare laboratories meet the CLIA '88 certification requirements.

While we have always required laboratories to identify and perform only the test for which the laboratory is approved and propose to continue to do so in this regulation, we are interested in receiving comments on whether we should consider some mechanism to permit physicians to conduct testing not included on the laboratory's certificate when the test is essential to emergency patient care or emergency treatment.

Since the tests would not be included on the laboratory's certificate, the laboratory would not be evaluated for compliance with the CLIA requirements for these tests. We would ask commenters to respond to these following questions.

What criteria should be developed to allow emergency testing when appropriate while providing assurance that these emergency tests are conducted in a manner to ensure quality results?

Should we require prior notification for approval of those laboratories that may need to perform emergency tests not included on their certificates?

Should we specify the tests that could be performed in emergency situations although not included on the laboratory's certificate?

How would we prevent physicians from using the emergency test authorization to bypass the regulatory requirements?

What are the circumstances that would require a physician to perform an emergency test for which the laboratory is not certified or for which access to a certified laboratory is not possible or feasible?

Section 493.10 Categories of Tests by Complexity

In § 493.10, Categories of tests by complexity, we propose to establish three levels of tests by complexity: certificate of waiver tests as defined in § 493.15; level I tests as defined in § 493.20; and level II tests as defined in § 493.25.

We propose only one certificate would be issued to a laboratory. This certificate would indicate the testing a laboratory performs. As such, laboratories performing only certificate of waiver tests would be issued a certificate of waiver; if the laboratory performs one or more tests not on the list of waivered tests, it would be issued a certificate. The certificate would reflect the complexity of tests the laboratory performs and would reflect testing performed in the waiver, level I or level II categories or any combination of complexity of testing. For example, if a laboratory performs certificate of waiver, and level I and level II tests, the certificate would specify Certificate of Waiver, level I including appropriate specialties/subspecialties and level II including appropriate specialties/subspecialties. Regardless of the combination of tests performed by a laboratory, level II standards will be applied only to level II testing, level I standards will be applied only to level I testing and no standards under section 353(f) of the PHS Act will be applied to certificate of waiver testing.

HHS has designated the PHS, specifically the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA), as the components within PHS responsible for providing scientific expertise in the evaluation of tests and methodologies as they relate to the provisions of certificate of waiver and testing complexity. Beyond certificate of waiver tests, which are not subject to regulation, we propose two levels of test complexity (level I and level II) that

would be subject to a standards enforcement program.

The tests proposed for the certificate of waiver and level I lists were selected after an extensive review of existing State licensure requirements and comments from voluntary professional organizations. Test classification was based upon specific criteria outlined in our discussion of §§ 493.15 and 493.20, respectively. Twenty-eight tests are proposed as tests qualifying for certificate of waiver. These are simple tests which we would propose as procedures that pose no reasonable risk of harm to the patient even if the test is performed incorrectly. Eleven tests are proposed for Level I testing complexity. We would propose that these tests are relatively simple to perform but there may be a reasonable risk of harm to the patient if they are performed incorrectly.

We recognize that a number of tests which can be performed by use of diagnostic medical devices deemed Class I or Class II under the Food and Drug Administration's (FDA) regulatory process will not be classed as waivered or level I tests under these proposed rules. This may be the case even for some relatively simple and reliable Class I in vitro diagnostic medical devices. (Class I is the FDA category for devices which, because they present little or no hazard to the patient, are subject to only general regulatory controls such as labeling requirements, reporting of adverse experiences, and good manufacturing practices.)

We believe it appropriate that many devices regulated under Class I or II standards be subject to the Level I or II laboratory requirements as proposed. The FDA mandate and regulatory effort have a different and narrower focus than does the legislation underlying these proposed rules. The FDA process is intended to assess a device when used according to the manufacturer's instructions, i.e., the assessment is based on information provided by the manufacturer. And, as the criteria above reflect, we feel that the technology is only one important factor in the overall quality of the testing process. Many contextual factors, such as the adequacy of the sample size, whether the device has been misused or maintained correctly, the skills of the person operating the machine or using the device, and the clinical context, will also affect the accuracy and reliability of tests.

Thus, we do not feel a one-on-one comparison between the FDA Class I category and the waiver category of this rule can be made.

In order to accommodate emerging technology, advances in instrumentation, new test methodologies, and changing clinical needs, we propose the creation of a technical advisory committee. This group would be comprised of individuals representing the providers and users of laboratory services and would have the responsibility for making recommendations to HHS. We propose that this committee have the following functions:

(1) An ongoing review of test complexity criteria;

(2) The periodic review of requests for test classification or reclassification; and

(3) The periodic review of quality control/quality assurance standards for Level I and Level II test performance.

Tests that involve a new methodology or new instrumentation will be considered Level II tests until the Technical Advisory Committee has evaluated the new tests and HHS makes a decision on the appropriate level of test complexity for publication in the **Federal Register**.

We are interested in receiving comments on this proposed review process.

Section 493.15 Laboratories Performing Certificate of Waiver Tests

In § 493.15, laboratories performing certificate of waiver tests, we would establish the requirements that a laboratory must meet to qualify for a certificate of waiver, including a list of proposed tests that may be performed by these laboratories.

As specified in section 353(d)(3) of CLIA '88, we considered the following criteria in the proposed selection of tests qualifying for certificate of waiver:

(1) No reasonable risk of harm to the patient if the test is performed incorrectly, such as tests which are used to detect non-pathologic conditions, tests which are not used as the only indication of underlying disease, or tests used in situations which do not usually require immediate clinical intervention and are generally followed-up with more specific testing or medical evaluation;

(2) The likelihood of erroneous results is negligible;

(3) Simplicity of testing method. Tests do not usually involve complicated instrumentation; calibration; extensive quality control; reagent preparation; multiple steps, or environmental control. In addition, they are characterized by stable test systems which have minimal or no calculations, require a minimal degree of independent judgment, a minimal degree of interpretation, minimal or no patient preparation, minimal or no sample preparation, and minimal training and experience; and

(4) Availability of home use methodology.

Note: Some home use tests may not meet all the criteria for certificate of waiver. Although CLIA '88 refers to tests which "have been approved by the FDA for home use, "the FDA uses the 510(k) process under the Medical Device Amendment of 1976 to clear products to market as "substantially equivalent," and the pre-market approval (PMA) process to evaluate products as safe and effective prior to marketing. To date, FDA has not approved through the PMA process any device for home use in as much as those in vitro diagnostic tests currently available for home use are pre-amendment devices which were cleared to market by the 510(k) process.

Laboratories performing certificate of waiver tests would not be subject to the requirements in the regulations for proficiency testing, patient test management, quality control, personnel, quality assurance, routine inspections or computer systems. Thus a laboratory issued a certificate of waiver would not need to meet requirements of subparts H, J, K, L, M and P of these rules. However, these laboratories would be subject to random inspections to verify that only certificate of waiver tests are performed, to investigate complaints, and to collect information for the addition, deletion, or continued inclusion of tests on the waiver list.

The concept of waivered tests should not be misconstrued to mean that these tests are "foolproof," or that the person performing the test need not adhere to the basic tenets of quality control and quality assurance. It only means that these tests, because they have met the criteria outlined above, are exempt from Federal regulation.

We are interested in receiving recommendations for tests that should be added, or deleted and the reasons for the recommendation.

The laboratory may only perform and report tests or examinations that are specified as a waivered test in § 493.15 of these regulations.

Laboratories issuing a certificate of waiver would be required to report to HHS within six months any deletions and/or changes in the test methodologies for which a certificate of waiver is issued. Prior to performing a non-waivered test or examination, the laboratory must notify HHS to upgrade its certificate of waiver to a certificate for the performance of level I or level II tests.

Section 493.20 Laboratories Performing Level I tests

To be certified for performance of level I tests laboratories must limit test performance to those tests listed under

certificate of waiver provisions in § 493.15 and one or more of the tests listed in § 493.20.

Eleven tests are proposed as tests to be classified as level I tests. The following criteria listed in priority order were used to classify these tests:

1. There may be a reasonable risk of harm to the patient if the test is performed incorrectly;

2. The risk of erroneous results is present, but is minimized because testing methodologies are not complex and are characterized by: few steps, previously prepared or minimal reagent preparation, equipment which requires few operational steps (minimal interaction between operator and equipment), is easy to maintain and troubleshoot, minimal calibration requirements—testing systems are often self-calibrated, quality control materials which are readily available, and limited analyst interpretation;

3. Test performance involves the exercise of some independent judgment and a basic knowledge of the method, instrumentation, and interpretation of data, but decision making is less complex because options for action steps are few and are well characterized; and

4. Interpretation of test results requires knowledge of a limited number of factors which can influence test results.

We are interested in receiving recommendations for tests that should be added, or deleted from the list of level I tests and the reasons for the recommendation.

We would require that laboratories performing level I tests, regardless of their setting must meet the applicable requirements of subparts G, H, J, K, L (for level I tests), M, N, and P of these regulations.

The proposed personnel standards in subpart L for laboratories performing level I tests will permit the director (who would be qualified under current requirements as an M.D., D.O., or Ph.D. or qualified under State law or "grandfather" provision) to select and train his or her analysts. Analysts will not be required to have baccalaureate degrees, but rather may be high school graduates or the equivalent. We understand that these requirements may exceed those in existing physician office and hospital-based settings. In particular, we are interested in receiving comments and data describing additional benefits and costs that may result from these new standards and alternative personnel standards that would most effectively achieve the CLIA '88 objectives.

Section 493.25 Laboratories Performing Level II Tests

We would define laboratories performing level II tests as those facilities performing one or more tests not included in the certificate of waiver or level I test list. The following criteria were used to classify level II tests:

(1) There is a reasonable risk of harm to the patient if the test is performed incorrectly and for some tests this risk is substantial;

(2) The risk of erroneous results is substantial because testing methodologies are often complex, usually involving multiple steps and are characterized by: complicated reagent preparation or the requirement for special reagents; equipment which requires multiple operational steps (maximum operator-equipment interaction), complicated/extensive maintenance, and troubleshooting; calibration requirements which may be extensive and require operator intervention; quality control which may require special materials and analyst interpretation;

(3) Test performance involves the exercise of independent judgment and decisions may require a comprehensive understanding of the method, instrumentation, physiology, interpretation of data and clinical significance of the result;

(4) Interpretation of test results requires knowledge of the myriad factors which can influence test results, including: Preanalytic, analytic and postanalytic variables; and

(5) Training is required prior to performing level II testing. In addition to more extensive procedure specific training (reflecting the greater complexity of level II testing) it includes training in all aspects of the total testing process.

Regardless of their setting, we would require that laboratories performing Level II tests comply with the applicable requirements of Federal, State and local laws, proficiency testing, patient test management, quality control, personnel, quality assurance, inspections and computer systems. However, we are soliciting public comments on whether there are specific additional in vitro diagnostic medical devices which should be subject to the lesser requirements of the Waiver or Level I category, rather than Level II.

§ 493.30 Determination of Test Levels and Waiver Requirements

We will establish a technical advisory committee to make recommendations to HHS on test complexity criteria and the periodic review of requests for test classification or reclassification as a waivered or level I test. Also, we would use the technical advisory committee to evaluate the appropriateness of applicable requirements of proficiency testing, patient test management, quality control, personnel, quality assurance, and computer services for Level I and Level II tests. This committee would be comprised of technical professionals representing both the providers and users of laboratory services and would meet on at least an annual basis. Following the publication of a final rule, individuals or organizations may submit to HHS in writing, requests for test classification or reclassification. These requests must include the following information:

- Name of analyte or test;
- Precise methodology to be employed;
- Degree of independent judgement involved by the individual performing the test;
- Amount of interpretation involved by the individual performing the test;
- Difficulty of the calculations involved;
- Calibration and quality control requirements of test methodology, including instrumentation or equipment used;
- Availability of quality control material;
- Number of reagents and difficulty of preparation of reagents;
- Stability of test systems;
- Patient preparation involved;
- Sample preparation involved;
- Amount of interaction between operator and instrumentation or equipment is operator dependent;
- Factors that can influence test results;
- Specific training required to perform the test or examination, including the operation of the instrumentation or equipment used in the test methodology;
- The specificity, sensitivity, accuracy and precision of the test or the examination and/or methodology;
- Risks to the patient if clinical intervention is initiated based on the results of an incorrectly performed or interpreted test;
- Data to support the validity, accuracy, and reliability of the test when used as intended;
- Intended use of the results; and
- Other factors that HHS may define.

We will develop fuller protocols when the regulation is implemented.

We invite comments regarding additional information necessary for review.

Subpart B—Certificate of Waiver

Section 493.35 Application for a Certificate of Waiver

We would require that all laboratories, performing only certificate of waiver tests, file a separate application for each laboratory location. The application must be filed on a form prescribed by HCFA and signed by the owner or an authorized representative of the laboratory. As required by section 353(d)(l)(A) of the PHS Act, the application must also describe the characteristics of the test procedures or examinations performed by the laboratory including: The total number and types of laboratory tests and examinations performed; the methodologies for laboratory procedures and examinations employed and the qualifications of the personnel directing and supervising the laboratory and performing the tests. As also required by the PHS Act, the laboratory must agree to make records available and submit reports to HHS, as necessary.

Additionally, we would require that laboratories performing certificate of waiver tests permit unannounced inspections by HHS, as discussed below, on a random basis to verify that they are performing only those tests specified on the waiver list in § 493.15, to collect information for the addition, deletion, or continued inclusion of tests on the waiver list, to evaluate complaints from the public, and to investigate, when HHS has substantive reason to believe that testing is being performed in a manner that constitutes a hazard to patient health and safety.

In § 493.37, Requirements for certificate of waiver, we would indicate that for HHS to issue a laboratory a certificate of waiver, the laboratory must meet the general application requirements as well as the specific certificate of waiver application requirements and pay the fee specified by HHS for certificate of waiver. It should be noted that laboratories performing only certificate of waiver tests would not be issued provisional certificates because these laboratories would not be subject to requirements and HHS would not need to determine compliance with the requirements of subparts G, H, J, K, L, M, and P. After issuance of a certificate of waiver, we would require laboratories, in accordance with § 493.39: to notify HHS before performing and reporting any test not listed as a waiver test in § 493.15; within six months of any deletions or changes in test methodologies; and within thirty days of all changes in ownership, name and location. In addition, we would propose that laboratories issued a certificate of waiver permit unannounced inspections by HHS:

(1) When HHS has substantive reason to believe that testing is being performed in a manner that constitutes a hazard to patient health and safety;

(2) To evaluate complaints from the public;

(3) On a random basis to determine whether the laboratory is performing non-waivered tests; and

(4) To collect information for the addition, deletion, or continued inclusion of waivered tests.

We believe that certificate of waiver laboratories, while exempted from routine inspections under section 353(d)(2)(C) of the PHS Act, are nevertheless subject to extraordinary inspections in these four specific areas through our enforcement authority contained in section 353(i) of the PHS Act. This section reserves to the Secretary the right to make reasonable requests to inspect a laboratory's operations if there is cause to question whether the laboratory is operating in a lawful and safe manner. While subsection (i) speaks to certificates, it is clear from sections 353(b) and (c) of the PHS Act that this term encompasses certificates of waiver as well. Such inspections would not be routine. Indeed, as a routine matter, certificate of waiver laboratories would not be subject to any inspections as the statute provides. We do not believe, however, that Congress wished to allow any laboratory to operate in a hazardous or otherwise unlawful manner and be beyond the reach of the statute to account for such conduct.

If the laboratory fails to meet the requirements for certificate of waiver, we would propose that the laboratory's certificate of waiver be suspended, revoked, or limited in conformance with procedures in subpart O, which are to be established through another rulemaking. Also, failure to meet the certificate of waiver requirements would result in a laboratory losing its Medicare approval and payments under Medicare would be suspended or denied. Ordinarily, a certificate of waiver would be valid for no more than two years. However, in the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke or suspend the laboratory's certificate of waiver. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing, we would extend the expiration date of the certificate of waiver until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health. In any case, Medicare payments would be suspended or denied pending a hearing decision.

Section 493.41 Requirements for a Renewal Application for a Certificate of Waiver

To renew a certificate of waiver, we would provide that a laboratory must complete and return a renewal application to HHS not less than 9 months or more than 1 year before the expiration of the certificate of waiver. The requirements for renewal are the same as the application requirements in §§ 493.35 and 493.37.

We would require the laboratory to remit the certificate of waiver fee and agree to permit unannounced inspections by HHS on a random basis to verify that they are performing only those tests specified on the waiver list in § 493.15, to collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15, evaluate complaints from the public and when HHS has substantive reason to believe testing is performed in a manner that constitutes a hazard to patient health and safety. If we determine that a laboratory does not meet the requirements and we do not grant a waiver, we would notify the laboratory in writing of the basis for denial, and offer an opportunity for a hearing in accordance with part 498.

Subpart C Provisional Certificate and Certificate

Under § 493.43, Requirements for initial application for provisional certificate and certificate encompassing Level I or Level II test performance or both, we would require that all laboratories performing level I or level II tests, or both, file a separate application for each laboratory location. The application must be filed on a form prescribed by HCFA, and signed by the owner or an authorized representative of the laboratory. In addition, the application, in accordance with section 353(d)(1)(A) of the PHS Act, must also describe the characteristics of the test procedures or examinations performed by the laboratory including; the total number and types of laboratory tests and examinations performed; the methodologies for laboratory procedures and examinations employed and the qualifications of the personnel directing and supervising the laboratory and

performing the tests. As required by CLIA '88, the laboratory must agree to make records available and submit reports to HHS, as necessary.

Section 493.45 Provisional Certificate Requirements.

A provisional certificate is a temporary certificate that is valid for no more than two years, which gives laboratories time to comply with CLIA '88 regulations and gives HHS sufficient time to determine laboratory compliance with the regulations prior to the expiration of the provisional certificate. HHS would reissue a provisional certificate to any laboratory that HHS or its designee has not determined compliance prior to the expiration date of the provisional certificate. We intend to use provisional certificates because of the practical impact of the different effective dates for the various elements of CLIA '88. Specifically, Congress has mandated that effective January 1, 1990 laboratories will be subject to certification requirements set forth at section 353 (b) and (c) of CLIA '88. In theory, issuance of a certificate under CLIA '88 reflects a judgment by HHS that a laboratory has provided satisfactory assurance that it will meet the substantive requirements set forth in CLIA and that it will accede to the inspection requirements of the statute. As the substantive requirements of CLIA '88 are being implemented through this rulemaking, and because HHS has no authority under CLIA '88 to perform inspections for purposes of determining compliance with CLIA '88 requirements until July 1, 1991 for laboratories not subject to CLIA '67 on December 31, 1988, it will be impossible for HHS to determine anything more than simple facial compliance with the statute's application requirements at the time certificates are issued.

Thus, while laboratories need to have CLIA certificates in order to operate lawfully, laboratories are not in a position to represent now that they will comply with the requirements imposed by HHS under subsection (f), which are the subject of this proposed rule, and HHS is without authority to inspect most laboratories for compliance with subsection (f) requirements until July 1, 1991. As a result, certificates will be issued in provisional form to allow laboratories to test until HHS can establish standards under CLIA '88 and inspect laboratories for compliance with these standards. Following the complete implementation of CLIA '88 through publication of the final rule, we intend to maintain the provisional certification in order to allow "new" laboratories to operate initially until an inspection can be conducted. A laboratory, therefore, holding a provisional certificate cannot assign any significance to its issuance insofar as it might represent a determination that the laboratory meets statutory requirements. We propose in § 493.45, that all laboratories performing level I and level II tests not currently licensed or exempt from licensure under CLIA '67 on December 31, 1988 will be issued a provisional certificate by HHS provided that the laboratory submits the appropriate information specified under the application section. Prior to issuance of a provisional certificate, we would require each laboratory to: (1) Comply with § 493.43, Requirements for application for provisional certificate; (2) Agree to treat PT samples as it would treat patient specimens; and (3) Achieve a satisfactory score for one testing event in an approved PT program in the applicable specialty or subspecialty for each test or examination it performs. Before the provisional certificate expires, the laboratory must demonstrate satisfactory performance in three consecutive proficiency testing events for each test or examination included in a proficiency testing program approved by HHS, remit the fee specified by HHS, and submit to HHS an application for a certificate from nine to twelve months before the provisional certificate expires. In addition, an on-site inspection will be conducted to determine compliance with the applicable requirements of Federal, State and local laws, proficiency testing, patient test management, quality control, quality assurance, inspections, personnel requirements and computer systems. HHS would not issue a certificate to any laboratory unless the laboratory demonstrates compliance with the applicable requirements. Therefore, if HHS or its designee has not conducted a compliance determination prior to the expiration of the provisional certificate, the provisional certificate would be reissued.

A certificate would be valid for no more than two years. However, in the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke, suspend, or limit the laboratory's certificate. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing, we would extend the expiration date of the certificate until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health. In any case, Medicare payments would be suspended or denied pending a hearing decision.

Section 493.47 Requirements for Initial Application for Certificate

In this section, we would provide that laboratories performing Level I or Level II tests, or both, meet the application requirements in §§ 493.43 and 493.45, Provisional certificate, if applicable, and permit unannounced inspections:

(1) To determine compliance with applicable requirements in subparts G, H, J, K, L, M, N, and P;

(2) To evaluate complaints from the public;

(3) When HHS has substantive reason to believe that the laboratory is performing any test, including those listed in § 493.15, in a manner that constitutes a hazard to patient health and safety; and

(4) To collect information for the addition, deletion, or continued inclusion of tests on the waiver and Level I lists.

If we find that the laboratory does not meet the requirements for a certificate, in whole or in part, we would notify the laboratory in writing of the basis for the denial, and offer an opportunity for a hearing in accordance with procedures in part 498.

In § 493.49, Requirements for a certificate, we would specify that laboratories not subject to CLIA '67 on December 31, 1988 meet the applicable requirements in § 493.45 to obtain a provisional certificate. Laboratories subject to CLIA '67 on December 31, 1988 need not obtain a provisional certificate. We would require that laboratories meet the general application requirements of § 493.43 and the specific application requirements of §§ 493.47 and 493.45, as applicable, and would be issued a certificate provided compliance is achieved with the applicable requirements of subparts G, H, J, K, L, M, N, and P. We propose that laboratories issued a certificate must comply with the notification requirements of § 493.51 to notify HHS prior to performance of any test not included on its certificate. If the laboratory performs only certificate of waiver and level I tests, we would require the laboratory to notify HHS prior to performing and reporting any test not included as a waiver test or in the Level I specialty and subspecialties listed on the laboratory's certificate or any Level II tests. For laboratories performing one or more level II tests, we would require notification prior to the performance of any test or examination

not included as a waiver test or included in the specialties and subspecialties of service listed on the laboratory's certificate. We would specify that all laboratories issued a certificate must notify HHS within six months of any deletions or changes in test methodologies. We reach this conclusion because of the statute's clear direction (at section 353(b) of the PHS Act) that a laboratory "* * * may not solicit or accept materials * * * for laboratory examination or other procedure * * * unless there is in effect for the laboratory a certificate issued by the Secretary * * * applicable to the category of examinations or procedures which includes such examination or procedure." Thus, unlike changes in methodologies for a category of examination which a laboratory may report up to six months after the change, the authority to perform a new test is unequivocally limited by the laboratory's ability to timely obtain HHS approval of a revised certificate if the test is to be performed lawfully. For administrative efficiency, we would require laboratories to notify HHS within thirty days of all changes in ownership, name, location, director(s), and supervisor(s). We propose that laboratories issued a certificate would be subject to applicable requirements of subparts G, H, J, K, L, M, N, and P and would be required to permit unannounced inspections:

(1) To determine compliance with the requirements of Part 493;

(2) To evaluate complaints from the public;

(3) When HHS has substantive reason to believe that any tests are being performed in a manner that constitutes a hazard to patient health and safety; and

(4) To collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15 as waivered tests or § 493.20 as level I tests.

In the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke, suspend, or limit the laboratory's certificate. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing, we would extend the expiration date of the certificate until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health. In any case, Medicare payments would be suspended or denied pending a hearing decision.

In § 493.53, Requirements for a renewal application for a certificate, we would require that within 9 months to 1 year prior to the expiration of the certificate the laboratory apply for a new certificate. To qualify for renewal of a certificate, a laboratory must continue to meet the application requirements in §§ 493.43 and 493.47, remit the certificate fee and agree to permit unannounced biennial as well as random inspections in accordance with subpart N to determine compliance with the applicable regulations, to collect information for tests listed in §§ 493.15 and 493.20, to evaluate complaints from the public and when HHS has substantive reason to believe that any tests are performed in a manner that constitutes a hazard to patient health and safety. If HHS determines that a laboratory does not meet the requirements for certificate renewal, HHS would give the laboratory a written statement of the basis for the denial, and opportunity for a hearing to be conducted in accordance with part 498.

Subpart D—Certificate of Accreditation

Subpart D would not be effective until the requirements for recognition of an accreditation program or State licensure program (to be developed in a separate rulemaking) are published as a final rule, become effective and HHS has recognized an accreditation program or State licensure program.

After HHS recognizes an accreditation or State program under subpart E, laboratories may choose to meet the applicable requirements of subparts H, J, K, L, M, N, and P by becoming accredited by an accreditation program or licensed under a State program provided the laboratory obtains a certificate of accreditation in accordance with this subpart. Laboratories that are accredited by an approved accreditation program or licensed by an approved State program will be issued a certificate of accreditation in lieu of a certificate. A certificate of accreditation will be equivalent to a certificate.

Under § 493.55, Requirements for initial application for certificate of accreditation, we would require a laboratory performing one or more Level I or Level II tests to file a separate application for each laboratory location. The application must be filed on a form prescribed by HHS, and signed by the owner or authorized representative of the laboratory. In addition, the application for the certificate of accreditation in accordance with section 353(d)(1)(A) of the PHS Act, must describe the characteristics of the test procedures or examinations performed by the laboratory including: the number and types of laboratory tests and examinations performed; the methodologies for laboratory procedures and examinations employed and the qualifications of the personnel directing and supervising the laboratory and performing the tests. As required by CLIA '88, the laboratory must agree to make records available and submit reports to HHS, as necessary.

In § 493.57, we propose that all laboratories seeking certification through participation in an approved accreditation program or State licensure program would be issued a provisional certificate unless the laboratory holds a valid certificate issued by HHS for performance of one or more Level I or Level II tests or both. Laboratories would be issued a provisional certificate provided they comply with the initial application requirements specified in § 493.55, agree to treat proficiency testing specimens in the same manner as patient specimens, achieve satisfactory performance for one testing event in an approved PT program for each test or examination performed, and remit the provisional certificate fee specified by HHS.

Prior to expiration of the provisional certificate, the laboratory must achieve successful participation, as defined in subpart H, for three consecutive proficiency testing events in a proficiency testing program approved by HHS for each test or examination performed. In addition, the laboratory must file an application for a certificate of accreditation as specified in § 493.55 not less than 9 months nor more than 1 year before expiration of the provisional certificate and notify HHS with proof of its accreditation or licensure in an approved accreditation or State program.

In accordance with the provisions of CLIA '88, that will be implemented as part of a separate rulemaking and located in subpart O, HHS would initiate suspension, revocation or limitation of a laboratory's provisional certificate and would deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements for provisional certificate or application requirements for certificate of accreditation.

A provisional certificate is not renewable and would be valid for a period of no more than 2 years. If the approved accreditation program or State licensure program is unable to conduct an inspection to determine compliance with its requirements before the provisional certificate expires, the

provisional certificate will be reissued for solely that period that is needed by the program to determine compliance with its standards. Laboratories that do not meet the requirementsfor application for certificate of accreditation in § 493.59 or the requirements of § 493.57 for provisional certificates would be issued a denial of the application for a certificate of accreditation. In this case, HHS would provide the laboratory with a statement of grounds on which the denial is based, offer an opportunity for a hearing as provided in part 498 and notify the laboratory if it is eligible for a certificate as described in subpart C.

In § 493.59, the requirements for application for certificate of accreditation are specified. We would require that all laboratories that perform Level I or Level II tests, or both, that are accredited by an approved accreditation organization or State licensure program meet the application requirements for a certificate of accreditation or the requirements for provisional certificate for new laboratories unless the laboratory already has a valid certificate issued by HHS. In order to meet the application requirements for certificate of accreditation, we would require laboratories to:

(1) Provide HHS with assurances that the laboratory would be operated in accordance with the accreditation or State program requirements;

(2) Agree to treat proficiency testing specimens in the same manner as patient samples;

(3) Authorize the accreditation or State licensure program to release to HHS the laboratory's proficiency testing results;

(4) Agree to permit random sample and complaint inspections as defined in subpart N;

(5) Allow HHS or its designee to monitor correction of any deficiencies identified in random sample or complaint inspections; and

(6) Authorize the accreditation program or State licensure program to release to HHS the laboratory's survey findings whenever HHS or its designee conducts random sample or complaint inspection surveys.

If HHS determines that the application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of the bases for denial of the application, and opportunity for a hearing as provided in part 498. If the laboratory is eligible for a certificate as described in subpart C, HHS will advise the laboratory.

In § 493.61, Requirements for a certificate of accreditation, we would specify that laboratories must meet the requirements of § 493.55, Application for certificate of accreditation, and if applicable, § 493.57, Requirements for a provisional certificate for laboratories. We would require the laboratory to pay the certificate of accreditation fee specified by HHS. We propose that laboratories must treat proficiency testing samples in the same manner as patient specimens; comply with notification requirements specified in § 493.63; meet the requirements of the accreditation or State licensure programs; permit random sample and complaint inspections by HHS or its designee; allow the State inspecting agency to monitor the correction of deficiencies found through the inspections; and authorize the accrediting body to release inspection findings to HHS.

In the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke, suspend, or limit the laboratory's certificate of accreditation. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing, we would extend the expiration date of the certificate of accreditation until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health. In any case, Medicare payments would be suspended or denied pending a hearing decision.

We propose in § 493.63, Notification requirements for laboratories issued a certificate of accreditation, that laboratories performing one or more of the Level I tests or examinations listed in § 493.20 must notify the approved accrediting body and HHS before performing any test not included as a waiver test or included in the specialties and subspecialties listed on the laboratory's certificate or any Level II tests. Laboratories issued a certificate of accreditation must notify the accrediting or State licensure program within 6 months of changes or deletions of test methodologies of Level I or certificate of waiver tests; and within 30 days of any changes in ownership, name, director(s), or supervisor(s). For laboratories performing one or more Level II tests, we would require notification to the approved accrediting body and HHS, prior to the performance of any test or examination not included as a waiver test or included in the specialties and subspecialties of service listed on the laboratory's certificate of accreditation. In addition, we would specify that those laboratories performing Level II tests issued a certificate of accreditation must notify the accreditation program or State licensure program within 6 months of any deletions or changes in test methodologies and within 30 days of all changes in ownership, name, location, director(s), and supervisor(s).

In § 493.65, Requirements for renewal application for a certificate of accreditation, we would require that within 9 months to 1 year prior to the expiration of the certificate of accreditation, the laboratory apply for a new certificate of accreditation. To qualify for renewal of a certificate of accreditation, the request must meet the requirements of § 493.55, Requirements for application for certification of accreditation and § 493.59, Requirements for application for a certificate of accreditation. We propose that the laboratory: provide HHS with satisfactory assurances that the laboratory will be operated in accordance with the requirements of the accreditation or State licensure program; agree to treat PT samples as it treats patient specimens; authorize the approved accrediting body to release the results of the laboratory's PT samples; agree to allow random sample and complaint inspections; authorize the accrediting body to release inspection findings whenever HHS or its designee conducts random sample or complaint inspections; authorize the State inspection agency to monitor the correction of deficiencies found by the inspection; and remit the fee specified by HHS.

If HHS determines that a laboratory does not meet the requirements for renewal of a certificate of accreditation, HHS would give the laboratory a written statement of the basis for the denial, and opportunity for a hearing to be conducted in accordance with part 498.

Categories of Tests

At present, tests are categorized in various specialties and subspecialties for approval in Medicare and licensure under CLIA '67. In the August 5, 1988 rule, we proposed very few changes from the current specialty/subspecialty categorization of tests.

In response to our August 5, 1988 proposed rule, we received a large volume of correspondence requesting expansion and revisions to our categories of testing procedures. However, we determined that the final rule of March 14, 1990 would not include any revision to the current system of categorizing tests in Medicare, Medicaid and CLIA '67 in order to allow maximum

flexibility in evaluating test procedures or examinations under CLIA '88. We did indicate in the final rule published March 14, 1999 that we would consider suggestions and recommendations for changes in the system of categorizing tests.

Many individual commenters suggested the addition of new subspecialties and we are interested in the views of additional members of the public on possible additions. Among those suggested were a subspecialty for viral markers to be included under diagnostic immunology, the establishment of a separate subspecialty for HIV antibody testing, and hepatitis testing procedures. In the specialty of diagnostic immunology, one commenter suggested adding a subspecialty of "proteins important to immunology," to include the immunoglobulins and complements. One State recommended the creation of the following new subspecialties within toxicology: Drugs of abuse and blood alcohol; toxic metals including mercury, cadmium, arsenic, and other trace metals; blood lead and erythrocyte protoporphyrin; and maintain the subspecialty of therapeutic drug monitoring. Other requests from commenters included a division of hematology into the subspecialties of general hematology and coagulation, the addition of electrophoresis and blood gases as two separate subspecialties under chemistry, and dermatopathology identified as a subspecialty under pathology.

This proposed rule implementing the requirements for CLIA '88 provides an opportunity for comments from the public on the categorization of tests. We welcome commenters opinions on these suggested specialty and subspecialty revisions and any additional recommendations for alternative categories or divisions of existing specialties with documentation and information supporting the additions or revisions in test categories.

Subparts H—P

We are proposing that the requirements in subparts G through N, published in the final rule on March 14, 1990 apply to all laboratories not issued a certificate of waiver. Subparts G through N were previously applicable only to laboratories licensed under CLIA '67 and/or participating in Medicare, and would now apply to laboratories performing any Level I or II tests. We have added a new subpart P, Computer systems, and we would require all laboratories, performing one or more Level I or Level II tests or both, to comply with applicable requirements. We are soliciting comments on these provisions.

Subpart G

To the requirement for compliance with Federal, State and local laws, we would add to the standard of Fire Safety at § 493.770(d), a requirement that laboratories comply with the standards of the National Fire Protection Association (NFPA) to ensure protection from hazards related to fires and explosions. This will provide consistency among laboratories since laboratories located in nursing homes and hospitals are already subject to NFPA standards.

Subpart H

At § 493.803 (b) and (c) we have specified the consequences of unsuccessful participation in an approved PT program. If the laboratory fails to participate successfully for a specialty or subspecialty, we will initiate action to suspend, revoke, or limit the laboratory's certificate for performing Level I or Level II tests, or both, and Medicare approval will be cancelled for the specialty or subspecialty or intermediate sanctions will be imposed (see intermediate sanctions below). If the laboratory fails to perform successfully on a given analyte, the laboratory's Medicare approval will be suspended or cancelled, and action will be initiated to suspend, revoke, or limit its certificate for the specialty or subspecialty in which the analyte is categorized or the laboratory will be subject to intermediate sanctions.

Under CLIA '88, it is possible that intermediate sanctions may be imposed upon a laboratory in lieu of cancellation of Medicare approval and certificate suspension. The specific requirements for the implementation of intermediate sanctions will be made through a separate rulemaking.

Subpart I

In Subpart I we are including two items. In accordance with CLIA '88, at § 493.901, we propose that PT programs be private non-profit organizations or State programs and provide technical assistance to laboratories seeking to qualify under their program(s). To § 493.903 we have added the reason for proposing that approved proficiency testing programs provide HHS with cumulative reports on individual laboratories' performances; that is, to make the results of PT available upon request of any person.

We propose, at § 493.907 of this subpart, to add or delete tests for PT based on the tests' certificate of waiver status.

We are proposing to amend a number of paragraphs throughout Subpart I. As provided by CLIA '88, tests that are waivered would not be subject to proficiency tests. Therefore, we would delete from the proficiency testing program the tests that we propose as waivered tests. Specific changes can be noted as follows: at § 493.911, Gram stain sources for PT would not include discharges and exudates; at § 493.917, Enterobius vermicularis (pinworm) is excluded from parasitology PT samples; at § 493.927, qualitative tests for antistreptolysin 0, infectious mononucleosis, and rheumatoid factor are removed; at § 493.933, qualitative human chorionic gonadotropin on urine specimens is excluded; and the entire subspecialty of urinalysis has been deleted (previously § 493.939) and references to urinalysis in subparts H and K are also removed.

We are proposing as a waiver test a spun microhematocrit. At § 493.941 the "hematrocrit" test is listed as one of the tests requiring proficiency testing and includes only hematocrit procedures such as an electronically derived or calculated hematocrit or a macro hematocrit by the Wintrobe method.

Subpart K

With the exceptions described herein, the quality control requirements are the same standards as specified in the final rule published March 14, 1990. We are interested in receiving comments on the applicability of these proposed requirements to new technology.

To § 493.1203 we would add the requirement for Level I and Level II tests for adequate ventilation to ensure proper removal of toxic fumes and that air exhausted from areas in which infectious materials are handled is appropriately filtered before discharge into the atmosphere.

Also in § 493.1203, we are proposing to add a requirement for laboratories to have and maintain a stable electrical power source to assure that the testing equipment is not adversely affected by power surges.

To § 493.1211(a)(12) we propose to add to the procedure manual requirements that appropriate specimen storage criteria be included in each test procedure.

We propose, in § 493.1217(e), to specify the control system to be employed in electrophoresis procedures. This requirement allows laboratories to include only one control in each electrophoresis cell rather than include two controls with each test run. We also propose, at § 493.1249, for drug abuse

screening using thin layer chromatography, that each plate be spotted with at least one calibrator containing all drugs identified by the thin layer procedure and that at least one control be included in each chamber and processed through every step of patient specimen testing. At present, we have provided these exceptions for electrophoresis and thin layer chromatography in drug abuse screening to the control requirements in the State Operations Manual; therefore, the addition of these requirements will support current policy interpretations.

Concerns have been expressed about the need for confirmation of urine drug screening test results for drugs of abuse as well as for screening results for HIV–1 antibody. We request the public to consider and comment on the following statements that could be included in future regulations—

HIV–1 Antibody Testing

A reactive screening test for HIV–1 antibody must be followed-up with a more specific supplemental test, before issuing a final report.

Urine Drug Testing for Drugs of Abuse

A positive screening test for drug(s) of abuse must be followed up with a more specific confirmatory test, before issuing a final report.

In cytology we propose that the limit on the number of slides an individual may examine by nonautomated microscopic technique in a 24-hour period would apply to that individual's total screening activity, irrespective of site or laboratory. We would propose that each laboratory would have to require each individual to account for any slides he or she examined by nonautomated microscopic technique for another employer or laboratory. Each laboratory would have to maintain a record of the number of slides examined by an individual for another employer or laboratory. This proposed requirement would reflect the language of the Committee on Energy and Commerce on CLIA '88, (H.R. Rep. No. 899, 100th Cong., 1st Sess., 31 (1988)).

In response to our proposed rule published August 5, 1988 to revise the laboratory regulations, we received a number of comments suggesting that standardized nomenclature should be required for reporting Pap smear results. We determined that we should not institute such a requirement through a final rule without soliciting public comment; therefore, in the final rule published March 14, 1990, we did not specify that a standardized classification be employed to report cytology results. However, we believe that the variations in reporting schemes in cytology creates confusion in the interpretation of these reports for patient diagnosis and treatment. This was demonstrated through a contract awarded to the American Society for Cytotechnology (ASCT) for specialized reviews of cytology laboratories for the period of June 1988–June 1989. During the first year of the contract, the ASCT inspected 18 laboratories and noted that all 18 laboratories used the Papanicolaou system for reporting results; however, each laboratory used the Papanicolaou classification in a different way. To assure consistency and improve communication of diagnostic information between laboratories and physicians, we are considering requiring the Bethesda system listed below be used to report pap smear results. We are interested in receiving public comment on the benefits and detriments of such a requirement.

The 1988 Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses

Format

It is recommended that a cervical/vaginal cytopathology report address each of the following elements:

(a) A statement on adequacy of the specimen for diagnostic evaluation;

(b) A general categorization of the diagnosis (within normal limits or other); and

(c) The descriptive diagnosis.

The format and terminology recommended for each of these three elements are presented below.

Statement of Specimen Adequacy

Satisfactory for Interpretation
Less Than Optimal
Unsatisfactory
Explanation for Less than Optimal/Unsatisfactory
—Scant cellularity
—Poor fixation or preservation
—Presence of foreign material (e.g. lubricant)
—Partially or completely obscuring inflammation
—Partially or completely obscuring blood
—Excessive cytolysis or autolysis
—No endocervical component in a premenopausal woman who has a cervix
—Not representative of the anatomic site
—Other

General Categorization

Within normal limits
Other:
See descriptive diagnosis
Further action recommended

Descriptive Diagnoses

Infection

Fungal
- Fungal organisms morphologically consistent with Candida sp.
- Other

Bacterial
- Microorganisms morphologically consistent with Gardnerella sp.
- Microorganisms morphologically consistent with Actinomyces sp.
- Cellular changes suggestive of Chlamydia sp. infection, subject to confirmatory studies
- Other

Protozoan
- Trichomonas vaginalis
- Other

Viral
- Cellular changes associated with Cytomegalovirus
- Cellular changes associated with Herpes simplex virus
- Other

(Note: for human papillomavirus (HPV) refer to "Epithelial Cell Abnormalities, Squamous Cell")

Other

Reactive and Reparative Changes

Inflammation
- Associated cellular changes
- Follicular cervicitis

Miscellaneous (as related to patient history)
- Effects of therapy
- Ionizing radiation
- Chemotherapy
- Effects of mechanical devices (e.g. intrauterine contraceptive device)
- Effects of non-steroidal estrogen exposure (e.g. diethylstilbestrol)
- Other

Epithelial Cell Abnormalities

Squamous Cell
- Atypical squamous cells of undetermined significance (recommend follow-up and/or type of further investigation: specify)
- Squamous intraepithelial lesion (SIL) (comment on presence of cellular changes associated with human papillomavirus (HPV) if applicable)
- Low grade squamous intraepithelial lesion, encompassing:
- Cellular changes associated with HPV Mild (slight) dysplasia/cervical intraepithelial neoplasia grade 1 (CIN 1)
- High grade squamous intraepithelial lesion, encompassing:
- Moderate dysplasia/CIN 2
- Severe dysplasia/CIN 3
- Carcinoma in situ/CIN 3
- Squamous cell carcinoma

Glandular Cell
- Presence of endometrial cells in one of the following circumstances:
- Out of phase in a menstruating woman
- In a post-menopausal woman
- No menstrual history available
- Atypical glandular cells of undetermined significance (recommended follow-up and/or type of further investigation: specify:)
- Endometrial
- Endocervical
- Not otherwise specified
- Adenocarcinoma
- Specify probable site of origin: endocervical, endometrial, extrauterine
- Not otherwise specified
- Other epithelial malignant neoplasm: specify

Non-Epithelial Malignant Neoplasm: Specify

Hormonal Evaluation (Applies to vaginal smears only)

Hormonal pattern compatible with age and history
Hormonal pattern incompatible with age and history
Specify:
Hormonal evaluation not possible
Cervical specimen
Inflammation
Insufficient patient history
Other

Explanatory Notes

The following comments are provided as explanatory notes to the Bethesda System for reporting cervical/vaginal cytologic diagnoses.

Statement of Specimen Adequacy

In The Bethesda System three possible responses are listed under the heading Statement of Specimen Adequacy:

(a) Satisfactory indicates the specimen is an adequate sample which can be interpreted without qualification.

(b) Less than Optimal indicates the specimen may provide useful diagnostic information but is less than optimal (for example, because of partially obscuring inflammation).

(c) Unsatisfactory indicates the specimen is not acceptable for diagnostic evaluation and repeat sampling may be warranted.

Use of the category Less than Optimal is optional.

An EXPLANATION should be provided for any specimen designated either Less then Optimal or Unsatisfactory. The Bethesda System includes the entry "No endocervical component in a premenopausal woman who has a cervix" to indicate that none of the following elements is present: (a) Endocervical cells, (b) endocervical mucus, or (c) squamous metaplastic cells.

The cytopathologist should recommend a repeat smear when reporting an "Unsatisfactory" specimen. For "Less than Optimal" specimens, the cytopathologist may choose to recommend a repeat smear or other follow-up.

General Categorization

The second element of the report format sorts reports (except the Unsatisfactory) to either: Within normal limits or Other. If Other is selected the report may include an additional notation if further action is recommended. The "General Categorization" is not a substitute for specific descriptive diagnoses, which can be included elsewhere in the report. Rather, it is to assist the referring physician and support personnel to sort cases for review and/or further action.

Descriptive Diagnosis

The final element of the recommended report format of the Bethesda System is the descriptive diagnosis which is largely self-explanatory as outlined. With the exception of two new terms, the others are in general use. However, a few points are clarified below.

A. Infection

The Bethesda System lists those infectious agents associated with cervical/vaginal disease whose presence can be suggested by cytologic examination. However, definitive diagnosis of some of these agents may require confirmatory studies. The qualifying phrases accompanying the identification of certain pathogens such as "fungal organisms morphologically consistent with Candida sp." reflect the level of diagnostic certainty by routine light microscopy alone. These phrases can be modified to suit the individual cytopathologist.

B. Epithelial Cell Abnormalities

1. Atypia.

The Bethesda System limits use of the term "atypical cells" to those cases in which the cytologic findings are of undetermined significance. "Atypia" should not be used as a diagnosis for otherwise defined inflammatory preneoplastic or neoplastic cellular changes.

To assist the referring physician, a report in which cells are described as "atypical" should include a recommendation for further evaluation that may help to determine the significance of the atypical cells.

2. Squamous intraepithelial lesion (SIL).

The only new diagnostic terms in the Bethesda System are Low grade squamous intraepithelial lesion and High grade squamous intraepithelial lesion. They encompass the spectrum of terms currently used for squamous cell precursors to invasive squamous cell carcinoma, including the grades of cervical intraepithelial neoplasia (CIN), the degrees of dysplasia and carcinoma in situ (CIS). "Grade", as used with SIL, does not connote invasive carcinoma.

While Low grade SIL and High grade SIL are preferred, use of these new terms does not preclude the addition of the degree of "dysplasia" or grade of "CIN" for cytopathologists who wish to retain these designations. For example, "low grade squamous intraepithelial lesion: cellular changes associated with human papillomavirus (HPV)," "low grade squamous intraepithelial lesion: mild dysplasia and cellular changes associated with human papillomavirus (HPV)," or "high grade squamous intraepithelial lesion: cervical intraepithelial neoplasia, grade 3 (CIN 3)."

The phrase cellular changes associated with human papillomavirus (HPV) is added to the report of either Low grade SIL or High grade SIL when appropriate. Cellular changes associated with HPV (without features of "dysplasia" or "CIN") may be used as a separate diagnostic phrase, although it is recommended that it be included under the designation of Low grade SIL. Terms such as "koilocytic atypia," "keratinizing atypia," and "dyskaryosis" are not included in the Bethesda System lexicon.

Developed and Approved at the National Cancer Institute Workshop in Bethesda, Maryland, December 12–13, 1988

At § 493.1257(j), we are proposing that the laboratory report the results of all premalignant and malignant gynecologic cases to its respective State health department. This would initiate and ultimately create an information bank from which laboratories may draw clinically useful Pap smear history to correlate findings from other laboratories on patients that their laboratory had not performed testing in the past.

Subpart L

The August 5, 1988 NPRM proposed uniform personnel standards for all CLIA '67 and Medicare/Medicaid laboratories. That proposal would have strengthened the personnel requirements in nursing homes and hospitals by adding requirements for supervision. We believed that any laboratory should employ at least one individual with supervisory credentials who would be on the premises when testing is performed. These requirements would have provided for maximum flexibility for the director to choose the laboratory staff except for cytology. Based on the comments received, it was apparent that many commenters did not realize that hospitals and nursing homes were required only to have a qualified laboratory director and were not required to employ personnel with specific training and experience to either supervise test performance or perform testing.

In view of the imminent implementation of the CLIA '88 requirements which require the establishment of personnel standards

based on test complexity, we determined that the final rule, published March 14, 1990, would retain the previously existing site specific personnel standards with only minimal changes.

This proposed rule, based on CLIA '88, for the first time would establish personnel requirements linked to the complexity of testing and risk of harm to the patient from an erroneous test result. Personnel standards would be site neutral and would not be applicable to laboratories possessing a certificate of waiver. We developed the personnel requirements to focus on the competency of individuals performing both Level I and Level II testing.

The approach we would take regarding personnel requirements is as follows:

Laboratories, performing less complex Level I tests, would have personnel requirements for the laboratory director and individual performing the testing. The director requirements would be essentially the same for Level I and Level II test performance. The director may serve as the technical and general supervisor. Since level I tests are less complex, the individual performing the testing could be a high school graduate or equivalent, provided the director assures that the individual has appropriate training commensurate with the testing performed. In addition, the director would be responsible for assuring that testing personnel are evaluated for competency on an ongoing basis.

We are proposing more stringent personnel standards for Level II test performance because testing is more complex. The director would be responsible for assuring that testing personnel have appropriate training and are evaluated for competency on an ongoing basis. A general supervisor would be required to be on the premises during all hours of testing in laboratories performing level II tests. Qualified supervisors would monitor performance through direct observation of the testing personnels' performance. Responsibilities are specified for the director, technical supervisor, general supervisor, technologist, technician, and cytotechnologist. The education, training, and experience required to qualify as a director, technical supervisor, general supervisor, technologist, technician, or cytotechnologist for laboratories performing Level II tests are based on the personnel requirements for independent laboratories, published in the final rule of March 14, 1990. However, the experience requirements for general supervisor would be reduced from six to three years. Currently, qualifications for laboratory personnel are based on location, stipulating director qualifications for all laboratories, but only addressing supervisor, cytotechnologist, technologist and technician qualifications for testing performed in independent laboratories. In accordance with the CLIA '88 mandate that personnel qualifications be based on test complexity, we are proposing minimum education, training, and experience requirements for individuals performing testing based on the complexity of tests performed and risk to patients. Based on the proposed proficiency testing specialty/subspecialty categories, we would establish specific requirements in § 493.1442 of this part for individuals performing tests in each specialty/subspecialty.

We are proposing that technicians with specific specialty/subspecialty training and experience are qualified to perform the majority of Level II laboratory tests. In cytology, microbiology, and immunohematology, in which testing involves independent judgment or when erroneous results are critical to patient health and safety, we would require personnel qualified as cytotechnologists and technologists, respectively.

The proposed requirements published August 5, 1988 contained the independent laboratory cytotechnologist requirements as the uniform personnel standards to be applicable to all laboratories offering cytology services. After November 3, 1988, the last day for responding to the proposed rule, we were notified by several individuals and professional organizations that the proposed requirements for cytotechnologists would not be met by some cytotechnologists currently working in hospitals. The independent laboratory requirements specified that individuals could qualify as cytotechnologists under one of the following three provisions: (1) An individual had to complete 2 years of college and have 12 months of training in cytotechnology; (2) Prior to January 1, 1969, an individual had to be a high school graduate and have completed 6 months of training in cytology in a laboratory directed by a physician or pathologist specialist in cytotechnology; or (3) An individual could have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS. Hospital laboratories were only subject to laboratory director requirements; therefore, individuals working in cytology laboratories in hospitals did not have to meet any Federal personnel qualification requirements.

The effect of applying the proposed requirements for cytotechnologists would be that individuals working in hospitals prior to 1969 who would have met the provision, could not now be qualified. In the final rule published March 14, 1990, we did not adopt the proposed uniform personnel requirements, but instead maintained the existing requirements based on location which had the effect of maintaining the status quo and not disqualifying individuals currently working in cytology laboratories in hospitals. Based on the mandate of CLIA '88, we must once again consider the establishment of uniform personnel requirements based on tests performed. Clearly cytology services require the same basic skills for slide preparation examination regardless of the laboratory location.

The proposed rule contains the current independent laboratory cytotechnologist qualification requirements which were published as a final rule because we have not decided on specific alternative standard(s) to the requirements. However, we are considering three options for qualifying cytotechnologists who do not meet the current independent laboratory requirements, and are seeking comments on the merits or disadvantages of each approach. One option would be to extend the July 1, 1969 period for qualifying individuals under appendix E. The second option would be to recognize an accrediting agency's credentials for qualifying cytotechnologists. The final option would be to approve an examination to be used to qualify cytotechnologists. Such examinations would be tested on a representative sample of individuals qualified by credential to determine the passing rate. We are interested in receiving comments and rationale on which option(s) would be preferable or alternative recommendations with supporting rationale for adoption of one or more options.

We are aware of concerns about overall personnel shortages in the laboratory testing field. Our proposed requirements for laboratories performing level I tests are not restrictive. We are proposing that certain level II tests, because they are less complicated, can be performed by technicians with specific specialty/subspecialty experience. Other level II tests can be performed by either a technician with specific specialty/subspecialty experience or a technologist. Only the most complex tests must be performed

by a technologist. Tests not currently included in the proficiency testing specialty/subspecialty categories can be performed by a technician with one year of experience in the subspecialty category or by a technologist until these tests have been appropriately classified through a formal review process.

The difficulty in addressing the issue of appropriate personnel requirements for the performance of laboratory testing is that there is at present, inadequate scientific information and data needed to guide policy development. Some studies have shown that for certain tests, especially those that are manual or require interpretation, proficiency testing performance is positively and significantly correlated with personnel education and experience. However, other studies have shown contradictory findings. Many of these studies have been criticized on the basis of methodologic shortcomings and limits to their capacity to be generalized. Nevertheless, it is the belief of many that certain kinds of laboratory tests, because of the difficulty in performing them and the sophistication required to interpret them, require an increased level of personnel education and experience.

The proposed standards for education and experience for directors, supervisors, and analysts are based on our best judgment and knowledge of laboratory practice. CLIA '88, in recognition of the absence of reliable information linking the performance of testing with specific personnel qualifications, requires PHS to study the relationship between personnel and test performance.

On a preliminary basis, we will attempt to evaluate existing information on personnel qualifications related to laboratory performance prior to publication of the final rule, and we specifically solicit any information or data commenters may have to assist in this analysis.

"Sec. 4 Studies" of CLIA '88 stipulates that "* * * the Public Health Service shall conduct studies of * * * (2) the correlation between established standards for personnel employed in clinical laboratories and the accuracy and reliability of the results or the tests performed by the laboratories which are subject to such standards * * *". The Department will be collecting information on the qualifications of personnel in clinical laboratories as part of the interim certification and fee procedures. We will use this information when the required study of personnel standards is conducted. We encourage comments from all affected individuals including specific recommendations and supporting benefit and cost data or information to assist with development of appropriate, reasonable, and cost-effective personnel requirements which assure quality patient testing.

Subpart N—Inspection

Section 493.1601 Condition: Inspection

Existing § 493.1601 provides that HHS may conduct an unannounced inspection of any laboratory at any time during its hours of operation. These inspections may include interviewing employees, observation of employees performing tests, data analysis and reporting of test results, and review of all records and data required by HHS to determine compliance with the requirements. Further, HHS may deny approval to a laboratory for at least one year for violation of any of the requirements in regulations at part 493. HHS may waive this one year period if the laboratory submits good cause for the waiver.

We propose to apply these same requirements to all laboratories under the authority of CLIA '88.

In the final rule published March 14, 1990, we specified that we would evaluate the methodology for conducting on site proficiency testing to enhance the survey process. In accordance with the requirement set forth in section 353(f)(3) of the PHS Act that on-site proficiency testing be conducted to evaluate mailed proficiency testing, we will select a sample of States which reflect regional characteristics in which a random sampling of laboratories will be chosen for the State survey agency to conduct unannounced onsite proficiency testing (PT) to compare laboratory performance of onsite PT with mailed PT. Following our evaluation, we will determine the feasibility of including onsite PT in the inspection process. The finalrule will specify the manner in which PT will be used to assess laboratory performance in accordance with section 353(f)(3)(D) of CLIA '88.

Failure to permit an inspection would result in revocation of a certificate of waiver, provisional certificate, certificate or certificate of accreditation, as applicable, in accordance with procedures to be specified in a separate proposed rule and will be located in subpart O. These requirements are found in §§ 493.1601, 493.1603, and 493.1605. Suspension or limitation of the operating certificate in such cases would be immediate as authorized by CLIA '88. In addition, for laboratories participating in Medicare, failure to permit an inspection would result in suspension or denial of payments.

In the new subpart P, Computer systems, we propose regulations for laboratories using any size computer system to assist in the performance of patient testing and identification of patient specific information for result reporting. In other parts of these regulations, we have regulated both computerized and noncomputerized recordkeeping and testing systems (e.g., by requiring accurate recordkeeping). However, we have proposed additional requirements specifically for computer systems, which are used very extensively in testing operation(s), recordkeeping, patient information collection, and access to records. We solicit comments on the necessity for and the content of this subpart. Addressed in this subpart are requirements for the computer system environment, operation of the computer, scheduled and unscheduled computer interruptions, computer programs, computer data entry, patient result reporting, data retrieval, computer security, and capacity.

In the past 10 to 15 years, an increasing number of laboratories have incorporated computer systems into their technical work areas and in many such laboratories, the patient identification as well as the testing and reporting of patient specimens is dependent upon the function of the computer it uses. We propose that laboratories of any size, using a computer to assist in the testing sequence, be able to demonstrate and assure that patient testing is ultimately reported accurately by a properly functioning system. Our proposed requirements are intended to minimize such computer related problems as: Unscheduled computer interruptions ("down time") due to electrical power variations, preventable hardware deficiencies, and preventable programming errors; unauthorized access to confidential patient information; performance of test(s) not ordered by the physician due to laboratory key punch errors from the original request; the release of test results before they are verified and, if appropriate, repeated or diluted; accidental entry and reporting of an incorrect result (clerical error during entry); interruption in the laboratory work flow or cessation of patient testing for an extended period of time until the system is repaired; or the computer is not of sufficient size or capacity to perform the functions specified by the laboratory for the provision of patient testing.

We are requesting comments from the public, particularly laboratories who are

familiar with computer systems for laboratory use, on any and all aspects of this new subpart.

VI. Regulatory Impact Statement

A. Introduction

Executive Order 12291 (E.O. 12291) requires us to prepare and publish a regulatory impact analysis for any notice that meets one of the E.O. 12291 criteria for a "major rule"; that is, that would be likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612) unless the Secretary certifies that a notice would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all independent, hospital-based, and physicians' office laboratories are treated as small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a notice may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital which is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

The purpose of this proposed regulation is to inform the public and to seek comments on the policy HCFA proposes to use in issuing certificates of waiver in accordance with sections 353(d) (2) and (3) of the PHS Act. Laboratories granted a certificate of waiver will be exempted from having to meet all Federal health and safety standards (including proficiency testing) required under the Clinical Laboratory Improvement Amendments of 1988 and implementing regulations, and will also be exempted from undergoing periodic inspections to determine if these standards are met. However, these laboratories would be subject to random inspections to collect data on laboratory practices, the addition, deletion or continued inclusion of tests on the waivered list, to verify that only certificate of waiver tests are performed, or to investigate complaints. Only laboratories performing examinations and procedures that HHS determines to be "simple" and having an insignificant risk of erroneous results in accordance with sections 353(d)(3) (B) and (C) of the PHS Act will be granted a certificate of waiver.

B. General

The Department plans to conduct a thorough Regulatory Impact Analysis (RIA) of the effects of this proposal. To do so will require data on the likely benefits and costs. In general, comments are sought on the extent to which affected entities already meet the requirements contained in the proposal. The Department is particularly interested in the effects of proposed requirements on the cost and availability of certain tests. In particular, we solicit information on whether the requirements will affect the number of entities offering level II tests? Are there alternative means by which the goals of the proposed regulation could be achieved at a lower cost?

C. Benefits

The primary purpose of this proposal is to improve health care by increasing the accuracy of test results, reducing both false negative and false positive results, and limiting or reducing the numbers of erroneous or incorrect laboratory test results that cause patient morbidity and mortality, more expensive care and drug regimen. The RIA will analyze the extent to which the proposal is likely to achieve this goal and the benefits that can be expected. The Department requests data on any savings that might accrue as a result of the implementation of these regulations, either directly or indirectly, through a reduction in future medical care costs. The Department also seeks detailed data for both level I and level II tests, preferably broken down by regulatory provision (e.g., training requirements, proficiency testing, quality controls, etc.) and by entity type (e.g., ambulatory surgical centers, home health care agencies, physician office laboratories, etc.), on the following:

(1) Current false negative and false positive rates;

(2) Likely reductions in false negative and false positive rates resulting from the proposal; and

(3) The consequences of false negative and false positive results.

The Department also seeks comments and data on any other beneficial effects of the requirements contained in the proposal, including whether savings would result from eliminating inappropriate testing.

D. Costs

The Department seeks data on the likely cost of the proposed requirements. Costs include, but are not limited to, the costs that would be incurred by the implementation of proficiency testing, patient test management, quality control, quality assurance, and inspections. The Department is particularly interested in data concerning any new costs associated with personnel requirements. For example, what is the cost of meeting appropriate training requirements and evaluation of testing personnel on an ongoing basis?

The Department is particularly interested in whether costs would be incurred if entities currently conducting level I or level II tests decided not to continue conducting these tests as a result of this proposal. Consequently, data are requested regarding the number or kind of entities that would choose not to conduct certain tests and whether this choice would affect the timing and costs of those tests. The types of data submitted should include whether fewer tests would be conducted; and, if fewer, whether such tests are necessary to patient care; whether additional costs for having the tests conducted elsewhere; and whether there would be undue time lags for receiving test results when alternative testing sites are necessary.

For laboratories that perform level II tests, examples of the type of data needed include: What is the increased cost of requiring a supervisor to be on the premises during all hours of testing or are such supervisors generally available at present? What are the likely costs of satisfying the performance levels of the proficiency testing requirements? What costs will be incurred to meet the various quality control standards? In cytology what is the cost of limiting the number of slides an individual may examine during a 24-hour period? Compared to the three options described in the preamble, what is the cost of meeting the cytotechnologist requirements currently in effect for independent laboratories? What is the cost of requiring personnel qualified as cytotechnologists and technologists in the case of cytology, microbiology, and immunohematology? Data on personnel requirements may be submitted as additional labor costs to laboratories in the form of higher wages and benefits necessary to compensate

individuals who meet higher requirements and in the form of labor costs for additional personnel over and above current levels.

The Department recognizes that this rule, in combination with the rule implementing the collection of fees, will constitute a major rule as defined by E.O. 12291. At this time, however, the Department does not have adequate data to perform a regulatory impact analysis. Consequently, we are soliciting comment on the benefits and costs of the rules and will conduct the analysis prior to issuing the final rule. To the extent that this preamble does not constitute a complete preliminary Regulatory Impact Analysis, OMB has waived the requirement, pursuant to section 6(a)(4) of E.O. 12291.

Response to Comments

Because of the large number of items of correspondence we normally receive on a proposed rule, we are unable to acknowledge or respond to them individually. However, in preparing the final rule, we will consider all comments that we receive by the date and time specified in the "**DATES**" section of this preamble, and we will respond to the comments in the preamble of that rule.

Revisions to the Regulations

We propose to make the following revisions to the regulations in title 42:

1. In parts 405, 416, 440, 482, 483, and 488, we would make technical and conforming changes in order to consolidate laboratory provisions in part 493.

1a. In part 493, in subpart A, we would revise § 493.3 to provide that the provisions of part 493 apply to all laboratories.

2. In subpart A, we would add new § 493.15, which would propose a list of the tests that have been evaluated by PHS using descriptive criteria to determine their eligibility for certificate of waiver tests.

3. In subpart A, we would add new § 493.20, which proposes a list of tests that may be classified as level I tests.

4. In subpart A, we would add new § 493.25, which specifies the requirements for testing for a laboratory performing tests classified as level II tests.

5. In subpart A, we would add new § 493.30, which provides that a Federal technical advisory committee would make recommendations to HHS on test complexity criteria and the periodic review of requests for test classification or reclassification, and the periodic review of quality control/quality assurance standards for level I and level II test performance.

6. We would add a new subpart B to part 493, which includes §§ 493.35, 493.37, 493.39, and 493.41 and specifies the application, and renewal of certificate of waiver for laboratories performing certificate of waiver tests, as well as certificate of waiver requirements and notification requirements.

7. We would add a new subpart C to part 493, which includes § 493.43, 493.45, 493.47, 493.49, 493.51 and 493.53 and specifies the certificate requirements applicable to laboratories performing level I or level II tests, or both.

8. We would add a new subpart D to part 493, which includes §§ 493.55, 493.57, 493.59 and 493.61, 493.63 and 493.65 and specifies the notification and certificate requirements applicable to laboratories performing level I or level II tests, or both, that seek a certificate of accreditation.

9. In existing subpart N, we would add new §§ 493.1601, 493.1603, and 493.1605 to provide for unannounced inspections of all laboratories, and requirements that laboratories must meet during these inspections.

10. We would add a new subpart P to part 493, which includes the use of computer systems.

Information Collection Requirements

Sections 493.30, 493.35, 493.40, 493.50, 493.55, 493.57, 493.70, 493.75, 493.77, 493.90, 493 801, 493.823, 493.825, 493.827, 493 829, 493.831, 493.835, 493.837, 493.841, 493.843, 493.845, 493.859, 493.861, 493.863, 493.865, 493.903, 493.911, 493.913, 493.915, 493.917, 493.919, 493.1101, 493.1209, 493.1211, 493.1213, 493.1215, 493.1217, 493.1219, 493.1221, 493.1257, 493.1259, 493.1265, 493.1267, 493.1273, 493.1285, 493.1439, 493.1501, 493.1601, 493.1603, and 493.1703 of this proposed rule contain information collection requirements that are subject to the Office of Management and Budget (OMB) review and approval under the Paperwork Reduction Act of 1980. Public reporting burden for this collection of information is estimated to average 0 minutes/hours to 4 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The public is invited to send comments regarding this burden or any other aspect of this collection of information, including suggestions for reducing this burden, to the agency contact indicated in the **ADDRESSES** section of this preamble, and the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 482

Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professions, Health records, Medicaid, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 488

Health facilities, Survey and certification, Forms and guidelines.

42 CFR Part 493

Laboratories, Medicare, Medicaid, Health facilities, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405 is amended as follows:

Subpart K—Conditions of Participation; Skilled Nursing Facilities

1. The authority citation for part 405, subpart K is revised to read as follows:

Authority: Secs. 1102, 1814, 1832, 1833, 1861, 1863, 1865, 1866, 1871, of the Social Security Act; and sec. 353 of the Public Health Service Act; 42 U.S.C. 1302, 1395f, 1395k, 13951, 1395x, 1395z, 1395bb, 1395cc, 1395hh.

2. Section 405.1128 is revised to read as follows:

§ 405.1128 Condition of participation—laboratory and radiologic services.

The skilled nursing facility has provision for promptly obtaining required laboratory, X-ray, and other diagnostic services.

(a) If the skilled nursing facility furnishes its own X-ray services, it must meet the applicable conditions established for certification of hospitals

in § 482.26 of this chapter. If the facility does not provide x-ray services, it makes arrangements to obtain these services from a physician's office, a participating hospital or skilled nursing facility, or a portable x-ray supplier.

(b) If the skilled nursing facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of hospitals and for certification of laboratories found in part 482 and part 493 of this chapter, respectively. If the facility does not provide laboratory services, it makes arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

(c) All x-ray and laboratory services are provided only on the orders of the attending physician, who is notified promptly of the findings. The facility assists the patient, if necessary, in arranging for transportation to and from the source of service. Signed and dated reports of a laboratory, X-ray, and other diagnostic services are filed with the patient's medical record.

(d) *Standard: Blood and blood products.* Blood handling and storage facilities are safe, adequate, and properly supervised. If the facility provides for maintaining and transfusing blood and blood products, it meets the applicable requirements established in §§ 493.1269 through 493.1285 of this chapter. If the facility does not provide its own facilities but does provide transfusion services alone, it meets at least the requirements of §§ 493.1275, 493.1277, 493.1279, 493.1283, and 493.1285 of this chapter.

Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services

3. The authority citation for part 405, Subpart U is revised to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act; Sec. 353 of the Public Health Service Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), unless otherwise noted.

4. In Subpart U, § 405.2163 is amended by revising paragraph (b) to read as follows:

§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.

* * * * *

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. Laboratory services are performed by an appropriately certified laboratory in accordance with part 493. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493. If the facility does not provide laboratory services, it makes arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493.

5. Paragraph (d) of § 405.2171 is revised to read as follows:

§ 405.2171 Condition: Minimal service requirements for a renal transplant center.

* * * * *

(d) *Standard: Laboratory services.* (1) The Renal Transplantation Center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter to participate in the Medicare program and, for histocompatibility testing purposes, also meets §§ 493.1421(j), 493.1237, 493.1265, and 493.1269 of this chapter and, when services are furnished in the subspecialty of histopathology, § 493.1421(g) and § 493.1259 of this chapter.

(2) Laboratory services for cross-matching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

B. Part 416 is amended as follows:

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1832(a)(2), 1833, 1863 and 1864 of the Social Security Act (42 U.S.C. 1302, 1395k(a)(2), 1395l, 1395z and 1395aa); and Sec. 353 of the Public Health Service Act.

Subpart B—Ambulatory Surgical Centers: Coverage and Benefits

2. Section 416.49 is revised to read as follows:

§ 416.49 Condition for coverage—Laboratory and radiologic services.

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

PART 440—SERVICES: GENERAL PROVISIONS

B.B. Part 440 is amended as follows:

1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In subpart A, § 440.30 (a) and (c) are revised and the introductory text is republished to read as follows:

§ 440.30 Other laboratory and X-ray services.

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law or ordered by a physician but provided by a referral laboratory;

* * * * *

(c) Furnished by a laboratory that meets the requirements of part 493.

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

C. Part 482 is amended as follows:

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1138, 1814(a)(6), 1861(e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act; Sec. 353 of the Public Health Service Act (42 U.S.C. 1302, 1338, 1395f(a)(6), 1395x (e), (f), (k), (r), (v)(1)(G), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396(a)).

Subpart C—Basic Hospital Functions

2. Section 482.27 is revised as follows:

§ 482.27 Condition of participation: Laboratory services.

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) Standard: Adequacy of laboratory services. The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

PART 483—CONDITIONS OF PARTICIPATION FOR LONG TERM CARE FACILITIES

D. Part 483 is amended as follows:

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1819(a)–(d), 1861(j) and (1), 1863, 1871, 1902(a)(28), 1905 (a) and (c), and 1919 (a)–(d) of the Social Security Act; and Sec. 353 of the Public Health Service Act (42 U.S.C. 1302, 1395(i)(3) (a)–(d), 1395x (j) and (1), 1395hh, 1396a(a)(28), and 1396d(c) and 1396r (a)–(d)), unless otherwise noted.

Subpart B—Requirements for Long Term Care Facilities

2. In subpart B, § 483.75 is amended by revising paragraph (l) to read as follows:

§ 483.75 Level A requirement: Administration.

* * * * *

(l) *Level B requirement: Laboratory services.* (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in Part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in Part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services only from a laboratory that is certified as a laboratory in accordance with part 493 of this chapter.

(2) The facility must—

(i) Provide or obtain laboratory services only when ordered by the attending physician;

(ii) Promptly notify the attending physician of the findings:

(iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance.

(iv) File in the resident's clinical record signed and dated reports of laboratory services.

* * * * *

Subpart D—Conditions of Participation for Intermediate care facilities for the Mentally Retarded

2. Section 483.460(n) is revised to read as follows:

§ 483.460 Condition of participation: Health care services.

* * * * *

(n) *Standard: Laboratory services.* (1) For purposes of this section, "laboratory" means a facility for the biological, microbiological, immunohematological, serological, chemical, hematological, biophysical, cytological, pathological or other examination of materials derived from the human body, for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(2) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(3) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the specialties and subspecialties of service in accordance with the requirements of Part 493 of this chapter.

PART 488—SURVEY AND CERTIFICATION PROCEDURES

E. Part 488 is amended as follows:

1. The authority citation is revised to read as follows:

Authority: Secs. 1102, 1814, 1861, 1865, 1866, 1871, 1880, 1881 and 1883 of the Social Security Act; and Sec. 353 of the Public Health Service Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt).

§ 488.52 [Removed]

2. Section 488.52 is removed and reserved.

PART 493—LABORATORY REQUIREMENTS

F. Part 493 is amended as follows:

1. The authority citation for part 493 continues to read as follows:

Authority: Secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12) and 1861(s)(13) of the Social Security Act and sec. 353 of the Public Health Service Act (42 U.S.C. 263a, 1302, the sentence following sec. 1395x(s)(11), and secs. 1395x(s)(12) and (13).)

2. The table of contents for subparts A through N and P for part 493 is revised to read as follows:

Subpart A—General provisions

Sec.

493.1 Basis and scope.
493.2 Definitions.
493.3 Applicability.
493.10 Categories of test by complexity.
493.15 Laboratories performing certificate of waiver tests.
493.20 Laboratories performing Level I tests.
493.25 Laboratories performing Level II tests.
493.30 Categorization of certificate of waiver, Level I and Level II tests.

Subpart B—Certificate of Waiver

493.35 Application for a certificate of waiver.
493.37 Requirements for a certificate of waiver.
493.39 Notification requirements for laboratories issued a certificate of waiver.
493.41 Requirements for renewal application for a certificate of waiver.

Subpart C—Provisional Certificate and Certificate

493.43 Requirements for initial application for provisional certificate and certificate.
493.45 Requirements for a provisional certificate.
493.47 Requirements for application for a certificate.
493.49 Requirements for a certificate.
493.51 Notification requirements for laboratories issued a certificate.
493.53 Requirements for a renewal application for a certificate.

Subpart D—Certificate of Accreditation

493.55 Requirements for initial application for provisional certificate and certificate of accreditation.
493.57 Requirements for a provisional certificate.
493.59 Requirements for application for a certificate of accreditation.
493.61 Requirements for a certificate of accreditation.
493.63 Notification requirements for laboratories issued a certificate of accreditation.
493.65 Requirements for renewal application for a certificate of accreditation.

Subpart E and F [Reserved]

Subpart G—Administration

493.770 Condition: Compliance with Federal, State and local laws.

Subpart H—Participation in Proficiency Testing for Laboratories Performing Level I and Level II Tests

493.801 Condition: Enrollment and testing of samples for laboratories performing Level I and Level II tests.
493.803 Condition: Successful participation.
493.805 Condition: Satisfactory participation before provisional certificate or revising a certificate to include additional specialties and subspecialties of service.
493.806 Condition: Successful participation before certification.
493.807 Condition: Reinstatement of laboratories performing Level I and Level II tests after failure to participate successfully.

Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Level I and Level II Tests

493.821 Condition: Microbiology.
493.823 Standard; Bacteriology: Level I and Level II tests.
493.825 Standard; Mycobacteriology: Level II tests.
493.827 Standard; Mycology: Level II tests.
493.829 Standard; Parasitology: Level II tests.
493.831 Standard; Virology: Level II tests.
493.833 Condition: Diagnostic immunology.
493.835 Standard; Syphilis serology: Level II tests.
493.837 Standard; General immunology: Level II tests.
493.839 Condition: Chemistry.
493.841 Standard; Routine chemistry: Level I and Level II tests.
493.843 Standard; Endocrinology: Level II tests.
493.845 Standard; Toxicology: Level II tests.
493.849 Condition: Hematology.
493.851 Standard; Hematology: Level I and Level II tests.
493.853 Condition: Pathology.
493.855 Standard; Cytology: Level II tests; gynecologic examinations.
493.857 Condition: Immunohematology.
493.859 Standard; ABO group and RHo (D) group: Level II tests.
493.861 Standard; Unexpected antibody detection: Level II tests.
493.863 Standard; Compatibility testing: Level II tests.
493.865 Standard; Antibody identification: Level II tests.

Subpart I—Proficiency Testing Programs For Level I and Level II Tests

493.901 Approval of proficiency testing programs.
493.903 Administrative responsibilities.
493.905 Nonapproved proficiency testing programs.
493.907 Process for updating proficiency testing programs.

Proficiency Testing Programs by Specialty and Subspecialty for Level I and Level II Tests

493.909 Microbiology.
493.911 Bacteriology: Level I and Level II tests.
493.913 Mycobacteriology: Level II tests.
493.915 Mycology: Level II tests.
493.917 Parasitology: Level II tests.
493.919 Virology: Level II tests.
493.921 Diagnostic immunology.
493.923 Syphilis serology: Level II tests.
493.927 General immunology: Level II tests.
493.929 Chemistry.
493.931 Routine chemistry: Level I and Level II tests.
493.933 Endocrinology: Level II tests.
493.937 Toxicology: Level II tests.
493.941 Hematology (including routine hematology and coagulation): Level I and Level II tests.
493.945 Cytology: Level II tests, gynecologic examinations.
493.959 Immunohematology: Level II tests.

Subpart J—Patient Test Management for Level I and Level II Testing.

493.1101 Condition: Patient test management: Level I and Level II Testing.

Subpart K—Quality Control for Level I and Level II Testing

493.1201 Condition: General quality control; Level I and Level II Testing.
493.1203 Standard; Facilities.
493.1205 Standard; Adequacy of methods and equipment.
493.1207 Standard; Temperature and humidity monitoring.
493.1209 Standard; Labeling of testing supplies.
493.1211 Standard; Procedure manual.
493.1213 Standard; Equipment maintenance, and function checks.
493.1215 Standard; Validation of methods.
493.1217 Standard; Frequency of quality control.
493.1219 Standard; Remedial actions.
493.1221 Standard; Quality control—records.
493.1223 Condition: Quality control—specialties and subspecialties.
493.1225 Condition: Microbiology.
493.1227 Standard; Bacteriology: Level I and Level II tests.
493.1229 Standard; Mycobacteriology: Level II tests.
493.1231 Standard; Mycology: Level II tests.
493.1233 Standard; Parasitology: Level II tests.
493.1235 Standard; Virology: Level II tests.
493.1237 Condition: Diagnostic immunology.
493.1239 Standard; Syphilis serology: Level II tests.
493.1241 Standard; General immunology: Level II tests.
493.1243 Condition: Chemistry.
493.1245 Standard; Routine chemistry: Level I and Level II tests.
493.1247 Standard; Endocrinology: Level II tests.
493.1249 Standard; Toxicology: Level II tests.
493.1253 Condition: Hematology: Level I and Level II tests.
493.1255 Condition: Pathology.
493.1257 Standard; Cytology: Level II tests.
493.1259 Standard; Histopathology: Level II tests.
493.1261 Standard; Oral pathology: Level II tests.
493.1263 Condition: Radiobioassay: Level II tests.
493.1265 Condition: Histocompatibility: Level II tests.
493.1267 Condition: Clinical cytogenetics: Level II tests.
493.1269 Condition: Immunohematology: Level II tests.
493.1271 Condition: Transfusion services and bloodbanking: Level II tests.
493.1273 Standard; Immunohematological collection, processing, dating periods, labeling, and distribution of blood and blood products.
493.1275 Standard; Blood storage facilities.
493.1277 Standard; Arrangement for services.
493.1279 Standard; Provision of testing.
493.1283 Standard; Retention of transfused blood.
493.1285 Standard; Investigation of transfusion reactions.

Subpart L—Personnel for Level I and Level II Testing

493.1401 General.
493.1402 Definitions.

Laboratories Performing Level I Testing

493.1403 Condition: Laboratories performing Level I testing; Laboratory director.
493.1405 Standard; Laboratory director qualifications.
493.1407 Standard; Laboratory director responsibilities.
493.1408 Standard; Technical supervisor.
493.1409 Standard; General supervisor.
493.1410 Condition: Laboratories performing Level I testing; testing personnel.
493.1411 Standard; Testing personnel qualifications.

Laboratories Performing Level II Testing

493.1413 Condition: Laboratories performing Level II testing; laboratory director.
493.1415 Standard; Laboratory director; qualifications.
493.1417 Standard; Laboratory director responsibilities.
493.1419 Condition: Laboratories performing level II testing; technical supervision.
493.1421 Standard; Technical supervisor qualifications.
493.1423 Standard; Technical supervisor responsibilities.
493.1425 Condition: Laboratories performing Level II testing; general supervisor.
493.1427 Standard; General supervisor qualifications.
493.1429 Standard; General supervisor responsibilities.
493.1431 Condition: Laboratories performing Level II testing; testing personnel.
493.1433 Standard; Technologist qualifications.
493.1437 Standard; Cytotechnologist qualifications.
493.1439 Standard; Cytotechnologist responsibilities.
493.1441 Standard; Technician qualifications.
493.1442 Standard; Personnel qualifications for test performance.

493.1443 Standard; Technologist and technician responsibilities.
493.1445 Standard; Technician trainee program.

Subpart M—Quality Assurance for Level I and Level II Testing

493.1501 Condition: Quality Assurance; Level I and Level II Testing.

Subpart N—Inspection

493.1601 Condition: Inspection of laboratories issued a certificate of waiver.
493.1603 Condition: Inspection of all laboratories not issued a certificate of waiver or certificate of accreditation.
493.1605 Condition: Inspection of accredited laboratories.

* * * * *

Subpart P—Computer Systems for Level I and Level II Testing

493.1801 Condition: Computer systems for Level I and Level II Testing.

Appendix A Laboratory Director Qualification Requirements Before July 1, 1971

Appendix B Technical Supervisor Qualification Requirements Before July 1, 1971

Appendix C General Supervisor Qualification Requirements Before July 1, 1971

Appendix D Technologist Qualification Requirements Before July 1, 1971

Appendix E Cytotechnologist Qualification Requirements Before January 1, 1969

Appendix F Technician Qualification Requirements Before December 31, 1977.

Authority: Secs. 1102, 1861(e), the sentence following 1861(s)(11), 1861(s)(12) and 1861(s)(13) of the Social Security Act and sec. 353 of the Public Health Service Act (42 U.S.C. 263a, 1302, the sentence following sec. 1395x(s)(11), and sec. 1395x(s) (12) and (13).)

Subpart A—General Provisions

3. In subpart A, § 493.1 is revised to read as follows:

§ 493.1 Basis and scope.

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). It implements sections 1861(e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in § 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

4. Section 493.2 is revised to read as follows:

§ 493.2 Definitions.

As used in this part—

Accredited laboratory, as defined in section 353(e)(1) of the Public Health Service Act, means a laboratory that meets the standards of an approved accreditation body, and authorizes the accreditation body to submit to HHS (or such State agency as HHS may designate) such records or other information as HHS may require as provided in section 353(e)(1) of the Public Health Service Act.

Analyte means a substance or constituent for which the laboratory conducts testing.

Authorized person under Medicare means a physician as defined in section 1861(r) of the Act who orders tests and receives test results on persons for which payment is sought under Medicare. If payment is not sought under Medicare, the tests may be ordered by individuals authorized under State law to order tests or receive test results.

Challenge means, for quantitative tests, an assessment of the amount of substance or analyte present in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

CLIA means the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). References to CLIA throughout the regulation mean CLIA '88.

HHS means the Department of Health and Human Services, or its designee.

Kit is all components of a test that are packaged together.

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting specimens or only serving as a mailing service and not performing testing are not considered laboratories. Laboratories that perform research testing on human specimens, but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of an individual patient are not considered laboratories under CLIA.

Referee laboratory means a laboratory that has had a record of satisfactory proficiency testing performance for all testing events for at least one year in a specific test specialty or subspecialty and has been nominated by an approved proficiency testing program and approved by HHS as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specialty or subspecialty.

Run means an interval within which the accuracy and precision of a testing system is expected to be stable but must not exceed a period of 24 hours and must not be less frequent than the manufacturer's specification for including controls and calibrators.

Sample in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

Screening test means a simple, rapid procedure, which is easily interpretable, carries minimal risk to the patient and is used to detect various diseases or conditions. Abnormal screening test results are generally followed up by a more specific confirmatory test.

Target value means either the mean of all responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System by the National Committee for Clinical Laboratory Standards. In instances where definitive or reference methods are not available, a comparative method may be used. If the method group is less than 20 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

5. In subpart A, new §§ 493.3, 493.10, 493.15, 493.20, 493.25 and 493.30 are added to read as follows:

§ 493.3 Applicability.

A laboratory, as defined in § 493.2, must have a current, unrevoked or unsuspended certificate of waiver, a provisional certificate, a certificate, or a certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory or be cited as out of compliance with section 353 of the Public Health Service Act. These rules do not apply to any component or function of a laboratory that possesses a

valid certification by the National Institute on Drug Abuse (NIDA) for the purpose of performing forensic urine drug testing under the Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53 FR 11970, April 11, 1988. This includes any component or function of any laboratory whose forensic functions have been certified by NIDA under authority of Executive Order 12564 and section 503 of Public Law 100–71, regulations adopted by the Nuclear Regulatory Commission and the Department of Transportation (54 FR 24468, June 7, 1989; 54 FR 49854, Dec. 1, 1989), and any other Federal law requiring performance of forensic urine drug testing under NIDA certification. Any laboratory, or any component or function of a laboratory, which performs clinical urine drug testing or forensic urine drug testing without NIDA certification remains subject to these rules.

§ 493.10 Categories of tests by complexity.

Laboratory tests are categorized as either waivered, Level I or Level II tests. A laboratory may perform only waivered tests, only Level I tests, or only Level II tests or any combination. Each laboratory must possess one of the following: provisional certificate, certificate of waiver, certificate, or certificate of accreditation, as defined in this part.

§ 493.15 Laboratories performing certificate of waiver tests.

A list of tests is provided which HHS has evaluated using descriptive criteria to determine tests for eligibility for a certificate of waiver. Following publication of the final rule, the technical advisory committee, defined in § 493.30 of this subpart, performs periodic review of requests for test classification or reclassification and makes recommendations to HHS for approval. Tests approved for certificate of waiver by HHS will be published in the **Federal Register**.

(a) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations and no others:

(1) Dipstick or Tablet Reagent Urinalysis for the following:

(i) Bilirubin;
(ii) Glucose;
(iii) Hemoglobin;
(iv) Ketone;
(v) Leukocytes;
(vi) Nitrite;
(vii) pH;
(viii) Protein;
(ix) Specific gravity; and
(x) Urobilinogen.

(2) Fecal occult blood;

(3) Spun microhematocrit;

(4) Microscopic examination of the following:

(i) Urine sediment;
(ii) Pinworm preparation; and
(iii) Vaginal wet mount preparation.

(5) Ovulation tests—visual color tests for human luteinizing hormone;

(6) Whole blood clotting time;

(7) Urine pregnancy tests.

(8) Antistreptolysin O (ASO) screen—slide card agglutination test;

(9) C reactive protein (CRP) screen—slide card agglutination test;

(10) Rheumatoid factor screen—slide card agglutination test;

(11) Gram stain (on discharges and exudates);

(12) Infectious mononucleosis screening—slide card agglutination test;

(13) Potassium hydroxide (KOH) preparation on cutaneous scapings;

(14) Erythrocyte sedimentation rate;

(15) Sickle cell screening—methods other than electrophoresis;

(16) Glucose screen whole blood dipstick method—visual color comparison determination; and

(17) Semen Analysis.

(b) Laboratories eligible for a Certificate of Waiver must meet the requirements in subpart B of this part.

§ 493.20 Laboratories performing level I tests.

(a) A laboratory may qualify for a certificate or provisional certificate to perform level I tests provided that it restricts its test performance to certificate of waiver tests or examinations and one or more of the following tests or examinations, and no others.

(1) Cholesterol screen—qualitative and semiquantitative determinations;

(2) Culture for colony counts for urinary tract infection—not to include identification and susceptibility;

(3) Hemoglobin, methods other than electrophoresis;

(4) White blood cell count;

(5) Red blood cell count;

(6) Hematocrit;

(7) Urea nitrogen (BUN);

(8) Creatinine;

(9) Uric acid;

(10) Glucose; and

(11) Direct Strep. Antigen test.

(b) A laboratory that restricts its test performance to certificate of waiver tests or examinations and Level I tests or examinations must meet the applicable requirements in subparts C, Provisional certificate and certificate, or if applicable, D, Certificate of accreditation; G, Administration; H, Participation in proficiency testing; J, Patient test management; K, Quality control; L, Personnel; M, Quality assurance; N, Inspections; and P, computer systems, of this part for tests listed in § 493.20 for performance by a laboratory.

(c) The laboratory must ensure that all abnormal Level I screening test results for previously undiagnosed conditions are referred to an appropriately certified laboratory for verification by a more specific Level II method and ensure that records are available to document that the screening tests are referred.

(d) If the laboratory performs certificate of waiver tests listed in § 493.15, compliance with subparts G, H, J, K, L, M, N, for routine inspections, and P are not required for the waivered tests.

(e) The technical advisory committee, defined in § 493.30 of this subpart, performs periodic reviews of requests for Level I test classification or reclassification and makes recommendations to HHS for approval as level I tests. The tests approved for the Level I category of tests will be published in the **Federal Register**.

§ 493.25 Laboratories performing Level II tests.

(a) A laboratory must obtain a certificate for Level II testing if it performs one or more tests not listed in §§ 493.15 and 493.20 of this subpart.

(b) A laboratory performing one or more Level II tests must meet the applicable requirements of subparts C, Provisional certificate and certificate, or if applicable, D, Certificate of accreditation; G, Administration; H, Participation in proficiency testing; J, Patient test management; K, Quality control; L, Personnel; M, Quality assurance; N, Inspections; and P, Computer systems, of this part.

(c) If the laboratory performs certificate of waiver tests, the requirements of subparts G, H, J, K, L, M, N for routine inspections and P are not applicable for the waivered tests.

(d) If the laboratory performs Level I tests, the personnel requirements of subpart L are applicable for the performance of Level I tests and subparts G, H, J, K, M, N, and P are applicable for Level I testing.

§ 493.30 Categorization of certificate of waiver, Level I and Level II tests.

(a) Effective no earlier than (date of publication of the final rule listing the initially approved waivered and Level I tests), a technical advisory committee will be established by HHS to assist in the classification of tests and make

recommendations to HHS on tests that have been suggested to be included or excluded as either certificate of waiver tests or Level I tests. The committee—

(1) Is composed of individuals with technical expertise in laboratory services, representing the providers and users of laboratory services; and

(2) Meets at least once each year to provide an ongoing review of test complexity criteria and review of requests for test classification or reclassification and the periodic review of quality control/quality assurance standards for Level I and Level II test performance.

(b) Any individual, group, institution or government entity may nominate specific tests or examinations for evaluation by the technical advisory committee. The request must be submitted to HCFA in writing and must include at least the following:

(1) Name of analyte or test;

(2) Precise methodology to be employed;

(3) Degree of independent judgment involved;

(4) Amount of interpretation involved;

(5) Difficulty of the calculations involved;

(6) Calibration and quality control requirements of test methodology, including instrumentation or equipment used;

(7) Availability of quality control material;

(8) Number of reagents to prepare and difficulty of preparation;

(9) Stability of test systems;

(10) Patient preparation involved;

(11) Sample preparation involved;

(12) Amount of interaction between operator and instrumentation or operator dependence required;

(13) Factors which can influence test results;

(14) Specific training required to perform the test or examination, including the operation of the instrumentation or equipment used in the test methodology;

(15) The specificity, sensitivity, accuracy and precision of the procedure or the examination and/or methodology;

(16) Risks to the patient if clinical intervention is initiated based on the results of an incorrectly performed or interpreted test;

(17) Data to support the validity, accuracy, and reliability of the test when used as intended;

(18) Intended use of results; and

(19) Other factors specified by HHS.

6. In part 493, a new subpart B is added containing §§ 493.35, 493.37, 493.39, and 493.41 to read as follows:

Subpart B—Certificate of Waiver

§ 493.35 Application for a certificate of waiver.

(a) A laboratory must file a separate application for each laboratory location.

(b) The application must—

(1) Be made on a form or forms prescribed by HHS;

(2) Be signed by the owner, or by an authorized representative of the laboratory; and

(3) Describe the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually;

(ii) The methodologies for each laboratory test and/or examination performed; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures.

(c) Laboratories that perform one or more tests listed in § 493.15 and no other tests must—

(1) Provide HHS with records and information necessary to determine compliance with this section;

(2) Agree to permit unannounced inspections by HHS in accordance with subpart N of this part—

(i) When HHS has substantive reason to believe that testing is being performed in a manner that constitutes a hazard to patient health and safety;

(ii) To evaluate complaints for the public;

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15; and

(d) If HHS determines that the application for a certificate of waiver is to be denied, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for a hearing as provided in part 498.

§ 493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this section; and

(2) Must permit unannounced inspections by HHS in accordance with subpart N—

(i) When HHS has substantive reason to believe that testing is being performed in a manner that constitutes a hazard to patient health and safety;

(ii) To evaluate complaints from the public;

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15.

(c) Laboratories must remit the certificate of waiver fee specified by HHS.

(d) In accordance with subpart O, HHS will suspend, revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare in accordance with subpart O.

(e) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing within the time specified by HHS, HHS will extend the expiration date of the certificate of waiver until a hearing decision by an Administrative Law Judge is issued unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In addition, for laboratories participating in Medicare, payments will be suspended or denied on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no hearing decision issued.

§ 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS—

(a) Before performing and reporting any test or examination that is not specified under § 493.15;

(b) Within six months of any deletions or changes in test methodologies specified under § 493.15; and

(c) Within 30 days of any change(s) in—

(1) Ownership;

(2) Name; or

(3) Location.

§ 493.41 Requirements for renewal application for a certificate of waiver.

(a) A laboratory seeking to renew its certificate of waiver must complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate.

(b) The renewal request must meet the requirements of § 493.35.

(c) The laboratory must—

(1) Remit the certificate of waiver fee specified by HHS; and

(2) Agree to permit unannounced inspections by HHS in accordance with Subpart N—

(i) When HHS has substantive reason to believe that testing is being performed in a manner that constitutes a hazard to patient health and safety;

(ii) To evaluate complaints from the public;

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15, and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15.

(d) If HHS determines that the application for the renewal of a certificate of waiver is to be denied, HHS will, notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for a hearing as provided in part 498. If the laboratory requests a hearing within the time specified by HHS, HHS will extend the expiration date of the certificate of waiver until a hearing decision by the Administrative Law Judge is issued, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. However, for laboratories participating in Medicare, payments will be suspended or denied on the effective date specified in the notice to the laboratory of nonrenewal of the certificate of waiver, even if there has been no hearing decision issued.

7. In part 493, a new subpart C is added containing §§ 493.43, 493.45, 493.47, 493.49, 493.51, and 493.53 to read as follows:

Subpart C Provisional Certificate and Certificate

§ 493.43 Requirements for initial application for provisional certificate and certificate.

(a) All laboratories encompassing Level I or Level II test performance, or both, must file a separate application for each laboratory location. The application must—

(1) Be made on a form or forms prescribed by HHS;

(2) Be signed by the owner, or by an authorized representative of the laboratory; and

(3) Describe the characteristics of the laboratory examinations and test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually;

(ii) The methodologies for each laboratory test and examination performed; and

(iii) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(b) All laboratories must provide HHS with records and information necessary to determine compliance with this section.

§ 493.45 Requirements for a provisional certificate.

A provisional certificate is required for all laboratories except those laboratories performing one or more certificate of waiver tests listed in § 493.15 and no other tests and those laboratories subject to the Clinical Laboratory Improvement Act of 1967 on December 31, 1988.

(a) HHS will issue a provisional certificate if the laboratory—

(1) Complies with the requirements of § 493.43;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, or location;

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Achieves satisfactory performance for one testing event in a proficiency testing program approved by HHS for each test or examination performed, if applicable.

(b) Prior to the expiration of the provisional certificate, a laboratory must—

(1) Achieve successful participation, as defined in subpart H, for three consecutive proficiency testing events in a proficiency testing program approved by HHS for each test or examination performed, if applicable;

(2) Submit to HHS an application for a certificate as specified in §§ 493.43 and 493.47 of this subpart not less than 9 months nor more than one year before the expiration of the provisional certificate;

(3) Remit the fee specified by HHS;

(4) Be inspected by HHS as specified in subpart N; and

(5) Demonstrate compliance with the applicable requirements of subparts C, G, H, J, K, L, M, N, and P.

(c) In accordance with subpart O, HHS will initiate suspension, revocation or limitation of a laboratory's provisional certificate and will deny the laboratory's application for a certificate for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare as specified in subpart O.

(d) A provisional certificate is—

(1) Not renewable; however, the provisional certificate may be re-issued if compliance has not been determined by HHS prior to the expiration date of the provisional certificate; and

(2) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter. In the event of a non-compliance determination resulting in an HHS denial of a laboratory's certificate of application, HHS will provide the laboratory with a statement of grounds on which the non-compliance determination is based and offer an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing within the time specified by HHS, HHS will extend the expiration date of the provisional certificate until a hearing decision by an Administrative Law Judge is issued unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In addition, for laboratories participating in Medicare, payments will be suspended or denied on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no hearing decision issued.

493.47 Requirements for application for a certificate.

Laboratories performing one or more tests not listed in § 493.15 must—

(a) Meet the requirements specified in §§ 493.43 and 493.45, if applicable;

(b) Provide HHS with satisfactory assurances that the laboratory will be operated in accordance with the applicable requirements of subparts G, H, J, K, L, M, N, and P, of this part, and this section;

(c) Agree to permit unannounced inspections by HHS in accordance with subpart N—

(1) To determine compliance with the applicable requirements of this part;

(2) To evaluate complaints from the public; and

(3) When HHS has substantive reason to believe that any test, including waiver tests listed in § 493.15, are being performed in a manner that constitutes a hazard to patient health and safety; and

(4) To collect information for the addition, deletion, or continued inclusion of tests listed in §§ 493.15 and 493.20.

(d) If HHS determines that the application for a certificate is to be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for a hearing as provided in Part 498.

§ 493.49 Requirements for a certificate.

(a) HHS will issue a certificate to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43, 493.45, and 493.47, if applicable.

(2) Remits the certificate fee specified by HHS; and

(3) Meets the applicable requirements of subparts C, G, H, J, K, L, M, N, and P.

(b) Laboratories issued a certificate—

(1) Are subject to the notification requirements of § 493.51 of this section; and

(2) Must permit unannounced inspections by HHS in accordance with subpart N—

(i) To determine compliance with the requirements of this part;

(ii) To evaluate complaints from the public;

(iii) When HHS has substantive reason to believe that any tests, including waiver tests listed in § 493.15, are being performed in a manner that constitutes a hazard to patient health and safety; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in §§ 493.15 and 493.20.

(c) In accordance with subpart O, HHS will suspend, revoke or limit a laboratory's certificate for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare in accordance with subpart O.

(d) A certificate issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing within the time specified by HHS, HHS will extend the expiration date of the certificate until a hearing decision by an Administrative Law Judge is issued, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In addition, for laboratories participating in Medicare, payments will be suspended or denied on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no hearing decision issued.

§ 493.51 Notification requirements for laboratories issued a certificate.

(a) Laboratories issued a certificate for performance of one or more Level I tests listed in § 493.20 and no tests classified as Level II tests must—

(1) Notify HHS before performing and reporting any test or examination not listed under §§ 493.15 and 493.20 of this part that are not included on the laboratory's certificate;

(2) Notify HHS within six months of any deletions or changes in test methodologies for tests or examinations included under §§ 493.15 and 493.20 of this part;

(3) Notify HHS within 30 days of any change(s) in—

(i) Ownership;

(ii) Name;

(iii) Location;

(iv) Director; or

(v) Supervisor.

(b) Laboratories issued a certificate that encompasses one or more Level II tests must—

(1) Notify HHS before performing any test or examination within a specialty or subspecialty that is not included on a laboratory's certificate for the applicable specialty or subspecialty of services;

(2) Notify HHS within 6 months of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate; and

(3) Notify HHS within 30 days of any change in—

(i) Ownership;

(ii) Name;

(iii) Location;

(iv) Director(s); or

(v) Supervisor(s).

§ 493.53 Requirements for a renewal application for a certificate.

(a) A laboratory seeking to renew its certificate must complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate.

(b) The renewal request must meet the reguirements of §§ 493.43 and 493.47.

(c) The laboratory must—

(1) Remit the certificate fee specified by HHS; and

(2) Agree to permit unannounced inspections by HHS in accordance with subpart N—

(i) To determine compliance with the applicable requirements of this part;

(ii) To evaluate complaints from the public;

(iii) When HHS has substantive reason to believe that any tests, including waiver tests listed in § 493.15, are being performed in a manner that constitutes a hazard to patient health and safety; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in §§ 493.15 and 493.20.

(d) If HHS determines that the application for the renewal of a certificate is to be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for a hearing as provided in part 498. If the laboratory requests a hearing within the time specified by HHS, HHS will extend the expiration date of the certificate until a hearing decision by an Administrative Law Judge is issued, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. However, for laboratories participating in Medicare, payments will be suspended or denied on the effective date specified in the notice to the laboratory of nonrenewal of the certificate even if there has been no hearing decision issued.

8. In part 493, a new subpart D is added containing §§ 493.55, 493.57, 493.59, 493.61, 493.63, and 493.65 to read as follows:

Subpart D—Certificate of Accreditation

§ 493.55 Requirements for initial application for provisional certificate and certificate of accreditation.

(a) A laboratory performing one or more Level I or Level II tests or both may be issued a certificate of accreditation in lieu of a certificate provided the laboratory meets the standards of a private non-profit accreditation or State licensure program approved by HHS in accordance with subpart E and files a separate application for each location.

(b) The application must—

(1) Be made on a form or forms prescribed by HHS;

(2) Be signed by the owner, or by an authorized representative of the laboratory; and

(3) Describe the characteristics of the laboratory examinations and test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually;

(ii) The methodologies for each laboratory test and examination performed; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(c) All laboratories must provide HHS with records and information necessary to determine compliance with this section.

§ 493.57 Requirements for a provisional certificate.

A provisional certificate is required for all laboratories seeking a certificate of accreditation, unless the laboratory holds a valid certificate issued by HHS for Level I or Level II test performance or both.

(a) HHS will issue a provisional certificate if the laboratory—

(1) Complies with the requirements of § 493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, or location;

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Achieves satisfactory performance for one testing event in a proficiency testing program approved by HHS for each test or examination performed, if applicable; and

(5) Remits the fee specified by HHS.

(b) Prior to the expiration of the provisional certificate, a laboratory must—

(1) Notify HHS of successful participation, as defined in subpart H, for three consecutive proficiency testing events in a proficiency testing program approved by HHS for each test or examination performed, if applicable;

(2) Submit to HHS an application for a certificate of accreditation as specified in § 493.55 not less than 9 months nor more than one year before expiration of the provisional certificate; and

(3) Notify HHS with proof of its accreditation or licensure in an approved accreditation program or State program.

(c) In accordance with subpart O, HHS will initiate suspension, revocation or limitation of a laboratory's provisional certificate and will deny the laboratory's application for a certificate for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare as specified in subpart O.

(d) A provisional certificate is—

(1) Not renewable; however, the provisional certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the provisional certificate; and

(2) Valid for a period of no more than two years although it may be reissued solely to cover that period needed by the accreditation program to determine compliance with its requirements.

(e) In the event that the laboratory does not meet the application requirements of § 493.59 or the requirements of this section, HHS will—

(1) Deny a laboratory's application for certificate of accreditation application;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C;

(3) Provide the laboratory with a statement of grounds on which the application denial is based; and

(4) Offer an opportunity for a hearing on the application denial as provided in part 498. If the laboratory requests a hearing within the time specified by HHS, HHS will—

(i) Extend the expiration date of the provisional certificate until a hearing decision by an Administrative Law Judge is issued unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(ii) For those laboratories participating in Medicare, suspend or deny payments on the effective date specified in the notice to the laboratory of denial of the application even if there has been no decision issued.

§ 493.59 Requirements for a certificate of accreditation.

(a) All laboratories performing any Level I or Level II tests or both that are accredited by an approved accrediting organization or licensed by an approved State program must—

(1) Meet the requirements specified in §§ 493.55 and 493.57 or if applicable, § 493.45, in which case the laboratory must provide HHS with proof of its accreditation or licensure in an approved accreditation or State program;

(2) Provide HHS with satisfactory assurances that the laboratory will be operated in accordance with the applicable requirements of the approved accreditation or State licensure program;

(3) Agree to treat proficiency testing specimens in the same manner as it treats patient samples;

(4) Authorize its accreditation or State licensure program to submit to HHS the results of the laboratory's proficiency testing results;

(5) Agree to permit—

(i) Random sample and complaint inspections as defined in subpart N; and

(ii) HHS to monitor the correction of any deficiencies found through inspections specified in paragraph (a)(5)(i) of this section; and

(6) Authorize the accreditation or the State licensure program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections.

(b) If HHS determines that the application for a certificate or accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C;

(3) The opportunity for a hearing on HHS' action to deny the application for certificate of accreditation as provided in part 498; and

(4) Termination or suspension of payments under Medicare for those laboratories approved to participate in Medicare on the effective date specified in the notice to the laboratory of denial of the application even if there has been no decision issued.

§ 493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of § 493.57 or, if applicable, §§ 493.45 and 493.59; and

(2) Remits the certificate of accreditation fee specified by HHS;

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of § 493.63;

(3) Comply with the requirements of the approved accreditation or State licensure program;

(4) Permit random sample validation and complaint inspections as defined in subpart N; and

(5) Permit HHS to monitor the correction of any deficiencies found

through the inspections specified in paragraph (b)(3) of this section;

(c) In accordance with subpart E, a laboratory failing to meet the requirements of this section—

(1) Will no longer be deemed to meet the requirements of this part by virtue of its accreditation or licensure in an approved accreditation or State licensure program;

(2) Will be subject to full determination or compliance by HHS;

(3) May be subject to suspension, revocation, or limitation of the laboratory's certificate of accreditation; and

(4) May be subject to suspension or denial or payments under Medicare.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with § 488.11 of this subchapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the application denial is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C; and

(3) Offer an opportunity for a hearing on the application denial as provided in part 498.

(f) If the laboratory requests a hearing, HHS will—

(1) Extend the expiration date of the provisional certificate until a hearing decision by an Administrative Law Judge is issued; and

(2) For those laboratories participating in Medicare, suspend or deny payments on the effective date specified in the notice to the laboratory even if there has been no hearing issued.

§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.

(a) Laboratories issued a certificate of accreditation for performance of one or more Level I tests listed in § 493.20 and no tests classified as Level II tests must notify—

(1) HHS and the approved accreditation or State licensure program before performing and reporting any test or examination not listed under §§ 493.15 and 493.20 of this part that are not included on the laboratory's certificate of accreditation; and

(2) The accreditation or State licensure program—

(i) Within six months of any deletions or changes in test methodologies for tests or examinations included under §§ 493.15, and 493.20 of this part; and

(ii) Within 30 days of any change in—

(A) Ownership;

(B) Name;

(C) Location;

(D) Director(s); or

(E) Supervisor(s).

(b) Laboratories issued a certificate of accreditation for performance of one or more Level II tests must notify—

(1) HHS and the approved accreditation or State licensure program before performing any test or examination within a specialty or subspecialty that is not included on a laboratory's certificate of accreditation for the applicable specialty or subspecialty of services; and

(2) The accreditation or State licensure program—

(i) Within 6 months of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation; and

(ii) Within 30 days of any change in—

(A) Ownership;

(B) Name;

(C) Location;

(D) Director(s); or

(E) Supervisor(s).

§ 493.65 Requirements for renewal application for a certificate of accreditation.

(a) A laboratory seeking to renew its certificate of accreditation must complete and return the renewal application to HHS not less than 9 months or more than one year before the expiration of the certificate.

(b) The renewal reguest must meet the requirements of §§ 493.55 and 493.57 or, if applicable, § 493.45, in which case the laboratory must provide HHS with proof of its accreditation or licensure in an approved accreditation or State program.

(c) The laboratory must—

(1) Provide HHS with satisfactory assurances that the laboratory will be operated in accordance with the applicable requirements of the approved accreditation or State licensure program;

(2) Agree to treat proficiency testing specimens in the same manner as it treats patient samples;

(3) Authorize its accreditation or State licensure program to submit to HHS the results of the laboratory's proficiency testing results;

(4) Agree to permit—

(i) Random sample validation and complaint inspections as defined in subpart N; and

(ii) HHS to monitor the correction of any deficiencies found through inspections specified in paragraph (a)(4)(i) of this section;

(5) Authorize the accreditation or the State licensure program to release to HHS the laboratory's inspection findings whenever HHS or its designee conducts random sample validations or complaint inspections; and

(6) Submit the fee specified by HHS.

(d) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C;

(3) The opportunity for a hearing on HHS' action to deny the renewal application for certificate of accreditation as provided in part 498; and

(4) Denial or suspension of payments under Medicare for those laboratories approved for coverage under Medicare.

9. Subpart G is revised to read as follows:

Subpart G—Administration

§ 493.770 Condition: Compliance with Federal, State and local laws.

The laboratory must be in compliance with all applicable Federal, State and local laws.

(a) *Standard; Federal laws.* The laboratory must be in compliance with applicable Federal laws related to laboratory employee health and safety and the health and safety of individuals whose specimens are submitted to it for testing.

(b) *Standard; State licensure.* The laboratory must be—

(1) Licensed if State or applicable local law requires licensure; or

(2) Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing laboratories.

(c) *Standard; licensed staff.* All personnel, including those individuals who collect specimens, must be licensed or meet other applicable standards that are required by State and local laws.

(d) *Standard; fire safety.* The laboratory must comply with State and local laws related to fire safety. The laboratory must comply with the applicable provisions of the National Fire Protection Association 99, Standard

for Health Care Facilities, 1987 edition (which is incorporated by reference.).

(e) Standard; environment and health. The laboratory must comply with Federal, State and local laws relating to the storage, handling and disposal of chemical, biological and radioactive materials.

10. Subpart H is revised to read as follows:

Subpart H—Participation in Proficiency Testing for Laboratories Performing Level I and Level II Tests

§ 493.801 Condition: Enrollment and testing of samples for laboratories performing Level I and Level II tests.

Each laboratory performing Level I and Level II tests must enroll as applicable in a proficiency testing program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in such a program for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens.

(a) *Standard; Enrollment.* The laboratory must notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. The laboratory must—

(1) Designate the program to be used for each specialty and subspecialty to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HHS;

(2) For each specialty and subspecialty, participate in one approved proficiency testing program for four quarters before designating a different program and must notify HHS before any change in designation; and

(3) Authorize the proficiency testing program to release to HHS all data required by HHS to determine the laboratory's compliance with this subpart.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test the samples with the same frequency of testing that it routinely tests patient samples.

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s). Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/location concerning proficiency testing sample results.

(4) The laboratory must not send the samples or portions of samples to another laboratory for analysis. Any laboratory that HHS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HHS of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples and must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results, for a minimum of two years from the date of the proficiency testing event.

§ 493.803 Condition: Successful participation.

(a) Each laboratory performing Level I and Level II tests must successfully participate in a proficiency testing program approved by HHS, if applicable, as described in subpart I of this part for each specialty and subspecialty in which the laboratory is certified under CLIA.

(b) If the laboratory fails to participate successfully in proficiency testing for a given speciality or subspecialty, as defined in this section, the laboratory's certificate will be suspended and Medicare/Medicaid approval will be terminated for the specialty or subspecialty or the laboratory will be subject to intermediate sanctions.

(c) If the laboratory fails to perform successfully for the challenges on a given analyte or test procedure, as defined in this section, the laboratory's Medicare or Medicaid approval will be terminated and the certificate under CLIA will be suspended for the speciality or subspecialty in which the analyte is categorized or the laboratory will be subject to intermediate sanctions.

§ 493.805 Condition: Satisfactory participation before provisional certification or revising a certificate to include additional specialties and subspecialties of services.

Before laboratories performing Level I and Level II tests are eligible for a certificate, they must demonstrate satisfactory performance in one proficiency testing event of a proficiency testing program approved by HHS, if applicable, for each specialty and subspecialty of service for which the laboratory requests provisional certification. In addition, before certified laboratories performing Level I and Level II tests are eligible to add a specialty or subspecialty to their certificate, they must demonstrate satisfactory performance in one proficiency testing event of a proficiency testing program approved by HHS, if applicable, for each additional specialty and subspecialty of service for which the laboratory requests a revised certificate.

§ 493.806 Condition: Successful participation before certification.

Prior to the expiration of the provisional certificate, laboratories performing Level I and Level II tests must demonstrate satisfactory performance in three consecutive testing events of a proficiency testing program approved by HHS, if applicable, for each specialty and subspecialty of service performed.

§ 493.807 Condition: Reinstatement of laboratories performing Level I and Level II tests after failure to participate successfully.

(a) If a laboratory's certificate is suspended and/or Medicare approval is terminated because it fails to participate successfully in proficiency testing for one or more specialties or subspecialties, or voluntarily withdraws its certification under CLIA for the failed specialty or subspecialty, the laboratory must then demonstrate sustained successful performance on three consecutive proficiency testing events, at least one of which will be on-site proficiency testing, before HHS will consider it for reinstatement for certification or Medicare approval in that specialty or subspecialty.

(b) The termination period for Medicare approval or period for suspension of certification under CLIA for the failed specialty or subspecialty is for a period of not less than six months from the date of termination or suspension.

Proficiency Testing by Speciality and Subspecialty for Laboratories performing Level I and Level II Tests

§ 493.821 Condition: Microbiology.

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

§ 493.823 Standard; Bacteriology: Level I and Level II Tests.

(a) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.825 Standard; Mycobacteriology: Level II Tests.

(a) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.827 Standard; Mycology: Level II Tests.

(a) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.829 Standard; Parasitology: Level II tests.

(a) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.831 Standard; Virology: Level II tests.

(a) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and

results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.833 Condition: Diagnostic immunology.

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

§ 493.835 Standard; Syphilis serology: Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.837 Standard; General immunology: Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.839 Condition: chemistry.

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

§ 493.841 Standard; Routine chemistry: Level I and Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.843 Standard; Endocrinology: Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.845 Standard; Toxicology: Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analytes in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.849 Condition: Hematology.

The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

§ 493.851 Standard; Hematology: Level I and Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.853 Condition: Pathology.

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

§ 493.855 Standard; Cytology: Level II tests; Gynecologic examinations.

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must require each individual engaged in the examination of gynecologic preparations to be tested twice per year. To insure this biannual examination, once a year one unannounced testing event will be conducted on-site in each laboratory and no less than four announced testing events will be conducted annually in each State. HHS will designate the testing sites.

(b) An individual is determined to have failed a testing event if he or she scores less than 80% on a test set. For any individual who fails a proficiency testing event, the laboratory must provide him or her with immediate remedial training and education in the area of failure, and must assure that all subsequent gynecologic slides are reexamined until the individual is retested and scores at least 80% on the next testing event. If a cytotechnologist qualified under § 493.1437 or § 493.1427(b)(5) of this part fails the testing event, at least the last 500 negative slides examined by the cytotechnologist before the failed testing event must be reexamined. The reexamination must be performed by a second cytotechnologist qualified under § 493.1427(b)(5) or § 493.1437 of this part or the technical supervisor in cytology qualified under § 493.1421(a) or § 493.1421(f) of this part who achieved a score of at least 80% on the most recent proficiency testing event. When a technical supervisor in cytology qualified under § 493.1421(a) or § 493.1421(f) fails a proficiency testing event, at least the last 500 slides examined by the individual before the failed testing event must be reexamined. The reexamination must be performed by an individual who qualifies under § 493.1421(a) or § 493.1421(f) and achieved a score of at least 80% on the most recent proficiency testing event.

(c) If a laboratory fails to take required remedial actions as described in paragraph (b) of this section when one or more individual fails a testing event, HHS will initiate intermediate sanctions or revoke it's certificate for gynecologic testing under CLIA, and, if applicable, terminate the laboratory's Medicare approval for gynecologic cytology testing.

§ 493.857 Condition: Immunohematology.

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and Rh_0 (D) group; unexpected antibody detection; compatibility testing; and antibody identification.

§ 493.859 Standard; ABO group and Rh_0 (D) group: Level II tests.

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.861 Standard; Unexpected antibody detection: Level II tests.

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.863 Standard; Compatibility testing: Level II tests.

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d) For any unsatisfactory testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

§ 493.865 Standard; Antibody identification: Level II tests.

(a) Failure to attain a score of at least 80% of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80% is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the timeframe allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the timeframe for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the timeframe specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e) For any unsatisfactory analyte performance or testing event, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. All remedial action taken must be documented and maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

11. Subpart I is revised to read as follows:

Subpart I—Proficiency Testing Programs for Level I and Level II Tests

§ 493.901 Approval of proficiency testing programs.

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency. The organization, government, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty and subspecialty for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate the testing results, and identify performance problems in a timely manner; and

(b) Demonstrate to HHS that it has—

(1) The technical ability required to—

(i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606 and 640; and

(ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and frequency to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide, Statewide or nationwide, reports to regulatory agencies on individual laboratory performance on testing events, cumulative reports about laboratory performance, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test; and

(6) A mechanism for participants to notify the proficiency testing program within seven days from the scheduled date of shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing.

(c) Meet the specific criteria for proficiency testing programs listed by specialty and subspecialty of services contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with a description of program content and grading criteria.

§ 493.903 Administrative responsibilities.

The proficiency testing program must—

(a) Issue reports in a format approved by HHS on each laboratory's performances for the individual CLIA-certified specialty or subspecialty of service within 45 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program. Copies of these laboratory reports must be sent to the State survey agency or, if applicable, to the approved accreditation organization at the same time reports are sent to the laboratory;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing results available, on a reasonable basis, upon reguest;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959; and

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings.

§ 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet the

criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, HHS will notify the program and all laboratories enrolled in the proficiency testing program of the nonapproval and the reasons for nonapproval.

§ 493.907 Process for updating proficiency testing programs.

HHS reviews the requirements for proficiency testing on a regular basis and considers revisions to the program based on the performance of laboratories. It will change requirements after soliciting comments from concerned groups regarding the need to modify the criteria for an approved proficiency testing program. Changes in the program may be made to incorporate new analytes, tests, or organisms of clinical significance, to delete obsolete or, in certain cases, well-performed tests; to improve the evaluation scheme; or to delete or add tests based on the tests' status in the certificate of waiver category. When HHS decides to include new challenges or evaluation criteria in future proficiency testing, it will notify all proficiency testing programs of the necessary changes in proficiency testing and require these changes to be provided by approved proficiency testing programs within two years of the notice of change.

Proficiency Testing Programs by Specialty and Subspecialty for Level I and Level II Tests

§ 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.

§ 493.911 Bacteriology: Level I and Level II tests.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are three types of laboratories:

(1) Those that interpret Gram stains from sources other than discharges and exudates, use direct antigen techniques to detect an organism, perform primary inoculation, or perform any combination of these;

(2) Those that—

(i) May use direct antigen techniques to detect an organism or isolate aerobic and anaerobic bacteria from mixed bacterial populations, and perform limited identification; and

(ii) Interpret Gram stains from sources other than discharges and exudates, and perform antimicrobial susceptibility tests on selected microorganisms isolated, or both; and

(3) Those that—

(i) Interpret Gram stains from sources other than discharges and exudates and are able to identify aerobic and anaerobic bacteria from mixed bacterial populations to both genus and species in most patient specimens and perform antimicrobial susceptibility tests on the microorganisms isolated; and

(ii) May use direct antigen techniques to detect an organism.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be four testing events per year. The samples may be provided to the laboratory through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigens detection and bacterial isolation and identification.

(1) An approved program must, prior to each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include two types of samples and each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a significant pathogen that is clearly responsible for a described illness (excluding immuno-compromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate.

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immunocompromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

Anaerobes:
- *Bacteroides fragilis group*
- *Clostridium perfringens*
- *Peptostreptococcus anaerobius*

Enterobacteriaceae:
- *Klebsiella pneumoniae*
- *Salmonella typhimurium*
- *Serratia marcescens*
- *Shigella sonnei*
- *Yersinia enterocolitica*

Gram-positive bacilli:
- *Listeria monocytogenes*
- *Corynebacterium* species CDC Group JK

Gram-positive cocci:
- *Staphylococcus aureus*
- *Streptococcus* Group A
- *Streptococcus* Group B
- *Streptococcus* Group D (*S. bovis* and *enterococcus*)
- *Streptococcus pneumoniae*

Gram-negative cocci:
- *Branhamella catarrhalis*
- *Neisseria gonorrhoeae*
- *Neisseria meningitidis*

Miscellaneous Gram-negative bacteria:
- *Campylobacter jejuni*
- *Haemophilis influenza*, Type B

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predictable pattern of sensitivity or resistance to the common antimicrobial agents.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (6) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain from sources other than discharges and exudates. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response, for Gram stain interpretation, organism detection and identification or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified

principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be $1/(1+1)\times100=50$ percent.

(3) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in § 493.911(c)(1) using criteria based on a consensus document such as the standards established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for *Enterobacteriaceae* using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an *Enterobacteriaceae,* and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be $2/3\times100=67$ percent.

(5) The score for a sample in bacteriology is the score determined under paragraph (c)(2) of this section for isolation and identification of organisms or, if the laboratory also performs antimicrobial susceptibility testing for the organism, the score determined by dividing the total number of correct organisms a laboratory identified plus the number of correct antimicrobial agent responses by the number possible organisms plus the number of additional erroneous organisms reported plus the actual number of correct susceptibility responses (see paragraph (c)(4) of this section) multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained three reportable organisms and a laboratory reported all three correctly, but reported one additional organism, which was not present, and reported correct results for two of three antimicrobial agents tested, its score for the sample would be:

$(3+2)/(3+1+3)\times100=71$ percent.

(6) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The performance criterion for Gram stain is gram positive or gram negative.

§ 493.913 Mycobacteriology: Level II tests.

(a) *Types of services offered by laboratories.* In mycobacteriology, there are three types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains or those that interpret acid-fast stains and refer cultures to another laboratory for identification;

(2) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis,* but refer other mycobacteria species to another laboratory for identification and/or susceptibility tests; and

(3) Those that interpret acid-fast stains, isolate and identify all Mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated, or interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS for on-site testing events. For types of laboratories specified in paragraphs (a)(2) and (3) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and correct responses for antimycobacterial susceptibility for any designated isolate.

(2) An approved program may vary over time. For example, the types of mycobacteria that might be included in an approved program over time are—

TB
Mycobacterium tuberculosis
Mycobacterium bovis
Group I
Mycobacterium kansasii
Group II
Mycobacterium szulgai
Group III
Mycobacterium avium-intracellulare
Group IV
Mycobacterium terrae
Group V
Mycobacterium fortuitum

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes *Mycobacterium tuberculosis* that has a predicatable pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraph (a)(1), the program must provide at least 5 samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c) (1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain and for isolation and identification. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional

erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $1 / (1+1) \times 100 = 50$ percent.

(3) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in § 493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be $2/3 \times 100 = 67$ percent.

(5) The score for a sample in mycobacteriology is the score determined under paragraph (c)(2) of this section for detection and identification of organisms. If the laboratory also performs antimycobacterial susceptibility testing, the score is determined by dividing the total number of correct organisms a laboratory identified plus the number of correct antimycobacterial agent responses as determined by the program by the number of possible organisms plus the number of additional erroneous organisms reported plus the actual number of correct susceptibility responses multiplied by 100. For example, if a sample contained one principal organism and a laboratory reported it correctly, and reported correct results for two of three antimycobacterial agents tested, its score for the sample would be:

$(1+2) / (1+3) \times 100 = 75$ percent

(6) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms.

§ 493.915 Mycology: Level II tests.

(a) *Types of services offered by laboratories.*—In mycology, there are two types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes: [1]

(1) Those that isolate and perform identification to the genus level; and

(2) Those that isolate and perform identification of organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be four testing events per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

Candida albicans
Candida (other species)
Cryptococcus neoformans
Sporothrix schenckii
Exophiala jeanselmei
Fonsecaea pedrosoi
Acremonium sp.
Trichophyton sp.
Aspergillus fumigatus
Nocardia sp.
Blastomyces dermatitidis [2]
Zygomycetes sp.

[1] KOH preparations are excluded from proficiency testing.

[2] Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c) (1) through (3) of this section.

(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be $1/(1+1) \times 100 = 50$ percent.

(3) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

§ 493.917 Parasitology: Level II tests.

(a) *Types of services offered by laboratories.* In parasitology there are two types of laboratories for proficiency testing purposes—

(1) Those that are able to determine the presence of parasites by direct observation (wet mount) and refer them to another laboratory for identification; and

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The samples may be provided through mailed shipments or, at HHS' option,

may be provided to HHS for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time and must exclude *Enterobius vermicularis*. As an example, the types of parasites that might be included in an approved program over time are—

Entamoeba histolytica
Entamoeba coli
Giardia lamblia
Endolimax nana
Dientamoeba fragilis
Iodamoeba butschli
Chilomastix mesnili
Hookworm
Ascaris lumbricoides
Strongyloides stercoralis
Trichuris trichiura
Diphyllobothrium latum
Cryptosporidium sp.
Plasmodium falciparum

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (4) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported or if the program has assured itself that the samples that were distributed were homogeneous, it could rely on the following method of determining 80 percent consensus. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. Sample scores must be averaged to determine the score for the testing event.

(2) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be $1/(1+1)\times 100=50$ percent.

(3) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

§ 493.919 Virology: Level II tests.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The samples may be provided to the laboratory through mailed shipments or, at HHS option, may be provided to HHS for onsite testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must, prior to each calendar year, furnish HHS with a description of samples that it plans to include in its annual program. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as *Herpes simplex*, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c)(1) through (4) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories. Each sample score must be averaged to determine the testing event score.

(2) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be $1/(1+1)\times 100=50$ percent.

(3) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen.

§ 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§ 493.923 and 493.927.

§ 493.923 Syphilis serology: Level II tests.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Challenges per quarter.* The minimum number of challenges per testing event a program must offer for syphilis serology is five.

(c) *Evaluation of analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (4) of this section.

(1) To determine the accuracy of a laboratory s response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in syphilis serology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations the response differs from the target value. The criterion for acceptable performance for quantitative syphilis serology tests is the target value ± 1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is positive or negative.

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.927 General immunology: Level II tests.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be four testing events per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS option, may be provided to HHS for on-site testing.

(b) *Challenges per quarter.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five.

Analyte or test procedure
Alpha-1 antitrypsin
Alpha-fetoprotein
Antinuclear antibody
Antistreptolysin O, quantitative
Anti-human immunodeficiency virus (HIV)
Complement C3
Complement C4
Hepatitis markers (HBsAg, anti-HBc, HBeAg)
IgA
IgG
IgE
IgM
Infectious mononucleosis, quantitative
Rheumatoid factor, quantitative
Rubella

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

Criteria for acceptable performance. The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin	Target value ±3 SD.
Alpha-fetoprotein	Target value ±3 SD.
Antinuclear antibody	Target value ±1 dilution or (pos. or neg.).
Antistreptolysin O	Target value ±1 dilution.
Anti-Human Immunodeficiency Virus.	Reactive or nonreactive.
Complement C3	Target value ±3 SD.
Complement C4	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or nonreactive (negative).
IgA	Target value ±3 SD.
IgE	Target value ±3 SD.
IgG	Target value ±3 SD.
IgM	Target value ±3 SD.
Infectious mononucleosis	Target value ±1 dilution.
Rheumatoid factor	Target value ±1 dilution.
Rubella	Target value ±1 dilution or (pos. or neg.).

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.929 Chemistry.

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

§ 493.931 Routine chemistry: Level I and Level II tests.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for chemistry, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing.

(b) *Challenges per quarter.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

Analyte or test procedure

Alanine aminotransferase (ALT/SGPT)
Albumin
Alkaline phosphatase
Amylase
Aspartate aminotransferase (AST/SGOT)
Bilirubin, total
Blood gas pH
pO_2
pCO_2
Calcium, total
Chloride
Cholesterol, total
Cholesterol, high density lipoprotein
Creatine kinase
Creatine kinase, isoenzymes
Creatinine
Glucose
Iron, total
Lactate dehydrogenase (LDH)
LDH isoenzymes
Magnesium
Potassium
Sodium
Total Protein
Triglycerides
Urea Nitrogen
Uric Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria (percentage difference from the target value) or the number of standard deviations (SDs) the response differs from the target value.

Criteria for acceptable performance. The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT).	Target value ±20%
Albumin	Target value ±10%
Alkaline phosphatase	Target value ±3 SD
Amylase	Target value ±3 SD
Aspartate aminotransferase (AST/SGOT).	Target value ±20%
Bilirubin, total	Target value ±0.3 mg/dL or ±20% (greater).
Blood gas pO_2	Target value ±3 SD
pCO_2	Target value ±5 mm Hg or ±8% (greater).
pH	Target value ±0.04
Calcium, total	Target value ±1.0 mg/dL.
Chloride	Target value ±5%
Cholesterol, total	Target value ±10%
Cholesterol, high density lipoprotein.	Target value ±3 SD
Creatine kinase	Target value ±3 SD
Creatine kinase isoenzymes.	MB elevated (+ or −) or Target value ±3 SD.
Creatinine	Target value ±0.3 mg/dL or ±15% (greater).
Glucose	Target value ±6 mg/dl or ±10% (greater).
Iron, total	Target value ±20%
Lactate dehydrogenase (LDH).	Target value ±20%
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ±3 SD.
Magnesium	Target value ±25%
Potassium	Target value ±0.5 mmol/L.
Sodium	Target value ±4 mmol/L
Total Protein	Target value ±10%
Triglycerides	Target value ±3 SD
Urea nitrogen	Target value ±2 mg/dL or ±9% (greater).
Uric acid	Target value ±17%

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.933 Endocrinology: Level II tests.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing.

(b) *Challenges per quarter.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

Analyte or test
Cortisol
Free Thyroxine
Human Chorionic Gonadotropin
T_3 Uptake
Triiodothyronine
Thyroid-stimulating hormone
Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria (percentage difference from the target value) or the number of standard deviations (SDs) the response differs from the target value.

Criteria for acceptable performance. The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cortisol	Target value ± 25%.
Free Thyroxine	Target value ± 3 SD.
Human Chorionic Gonadotropin.	Target value ± 3 SD.
T_3 Uptake	Target value ± 3 SD by Method.
Triiodothyronine	Target value ± 3 SD.
Thyroid-stimulating hormone.	Target value ± 3 SD.
Thyroxine	Target value ± 3 SD.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte event samples}} \times 100 = \text{Analyte score for the testing event}$$

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.937 Toxicology: Level II tests.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be four testing events per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS option, may be provided to HHS for on-site testing.

(b) *Challenges per quarter.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

Analyte or test procedure
Alcohol (blood)
Blood lead
Carbamazepine
Digoxin
Ethosuximide
Gentamicin
Lithium

Phenobarbital
Phenytoin
Primidone
Procainamide (and metabolite)
Quinidine
Theophylline
Valproic Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative and qualitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80 percent of ten or more referee laboratories or 80 percent or more of all participating laboratories. The score for a sample in toxicology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria (percentage difference from the target value) or the number of standard deviations (SDs) the response differs from the target value.

Criteria for acceptable performance. The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood	Target value — 25%.
Blood lead	Target value — 15% or — 6 mcg/dL (greater).
Carbamazepine	Target value — 25%.
Digoxin	Target value — 20% or — 0.2 ng/mL (greater).
Ethosuximide	Target value — 20%.
Gentamicin	Target value — + 25%.
Lithium	Target value — 0.2 mmol/L or — 20% (greater).
Phenobarbital	Target value — + 20%.
Phenytoin	Target Value — 25%.
Primidone	Target Value — 25%.
Procainamide (and metabolite).	Target Value — 25%.
Quinidine	Target Value — 25%.
Theophylline	Target Value — 25%.
Valproic Acid	Target Value — 25%.

(3) The criterion for acceptable performance for qualitative toxicology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testin event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.941 Hematology (including routine hematology and coagulation): Level I and Level II tests.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing.

(b) *Challenges per quarter:* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or test procedure

Cell identification
White cell differential
Erythrocyte count
Hematocrit
Hemoglobin
Leukocyte count
Platelet count
Fibrinogen
Partial thromboplastin time
Prothrombin time

(1) An approved program for cell identification may vary over time. For example, the types of cells that might be included in an approved program over time are—

Neutrophilic granulocytes
Eosinophilic granulocytes
Basophilic granulocytes
Lymphocytes
Monocytes
Major red and white blood cell abnormalities
Immature red and white blood cells

(2) White cell differentiation should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 80% of ten or more referee laboratories or 80% or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria (percentage difference from the target value) or the number of standard deviations (SDs) the response differs from the target value.

Criteria for acceptable performance. The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification	80% or greater consensus on identification.
White cell differentiation.	Target ±3 SD based on the percentage of different types of white cells in the samples.
Erythrocyte count	Target ± 3SD or ±6% (lesser).
Hematocrit	Target ±3 SD or ±6% (lesser).
Hemoglobin	Target ±3 SD or ±7% (lesser).
Leukocyte count	Target ±3 SD or ±15% (lesser).
Platelet count	Target ±3 SD or ±25% (lesser).
Fibrinogen	Target ±3 SD.
Partial thromboplastin time.	Target ±3 SD or ±15% (greater).
Prothrombin time	Target ±3 SD or ±15% (greater).

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

§ 493.945 Cytology: Level II tests; Gynecologic examinations.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide 20 glass slide preparations per test set. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been maintained by the laboratory for the required periods specified in § 493.1257 or the proficiency testing program must ensure that slides loaned to it are retrievable upon request if necessary. Each test set should include slides representing some but not necessarily all of the following: unsatisfactory preparations; normal challenges; infectious agents; and benign reactive processes, premalignant processes, and malignant processes.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on a 20 slide test set in which the slides have been referenced in a scientifically defensible manner.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects consensus agreement or confirmation. For slide preparations that are normal, unsatisfactory, benign reactive processes or contain infection agents, an 80% consensus agreement of at least five physicians certified in anatomic pathology is required. For premalignant or malignant slide preparations, confirmation by tissue biopsy is required. An 80% consensus agreement of at least five physicians certified in anatomic pathology is also required on tissue biopsies that confirm the premalignant or malignant cytology slides used in proficiency testing events.

(2) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(2)(i) and (ii) of this section.

(i) Each slide set must contain 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition. Total points for slide set must be established by the proficiency testing program and need not be 100.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) In accordance with the criteria for the scoring system, the chart in paragraph (b)(2)(ii)(B) of this section, provides a maximum of 2 points is awarded for a correct response and a minimum of minus one (−1) point is assessed for misinterpretation of malignant and premalignant smears. For example, if the correct response on a slide is "squamous abnormality, high grade" (category "D" on the scoring system chart) and an examinee calls it "normal/negative" (category "B" on the scoring system chart), then the examinee's point value on that slide is calculated as minus one (−1). Each slide is scored individually in the same manner.

The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, divided by the total points for the testing event and multiplied by 100. For example, if a testing event has a total point score of 40 and an individual has a point score of 32, the individual's testing event score is $32/40 \times 100 = 80\%$.

(B) Criteria for scoring system.

Response categories (Bethesda system description in § 493.958 of this subpart)	A	B	C	D
A Unsatisfactory	2	0	0	0
B Normal/Negative Infection Reactive and Reparative Changes	0	2	1	0
C Squamous cell abnormalities (low grade)	−1	−1	2	1
D Squamous cell abnormalities (high grade); Glandular cell abnormalities; Non-epithelial malignant neoplasm	−1	−1	1	2

(c) Proficiency testing reporting for cytology. The format and terminology for reporting cytopathology proficiency testing results is taken from the 1988 Bethesda System for Reporting

Cervical/Vaginal Cytologic Diagnoses, including a statement on adequacy of the specimen, a general categorization of the diagnosis and the descriptive diagnosis as follows:

(1) *Statement on specimen adequacy.*
(i) Satisfactory for interpretation;
(ii) Less than optimal;
(iii) Unsatisfactory.

(2) *Explanation for "less than optimal/unsatisfactory samples":*
(i) Scant cellularity;
(ii) Poor fixation or preservation;
(iii) Presence of foreign material (e.g., lubricant);
(iv) Partially or completely obscuring inflammation;
(v) Partially or completely obscuring blood;
(vi) Excessive cytolysis or autolysis;
(vii) No endocervical component in a premenopausal woman who has a cervix;
(viii) Not representative of the anatomic site;
(ix) Other.

(d) *General categorization.* (1) Within normal limits;
(2) Other. See descriptive diagnosis. Further action recommended.

(e) *Descriptive diagnoses*—(1) *Infection*—(i) *Fungal.* (A) Fungal organisms morphologically consistent with *Candida species;*
(B) Other.
(ii) *Bacterial.* (A) Microorganisms morphologically consistent with *Gardnerella species;*
(B) Microorganisms morphologically consistent with *Actinomyces species;*
(C) Cellular changes suggestive of *Chlamydia species* infection, subject to confirmatory studies;
(D) Other.
(iii) *Protozoan.* (A) *Trichomonas vaginalis;*
(B) Other.
(iv) *Viral.* (A) Cellular changes associated with cytomegalovirus;
(B) Cellular changes associated with herpes simplex virus;
(C) Other.

[Note: For human papillomavirus (HPV), refer to "Epithelial cell abnormalities, Squamous Cell," in paragraph (e)(3)(i) of this section.]

(v) *Other.*
(2) *Reactive and reparative changes.*
(i) Inflammation—
(A) Associated cellular changes;
(B) Follicular cervicitis.
(ii) Miscellaneous (as related to patient history)—
(A) Effects of therapy;
(B) Ionizing radiation;
(C) Chemotherapy;
(D) Effects of mechanical devices (e.g., intrauterine contraceptive device);
(E) Effects of non-steroidal estrogen exposure (e.g., diethylstilbestrol);
(F) Other.

(3) *Epithelial cell abnormalities*—(i) *Squamous cell.* (A) Atypical squamous cells of undetermined significance (recommended follow-up and/or type of further investigation; specify).
(B) Squamous intraepithelial lesion (SIL) (comment on presence of cellular changes associated with HPV if applicable)—
(*1*) Low-grade squamous intraepithelial lesion, encompassing—
(*i*) Cellular changes associated with HPV;
(*ii*) Mild (slight) dysplasia/cervical intraepithelial neoplasia grade 1 (CIN 1).
(*2*) High-grade squamous intraepithelial lesion, encompassing—
(*i*) Moderate dysplasia/CIN 2;
(*ii*) Severe dysplasia/CIN 3;
(*iii*) Carcinoma in situ/CIN 3.
(C) Squamous cell carcinoma.
(ii) *Glandular cell.* (A) Presence of endometrial cells in one of the following circumstances—
(*1*) Out-of-phase in a menstruating woman;
(*2*) In a postmenopausal woman;
(*3*) No menstrual history available.
(B) Atypical glandular cells of undetermined significance (recommended follow-up and/or type of further investigation: specify)
(*1*) Endometrial;
(*2*) Endocervical;
(*3*) Not otherwise specified.
(C) Adenocarcinoma.
(*1*) Specify probable site of origin: endocervical, endometrial, extrauterine;
(*2*) Not otherwise specified.
(D) Other epithelial malignant neoplasm: specify.

(4) *Non-epithelial malignant neoplasm:* specify.

§ 493.959 Immunohematology: Level II tests.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—
(1) Those that perform ABO and/or Rh_0 (D) group;
(2) Those that perform ABO and/or Rh_0 (D) group, and unexpected antibody detection;
(3) Those that perform ABO and/or Rh_0 (D) group, unexpected antibody detection, and compatibility testing; and
(4) Those that perform ABO and/or Rh_0 (D) group, unexpected antibody detection, compatibility testing, and antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be four testing events per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS for on-site testing.

(c) *Challenges per quarter.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

Analyte or test procedure
ABO group (excluding subgroups)
Rh_0 (D) group
Unexpected antibody detection
Compatibility testing
Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100% of ten or more referee laboratories or 95% or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95% of ten or more referee laboratories or 95% or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d) (2) or (3) of this section.

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group	100% accuracy.
Rh_0 (D) group	100% accuracy.
Unexpected antibody detection.	80% accuracy.
Compatibility testing	100% accuracy.
Antibody identification.	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable

analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of analyte samples}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

12. Subpart J is revised to read as follows:

Subpart J—Patient Test Management For Level I and Level II Testing

§ 493.1101 Condition: Patient test management; Level I and Level II testing.

Each laboratory performing Level I or Level II testing, or both, must employ and maintain a system that provides for proper collection, receipt, and processing and accurate result reporting of patient specimens, and that meets the standards in paragraphs (a) through (e) of this section.

(a) *Standard; Procedures for specimen submission.* The laboratory must have available and follow written policies and procedures regarding specimen collection to include patient preparation, if applicable, labeling, preservation or fixation, including conditions for proper transportation and processing or preparation of specimens that, when followed, will assure the optimum condition of patient specimens for testing. The laboratory must make available to clients written instructions for specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation and conditions necessary for transportation to ensure that specimens submitted are received in a condition acceptable for testing.

(b) *Standard; Specimen requisition.* The laboratory must perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days of the request. Records of test requisitions must be maintained for at least two years. The laboratory must assure that the requisition includes—

(1) The patient's name or other method of specimen identification to assure accurate reporting of results;

(2) The name and address or other suitable identifiers of the authorized person who ordered the test or the name and address of the laboratory submitting the specimen;

(3) The date of specimen collection;

(4) The time of specimen collection, when pertinent to testing;

(5) The source of specimen, if pertinent, and name or identifying laboratory code number of test(s) ordered;

(6) Patient sex and age or date of birth;

(7) Pertinent clinical information; and

(8) For Pap smears, the last menstrual period and indication of whether the patient had a previous abnormal report, treatment or biopsy and, if available, information indicating whether the patient is at risk for developing cervical cancer or its precursors.

(c) *Standard; Specimen records.* The laboratory must maintain a system to ensure reliable specimen identification, and must document each step in the processing and testing of patient specimens to assure that accurate test results are reported. Records of patient testing must be maintained for at least two years, and immunohematology records must be maintained for five years. This system must provide documentation of information specified in paragraphs (b)(1) through (b)(8) of this section and—

(1) The accession number or other identification of the specimen;

(2) The date and time of specimen receipt into the laboratory;

(3) The condition, and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and

(4) The records and dates of performance of each step in patient testing leading to the final report to assure proper identification and reliable reporting of test results.

(d) *Standard; Test report.* The laboratory report must be sent promptly to the authorized person or laboratory that initially requested the test. A legally reproduced record of each test result, including preliminary reports, must be preserved by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports must be maintained by the laboratory for a period of five years. For pathology, test reports must be maintained at least ten years after the date of reporting.

(1) The laboratory must have adequate systems in place to report results in a timely, accurate and reliable manner and, when appropriate, these systems should also ensure the confidentiality of test results.

(2) The legally reproduced copies of test reports must be filed in the laboratory in a manner that permits ready identification and accessibility.

(3) The results or transcripts of laboratory tests or examinations must be released only to authorized persons.

(4) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered or who utilizes the test results.

(5) The laboratory must establish special reporting procedures for imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual requesting the test or the individual responsible for utilizing test results when any test result indicates an imminent life-threatening condition.

(6) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(7) The laboratory must upon request make available to clients a list of test methods employed by the laboratory

and a basis for the listed "reference" or "normal" ranges. In addition, information that may affect the interpretation of test results, such as test interferences, if known, and performance claims including, where applicable, detection limits, sensitivity, specificity, accuracy, precision and validity of test measurement and other pertinent test characteristics must be provided upon request. Updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(8) The test report must indicate the name and address of each laboratory location at which each test was performed.

(e) *Standard; Referral of specimens.* A laboratory may refer specimens for testing only to a laboratory that is certified to perform testing for the appropriate level of testing and specialty or subspecialty of services.

(1) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

(2) If the referring laboratory interprets or revises in any way the test results provided by the testing laboratory, the referring laboratory must notify the authorized person who requested the test or examination and the testing laboratory. The referring laboratory must maintain a legally reproduced copy of such interpretations, alterations or revisions and of the notice to the client and testing laboratory.

(3) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must maintain a legally reproduced copy of each testing laboratory's report.

13. Subpart K is revised to read as follows:

Subpart K—Quality Control for Level I and Level II Testing

§ 493.1201 Condition: General quality control; Level I and Level II testing.

(a) Quality control requirements are specified in this subpart unless HHS approves a lesser frequency in appendix C of the State Operations Manual (HCFA Pub. 7)

(b) The laboratory must impose and practice quality control procedures that provide and assure accurate, reliable and valid test results and reports and that meet the standards in §§ 493.1203 through 493.1221 of this subpart.

§ 493.1203 Standard; Facilities.

The laboratory must be constructed, arranged and maintained to ensure adequate space, ventilation and essential utilities for the performance and reporting of tests. The laboratory must ensure that an adequate, stable, electrical source is maintained for laboratory equipment. The laboratory is responsible for identifying power surges, fluctuations, or loss of voltage which affect laboratory instrumentation and documenting the remedial action taken to correct problems related to electrical power variances.

§ 493.1205 Standard; Adequacy of methods and equipment.

The laboratory must employ methodologies and equipment that provide accurate and reliable test results and reports.

(a) The laboratory must have appropriate and sufficient equipment and instruments for the type and volume of testing performed.

(b) The equipment and instrumentation used must be capable of providing test results within the laboratory's stated performance characteristics. These performance characteristics include detection limits, precision, accuracy, specificity, and sensitivity as well as freedom from interferences and related test variables.

(c) Test procedures or examinations, or both, must be performed in a manner that provides test results within the laboratory's stated performance characteristics for its test method, including precision, accuracy, sensitivity, specificity, and detection limits as well as freedom from interference and related test variables.

§ 493.1207 Standard; Temperature and humidity monitoring.

Temperature and humidity must be maintained and monitored within a defined acceptable range to assure—

(a) Proper storage of specimens, tissue, reagents and supplies; and

(b) Accurate and reliable test performance and reporting.

§ 493.1209 Standard; Labeling of testing supplies.

(a) Reagents, solutions, culture media, controls, calibrators and other materials must be labeled to indicate—

(1) Identity and, when significant, titer, strength or concentration;

(2) Recommended storage requirements;

(3) Preparation or expiration date; and

(4) Other pertinent information.

(b) The laboratory may not use materials that have exceeded their expiration date, are of substandard reactivity, or have deteriorated. The laboratory must comply with the Food and Drug Administration licensed product dating requirements of 21 CFR 610.53. Any exception to these product dating requirements will be granted by the Food and Drug Administration in accordance with 21 CFR 610.53(d).

(c) Components of each kit of reagents may not be interchanged with other kit reagents of different lot numbers unless otherwise specified by the manufacturer.

§ 493.1211 Standard; Procedure manual.

(a) Personnel examining specimens and performing related procedures within a specialty or subspecialty must have available in the testing area complete written instructions and descriptions related to the current analytical methods or procedures used by personnel concerning:

(1) Specimen requirements and processing;

(2) Microscopic examination, including procedures for detecting inadequately prepared slides;

(3) Preparation of slides, solutions, reagents, materials, and stains;

(4) Calibration;

(5) Quality control;

(6) Quality assurance;

(7) Limitations in methodologies;

(8) Actions to be followed when quality control results deviate from expected values or patterns;

(9) Reporting patient results, including test calculations;

(10) Pertinent literature references;

(11) Alternative methods for performing tests or preserving the test specimens in the event that a test system becomes inoperable; and

(12) Appropriate criteria for specimen storage to ensure specimen integrity until testing can be conducted.

(b) Procedures must be initially approved, signed and dated by the current director of the laboratory.

(c) Each change in a procedure must be approved, signed and dated by the current director of the laboratory.

(d) The laboratory must maintain copies of each procedure it uses and the length of time the procedure was in use. These records must be maintained for two years after a procedure has been discontinued.

(e) Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

§ 493.1213 Standard; Equipment maintenance and function checks.

The laboratory establishes and employs policies and procedures for—

(a) The proper maintenance of equipment, instruments and test systems by—

(1) Defining its preventive maintenance program for each instrument and piece of equipment based on the manufacturer's instructions. A laboratory must document that preventative maintenance has occurred with at least the frequency recommended by the manufacturer. If the manufacturer does not specify a frequency, the laboratory must document the validity of its preventive maintenance program; and

(2) Documenting the performance of its preventive maintenance program.

(b) Performing and documenting function checks on equipment, including but not limited to spectrophotometers, radioactive counters, particle counters, automated analyzers, centrifuges, densitometers and data processors to assure proper performance and accurate and reliable test results by—

(1) Rechecking, calibrating or recalibrating each instrument, device or test system at least once each day of use or more frequently, as specified by the manufacturer;

(2) Performing the function checks with at least the frequency specified by the manufacturer. The laboratory must establish performance criteria for each test or procedure if the manufacturer of the test system or equipment has not specified the type of maintenance and function checks to perform; and

(3) Performing all necessary baseline or background checks each day of use on radioactive counters, particle counters, refractometers, spectrophotometers and other equipment requiring such measurements. Background or baseline checks must be performed and be within acceptable limits before patient testing.

§ 493.1215 Standard; Validation of methods.

The laboratory must have a written protocol and documentation for the validation of each method that verifies that the method produces test results within the laboratory's stated performance characteristics. Method validation must be performed before a test procedure is placed into routine use, thereafter, each method must be checked through calibration requirements specified in § 493.1217 of this subpart.

(a) The reportable range of each quantitative method, if applicable, must be established.

(b) In the case of qualitative and screening tests, the laboratory must determine and document the basis for specifying reportable results as positive, negative, or degree of reactivity. The laboratory must follow these established limits in reporting test results.

(c) A method used by the laboratory must be validated before it is used and documentation of the validation must be available for the period during which the procedure is used by the laboratory or for two years, whichever is longer.

(d) The laboratory must have documentation of the level of precision, accuracy, sensitivity, and specificity that the laboratory claims for each method in use and for which it reports results.

(e) The laboratory must maintain documentation verifying that test systems perform according to the laboratory's specifications. This documentation must be available to the authorized persons ordering or receiving test results.

(f) The laboratory must establish its reference range for each method before reporting patient test results.

(g) The laboratory may not report patient test results if it does not have data to verify the specified test performance characteristics and reporting limits.

§ 493.1217 Standard; Frequency of quality control.

The laboratory must perform quality control at the frequencies specified in this section unless another frequency is specified in §§ 493.1223 through 493.1285 of this subpart or HHS approves a lesser frequency in Appendix C of the State Operations Manual (HCFA Pub. 7).

(a) The laboratory must establish and document a schedule for calibration, recalibration or calibration verification of each automated and manual method.

(1) The laboratory must perform calibration, calibration verification or recalibration of each automated and manual procedure at least once every six months, or more frequently if specified by the manufacturer, using a complete range of calibrators and, in addition, when any of the following occur:

(i) A complete change of reagents for a procedure is introduced. If all of the reagents for a test are packaged together, the laboratory is not required to recalibrate for each package of reagents, provided the reagents are received in the same shipment and contain the same lot number;

(ii) There is major preventive maintenance or replacement of critical parts, such as an excitor lamp;

(iii) Controls begin to reflect an unusual trend or are outside of acceptable limits;

(iv) The manufacturer's recommendations specify more frequent recalibration; or

(v) The laboratory's established schedule requires more frequent recalibration.

(2) The number of calibrators the laboratory uses to calibrate, recalibrate, or verify calibration varies by method—

(i) For methods in which a linear relationship exists between concentration and direct instrument reading, at least three points and a zero or minimum value are required; and

(ii) For methods in which a nonlinear relationship exists between concentration and direct instrument readings, at least five points and a zero or minimum value are required unless the manufacturer specifies more points for calibration. If the manufacturer specifies more than five points of calibration and a zero, the laboratory must follow the manufacturer's recommendation or document the validity of performing procedural calibration using fewer, but not less than five points.

(3) The calibrators must cover the entire range of patient values, with dilution as necessary, to be reported for the test procedures.

(4) For patient values above the maximum calibration point or below the minimum calibration point—

(i) The laboratory must report the patient results as greater than the upper limit or less than the lower limit or an equivalent designation; or

(ii) For patient samples greater than the upper limit, the laboratory must dilute the sample and the diluted sample must fall within the laboratory's reportable range for the method. If a dilution method is employed, the laboratory must be able to provide evidence that the dilution process can yield accurate, reliable and valid test results.

(b) For each procedure, the laboratory must evaluate instrument and reagent stability and operator variance in determining the frequency of testing quality control samples with each run as defined in § 493.2 of this part.

(c) For quantitative tests, the laboratory must include two calibrator samples, one calibrator sample and one control sample, or two control samples in each run of unknown samples when these reference samples are available.

(d) The laboratory must use the calibrator samples, the control samples, or combination thereof, and monitor

both the abnormal and normal range of reportable patient values.

(1) If calibrators are not used, two controls of different concentrations must be used;

(2) If controls are not used, two calibrators of different concentrations must be used. Two separate dilutions from a stock calibrator must be prepared or a calibrator and a sample spiked with a calibrator must be used;

(3) If calibrators and controls are not available, the laboratory must have a mechanism to assure the quality, accuracy and precision of the test results.

(e) For electrophoretic determinations—

(1) At least one control sample must be used in each electrophoretic cell; and

(2) The control sample must contain each of the fractions to be reported in patient samples.

(f) For qualitative tests, the laboratory must include a positive and negative control with each run of specimens.

(g) The laboratory must determine its statistical limits (e.g., mean and standard deviation) for each lot number of controls through repetitive testing. The laboratory may use the assayed control limits established by the manufacturer, provided the limits are verified by the laboratory and the manufacturer's limits correspond to the methodology and instrumentation employed by the laboratory. Acceptable limits for unassayed materials must be established over time by the laboratory through concurrent testing with a control material having previously determined ranges.

(h) Initially, the laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates and antigen detection systems) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.

(i) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(j) The laboratory must check positive and negative reactivity each time of use for fluorescent stains.

(k) Each day of use, the laboratory must test direct antigen detection systems using positive and negative control organisms that evaluate all phases of the system including the extraction and reaction phases, if appropriate.

(l) The laboratory must check each batch or shipment of media for sterility when labeled sterile, ability to support growth and, as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use a commercial manufacturer's quality control checks of media if the laboratory has documentation to verify that the manufacturer has used the quality assurance practices that have been approved by HHS in appendix C of the State Operations Manual (HCFA Pub. 7). The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results. A batch of media (solid, semi-solid, or liquid)—

(1) Consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or

(2) If received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

(m) Quality control samples must be tested in the same manner as patient specimens.

(n) Patient results may not be reported unless control results meet the laboratory's quality control criteria.

§ 493.1219 Standard; Remedial actions.

The laboratory must establish and employ policies and procedures and document actions taken when—

(a) Test systems do not meet the laboratory's established criteria, as determined in § 493.1215, including—

(1) Quality control results that are outside of acceptable limits;

(2) Equipment or methodologies that perform outside of established operating parameters or specifications; and

(3) Test results that are outside of the laboratory's reportable range, established on the basis of maximum and minimum calibration values;

(b) It cannot test samples within specified timeframes that it has established. The laboratory must establish and follow criteria for referring or for storing specimens. The laboratory must notify the individual responsible for utilizing test results if the laboratory cannot test a specimen within the laboratory's established timeframe for testing specimens;

(c) It detects errors in the reported patient results. The laboratory must promptly—

(1) Notify the authorized person ordering or individual utilizing the test results of reporting errors;

(2) Issue corrected reports to the authorized person ordering the test; and

(3) Maintain copies of the original report as well as the corrected report for two years.

(d) It does not report test results within its established time frames; and

(e) Proficiency test results are unacceptable or unsatisfactory.

§ 493.1221 Standard; Quality control—records.

(a) The laboratory must document all quality control activities specified in §§ 493.1203 through 493.1285 of this subpart and retain records for at least two years. Immunohematology quality control records must be maintained for a period of five years as specified in 21 CFR part 606, subpart I.

(b) The laboratory must maintain records of each step in the processing and testing of quality control samples to assure that the quality control samples are tested in the same manner as patient specimens.

§ 493.1223 Condition: Quality control—specialties and subspecialties.

The laboratory must establish and follow policies and procedures for an acceptable quality control program that include verification and assessment of accuracy, measurement of precision and detection of error for all analyses and procedures performed by the laboratory. In addition to the general requirements specified in §§ 493.1201 through 493.1221 of this subpart, the laboratory must meet the applicable requirements of §§ 493.1225 through 493.1285 for each specialty and subspecialty for which the laboratory is certified. Failure to meet any of the applicable conditions in §§ 493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare approval and/or revocation of CLIA certification for the entire specialty to which the condition applies. Failure to meet any of the standards in §§ 493.1227 through 493.1285 will initiate intermediate sanctions, loss of Medicare approval and/or revocation of CLIA certification for the subspecialty to which the standard applies.

§ 493.1225 Condition: Microbiology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and in §§ 493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.

§ 493.1227 Standard; Bacteriology: Level I and Level II tests.

To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201

through 493.1221 and with paragraphs (a) and (b) of this section.

(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, and oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, V, and XV discs or strips; and

(3) Each month of use for antisera.

(b) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

(1) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure, unless the laboratory can establish precision and accuracy to be within the limits established by HHS in Appendix C of the State Operations Manual (HCFA Pub. 7).

§ 493.1229 Standard; Mycobacteriology: Level II tests.

To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each day of use.

(c) The laboratory must check each week of use acid-fast stains with an acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on *Mycobacterium tuberculosis* isolates, the laboratory must check the procedure each week of use with a control strain of *Mycobacterium tuberculosis.*

§ 493.1231 Standard; Mycology: Level II tests.

To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section.

(a) Each day of use, the laboratory must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(c) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for control results must be met prior to reporting patient results.

§ 493.1233 Standard; Parasitology: Level II tests.

To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section.

(a) The laboratory must have available a reference collection of slides, or photographs, and, if available, gross specimens for identification of parasites available and use it in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must use a calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.

§ 493.1235 Standard; Virology: Level II tests.

To meet the quality control requirements for virology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

(b) The laboratory must maintain records that reflect the systems used and the reactions observed.

(c) In tests for the identification of viruses, the laboratory must employ uninoculated cells or cell substrate controls to detect erroneous identification results.

§ 493.1237 Condition: Diagnostic immunology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1239 through 493.1241 of this subpart for the subspecialties for which it is certified under the specialty of diagnostic immunology.

§ 493.1239 Standard; Syphilis serology: Level II tests.

To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control unless otherwise specified by HHS in appendix C of the State Operations Manual (HCFA Pub. 7).

(c) The laboratory must employ controls for all test components to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

§ 493.1241 Standard; General immunology: Level II tests.

To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§ 493.1202 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control unless otherwise specified by HHS in appendix C of the State Operations Manual (HCFA Pub. 7).

(b) The laboratory must employ controls for all test components (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages.

(c) The laboratory may not report test results unless the predetermined reactivity pattern is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet:

(1) The HIV testing requirements of 21 CFR 610.45; and

(2) Hepatitis testing requirements of 21 CFR 610.40.

§ 493.1243 Condition: Chemistry.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1245 through 493.1251 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

§ 493.1245 Standard; Routine chemistry: Level I and Level II tests.

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate, recalibrate or verify calibration each eight hours using two calibrators;

(b) Test control materials each eight hours of testing; and

(c) Include a calibrator or control each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

§ 493.1247 Standard; Endocrinology: Level II tests.

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§ 493.1201 through 493.1221 of this subpart.

§ 493.1249 Standard; Toxicology: Level II tests.

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart. In addition, for drug abuse screening using thin layer chromatography—

(a) Each plate must be spotted with at least one calibrator containing all drugs identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

§ 493.1253 Condition: Hematology: Level I and Level II tests.

To meet the quality control requirements for hematology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section.

(a) For hematology tests excluding coagulation, the laboratory must include two levels of control each eight hours of operation except for manual cell counts, in which one level of control is required for each eight hours of operation.

(b) For all coagulation tests the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(c) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples; and

(2) Patient and control specimens must be tested in duplicate.

§ 493.1255 Condition: Pathology.

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of pathology.

§ 493.1257 Standard; Cytology: Level II tests.

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and paragraphs (a) through (j) of this section.

(a) The laboratory must assure that—

(1) All gynecologic smears are stained using a Papanicolaou staining method;

(2) Staining solutions must be filtered or changed between the staining of gynecologic specimen batches and nongynecologic specimen batches;

(3) Prior to routine staining, all body cavity fluids are assessed for their potential to cross-contaminate other non-gynecological specimens. Those specimens found to have a high potential for cross-contamination are stained separately from other non-gynecological specimens, and the stains are filtered between batches; and

(4) Diagnostic interpretations are not reported on unsatisfactory smears.

(b) The laboratory is responsible for ensuring that—

(1) Each individual engaged in the evaluation of cytology preparations by non-automated microscopic techniques examines no more than 120 slides, which include both gynecologic and nongynecologic preparations, in a 24 hour period irrespective of the site or laboratory. Of the slide limit established by the technical supervisor for each individual in accordance with paragraph (c)(4) of this section, no more than two-thirds, up to a maximum of 80 unevaluated slides may be examined; the remaining slides that may be examined must be for quality control and quality assurance or proficiency testing purposes. Previously examined premalignant or malignant gynecologic cases defined in paragraph (c)(1) of this section, previously examined non-gynecologic cytology preparations, and tissue pathology slides examined by a person qualified under § 493.1421(a) or § 493.1421(f) are not included in the 120 slide limit.

(2) Records are maintained of the total number of slides examined by each individual during each 24 hour period irrespective of the site or laboratory and the number of hours each individual spends examining slides in the 24 hour period.

(i) The maximum number of 120 slides described in paragraph (b)(1) of this section may be examined in no less than 6 hours.

(ii) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on a part-time basis, a period of 8 hours must be used to prorate the number of slides that may be examined. Use the formula

$$\frac{\text{No. of hours} \times 120}{8}$$

to determine maximum slide volume to be examined. No more than two-thirds of the slides examined by individuals on a part-time basis may be unevaluated slides; the remaining slide preparations must be for quality control and quality assurance, or proficiency testing purposes only.

(c) The individual qualified under § 493.1421(a) or § 493.1421(f) who provides technical supervision of cytology must assure that—

(1) All gynecological smears interpreted to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus associated changes) or malignant category are confirmed by the technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology.

(2) All nongynecological cytological preparations, are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor.

(3) Provision is made for documenting and evaluating the slide examination performance of each cytotechnologist, including performance evaluation through the re-examination of normal and negative cases and feedback on the malignant or premalignant cases as defined in paragraph (c)(1) of this section referred to the technical supervisor in cytology.

(4) A maximum number of slides, not to exceed 120 slides, to be examined in 24 hours or in the period spent examining slides is established by the technical supervisor for each individual examining slide preparations by non-automated microscopic technique.

(i) The workload limit must be documented for each individual and established in accordance with the individual's capability based on the quality assurance evaluations required in § 493.1501 of this subpart.

(ii) Records are available to document that each individual's workload limit is reassessed monthly and adjusted when necessary.

(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytological examinations and the reporting of results.

(1) The laboratory must establish a program that includes a review of slides examined by each individual not qualified under § 493.1421(a) or § 493.1421(f); records of initial examinations and rescreening results must be available. The review must be complete before reporting patient results and must meet the requirements of paragraph (d)(1) (i) and (ii) of this section.

(i) At least ten percent of all gynecologic cases interpreted to be negative for malignant or premalignant conditions as defined in paragraph (c)(1) of this section must be reexamined by another cytotechnologist who meets the cytotechnologist supervisor qualifications under § 493.1427(b)(5) of this part or the technical supervisor in cytology qualified under § 493.1421(a) or § 493.1421(f) of this part; and

(ii) Gynecologic cases that are interpreted to be negative for malignant or premalignant conditions as defined in paragraph (c)(1) of this section and that are from patients who are identified as having a high probability of developing cervical cancer, as referred to at § 493.1101(b)(8), must be included in the ten percent of cases to be reexamined by another cytotechnologist qualified as a cytotechnologist supervisor under § 493.1427(b)(5) of this part or the technical supervisor of cytology qualified under § 493.1421(a) or § 493.1421(f) of this part.

(2) The laboratory must compare clinical information with cytology reports and must compare all malignant and premalignant (as defined in paragraph (c)(1) of this section) gynecology reports with the histopathology report, if available, in the laboratory (either on-site or in storage) or available through the State Health Department and determine the causes of any discrepancies.

(3) The laboratory must review all normal or negative gynecologic specimens, within the last five years, if available in the laboratory (either on-site or in storage), for each patient with a current malignant or premalignant (as defined in paragraph (c)(1) of this section) gynecologic result.

(4) The laboratory must establish and document an annual statistical evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patients reported by diagnosis, number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, as defined in paragraph (c)(1) of the section, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases as defined in paragraph (c)(1) of this section. Also, document the number of unsatisfactory specimens submitted by each physician or laboratory.

(5) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate.

(e) The laboratory report must—

(1) Clearly distinguish smears that are unsatisfactory for diagnostic interpretation;

(2) Contain narrative descriptions for any premalignant or malignant results;

(3) Include the presence of endometrial cells if endometrial cells are present out of cycle;

(4) Indicate evidence of viral infection if present;

(5) Contain appropriate provisions for follow-up recommendations; and

(6) Notify physicians if specimens and/or smears are unsatisfactory for diagnostic interpretation.

(f) Corrected reports issued by the laboratory must indicate the basis for correction.

(g) The laboratory must retain all normal, negative and unsatisfactory slide preparations for five years from the date of examination.

(h) The laboratory must retain all malignant and premalignant. as defined in paragraph (c)(1) of this section, slide preparations for ten years from the date of examination.

(i) Slides may be loaned to approved proficiency testing programs, as specified in Subparts H and I of this part, in lieu of maintaining slides for the time periods specified in paragraphs (g) and (h) of this section, only if authorized by HHS.

(j) The laboratory must report results of all malignant and premalignant gynecologic cases as defined in paragraph (c)(1) of this section to its respective State health department.

§ 493.1259 Standard; Histopathology: Level II tests.

To meet the quality control requirements for histopathology, a laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and paragraphs (a) through (f) of this section.

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stain. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination.

(c) The laboratory must retain remnants of tissue specimens in a fixative solution until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under § 493.1421(g)(1) or § 493.1421(g)(2) of this part. In addition, an individual who meets the requirements of § 493.1421(g)(1), § 493.1421(g)(2) or § 493.1421(g)(3), may examine and provide reports for specimens for skin pathology; an individual meeting the requirements of § 493.1421(a) or § 493.1421(h) may examine and provide reports for oral pathology specimens.

(d) All tissue pathology reports must be signed by an individual qualified as specified in paragraph (c) of this section. If a computer report is generated with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section.

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

(f) The laboratory must report results of all biopsy-confirmed cases of cervical

cancer to the State health department for the State in which the laboratory is located.

§ 493.1261 Standard; Oral pathology: Level II tests.

To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and § 493.1259 of this subpart.

§ 493.1263 Condition: Radiobioassay: Level II tests.

To meet quality control requirements for radiobioassay, the laboratory must meet the specific requirements of §§ 493.1201 through 493.1221 of this subpart.

§ 493.1265 Condition: Histocompatibility: Level II tests.

In addition to meeting the requirements for general quality control in §§ 493.1201 through 493.1221, for quality control for general immunology in § 493.1241 of this subpart and for immunohematology in § 493.1269 of this subpart, if applicable, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section.

(a) For renal allotransplantation the laboratory must meet the requirements of paragraphs (a)(1) through (a)(24) of this section.

(1) The laboratory must have available and follow criteria for selecting appropriate patient serum samples for crossmatching;

(2) The laboratory must have available results of final crossmatches before an organ or tissue is transplanted;

(3) The laboratory must have available and follow criteria for the technique used in crossmatching;

(4) The laboratory must have available and follow criteria for preparation of donor lymphocytes for crossmatching;

(5) The laboratory must have available and follow criteria for reporting crossmatch results;

(6) The laboratory must have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pretransplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

(7) The laboratory's storage and maintenance of both recipient sera and reagents must—

(i) Be at an acceptable temperature range for sera and components;

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and

(iii) Be well-organized with all specimens properly identified and easily retrievable;

(8) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;

(9) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;

(10) The laboratory must HLA type all potential transplant recipients;

(11) The laboratory must type cells from organ donors referred to the laboratory;

(12) The laboratory must have available and follow criteria for the preparation of lymphocytes for HLA–A, B and DR typing;

(13) The laboratory must have available and follow criteria for selecting typing reagents, whether locally or commercially prepared;

(14) The laboratory must have available and follow criteria for the assignment of HLA antigens;

(15) The laboratory's reagents for typing recipients and donors must be adequate to define all major and International Workshop HLA–A, B and DR specificities for which reagents are readily available;

(16) The laboratory must include positive and negative controls on each tray;

(17) The laboratory must have a written policy that it follows that establishes when antigen redefinition and retyping are required;

(18) The laboratory must screen recipient sera for preformed antibodies with a suitable lymphocyte panel that assures that—

(i) Potential transplant recipient sera are screened for HLA–A and B antibody content at the time of the recipient's initial HLA typing; and

(ii) Screening must be performed on samples collected at monthly intervals thereafter and following sensitizing events;

(19) The laboratory must use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits—

(i) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and

(ii) If the laboratory uses frozen panels, there must be a suitable storage system.

(20) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

(21) If the laboratory reports the recipient's and/or donor's ABO blood group and $Rh_o(D)$ group, the testing must be performed in accordance with § 493.1269 of this subpart;

(22) If the laboratory utilizes ABO agglutinins to remove red blood cells during lymphocyte isolation, the specificity of the ABO reagents must be verified with control cells;

(23) The laboratory must, at least once each month, give each individual performing tests a previously tested specimen as an unknown to verify his or her ability to reproduce test results. The laboratory must maintain records of the results for each individual; and

(24) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate interlaboratory reproducibility.

(b)(1) For laboratories performing histocompatibility testing only for transfusions and other nonrenal transplantation, excluding bone marrow, the laboratory must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures.

(2) For laboratories performing histocompatibility testing for bone marrow transplantation, the laboratory must meet all the requirements specified in this section including the performance of mixed lymphocyte cultures.

(3) For laboratories performing histocompatibility testing for non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening.

(c) Laboratories performing HLA typing for disease-associated studies, or parentage testing must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures.

(d) For laboratories performing tests for organ transplantation, the laboratory must assure the donor is tested for HIV reactivity using the same protocols as required under § 493.1241 of this subpart for the transfusion of blood and blood products, unless the organ recipient (or an individual authorized to act on his or her behalf) waives the tests because of medical circumstances.

§ 493.1267 Condition: Clinical cytogenetics: Level II tests.

To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §§ 493.1201

through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that document the number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an adequate patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.

§ 493.1269 Condition: Immunohematology: Level II tests.

To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section.

(a) The laboratory must perform ABO group and Rh_0 (D) group, unexpected antibody detection, antibody identification and compatibility testing in accordance with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR part 640 et seq.

(b) The laboratory must perform ABO group by testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A_1 and B red cells.

(c) The laboratory must determine the Rh_0 (D) group by testing unknown red cells with anti-D (anti-Rh_0) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive Rh_0 test results.

§ 493.1271 Condition: Transfusion services and bloodbanking: Level II tests.

If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart L for technical supervision in immunohematology, transfusion services. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in §§ 493.1273 through 493.1285 of this subpart.

§ 493.1273 Standard; Immunohematological Collection, processing, dating periods, labeling and distribution of blood and blood products.

In addition to the requirements in this section, the facility must also meet the applicable quality control requirements in §§ 493.1201 through 493.1221 of this part.

(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606, and the testing laboratory must be certified to perform Level II laboratory testing.

(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.

(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.

§ 493.1275 Standard; Blood storage Facilities.

(a) The blood must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.

(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

§ 493.1277 Standard; Arrangement for services.

In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.

§ 493.1279 Standard; Provision of testing.

There must be provision for prompt blood group, Rh_0 (D) group, unexpected antibody detection, compatibility testing in accordance with § 493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of § 493.1421(a) or § 493.1421(l).

§ 493.1283 Standard; Retention of transfused blood.

According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

§ 493.1285 Standard; Investigation of transfusion reactions.

The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in its own facility for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

14. Subpart L is revised to read as follows:

Subpart L—Personnel for Level I and Level II Testing

§ 493.1401 General.

This subpart consists of the personnel requirements that must be met by laboratories performing Level I or Level II testing, or both.

§ 493.1402 Definitions.

For purposes of this subpart, the following definitions apply:

Subsequent to graduation means laboratory training and experience acquired after receipt of the degree specified. However, for purposes of § 493.1415 or § 493.1427, experience as a technologist in a laboratory, which was gained prior to acquiring such degree, may be substituted on an equivalency basis of 1.5 years of such experience for every 1 year of postdegree training and experience; and experience as a general supervisor in a laboratory, which was gained prior to acquiring such degree, may be substituted on a 1-for-1 basis.

Technician trainee means a high school graduate or equivalent who is

gaining the required 2 years of clinical laboratory on-the-job experience to qualify as a technician, and is participating in a structured training program designed to provide the trainee with a broad range of laboratory procedures of progressive technical difficulty and the training program is documented by the laboratory.

Laboratories Performing Level I Tests

§ 493.1403 Condition: Laboratories performing Level I testing; laboratory director.

The laboratory must have a director who meets the requirements of § 493.1405 of this subpart and provides overall management and direction in accordance with § 493.1407 of this subpart.

§ 493.1405 Standard; Laboratory director qualifications.

(a) The laboratory director must be qualified to manage and direct the laboratory personnel and test performance and

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy; and

(ii) Possess a license to practice medicine or osteopathy in the State in which the laboratory is located; or

(2) Hold an earned doctoral degree from an accredited institution with a chemical, physical or biological science as a major subject and—

(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or

(ii) Subsequent to graduation has had 4 or more years of full time general laboratory training and experience;

(3) Qualify under State law to direct the laboratory in the State in which the laboratory is located;

(4) Before July 1, 1971, be an individual who qualified as a laboratory director in accordance with the requirements specified in paragraph (a) of appendix A of this part; or

(5) On or before July 1, 1970, be an individual who qualified as a laboratory director in accordance with the requirements specified in paragraph (b) of appendix A of this part.

§ 493.1407 Standard: Laboratory director responsibilities.

The laboratory director must be responsible for the overall management and competency of the laboratory personnel, for the performance of test procedures and reporting of test results promptly, accurately, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director must—

(1) Assure that tests, examinations and procedures are properly performed, recorded and reported;

(2) Assure compliance with applicable regulations of this part;

(3) Establish a process for review of test results prior to issuance of patient reports; and

(4) Ensure that all abnormal level I screening test results for previously undiagnosed conditions are referred to an appropriately certified laboratory for verification by a more specific Level II method and ensure that records are available to document that the abnormal screening test results are referred.

(b) The laboratory director must establish policies and procedures to document and ensure that prior to conducting testing on patient specimens the staff—

(1) Has the appropriate education, experience and training to perform and report results of laboratory tests promptly, accurately, reliably and proficiently;

(2) Is sufficient in number for the scope and complexity of the services provided; and

(3) Receives adequate orientation appropriate for the type and complexity of the laboratory services offered.

§ 493.1408 Standard; Technical Supervisor.

(a) The laboratory director who meets the requirements of § 493.1405 of this subpart is qualified to function as the technical supervisor of a laboratory performing level I testing and to provide technical expertise in all areas of testing performed in the laboratory.

(b) The technical supervisor is readily available and responsible for—

(1) Establishing policies and procedures for over-all test performance;

(2) Technical consultation;

(3) Selecting, evaluating and validating test methodologies;

(4) Resolution of technical problems related to testing of patient specimens and reporting patient results; and

(5) Ensuring that there is a complete procedure manual available to the testing personnel.

(c) The technical supervisor establishes policies and procedures for evaluating the competency of the testing personnel and assures that the staff maintains competency to perform test procedures and reports test results promptly, accurately and proficiently.

(1) The individual performing tests must receive regular inservice training and education appropriate for the type and complexity of the laboratory services offered.

(2) The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind proficiency test samples or external proficiency test samples as specified in subpart M, Quality Assurance; and

(vi) Assessment of problem solving skills.

(3) The performance of individuals performing tests must be evaluated and documented at least quarterly during the first year the individual tests patient specimens. Thereafter, semiannual evaluations are required unless test metholology or instrumentation changes, in which case quarterly evaluations are required for an additional year.

§ 493.1409 Standard; General supervisor.

(a) The general supervisor provides supervision of individuals performing testing and reporting patient test results. The director of a laboratory performing level I testing must function as the general supervisor or delegate the responsibility to an individual who is qualified as a—

(1) Director under § 493.1405 of this subpart; or

(2) General supervisor under § 493.1427(b) (1), (2), (3), (4), or (6) of this subpart.

(b) If the general supervisor is an individual qualified under § 493.1405, he or she must be accessible to the staff during all hours in which testing is performed. If the general supervisor is an individual qualified under § 493.1427(b) (1), (2), (3), (4), or (6) of this subpart, he or she must be on-site during all hours of testing except as specified in § 493.1429(c) of this part. Under the direction and technical supervision of the laboratory director, the general supervisor is responsible for—

(1) Monitoring patient testing;

(2) Monitoring the technical personnel's competency in test performance, recording and reporting test results;

(3) Monitoring compliance with standard laboratory procedures and the applicable regulations in this part;

(4) Monitoring instrument calibration, trouble shooting and maintenance;

(5) Monitoring quality assurance practices;

(6) Assessing and verifying the validity of patient test results through the evaluation of quality control sample values prior to reporting of patient test results; and

(7) Monitoring competency in problem solving skills.

§ 493.1410 Condition: Laboratories performing level I testing; Testing personnel.

The laboratory has a sufficient number of properly qualified individuals as specified in § 493.1411, for the volume and complexity of tests performed.

§ 493.1411 Standard; Testing Personnel qualifications.

Each individual performing testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required;

(b) Have earned an academic high school diploma or equivalent; and

(c) Have adequate training prior to performing testing on patient specimens which demonstrates—

(1) An understanding of specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(2) An understanding of standard laboratory procedures and applicable regulations;

(3) The ability to perform the required preventive maintenance and calibration procedures for each test performed;

(4) The ability to perform quality control; and

(5) The ability to perform tests, record and report results accurately and reliably.

Laboratories Performing Level II Testing

§ 493.1413 Condition: Laboratories performing level II testing; laboratory director.

The laboratory must have a director who meets the requirements of § 493.1415 of this subpart and providesoverall management and direction in accordance with § 493.1417 of this subpart.

§ 493.1415 Standard; Laboratory director, qualifications.

(a) The laboratory director must be qualified to manage and direct the laboratory personnel and test performance;

(b) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(c) The laboratory director must:

(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(2) Be a physician who—

(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or

(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties, or

(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification, or

(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification;

(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (i) is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties, or (ii) subsequent to graduation has had 4 or more years of fulltime general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;

(5) Qualify under State law to direct the laboratory in the State in which the laboratory is located;

(6) Before July 1, 1971, be an individual who qualified as a laboratory director in accordance with the requirements specified in paragraph (a) of appendix A of this part; or

(7) On or before July 1, 1970, be an individual who qualified as a laboratory director in accordance with the requirements specified in paragraph (c) of appendix A of this part.

§ 493.1417 Standard; Laboratory director responsibilities.

The laboratory director must be responsible for the overall management and competency of the laboratory personnel, for the performance of the test procedures and reporting of test results promptly, accurately, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director must assure that technical supervision is provided by individuals as required under § 493.1419 of this subpart.

(b) The laboratory director must—

(1) Assure that tests, examinations and procedures are properly performed, recorded and reported;

(2) Assure compliance with the applicable regulations;

(3) Establish a process for review of test results prior to issuance of patient reports; and

(4) Assure that when tests are being performed there is a general supervisor on the premises who meets the qualifications of § 493.1427 of this subpart.

(c) The laboratory director must establish policies and procedures to document and ensure that prior to conducting testing on patient specimens the staff—

(1) Has the appropriate education, experience as required in § 493.1442 and training to perform and report results of laboratory tests promptly, accurately, reliably and proficiently;

(2) Is sufficient in number for the scope and complexity of the services provided; and

(3) Receives adequate orientation appropriate for the type and complexity of the laboratory services offered.

§ 493.1419 Condition: Laboratories performing level II testing; technical supervision.

For each specialty or subspecialty of services performed, the laboratory must have an individual who is qualified under § 493.1421 of this subpart to provide technical supervision in accordance with § 493.1423 of this subpart.

§ 493.1421 Standard; Technical supervisor qualifications.

Specific qualifications are required for the individual providing technical supervision for each of the specialties and subspecialties in which the laboratory performs tests or procedures.

(a) The laboratory may perform anatomical and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the technical supervisor is a physician and—

(1) Is certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (a)(1) of this section.

(b) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, mycobacteriology, mycology, parasitology, and virology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (b)(1)(i) of this section; or

(2) (i) Holds an earned doctoral or master's degree in microbiology from an accredited institution or is a physician; and

(ii) Subsequent to graduation has had at least 4 years of experience in clinical microbiology.

(c) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (c)(1)(i) of this section; or

(2)(i) Holds an earned doctoral or master's degree in biology, chemistry, immunology, or microbiology from an accredited institution or is a physician; and

(ii) Subsequent to graduation has had at least 4 years of experience in immunology.

(d) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of chemistry, the testing must be performed under the supervision of an individual who—

(1) Is a physician and

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (d)(1)(i) of this section; or

(2)(i) Holds an earned doctoral or master's degree in chemistry from an accredited institution or is a physician, and

(ii) Subsequent to graduation has had at least 4 years of experience in clinical chemistry.

(e) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of hematology, the testing must be performed under the supervision of an individual who

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (e)(1)(i) of this section; or

(2)(i) Holds a master's or a bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution, and

(ii) Subsequent to graduation has had at least 4 years of experience in hematology.

(f) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the testing must be performed under the supervision of a physician who—

(1) Is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(2) Is certified by the American Society of Cytology to practice cytopathology; or

(3) Possesses qualifications that are equivalent to those required for certification specified in paragraphs (f)(1) or (f)(2) of this section.

(g) If the laboratory performs tests in the subspecialty of histopathology, the testing must be performed under the supervision of an individual who

(1) Meets the requirements of paragraph (a) of this section; or

(2) Is a physician and—

(i) Is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (g)(2)(i) of this section; or

(3) For tests in dermatopathology, the individual—

(i) Meets the requirements of paragraph (a) of this section;

(ii) Is a physician and is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;

(iii) Is certified in dermatopathology by the American Board of Dermatology or the American Osteopathic Board of Dermatology; or

(iv) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (g)(3) (ii) or (iii) of this section.

(h) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in anatomical pathology by The American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (h)(1)(i) of this section; or

(2)(i) Is certified in oral pathology by the American Board of Oral Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by the Board specified in paragraph (h)(2)(i) of this section.

(i) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by The American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (i)(1)(i) of this section; or

(2)(i) Holds an earned doctoral, master's, or bachelor's degree in chemistry, physics, biology, or medical

technology from an accredited institution or is a physician; and

(ii) Subsequent to graduation has had at least 4 years of experience in radiobioassay.

(j) If the laboratory performs tests in the specialty of histocompatibility, the testing must be performed under the supervision of an individual who—

(1) Holds an earned doctoral degree in a biological science or is a physician; and

(2) Subsequent to graduation has had 4 years of experience in immunology, 2 of which have been in histocompatibility testing.

(k) If the laboratory performs tests in the specialty of clinical cytogenetics, the testing must be performed under the supervision of an individual who—

(1) Holds an earned doctoral degree in a biological science or is a physician, and

(2) Has had four years of experience in genetics, two of which have been in clinical cytogenetics.

(l) If the requirements of paragraph (a) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the testing must be performed under the supervision of an individual who—

(1) Is a physician and—

(i) Is certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or

(ii) Possesses qualifications that are equivalent to those required for certification by one of the boards specified in paragraph (l)(1)(i) of this section;

(2) Is a physician with at least 2 years of experience in immunohematology subsequent to graduation; or

(3) Within the specialty of immunohematology, the laboratory performs tests in the subspecialties of ABO group and Rh group, unexpected antibody detection, antibody identification, and titering only, the supervisor holds a master's or bachelor's degree in biology, immunology, microbiology, chemistry, or medical technology from an accredited institution and subsequent to graduation has had at least 4 years of experience in immunohematology.

(m) Before July 1, 1971, an individual who served as a technical supervisor in accordance with the requirements specified in appendix B of this part is qualified as a technical supervisor.

§ 493.1423 Standard; Technical supervisor responsibilities.

(a) The technical supervisor spends an adequate amount of time in the laboratory to supervise the technical operation of the laboratory in the specialty for which the technical supervisor is responsible and is readily available for technical consultation.

(b) The technical supervisor is responsible for—

(1) Establishing policies and procedures for overall testing performance;

(2) Selecting, evaluating and validating test methodologies;

(3) Resolution of technical problems related to testing of patient specimens and reporting patient results;

(4) Ensuring that there is a complete and current procedure manual available to the testing personnel; and

(5) Establishing policies and procedures to assure that individuals performing tests maintain the competency to perform test procedures and report test results promptly, accurately, and proficiently.

(c) The individuals performing tests must receive regular inservice training and education established by the technical supervisor which is appropriate for the type and complexity of the services offered.

(d) The procedures for evaluation of the competency of the staff must be established by the technical supervisor and include, but are not limited to—

(1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(2) Monitoring the recording and reporting of test results;

(3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(4) Direct observation of performance of instrument maintenance;

(5) Assessment of test performance through testing previously analyzed specimens, internal blind proficiency test samples or external proficiency test samples as specified in subpart M, Quality Assurance; and

(6) Assessment of problem solving skills.

(e) The performance of individuals performing tests must be evaluated and documented at least quarterly during the first year the individual tests patient specimens. Thereafter, semiannual evaluations are required unless test methodology or instrumentation changes, in which case quarterly evaluations are required for an additional year.

(f) The technical supervisor in cytology must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24 hour period to screen cytology slides.

§ 493.1425 Condition: Laboratories performing level II testing; general supervisor.

The laboratory must have one or more general supervisors who are qualified under § 493.1427 of this subpart to provide general supervision in accordance with § 493.1429 of this subpart.

§ 493.1427 Standard; General supervisor qualifications.

The laboratory has one or more supervisors who, under the direction of the laboratory director, supervise technical personnel and reporting of test results, perform tests requiring special scientific skills, and, in the absence of the director and technical supervisor, are held responsible for the proper performance of all laboratory procedures and reporting of test results.

(a) Each supervisor possesses a current license as a laboratory supervisor issued by the State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor—

(1) Who qualifies as a laboratory director under § 493.1415(b) (1), (2), (4), (5), (6) or (7) is also qualified as a general supervisor; therefore, depending upon the services offered and volume of testing performed by the laboratory, the director may also serve as the general supervisor;

(2)(i) Is a physician or has earned a doctoral degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation, has had at least 1 year of pertinent full time laboratory experience;

(3)(i) Holds a master's degree from an accredited institution with a major in one of the chemical, physical, or biological sciences; and

(ii) Subsequent to graduation has had at least 2 years of pertinent full-time laboratory experience.

(4)(i) Is qualified as a technologist under § 493.1433(b) (1), (2), (3), (4) or (5) of this subpart; and

(ii) After qualifying as a laboratory technologist, has had at least 3 years of pertinent full-time laboratory experience.

(5) With respect to the specialty of diagnostic cytology, qualifies as a supervisory cytotechnologist because he or she—

(i) Is qualified as a cytotechnologist under § 493.1437; and

(ii) Has had 3 years of full-time experience as a cytotechnologist in a laboratory directed or supervised by a pathologist or other physician recognized as a specialist in diagnostic cytology within the preceding 10 years.

(6) Before July 1, 1971, was qualified as a general supervisor in accordance with the requirements in appendix C.

(c) The general supervisor requirement is met in histopathology, oral pathology, and dermatopathology because all tests and examinations, including microscopic and gross examinations of tissues, must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§ 493.1421(a), 493.1421(g)(1) or § 493.1421(g)(2);

(2) In oral pathology, by an individual who is qualified as a technical supervisor under § 493.1421(a) or § 493.1421(h); and

(3) In dermatopathology, by an individual who is qualified as a technical supervisor under § 493.1421(a) or § 493.1421(g)(3).

§ 493.1429 Standard; General supervisor responsibilities.

The general supervisor, under the direction of the laboratory director and the technical supervision of the technical supervisor, supervises laboratory personnel, test performance, and test reporting. The general supervisor—

(a) Is on the laboratory premises during all hours in which tests are being performed;

(b) In cytology must be on the premises when nonsupervisory cytotechnologists examine cytologic preparations unless a technical supervisor who qualifies under § 493.1421 (a) or (f) of this subpart is present;

(c) Is not required to be on the premises, when emergencies arise outside regularly scheduled hours of duty, provided the individual that is performing tests is qualified to perform such tests, the supervisor who is responsible for the results of the work reviews them during the next duty period, and a record is maintained to reflect the actual review; and

(d) Is responsible for—

(1) Monitoring patient testing;

(2) Monitoring compliance with standard laboratory procedures, and the applicable regulations in this part;

(3) Monitoring technical personnel's competency in test performance and recording and reporting test results;

(4) Monitoring instrument calibration, trouble-shooting and maintenance;

(5) Monitoring quality assurance practices;

(6) Assessing and verifying the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results; and

(7) Monitoring competency in problem solving skills.

§ 493.1431 Condition: Laboratories performing level II testing; Testing personnel.

The laboratory has a sufficient number of properly qualified technical personnel for the volume and complexity of tests performed.

§ 493.1433 Standard; Technologists qualifications.

Each technologist must—

(a) Possess a current license as a laboratory technologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) (1) Have earned a bachelor's degree in medical technology from an accredited college or university;

(2) Have successfully completed 3 years of academic study (a minimum of 90 semester hours or equivalent) in an accredited college or university, which met the specific requirements for entrance into a school of medical technology accredited by an accrediting agency approved by HHS, and have successfully completed a course of training of at least 12 months in such a school;

(3) Have earned a bachelor's degree in one of the chemical, physical, or biological sciences and, in addition, have at least 1 year of pertinent full-time laboratory experience or training, or both;

(4) Have successfully completed 3 years (90 semester hours or equivalent) in an accredited college or university with the following distribution of courses—

(i) *For those whose training was completed before September 15, 1963.* At least 24 semester hours in chemistry and biology courses of which—

(A) At least 6 semester hours were in inorganic chemistry and at least 3 semester hours were in other chemistry courses; and

(B) At least 12 semester hours in biology courses pertinent to the medical sciences; or

(ii) *For those whose training was completed after September 14, 1963.* (A) 16 semester hours in chemistry courses that included at least 6 semester hours in inorganic chemistry and that are acceptable toward a major in chemistry;

(B) 16 semester hours in biology courses that are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and

(C) 3 semester hours of mathematics; and

(iii) Has experience, training, or both, covering several fields of medical laboratory work of at least 1 year and of such quality as to provide him or her with education and training in medical technology equivalent to that described in paragraphs (b) (1) and (2) of this section;

(5) Have achieved a satisfactory grade to qualify as a technologist in a proficiency examination approved by HHS; or

(6) Before July 1, 1971, have qualified as a technologist in accordance with the requirements in appendix D.

§ 493.1437 Standard; Cytotechnologist qualifications.

Each person examining cytology slide preparations must meet the qualifications of §§ 493.1421(a), 493.1421(f) or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) (1) Has successfully completed 2 years in an accredited college or university with at least 12 semester hours in science, 8 hours of which are in biology, and

(i) Has had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(ii) Has received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training;

(2) Achieves a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists.

(3) Before January 1, 1969, was properly qualified as a cytotechnologist in accordance with the requirements specified in appendix E.

§ 493.1439 Standard; Cytotechnologist responsibilities.

(a) The cytotechnologist must document:

(1) The slide interpretation results of each gynecologic and non-gynecologic cytology case examined or reviewed.

(2) The total number of slides examined in the laboratory as well as any other laboratory or employer for

each twenty-four hour period including the number of slides—

(i) Examined for initial interpretation;

(ii) Reviewed for quality control purposes in accordance with subpart K;

(iii) Examined for proficiency testing purposes; and

(iv) Examined for quality assurance purposes in accordance with subpart M.

(3) The number of hours within each 24 hour period spent examining slides in the laboratory and any other laboratory or employer.

(b) The laboratory must employ a sufficient number of cytotechnologists to proficiently perform slide examinations under the supervision of a general supervisor in cytology.

§ 493.1441 Standard; Technician qualifications.

Each laboratory technician—

(a) Possesses a current license as a technician, issued by the State in which the laboratory is located, if such licensing is required; and

(b)(1) Has successfully completed 60 semester hours of academic credit including chemistry and biology as well as a structured curriculum in medical laboratory techniques at an accredited institution or has an associate degree from an accredited institution which includes courses in chemistry, biology, and medical laboratory techniques;

(2) Is a high school graduate or equivalent and has completed at least 1 year in a technician training program in a school accredited by an accrediting agency approved by HHS;

(3) Is a high school graduate or equivalent and has 2 years of pertinent full-time laboratory experience as a technician trainee in a laboratory performing level II testing;

(4) Is a high school graduate or equivalent and has successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician);

(5) Before December 31, 1977, qualified as a technician in accordance with the requirements specified in paragraph (a) of appendix F; or

(6) Before January 1, 1968, was properly qualified as a technician in accordance with the requirements specified in paragraph (b) of appendix F.

§ 493.1442 Standard; Personnel qualifications for test performance.

All level II laboratory testing must be performed by a qualified technologist or technician.

(a) The tests listed under the following specialty/subspecialty sections, as described in subpart I must be performed only by an individual qualified as a technologist under § 493.1433 of this subpart;

Specialty/subspecialty	Section
Bacteriology	493.911(a)(3)
Mycobacteriology	493.913(a)(3)
Mycology	493.915(a)(2)
Parasitology	493.917(a)(2)
Virology	493.919(a)(2)
Immunohematology	493.950(a) (3) & (4)

(b) The tests listed under the following specialty/subspecialty sections, as described in subpart I must be performed by an individual qualified as a technologist under § 493.1433 or by an individual qualified as a technician under § 493.1441 of this subpart with specific speciality/subspecialty full time experience as follows:

Specialty/ subspecialty	Section	Technician experience
Bacteriology	493.911(a)(2)	one year.
Mycobacteriology	493.913(a)(1)	six months.
	493.913(a)(2)	one year.
Mycology	493.915(a)(1)	one year.
Parasitology	493.917(a)(1)	six months.
Virology	493.919(a)(1)	one year.
Syphilis serology	493.923	six months.
General Immunology.	493.927	one year.
Routine Chemistry.	493.931	one year.
Endocrinology	493.933	one year.
Toxicology	493.937	one year.
Hematology	493.941	one year.
Immunohematology.	493.959(a) (1) & (2)	six months.

(c) All other Level II laboratory testing, except cytology, must be performed by an individual qualified as a technician under § 493.1441 with one year full time experience in each speciality/subspeciality in which testing is performed or qualified as a technologist under § 493.1433. The performance of certificate of waiver or level I tests or examinations cannot be used as the required experience to qualify an individual as a technician to perform level II testing. In order for a technician to perform Level II testing, the technician must acquire the specified experience performing Level II testing in the appropriate specialty or subspeciality of a laboratory performing level II tests. The testing experience must be performed under the direct supervision of an individual qualified as a technologist under § 493.1433, and be on a full-time basis. When the technician fulfills the necessary requirements, he or she may perform applicable Level II testing only in the speciality or subspeciality in which he or she has gained the required experience.

(d) In cytology, all slide examinations must be performed by an individual qualified under § 493.1421 (a), (f), or § 493.1427(b)(5), or § 493.1437.

§ 493.1443 Standard; Technologist and Technician responsibilities.

(a) The technologist must adequately and directly supervise technicians gaining experience in each speciality/ subspeciality and technician trainees in the immediate bench area.

(b) The technician—

(1) Performs only those laboratory procedures that require a degree of skill commensurate with the technician's education, training, and technical abilities and involve limited exercise of independent judgment; and

(2) Must not perform procedures in the absence of a qualified general supervisor.

§ 493.1445 Standard: Technician trainee program.

A technician trainee program must be documented and under the direction of the laboratory director.

(a) The program must assure that the trainee—

(1) Receives appropriate inservice education training and experience to competently perform Level II tests;

(2) Is able to report results promptly, accurately, reliably, and proficiently; and

(3) Performs all aspects of patient specimen testing and reporting under the direct supervision of a qualified general supervisor or technologist.

(b) The program must—

(1) Be the equivalent of two full years; and

(2) Must encompass all facets of testing and reporting of patient specimens, including, but not limited to—

(i) Patient preparation;

(ii) Specimen collection, preservation, handling and storage;

(iii) Calibration, maintenance, troubleshooting, and quality control requirements of the instruments and methods;

(iv) Reagent preparation, stability, and storage;

(v) Factors that influence test results; including specificity, sensitivity, accuracy and precision of test procedures and test methods; and

(vi) Test system stability.

(c) At the completion of the program, there must be documentation that the technician trainee has a comprehensive understanding of methods,

instrumentation, interpretation of data, and clinical significance of Level II test results.

(d) The experience requirements for technicians performing Level II tests in a particular specialty/subspeciality specified in § 493.1442 may be gained concurrently with the technician trainee program.

15. Subpart M is revised to read as follows:

Subpart M—Quality Assurance For Level I and Level II Testing

§ 493.1501 Condition: Quality assurance; Level I and Level II Testing.

Each laboratory performing Level I or Level II testing, or both, must establish and follow policies and procedures for an ongoing quality assurance program designed to monitor and evaluate quality; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; assure the adequacy and competency of the staff; and the laboratory's quality assurance program must meet standards (a) through (l) of this section.

(a) *Standard.* The laboratory must have an ongoing system under which it monitors and evaluates quality control and proficiency testing data for the purpose of substantiating that all tests performed and reported by the laboratory conform to the laboratory's specified performance criteria. These criteria include: Precision, accuracy, detection limits, interferences, linearity, sensitivity, specificity, validity and adequacy.

(b) *Standard.* The laboratory must have a mechanism for assuring the accurate and timely reporting of test results. Reporting times must be within the acceptable time periods established by the laboratory.

(c) *Standard.* The laboratory must have a mechanism for assuring that—

(1) All quality control data are reviewed;

(2) Patient test results are not reported when control values are outside the acceptable range established by the laboratory;

(3) All patient test results analyzed in the same test run before a failure in quality control or since the last acceptable quality control must be evaluated before reporting to determine that the patient values are accurate and reliable;

(4) Actions are taken to correct the problems that led to the unsatisfactory quality control results and the corrective actions are documented; and

(5) For laboratories that are not certified to perform Level II tests, all abnormal Level I screening test results for previously undiagnosed conditions are referred to an appropriately certified laboratory for verification by a more specific level II method and that records are available to document that the screening tests are referred.

(d) *Standard.* The laboratory must have a mechanism for assuring that corrective action is taken and is documented on all unacceptable or unsatisfactory proficiency testing results.

(e) *Standard.* The laboratory must have a mechanism to assure that specimens are not tested when they do not meet the laboratory's established criteria for acceptability and that the authorized person ordering the test is notified of the condition of specimens not meeting the laboratory's criteria for a satisfactory specimen suitable for testing or any limitations on the reliability of the test results.

(f) *Standard.* The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with clinically relevant criteria such as—

(1) Patient age;

(2) Sex;

(3) Diagnosis or pertinent clinical data;

(4) Distribution of patient test results; and

(5) Relationship with other test parameters.

(g) *Standard.* The laboratory must have a system in place to document problems that occur related to breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Records of the corrective action taken to minimize or resolve the problems must be available.

(h) *Standard.* The laboratory must have policies and procedures for an ongoing program to assure that employees are competent, and maintain their competency, to perform their duties as specified by the laboratory. Policies and procedures must include direct observation of routine patient test performance as well as analysis of unknown, monitoring the reporting of test results, other activities identified by the laboratory, and the applicable activities as specified in §§ 493.1407 and 493.1417 of subpart L. The laboratory must have an established program for providing orientation and inservice training, to employees to improve performance when problems are identified. The laboratory must evaluate employee performance by—

(1) Retesting of previously analyzed specimens, internal blind proficiency test samples, or external proficiency test samples (that have already been reported to approved proficiency testing programs) to assess the performance levels of each staff member responsible for performing and/or supervising testing; or

(2) Enrolling in external proficiency testing programs to the extent that there are programs available to cover all analyses performed, to assess an individual's laboratory performance. (The proficiency test samples are in addition to those required in subpart H of this part.) For cytology, the laboratory may insert into the workload slides from previously reported cases as blind samples or may arrange to exchange cases with another laboratory for the purpose of rescreening slides and comparing results.

(i) *Standard.* The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take necessary corrective actions to prevent recurrences.

(j) *Standard.* The laboratory must evaluate all data analysis and test reporting systems to assure that the systems perform according to specifications and provide accurate and reliable reporting, transmittal, storage and retrieval of data.

(k) *Standard.* The laboratory must establish and follow policies and procedures to assure that all complaints and problems reported to the laboratory are documented. If necessary, these complaints are investigated and, where appropriate, corrective actions are instituted and documented.

(l) *Standard.* The laboratory must maintain records of its quality assurance program, document all corrective actions taken to remedy problems it has identified and make records of corrective action available to HHS or its designee.

16. Subpart N is revised to read as follows:

Subpart N—Inspection

§ 493.1601 Condition: Inspection of laboratories issued a certificate of waiver.

(a) HHS or its designee will conduct unannounced inspections of any laboratory at any time during its hours of operation.

(b) The laboratory may be required, as part of this inspection, to—

(1) Permit HHS or its designee to interview all employees of the laboratory;

(2) Permit employees to be observed performing tests, data analysis and reporting; and

(3) Provide copies to HHS or its designee of all records and data that the agency requires.

(c) Failure to permit an inspection under the subsection will result in the automatic termination of the laboratory's participation in Medicare; and revocation or immediate limitation or suspension of the laboratory's CLIA certificate.

(d) If a laboratory's certificate of waiver is revoked, HHS will not approve the laboratory's application for a period of 1 year following the effective date of the revocation. If the laboratory submits good cause, HHS may waive this one year period.

§ 493.1603 Condition: Inspection of all laboratories not issued a certificate of waiver.

(a) HHS or its designee will conduct unannounced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. HHS will inspect a laboratory possessing a provisional certificate before issuance of a certificate. The laboratory must submit evidence of successful participation in an approved proficiency testing program for three consecutive testing events.

(b) The laboratory may be required, as part of this inspection, to—

(1) Test samples (including proficiency testing samples) or perform procedures as HHS or its designee requires;

(2) Allow HHS or its designee to interview all employees of the laboratory;

(3) Permit employees to be observed performing tests (including proficiency testing specimens provided by the inspection team), data analysis and reporting; and

(4) Provide copies to HHS or its designee of all records and data it requires.

(c) The laboratory must have all records and data readily accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) The laboratory must retain immunohematology records for a period of at least 5 years, as specified in 21 CFR part 606, subpart I, and all other laboratory records must be maintained for at least 2 years.

(e) The laboratory must provide upon request all information and data needed by HHS or its designee to make a determination of the laboratory's status.

(f) HHS or its designee may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results.

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare payments to the laboratory, or termination of the laboratory s participation in Medicare and suspension of or action to revoke the laboratory's CLIA certificate.

(h) If a laboratory's certificate is revoked under this section, HHS will not approve the laboratory's application for a period of l year following the effective date of the revocation. If the laboratory submits good cause, HHS may waive this one year period.

§ 493.1605 Condition: Inspection of accredited laboratories.

(a) HHS conducts unannounced, random validation inspections of any accredited laboratory at any time during its hours of operation.

(b) HHS conducts unannounced complaint inspections of an accredited laboratory at any time during its hours of operation upon receiving a complaint about that laboratory.

(c) The laboratory may be required, as part of either of the above inspections, to—

(1) Test samples (including proficiency testing samples) or perform procedures as required by HHS;

(2) Allow HHS to interview all employees of the laboratory;

(3) Permit employees to be observed performing tests (including proficiency tests of specimens provided by the inspection team), and performing data analysis and reporting activities; and

(4) Provide copies of all records and data required under these regulations to HHS.

(d) The laboratory must provide, upon request, all information and data needed by HHS to make a determination of compliance or noncompliance.

(e) The laboratory must have all records and data readily accessible and retrievable within a reasonable time during the inspection.

(f) The laboratory must retain immunohematology records for a period of at least 5 years, as specified in 21 CFR part 606, subpart I, and all other laboratory records must be maintained for at least 2 years unless otherwise specified in part 493.

(g) Failure to permit an inspection under this subsection will result in the automatic termination of the laboratory's Medicare approval; and revocation or immediate limitation or suspension of the laboratory's CLIA certificate.

(h) If a laboratory's certificate is revoked under this subsection, HHS will not approve the laboratory's application for either accreditation or a CLIA certificate for a period of one year. If the laboratory submits good cause, HHS may waive this one year period.

17. In part 493, a new subpart P containing § 493.1801 is added to read as follows:

Subpart P—Computer Systems for Level I and II Testing

§ 493.1801 Condition: Computer Systems; Level I and Level II Testing.

Laboratories performing Level I or Level II testing, or both, that use mini, macro or mainframe computer systems for any aspect of specimen testing and/or reporting must employ and maintain procedures that assure accurate and reliable reporting of patient results.

(a) *Standard: Computer system facilities.* If the computer is a dedicated system used only in the laboratory, the laboratory must maintain the environmental conditions and safeguards necessary for proper system operation. The laboratory must assure that—

(1) Ventilation, humidity levels and ambient temperature are maintained according to the computer manufacturer's recommendations;

(2) Adequate and appropriate fire prevention apparatus is available and maintained; and

(3) Provisions are made to minimize power surges and, where possible, power interruptions.

(b) *Standard: Computer system operations.* If the computer is a dedicated system used only in the laboratory, the laboratory must provide and document preventive maintenance schedules for the computer and its devices, system operating limits, and contingency procedures for operation interruptions.

(1) Computer system operating limits must be documented and include—

(i) Environmental limits;

(ii) Electrical power requirements;

(iii) The maximum number of ports;

(iv) The maximum number of active instruments controlled; and

(v) The maximum number of active ports.

(2) The laboratory must maintain and document a preventive maintenance schedule recommended by the computer manufacturer. This schedule must—

(i) Assure that the downtime required to fulfill the preventive maintenance procedures is scheduled during a time that will cause minimal laboratory interruption.

(ii) Be available prior to implementation and communicated to

individuals affected by the computer operation interruption.

(3) All input/output devices, such as printers, CRTs, and modem transmission equipment must be maintained in such a manner to assure accurate, clear and interference-free transmission.

(4) When unscheduled computer operation interruptions occur the laboratory must—

(i) Have emergency service for hardware during the hours of operation of the laboratory;

(ii) Assure that the computer operations staff gives immediate notification to the technical staff users that the computer has gone down;

(iii) Have readily available a backup system, either computerized or manual, that is adequate to maintain the laboratory operation. Directions for the use of the backup system must include the name(s) and locations of the individual(s) authorizing the conversion to backup system use;

(iv) Assure, when possible, that patient data is protected from loss due to unscheduled computer operation interruptions; and

(v) If alarms, of any type, are in place to alert computer operators of an imminent problem, such as a power fluctuation or interruption, that the alarms are monitored, and tested periodically.

(5) Procedure manuals must be readily available to all computer system operators. The procedure manuals must contain all information necessary for proper operation. Operators must be aware of all critical operating information.

(c) *Standard: Computer system programs.* Computer system programs must be adequate for the laboratory activities.

(1) Access to computer system programs must be limited to authorized personnel by a security system that limits random entry.

(2) When a computer system program is newly created or an existing program is changed—

(i) It must be tested to the degree necessary to assure proper function;

(ii) It must be documented; and

(iii) Its use and function must be communicated to all users.

(d) *Standard: Computer system data*—(1) *Test requisition information entry.* If the computer system is used for test requisition information—

(i) It must have fields or prompts for the patient information, test(s) requested, name and location of authorized individual ordering the test(s) and other information specified in Subpart J, Patient Test Management; and

(ii) Verification of the tests requested on the requisition must be made prior to performance of the tests.

(2) *Test result entry.* (i) The laboratory must maintain current procedure manuals with appropriate information for result entry. The procedure manual must be available to all technical personnel responsible for entering test results and contain directions and the names of the individual(s) to notify if the computer system goes down or if a system error occurs.

(ii) Entries of laboratory results into the computer, either manually or through interfaced instrumentation, must be verified before release for reporting.

(iii) Patient results that are above or below the laboratory's reporting limits must be verified prior to entry.

(iv) If the computer system performs any calculations required to produce a laboratory test result, periodic verifications of these calculations must be performed and documented.

(v) Laboratory reports generated by the computer must be reviewed for errors prior to being sent to the authorized individual ordering the test(s).

(vi) The computer generated laboratory report must include a description of specimen condition, such as hemolyzed, or lipemic, if applicable.

(vii) When an erroneous result has been corrected, the corrected or amended report must clearly state which result was corrected.

(3) *Computer system data retrieval.* (i) Laboratory test data must be retrievable in a timely manner, including information in the computer system as well as in storage.

(ii) The computer system must be able to generate an exact duplicate of the patient test information on the original report.

(iii) If a test result has been corrected or amended, there must be a mechanism in place to prevent the original incorrect result from being reported again. However, the original incorrect result must be retrieved or stored for a period of two years from its original printing.

(iv) The computer system must be capable of holding sufficient current data from previous patient testing to fulfill the needs of the authorized individuals who ordered the tests and the technical staff performing the tests.

(v) There must be a mechanism in place to retrieve current test data in the event of an unexpected computer system interruption.

(vi) Computer system operators must maintain a sufficient storage capacity for current data entry by scheduled and documented data deletion for subsequent storage.

(viii) The mechanism used for data storage, such as tape, disks, or microfilm must be—

(A) Stored according to the manufacturer's recommendations;

(B) Properly labeled for content identification;

(C) Secure and protected from unauthorized use; and

(D) Able to produce an exact duplicate of the original test report.

(ix) Backups of input data must be secure from alteration, loss, or inadvertent erasure. Backups need not be paper, but may be duplicate tapes, disks or microfilm.

(x) The proper maintenance and storage of master packs or master memory components must be included in the computer system procedure manual and followed.

(e) *Standard: Computer system security.* The computer system data and programs must be protected from an unauthorized entry.

(1) Access to the computer system must be protected from unauthorized entry by user codes or passwords. The user codes or passwords must be—

(i) Changed on a regular basis, deleted when an employee resigns, and not reused for another employee; and

(ii) Assigned to each individual allowing access only to functions that the individual is authorized to use, edit, and/or create.

(2) The security system must—

(i) Assure that data access is protected on shared systems;

(ii) Allow only designated individuals to enter laboratory results, correct or amend results, access patient results and/or edit or create computer programs; and

(iii) Contain a mechanism such as an audit trail that tracks individuals entering, or correcting patient results and individuals editing or creating computer programs.

(f) *Standard: Computer system capability.* The computer system must be of sufficient capability to fulfill the requirement of the laboratory.

(1) The computer system must be of a size adequate for the needs of the laboratory and its patient testing requirements;

(2) There must be sufficient input/output devices to serve the needs of the laboratory; and

(3) The laboratory director must acknowledge that the computer system is appropriate for the laboratory and enables the laboratory to meet the requirements of subpart J, Patient Test management.

18. In part 493, appendices A–F are added following § 493.1801 to read as follows:

Appendix A—Laboratory Director Director Qualification Requirements Before July 1, 1971

(a) Except as specified in paragraph (c), with respect to individuals first qualifying as laboratory directors before July 1, 1971, an individual who was responsible for the direction of a clinical laboratory for 12 months between July 1, 1961 and January 1, 1968, and, in addition, met one of the following requirements in paragraph (b) (1)(2) or (3) is now qualified to be a laboratory director under §§ 493.1405 and 1493.1415.

(b) The individual—

(1) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;

(2) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; or

(3) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience.

(c) With respect to individuals first qualifying as laboratory directors on or before July 1, 1970, an individual who was responsible for the direction of a clinical laboratory and achieved a satisfactory grade to qualify as a laboratory director in an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970 is now qualified to be a laboratory director under §§ 493.1405 and 493.1415.

Note: The January 1, 1968, date for meeting the 12 months laboratory direction requirement in paragraph (a) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1968 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (a) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

Appendix B—Technical Supervisor Qualification Requirements Before July 1, 1971

With respect to individuals first qualifying as technical supervisors before July 1, 1971, an individual who meets the following requirements is qualified as a technical supervisor.

(a) A laboratory whose director qualifies as a director under paragraph (c) of appendix A is qualified as a technical supervisor in the laboratory specialties in which the director achieved a satisfactory grade in the examination conducted or sponsored by the Public Health Service. Further, a director who achieved a satisfactory grade in chemistry or ABO and Rh°(D) grouping, or both, is deemed to meet the requirements of § 493.1421(i), (1)(2), or both.

(b) When a laboratory director qualifies under paragraph (a)(3) of appendix A, the laboratory may perform tests in the specialty of microbiology, if the director has a bachelor's degree in a biological science and subsequent to graduation has had at least 6 years of experience in microbiology;

(c) When a laboratory director qualifies under paragraph (a)(3) of appendix A, the laboratory may perform tests in the specialty of hematology, if the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of laboratory experience of which at least 4 years of experience are in hematology;

(d) When a laboratory director qualifies under paragraph (a)(3) of appendix A, the laboratory may perform tests in the specialty of diagnostic immunology, if the director has a bachelor's degree in biology, chemistry, immunology, or microbiology and subsequent to graduation has had at least 6 years of experience in immunology;

(e) When a laboratory director qualifies under paragraph (a)(3) of appendix A of this subpart, the laboratory may perform tests in the specialty of radiobioassay, if the director has a bachelor's degree in a chemical, physical, or biological science and subsequent to graduation has had at least 6 years of laboratory experience at least 1 year of which is in radiobioassay;

(f) When a laboratory director qualifies under paragraph (a)(3) of appendix A of this subpart, the laboratory may perform ABO group and Rh°(D) group, unexpected antibody detection, antibody identification, and titering, if the director has a bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 6 years of laboratory experience of which at least 4 years of experience are in immunohematology;

(g) When a laboratory director qualifies under paragraph (a)(3) of appendix A of this subpart, the laboratory may perform tests in the specialty of chemistry, if the director has a bachelor's degree in a chemical science or its equivalent and subsequent to graduation has had at least 6 years of experience in chemistry;

(h) When a laboratory director qualifies under paragraph (a)(3) of appendix A of this subpart, the laboratory may perform tests referred to in paragraphs (b) through (g) of this section, if the director has a bachelor's degree in medical technology and subsequent to graduation has had at least the designated years of specialized experience.

Appendix C—General Supervisor Qualification Requirements Before July 1, 1971

An individual first qualifying as a general supervisor before July 1, 1971 is now qualified to be a general supervisor under § 493.1427 if he or she has had at least 15 years of pertinent full time laboratory experience before January 1, 1968. The required experience may be met by the substitution of education for experience.

Appendix D—Technologist Qualification Requirements Before July 1, 1971

An individual first qualifying as technologist before July 1, 1971, who met the following requirements is now qualified to be a technologist under § 493.1433. The individual—

(a) Was performing the duties of a laboratory technologist at any time between July 1, 1961 and January 1, 1968; and

(b) Has had at least 10 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience).

Appendix E—Cytotechnologist Qualification Requirements Before January 1, 1969

An individual who met the following requirements before January 1, 1969 is now qualified to be a cytotechnologist under § 493.1437. Before January 1, 1969, an individual must have—

(a) Graduated from high school;

(b) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician recognized as a specialist in cytology; and

(c) Completed 2 years of full-time supervised experience in cytotechnology.

Appendix F—Technician Qualification Requirements Before December 31, 1977

An individual first qualifying as technician before—

(a) December 31, 1977, who achieved a satisfactory grade to qualify as a technician in a proficiency examination approved by HHS is now qualified to be a technician under § 493.1441. However, after December 31, 1977, initial certification as a technician must be in accordance with § 493.1441(b) (1), (2), (3), or (4).

(b) January 1, 1968, an individual who met the following requirements is now qualified to be a technician under § 493.1441. The individual—

(1) Was performing the duties of a laboratory technician any time between July 1, 1961, and January 1, 1968; and

(2) Has had at least 5 years of pertinent laboratory experience prior to January 1, 1968. (This required experience may be met by the substitution of education for experience.)

Substitution of education for experience applies only to appendix C, appendix D, and appendix F(b) and means that a minimum of 30 semester hours of credit from an approved school of medical technology, or toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject is considered equivalent to 2 years of experience. Additional education is equated at the rate of 15 semester hours of credit for 1 year of experience.

(Catalog of Federal Domestic Programs No. 13.714—Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance Program; No. 13.774, Medicare—Supplementary Medical Insurance Program).

Dated: April 6, 1990.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

Approved: April 19, 1990.

Louis W. Sullivan,

Secretary.

[FR Doc. 90–11451 Filed 5–14–90; 11:25 am]

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Monday
May 21, 1990

Part III

Department of Transportation

Research and Special Programs Administration

49 CFR Parts 107, 171, and 176

Transportation of Explosives by Vessel and Miscellaneous Amendments; Notice of Proposed Rulemaking

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

49 CFR Parts 107, 171, and 176

[Docket No. HM-204; Notice No. 90-6]

RIN 2137-AA10

Transportation of Explosives by Vessel and Miscellaneous Amendments

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: RSPA and the United States Coast Guard (USCG) are proposing to amend existing requirements of the Hazardous Materials Regulations (HMR) pertaining to the handling, stowage, and transport of explosives by vessel. This notice proposes to revise provisions currently found in 46 CFR part 146 applicable to the carriage of military explosives by vessel and to consolidate them with the provisions for transporting commercial explosives by vessel that are currently found in 49 CFR part 176.

The purpose of this notice is to simplify, clarify, and remove duplicative requirements for the transport of explosives by vessel. RSPA has also proposed minor editorial changes intended to harmonize the modal requirements of part 176 applicable to the transport of hazardous materials by vessel with the proposed changes to hazard class terminology and units of measurement set forth in Docket HM-181. Notice 87-4 (52 FR 42772: November 6, 1987). Docket HM-181, Notice 87-4, indicated these changes would be forthcoming.

The intended effect of this notice is to enhance transportation safety, make the regulations pertaining to the transport of explosives by vessel easier to use and enforce, and facilitate the international transportation of hazardous materials by vessel.

DATES: Comments must be received on or before July 16, 1990.

ADDRESSES: Written comments should be submitted to the Dockets Unit, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590-0001. Comments should identify the docket and notice number and should be submitted, if possible, in five copies. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the docket number (i.e., Docket HM-204). The Dockets Unit is located in room 8221 of the Nassif Building, 400 Seventh Street SW., Washington, DC 20590-0001. The docket may be reviewed between the hours of 8:30 a.m. and 5 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Frank K. Thompson, Office of Marine Safety, Security, and Environmental Protection (G-MTH-1), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593-0001, telephone (202) 267-1577; or, Mr. Carl V. Strombom, Office of Hazardous Materials Transportation, Research and Special Programs Administration, U.S. Department of Transportation, 400 7th Street SW., Washington, DC 20590-0001, telephone (202) 366-4488.

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. General discussion.
II. Review by sections.
III. Related rulemakings.
IV. Administrative notices.

I. General Discussion

In a final rule issued under Docket No. HM-112 on January 24, 1971 (41 FR 15972), requirements for the transport of hazardous materials by vessel were reissued under the Hazardous Materials Transportation Act (HMTA) and relocated to 49 CFR part 176. Not included in the reissued regulations were provisions applying to hazardous materials transported in bulk by vessel, found in 46 CFR chapter I, subchapters D, I, O, and N, and requirements applying to military explosives, found in 46 CFR part 146. This notice proposes to revise the provisions of 46 CFR part 146 and incorporate them into the Hazardous Materials Regulations (HMR) at 49 CFR part 176. Requirements concerning the carriage of hazardous materials by bulk are not under authority of the HMTA and would remain in 46 CFR.

Since the Second World War, vessels transporting explosives have been required to comply with different requirements depending on the end use of the explosives. If a vessel is transporting military explosives, the applicable regulations are in 46 CFR part 146; on the other hand, if a vessel is transporting explosives other than military explosives, the applicable regulations are in 49 CFR part 176. One major difference between the requirements in 46 CFR and those in 49 CFR is the complexity of the segregation rules. Historically, greater emphasis has been placed on the segregation of military explosives due to the destructive threat posed by these materials. However, since non-military explosives are potentially as hazardous as military explosives, the USCG and RSPA believe their safety requirements should be consistent with those for military explosives. Consequently, the regulations regarding handling, fire, electrical safety, stowage, segregation, and transport should be the same for both types of explosives.

Further complicating the international transport of explosives is the adoption by most major nations of the International Maritime Dangerous Goods (IMDG) Code which incorporates the United Nations (U.N.) classification system for explosives and other hazardous materials. The HMR do not authorize compliance with the IMDG for the transport of Class A and B explosives; thus, a system of dual compliance is in effect for transporters of explosives in international commerce. Currently, international shippers of explosives by vessel must ensure that cargoes of Class A or B explosives are prepared, identified, and stowed to meet the HMR, or 46 CFR part 146, as applicable, to be in compliance with U.S. regulations while in waters under U.S. jurisdiction; and must concurrently prepare, identify, and stow the same explosive cargo in accordance with the IMDG Code to meet the regulations of the originating or destination country. This rulemaking proposes to eliminate the need for such dual compliance by revising 49 CFR requirements governing the transport of explosives by vessel to be consistent with provisions in the IMDG Code pertaining to the transport of substances and articles of United Nations (U.N.) Class 1, i.e., explosives.

At its 37th session in May 1985, the International Maritime Organization's (IMO) Subcommittee on the Carriage of Dangerous Goods initiated a complete revision of the provisions of the IMDG Code which deal with the transport of Class 1 materials. After receiving numerous recommendations from many maritime nations, including the U.S., the revisions were finalized in 1989. The rewritten Class 1 provisions will enter the IMDG Code and become effective 1 January 1991. The revised introduction and schedules for Class 1 substances and articles are expected to be adopted as regulations by most nations which are trading partners of the United States.

In this notice, it is proposed to revise and relocate provisions currently contained in the Military Explosives Regulations of 46 CFR part 146, and to revise existing 49 CFR requirements for explosives found in 49 CFR part 176, subpart G. RSPA and the USCG do not

believe that the burden of compliance on shippers or carriers would be significantly increased by the proposed regulations because they now must comply with very similar regulations in foreign ports, in addition to complying with the HMR in U.S. ports.

A second aspect of this notice, is to propose the adoption of the IMDG Code system of hazardous materials segregation. Before July 1, 1988, the requirements for the segregation of incompatible hazardous materials in 49 CFR 176.83 were identical to those in the IMDG Code. With the 24th Amendment of the IMDG Code, however, the IMO has adopted significant changes to its segregation system. The most notable change allows the mixed stowage of materials such as flammable liquids with materials such as corrosives which were formerly considered incompatible. Also, new tables have been introduced to illustrate the separations required between freight containers or transport vehicles containing hazardous materials. A number of shipping line operators have requested and received a DOT exemption (DOT–E 9785) authorizing them to comply with the IMDG segregation system in place of the requirements of 49 CFR 176.83. In Docket HM–166W (54 FR 38790, September 20, 1989), RSPA further authorized all shipments in international commerce, except shipments of explosives and radioactive materials, to be stowed and segregated in accordance with the IMDG Code. In this notice, the present requirements for hazardous materials segregation in 49 CFR 176.83 would be revised for consistency with the recent changes of the IMDG Code.

This notice also proposes various revisions to the requirements for handling explosives on vessels in port. Based on the 1983 IMO publication *Recommendations on the Safe Transport, Handling and Storage of Dangerous Goods in Port Areas*, the changes proposed in 49 CFR 176.176 through 176.190, are similar to the requirements of 46 CFR part 146 which now apply only to vessels on which military explosives are handled and stowed. In the future, they would apply to all vessels on which any type of explosive is loaded, handled, or unloaded in a U.S. port. These proposed rules would not apply to the handling and storage of explosives at a waterfront facility, which is governed by 33 CFR part 126.

In addition to revising provisions for handling explosives on vessels in port areas, proposals are included to provide standard requirements for the transportation by vessel of explosives in freight containers and transport vehicles (i.e., trucks and semitrailers). At present, all commercial Class A explosives and nearly all military explosives may be transported by vessel in freight containers and transport vehicles only after specific approval for the operation has been granted by the Commandant, USCG. For several years, the USCG has authorized and controlled the movement of explosives in freight containers through its approval program. During this period, the USCG has gained information on various safety benefits resulting from the use of the freight container for the transportation of explosives; including increased cargo security and reduced handling of explosives. The USCG also has participated in developing the international standards for freight container design and construction, and in implementing an inspection and certification program to ensure the safe cargo-carrying capability of freight containers. This proposal would eliminate the requirements for special USCG approval of freight containers carrying Class A explosives (Division 1.1 and 1.2 materials). The approval provisions would be incorporated into the proposed regulations of 49 CFR part 176.

Other changes proposed include various revisions for the carriage of Class 1 (explosive) materials on passenger vessels and the removal of requirements for the use of asbestos. The proposals for passenger vessels are based on revisions contained in the forthcoming Amendment 25 of the IMDG Code. Amendment 25 will specify that Division 1.4S (Class C explosives) materials, other Class 1 materials in compatibility groups B, C, D, E, and G, and Class 1 (explosive) materials used for lifesaving purposes may be carried on board passenger vessels if certain restrictive quantity and stowage provisions are met. The proposed revisions for asbestos would remove a requirement for the use of asbestos board in the construction of 'tween deck magazines. Present HMR requirements predate the recognition of the health hazard associated with asbestos.

Besides the changes necessary to consolidate military and commercial explosives requirements in the HMR and align the explosives regulations of 49 CFR part 176 with the IMO and IMDG Code requirements regarding segregation, vessels in port facilities, passenger vessels and asbestos, various editorial changes are proposed to further align 49 CFR part 176 with the proposals in Docket HM–181, Notice 87–4, as published on November 6, 1987 (52 FR 42772). Docket HM–181, Notice 87–4, proposed to revise the HMR to incorporate features found in the United Nations Committee of Experts' Recommendations on the Transport of Dangerous Goods (U.N. Recommendations) and the Technical Instructions for the Safe Transportation of Dangerous Goods by Air of the International Civil Aviation Organization (ICAO Technical Instructions).

Proposals in Docket HM–181, Notice 87–4, are intended to: (1) Simplify the HMR, (2) reduce the volume of the regulations, (3) promote flexibility and technological advances in packaging, (4) promote safety through better packaging, (5) reduce the need for exemptions, and (6) facilitate international commerce. The proposals of Docket HM–181, Notice 87–4, would align the HMR with the U.N. Recommendations and ICAO Technical Instructions in the areas of classification, packaging, and hazard communication in the transport of hazardous materials.

In Docket HM–181, Notice 87–4, proposals were not included for part 176 due to time constraints. It has been RSPA's intent to develop complementary rulemakings for each modal section of 49 CFR to harmonize current requirements with those proposals set forth in Docket HM–181, Notice 87–4. In this notice, part 176 would be revised for consistency with Docket HM–181 proposals in regard to: (1) Use of international numeric hazard class nomenclature (e.g., "Class 4" rather than "flammable solid") and, (2) use of both metric and U.S. standard measurements. Most of the changes that align 49 CFR part 176 with Docket HM–181, Notice 87–4, proposals are editorial in nature and have been identified in the Review by Sections part of this preamble. The classifications proposed in Docket HM–181, 87–4, and used throughout this NPRM are listed as follows:

Class division	Name of class or division
1.1	Explosives (mass explosion hazard)
1.2	Explosives (projectory/fragment hazard)
1.3	Explosives (predominately fire hazard)
1.4	Explosives (no significant blast hazard)
1.5	Very insensitive explosives, blasting agents
1.6	Extremely insensitive explosive articles or devices
2.1	Flammable gas
2.2	Non-flammable gas

Class division	Name of class or division
2.3	Poisonous gas
3	Flammable and combustible liquids
4.1	Flammable solids
4.2	Spontaneously combustible materials
4.3	Dangerous when wet materials
5.1	Oxidizers
5.2	Organic peroxides
6.1	Poisonous materials
6.1	Irritating materials
6.2	Etiological or infectious substances
7	Radioactive materials
8	Corrosive materials
9	Miscellaneous (hazardous) materials

The proposed classifications would be used throughout 49 CFR part 176 in place of current DOT classifications. As an aid to the reader, current DOT classifications would remain in parentheses immediately following the proposed classifications. To further align 49 CFR part 176 with Docket HM–181, Notice 87–4, and other international requirements, current measurements in 49 CFR part 176 would be converted to their metric system equivalents. U.S. measurements would remain in parentheses immediately following the metric measurements. Editorial revisions for classifications and metric system measurements necessary to align 49 CFR part 176 with Docket HM–181, Notice 87–4, and international regulations are proposed for subparts H, I, J, L, N, and O. These subparts have been reprinted in their entirety to aid the reader. Subpart M of 49 CFR part 176 has not been included in this notice, as changes to the requirements for radioactive materials will be proposed in a future rulemaking action.

Concurrently with this proposed action, USCG and RSPA are proposing to revoke the military explosives regulations in 46 CFR part 146. A notice of proposed rulemaking concerning that action appears elsewhere in this issue of the Federal Register.

II. Review by Sections

The following review by sections addresses all of the proposed changes of this NPRM. Proposals are broken down into two categories: (1) Proposals to amend the existing HMR; and (2) proposals in §§ 171.7 and 176.84 to modify our earlier proposal, initiated under Docket HM–181, Notice 87–4 (52 FR 42772; November 6, 1987), to amend the HMR. For these two sections, reference is made to the Federal Register volume, page number, and date the previous proposal was published in the Federal Register.

Part 107: Hazardous Materials Program Procedures

Section 107.101. In § 107.101, the text would be revised to remove the words "or part 146" from the paragraph as all requirements for vessel transportation of hazardous materials will be contained in 49 CFR and 46 CFR part 64.

Section 107.103. In § 107.103, the text of paragraph (a) would be revised to remove the words "or part 146" as all requirements for vessel transportation of hazardous materials will be contained in 49 CFR and 46 CFR part 64.

Section 107.113. In § 107.113, the text of paragraph (a) would be revised to remove the words "or part 146" as all requirements for vessel transportation will be contained in 49 CFR and 46 CFR part 64.

Section 107.201. In § 107.201, the text of paragraph (c) would be revised to remove the words "or part 146" as all requirements for the vessel transportation of hazardous materials would be contained only in 49 CFR and 46 CFR part 64.

Part 171: General Information, Regulations, and Definitions

Section 171.7. In Docket HM–181, Notice 87–4, in the proposed table of material incorporated by reference in § 171.7(c) (52 FR 42778; November 6, 1987), an entry would be added to include a reference to appendix B of Association of American Railroads Specification M–931–Highway Trailers, All Types, for TOFC Service, 1985 edition and the entry for the International Maritime Organization's IMDG Code would be revised to reflect the current edition of the Code.

Section 171.8. In § 171.8 the definitions of "Away from", "Separated by a complete hold or compartment from", "Separated from", and "Separated longitudinally by a complete hold or compartment from" would be removed. In addition, the definitions of "Captain of the Port (COTP)", "Passenger vessel", "Trailership" and the last sentence of the definition of "Competent authority" would be revised to aid in understanding the terms used in the proposed changes of this NPRM.

Part 176—Carriage by Vessel

The table of sections for part 176 would be revised to ensure all section number references correspond to the renumbered and new section numbers proposed in this NPRM.

Section 176.2. A new § 176.2 would be added to include definitions of terms that would be used extensively in part 176. Words and terms defined include "Cantline", "Cargo net", "Closed freight container", "Commandant (G-MTH)", "Compartment", "CSC safety approval plate", "Deck structure", "Draft", "Dunnage", "Explosives anchorage", "Explosive article", "Explosives handling facility", "Explosive substance", "Handling", "Hold", "In containers or the like", "Incompatible materials", "Landing mat", "Machinery spaces of category A", "Magazine", "Master of the Vessel", "Open freight container", "Overstowed", "Pallet", "Palletized unit", "Pie plate", "Portable magazine", "Readily combustible material", "Responsible person", "Safe working load", "Skilled person", "Skipboard", "Splice", "Transport unit", and "Tray".

Section 176.3. In § 176.3, paragraph (b) would be revised to remove the reference to § 176.5(c) and to refer the reader to § 173.54, Forbidden Explosives (see Docket HM–181A, Notice 90–5 of the Related Rulemakings section of this preamble). Readers of the current regulations will notice that § 176.5(c) is a reserved section which contains no regulatory text. The revision of § 176.3 would remove the inappropriate reference to § 176.5(c).

Section 176.4. A new § 176.4 would be added to transfer the port security regulations of 46 CFR part 146.29–7 to the HMR.

Section 176.5. In § 176.5, paragraph (e) would be removed. This section refers to the military explosives requirements of 46 CFR part 146. The requirements of 46 CFR regarding military explosives shipments have been incorporated into this NPRM: therefore, the reference in § 176.5(e) would no longer be needed. In addition, paragraph (b)(6) would have minor editorial revisions to align the paragraph with the classifications proposed in Docket HM–181, Notice 87–4.

Section 176.9. In § 176.9, paragraph (a) would be revised to replace the current DOT classification Class A explosives with Divisions 1.1 and 1.2.

Section 176.11. In § 176.11, paragraphs (a), (c), and (f) would be revised to clarify the use of the IMDG code for transportation by vessel.

Section 176.30. In § 176.30, the reference to § 172.102 would be removed from paragraph (a)(3). Under the proposals of Docket HM–181, Notice 87–4, the § 172.102 Optional Table would be consolidated into the § 172.101 Hazardous Materials Table. Reference to § 172.102 would no longer be necessary. Also, paragraph (a)(5) would be revised to remove references to international classifications that are duplicative of proposals in Docket HM–181, Notice 87–4.

Section 176.54. Section 176.54 would be revised by changing the section heading to include power actuated tools. In addition, paragraph (b)(1) would be modified to refer to the Captain of the Port's (COTP) authority in 33 CFR 126.15(c), and paragraph (b)(2) would be revised to require notification of the nearest COTP before any repairs are made.

Section 176.57. Section 176.57 would have minor editorial revisions. Throughout the section the phrase "qualified person" would be replaced by "responsible person".

Section 176.58. Section 176.58 would be revised to include more detailed requirements for preparing a vessel for loading hazardous materials. The proposed regulations would require that all decks, gangways, hatches, and cargo ports over or through which hazardous materials must be passed or handled in loading or unloading must be free of all loose material before cargo handling operations begin. The proposed provisions would not allow any debris that might create a fire hazard or a hazardous condition for persons engaged in loading or unloading operations and would also prohibit the stowage of hatch beams and hatch covers in a location that would interfere with cargo handling.

Section 176.69. In § 176.69, paragraph (a) would be revised to change the reference from ORM material to Class 9 (miscellaneous hazardous materials). This minor editorial revision would be necessary to align this section with the classifications proposed in Docket HM–181, Notice 87–4. In addition, paragraph (d) and (e) would be added to outline additional general stowage requirements for hazardous materials.

Section 176.74. Section 176.74(c) would be revised to change the reference from ORM material to Class 9 (miscellaneous hazardous materials) materials. This minor editorial correction would be necessary to align this section with the classifications proposed in Docket HM–181, Notice 87–4.

Section 176.76. Section 176.76 would be revised to eliminate the requirements for USCG approval for freight containers containing Division 1.1 or 1.2 (Class A explosive) materials. The USCG approval provisions would be incorporated into the requirements of §§ 176.170, 176.172, and 176.194. In addition, the requirements of paragraph (a)(9) for loading solids on top of liquids would be removed as would the requirements of paragraph (c) limiting railroad vehicles to transport only on board a trainship, railroad car ferry, or a car float.

Section 176.78. Section 176.78 would be revised to provide for the use of certain specified forklift trucks for handling Class 1 (explosive) materials. Generally, Series EE or EX electric trucks as defined in Underwriters Laboratories (UL) Standard UL583 could be used in all situations. UL Series GS, LPS, D, or DS could be used only under conditions acceptable to the COTP. For safety reasons, forklifts used to handle small or unstable loads would be required to have backrests sufficient to prevent loads from falling towards the mast of the truck and onto the driver. Paragraph (1) would be revised to make the provisions for the storage of industrial truck fuel consistent with the recently-revised Ships Stores regulations in 46 CFR part 147. In addition, paragraph (e) and (1) would be revised to align the section with the classifications and metric system measures proposed in Docket HM–181, Notice 87–4.

Section 176.83. Section 176.83 would be revised to harmonize the U.S. stowage and segregation requirements and charts with the IMDG Code stowage and segregation requirements. The IMDG Code at present does not contain provisions for the stowage and segregation of explosive materials in Division 1.6. In proposed Table 176.83(a), the requirements for Division 1.4 would also apply to Division 1.6. Two new tables containing the segregation requirements for freight containers on board container ships and transport vehicles on trailerships (RO/RO vessels) would be added to this section. As proposed in this notice, the stowage provisions for transport vehicles would differ from those for freight containers. This is not consistent with the present regulations; however, in the IMDG Code, the stowage requirements for transport vehicles are more stringent because the IMO Carriage of Dangerous Goods Subcommittee believed that "the general circumstances of many RO/RO ships required separate consideration." In order to determine what these "general circumstances" are, and whether "separate considerations" are necessary, comments from shippers and carriers engaged in this trade are invited.

Section 176.84. In proposed § 176.84 of Docket HM–181, Notice 87–4 (52 FR 42989; November 6, 1987), paragraph (c) would be added to provide provisions for the stowage of Class 1 (explosive) materials. Specific provisions would be added to provide for the shipment of small quantities of Class 1 (explosive) materials in compatibility groups other than A, H, J, K, and L. This section would also contain a chart that would list the notes found in column 10(c) of the § 172.101 Table and their meaning.

Section 176.90. In § 176.90, the word "explosive" would be amended to read "Class 1 (explosive) material".

Section 176.91. In § 176.91, the words "six gallons" would be amended to read "23 liters (six gallons)".

Section 176.92. In § 176.92, the words "compressed gas" would be amended to read "Class 2 (compressed gas) material".

Section 176.93. In § 176.93, paragraph (a) the words "flammable liquid and gas" would be revised to read flammable liquid and Division 2.1 (flammable gas) materials". This editorial revision would align this section with the classifications proposed in Docket HM–181, Notice 87–4.

Section 176.96. Section 176.96 would have a minor editorial correction. The section would be revised to read "Barges used to transport hazardous materials must be constructed of steel" instead of the present wording, "Only barges constructed of steel may be used to transport hazardous materials."

Section 176.98. In § 176.98, the words "column (7)" would be changed to read "column (10)". This editorial correction would align this section with the new § 172.101 Hazardous Materials Table proposed in Docket HM–181, Notice 87–4.

Section 176.99. In § 176.99. the words "Class A Explosives" would be replaced with Division numbers 1.1 and 1.2 and the words "Blasting agents" would be replaced with Division 1.5. The remainder of this section would remain unchanged.

Section 176.100. In § 176.100, the words "Class A explosives" would be replaced with Division numbers 1.1 and 1.2. The remainder of this section would remain unchanged.

Section 176.102. Section 176.102 would be added to authorize the COTP to assign a USCG detail to supervise the loading and unloading of Class 1 (explosive) materials. This requirement has been a long-standing provision for military Class 1 (explosive) materials but, apart from the COTP's broad authority under 33 CFR part 126, it is a new requirement for nonmilitary Class 1 (explosive) materials.

Section 176.104. Section 176.104 would be added to consolidate the loading and unloading requirements for nonmilitary Class 1 (explosive) found in current § 176.105 with those for military Class 1 (explosive) materials. This consolidation will essentially mean no change in the requirements for nonmilitary Class 1 (explosive) materials, but many detailed

requirements for military Class 1 (explosive) would be eliminated. Current § 176.105 would be removed.

Section 176.108. A new 176.108 would be added to define the responsibilities of the responsible person in charge of the loading, unloading, stowage and handling operations for Class 1 (explosive) materials aboard a vessel.

Section 176.112. A new § 176.112 would be added to state the applicable stowage requirements for Division 1.4 (Class C explosive) materials, compatibility group S items. Because of the limited hazards associated with items in this category, their stowage would be allowed with all other Class 1 (explosive) materials except those in compatibility groups A or L.

Section 176.116. A new § 176.116 would be added to include many of the requirements for stowage conditions for Class 1 (explosive) materials that are found in the IMDG code. The requirements would require the stowage of Class 1 (explosive) materials in a cool, dry location and Class A steel bulkheads would be required between Class 1 (explosive) materials stowage and accommodation spaces. In addition, machinery space bulkheads would have to be insulated to a "Class A–60" standard.

Section 176.118. A new § 176.118 would be added to specify the requirements for electrical equipment and cables installed in compartments where Class 1 (explosive) materials are carried. This section would permit the use of energized electrical circuits in explosive storage locations if certain conditions are met.

Section 176.120. A new § 176.120 would be added to include lightning protection requirements for ships carrying Class 1 (explosive) materials. The requirements for the cleaning of decks, hatches, and gangways that are currently found in § 176.120 would be covered by revised § 176.58. The requirements of present § 176.120(b) concerning the closing of hatches would be relocated to proposed § 176.182(g).

Section 176.122. A new 176.122 would be added to list the requirements for explosive stowage under deck. Generally, explosive stowage under deck would be allowed as described in §§ 176.124 through 176.136 of this NPRM.

Section 176.124. A new § 176.124 would be added for "ordinary" stowage provisions. New "ordinary" stowage replaces present stowage provisions for nonmilitary Class 1 (explosive) materials not requiring magazine stowage and present "ammunition stowage" provisions for military Class 1 (explosive) materials.

Section 176.128. A new § 176.128 would be added to list the general stowage requirements for explosive substances. Generally, all explosive substances, with some limited exceptions for compatibility groups G, L, or S, would require magazine stowage. Depending on their characteristics, Class 1 (explosive) materials would be required to be stowed in one of three different types of magazines designated by the letters A, B, and C.

Section 176.130. Section 176.130 would be revised to reflect the design, construction, and location requirements for Magazine Stowage Type A as well as the requirements for the stowage of Class 1 (explosive) materials therein. The requirements for securing, blocking and bracing Class 1 (explosive) materials that are currently found in § 176.130 would be relocated to § 176.69, where they would apply to all hazardous materials. The stowage requirements for kegs of black powder in the present paragraph (c) of this section are not consistent with the IMDG Code and would be removed.

Section 176.132. A new § 176.132 would be added to reflect the design, construction, and location requirements for Magazine Stowage Type B on vessels. The section also addresses the requirements for explosive stowage within a Type B area.

Section 176 133. A new § 176.133 would be added to reflect the design, construction, and location requirements for Magazine Stowage Type C on vessels. The section would also address the requirements for explosive stowage within a Type C area.

Section 176.134. A new § 176.134 would be added to allow the use of closed transport vehicles as magazine stowage locations if they meet the requirements of the appropriate magazine stowage type. Additional requirements for the use of transport vehicles as explosive stowage locations would be found in § 176.168.

Section 176.136. A new § 176.136 would be added to address special stowage provisions for Class 1 (explosive) materials that present unique hazards. Special stowage requirements would be included for Class 1 (explosive) that have smoke hazards (compatibility groups G or H), are toxic (compatibility group K), or are materials that could have a chemical reaction when in contact with water (compatibility group L).

Section 176.137. A new § 176.137 would be added to contain the requirements of the design and fabrication of portable magazines meeting the requirements of the Bureau of Alcohol, Tobacco, and Firearms; and would authorize COTP's, instead of Commandant (G–MTH–1), to approve oversize portable magazines.

Section 176.138. Section 176.138 would be revised to include the requirements for the on-deck stowage of Class 1 (explosive) materials. This section would require that Class 1 (explosive) materials stowed on deck must be at least 20 feet away from any fire, machinery exhaust, galley uptake, or other potential sources of ignition. The section would also require any on-deck explosive stowage to be clear of walkways, fire hydrants, means of access, or any facility necessary for the safe working operations of the vessel. The construction requirements for magazines that are currently found in § 176.138 would be moved to §§ 176.128 through 176.133.

Section 176.140. A new § 176.140 would be added to list the requirements for the segregation of Class 1 (explosive) materials in relation to bulk cargoes of hazardous materials. For specific instructions, the reader would be referred to the General Introduction to the IMDG Code.

Section 176.142. A new § 176.142 would be added to address the stowage requirements for certain hazardous materials of extreme flammability. These exceptions would be listed as paragraphs (b) and (c) of § 176.142.

Section 176.144. A new § 176.144 would be added to include provisions for mixed stowage in the same compartment, container, or transport vehicle of explosives in different compatibility groups. Table 176.144(a) would contain compatibility requirements for Class 1 (explosive) materials in compatibility group N which are not currently found in the IMDG Code. The requirements for the ventilation of magazines that are currently found in § 176.144 are not consistent with the IMDG Code and would be removed.

Section 176.145. A new § 176.145 would be added to include provisions for stowing Class 1 (explosive) materials on board small vessels having only a single hold when certain segregation provisions of § 176.83 cannot be met.

Section 176.146. A new § 176.146 would be added to include new provisions for the segregation of Class 1 (explosive) materials from nonhazardous materials. These requirements are new for non-military Class 1 (explosive) materials, but are not materially different from the present requirements for military Class 1 (explosive) materials found in the 46 CFR.

Section 176.147. The requirements for metal stowage lockers for fireworks that are currently found in § 176.147 are not consistent with the IMDG Code stowage requirements and would not be included in the revised explosives regulations of part 176.

Section 176.148. A new § 176.148 would be added to allow the use of electric lights as the only form of artificial lighting permitted when loading and unloading Class 1 (explosive) materials.

Section 176.150. Section 176.150 would be revised to include provisions for the use and deenergization of sources of electromagnetic radiation (radio transmitters, radars) during Class 1 (explosive) materials handling operations. In addition, the section would permit low-power VHF transmitters to be used and would add stowage requirements for items which are sensitive to electromagnetic radiation. The design and fabrication requirements for portable magazines that are currently found in § 176.150 would be relocated to proposed § 176.137.

Section 176.154. A new § 176.154 would be added that prohibits the loading or unloading of Class 1 (explosive) materials aboard a vessel while bunkering (fueling) is in progress. Bunkering would also not be permitted while the hatches of cargo spaces containing Class 1 (explosive) materials are open. The only allowable exceptions to these requirements would be for the stowage of Class 1 (explosive) materials in compatibility group S or with prior permission of the COTP.

Section 176.156. Section 176.156 would be revised to require that defective, leaking, or damaged packages of Class 1 (explosive) material must be handled in accordance with the recently adopted emergency response communication regulations (54 FR 27138 & 55 FR 870) (see Docket HM–126C in the related rulemakings section of this NPRM). The requirements for the stowage of Class 1 (explosive) materials with combustible liquids that are currently found in § 176.156 are redundant to the proposed segregation requirements of § 176.83 and would be removed.

Section 176.160. A new § 176.160 would be added to specify requirements for loading and unloading Class 1 (explosive) materials during rainstorms. This section would require that care must be taken to prevent packages containing Class 1 (explosive) materials from becoming wet.

Section 176.162. A new § 176.162 would be added to list security requirements and to restrict entry by unauthorized persons into spaces containing Class 1 (explosive) materials. This requirement is new for nonmilitary Class 1 (explosive) materials although similar provisions presently exist for military Class 1 (explosive) materials in 46 CFR.

Section 176.164. A new § 176.164 would be added to include fire prevention provisions that are similar to those now in force for nonmilitary Class 1 (explosive) materials. Many existing detailed requirements for military Class 1 (explosive) materials would be eliminated.

Section 176.166. A new § 176.166 would be added to list the requirements for carrying Class 1 (explosive) materials on passenger vessels. The proposed requirements of this section would revise current regulations regarding explosive transport on passenger ships to be consistent with Amendment 25 of the IMDG Code. Generally, Division 1.4S (Class C explosive) materials, explosive articles for lifesaving purposes, and Class 1 (explosive) materials in compatibility groups C, D, E, and G if the net explosive weight does not exceed 10 kg (22 pounds) per vessel, would be authorized to be carried on a passenger vessel. In addition, materials in compatibility group B would be allowed if the net explosive weight did not exceed 5 kg (11 pounds).

Section 176.168. A new § 176.168 would be added to include new provisions governing the carriage of Class 1 (explosive) materials in motor vehicles aboard "roll-on/roll-off" (RO/RO) vessels. Transport vehicles carrying Class 1 (explosive) materials would be required to be structurally serviceable as defined in § 176.172(a)(2) and would need to be in compliance with the loading and unloading requirements of §§ 177.834 and 177.835. In addition, all explosive-laden transport vehicles would be required to be secured to the ship in such a manner to prevent the movement of the vehicle during the sea passage.

Section 176.170. A new § 176.170 would be added to include the requirements for the transport of Class 1 (explosive) materials in freight containers. The proposed provisions of §§ 176.170 and 176.172 would eliminate the present requirements of 49 CFR 176.76(a) and 46 CFR 146.29–11(c)(16) for Commandant, USCG approval of freight containers containing Division 1.1 or 1.2 (Class A explosive) materials. In addition, § 176.170 would also cover loading and stowage provisions for freight containers.

Section 176.172. A new § 176.172 would be added to specify the structural serviceability requirements for freight containers and transport vehicles that are used for stowage of Class 1 (explosive) materials aboard ship. Proposed §§ 176.172, 176.170 and 176.192 would eliminate the approval requirements for freight containers that are currently found in 49 CFR 176.76(a) and 46 CFR 146.29–11(c)(16). The definition of the term "splice" as used in regard to freight containers is also included.

In addition, § 176.172(c) would contain a requirement for a written statement to accompany shipments of Class 1 (explosive) materials in freight containers or vehicles aboard vessels certifying that the freight containers or motor vehicles meet the structural serviceability requirements of § 176.172(a). To help determine what burden might result to shippers from a certification statement requirement, RSPA encourages readers to comment on this aspect of the NPRM.

Section 176.174. A new § 176.174 would be added to include the requirements for the transport of Class 1 (explosive) materials in shipborne barges. Generally, all types of Class 1 (explosive) materials would be allowed to be transported in shipborne barges except that Class 1 (explosive) materials in compatibility group G or H would be required to be stowed in steel portable magazines or freight containers, and Class 1 (explosive) materials in compatibility groups K or L would be required to be stowed in steel portable magazines.

Section 176.176. A new § 176.176 would be added that would require vessels to display signals while loading or unloading Class 1 (explosive) materials. These requirements are the same as those currently required for military Class 1 (explosive) materials, but are new requirements for the vessel transportation of nonmilitary Class 1 (explosive) materials.

Section 176.178. A new § 176.178 would be added that would specify the requirements for the proper use of mooring lines on vessels transporting Class 1 (explosive) materials. The requirements are similar to those currently contained in 46 CFR for military Class 1 (explosive) materials but would be new for nonmilitary Class 1 (explosive) materials.

Section 176.180. A new § 176.180 would be added that would require manning of an explosive-laden vessel while in port. This section would require a sufficient crew on board at all times necessary to maintain a proper watch and to operate the propulsion and firefighting equipment in case of an emergency.

Section 176.182. A new § 176.182 would be added that would include general operating requirements for safety in port. This section would include the provisions concerning lighting, smoking, and the use of drugs or alcohol that are currently found in §§ 176.167, 176.171, and 176.173. Requirements concerning operations during adverse weather conditions would also be included in § 176.182. Current §§ 176.167, 176.171, and 176.173 would be removed.

Section 176.184. A new § 176.184 would be added that would not allow the handling of Class 1 (explosive) materials in compatibility group L in any port area without the special permission of the COTP. Group L explosives would also be subject to any special handling precautions specified by the COTP.

Section 176.190. A new § 176.190 would be added that would direct a vessel to leave port as soon as possible after the loading of Class 1 (explosive) materials is completed.

Section 176.192. A new § 176.192 would be added that would provide provisions concerning freight container handling equipment. These provisions are the same as those issued under Commandant, USCG approval procedures for Division 1.1 and 1.2 (Class A explosive) materials shipped in freight containers except certain inspection and approval provisions of the approval which are covered by U.S. Occupational Safety and Health Administration (OSHA) regulations are omitted. The provisions of proposed §§ 176.192, 176.170 and 176.172 would eliminate the requirements in 49 CFR 176.76(a) and 46 CFR 146.29–11(c)(16) for Commandant, USCG approval of freight containers.

Section 176.194. A new 176.194 would be added to include the regulations that are currently found in § 176.177 and 46 CFR 146.29–53. This section would remain unchanged from current provisions with the exception of § 176.194(m). Section 176.194(m) would be revised to include current requirements for fire extinguishing equipment. In addition, paragraph (p) would refer the reader to the recently issued emergency response requirements of Docket HM–126C. Interested readers should refer to the Related Rulemakings section of this preamble for further information on Docket HM–126C. Current § 176.177 would be removed.

Subpart H—Sections 176.200 through 176.230. The subpart heading and the sections of subpart H would be revised to align the subpart with the classifications for hazardous materials proposed in Docket HM–181, Notice 87–4. The text of subpart H would be modified to read Class 2 for all compressed gases, Division 2.1 for flammable gases, and Division 2.2 for nonflammable compressed gases. In addition, the text of § 176.225 for the stowage of chlorine would be revised to specifically prohibit the stowage of chlorine with only copper or brass leaf sheets and finely divided organic material. Current prohibitions against the stowage of chlorine with metallic sodium or potassium, turpentine, ammonia, coal gas, hydrogen, or acetylene would be covered by changes in the stowage and segregation tables proposed in this notice and in Docket HM–181, Notice 87–4.

Subpart I—Sections 176.305 through 176.340. The sections of subpart I and the subpart heading would be revised to align the subpart with the classifications for hazardous materials proposed in Docket HM–181, Notice 87– 4. Editorial revisions would convert all measurements in subpart I to their metric system equivalents. Section 176.340(a)(2)(ix) would be revised to clarify that the non-DOT specification portable tanks authorized under this section must be periodically retested as presently required for DOT specification 57 portable tanks. In addition, recent Docket HM–166W [54 FR 38796] changes to § 176.340 (see the Related Rulemakings section of this preamble) have been reprinted in their entirety to aid in reader understanding of the section. Other changes would include the deletion of the reference to "bulk asbestos" in § 176.305(b)(2)(ii) and the addition of a provision in § 176.331 that would require flammable liquids with CORROSIVE or KEEP AWAY FROM FOOD labels to be stowed away from foodstuffs.

Subpart J part heading. The subpart heading for subpart J would be revised to make it consistent with the classifications for hazardous materials proposed in Docket HM–181, 87–4. Editorial revisions to the subpart heading would change the heading to read Class 4 for flammable solids, Class 5 for oxidizers and organic peroxides, and Division 1.5 for blasting agents.

Section 176.400. Section 176.400 would receive various editorial corrections to align it with the classifications proposed in Docket HM–181, Notice 87–4. Blasting agents would be referred to as Division 1.5 materials, oxidizers and organic peroxides would be referred to as Class 5 materials, and flammable solids would be referred to as Class 4 materials. In addition, new provisions would be added to require Class 4 and Division 5.2 (organic peroxide) materials to be stowed away from heat or ignition sources.

Section 176.405. Section 176.405 would be revised editorially to include metric units of measurement. The term "broom clean" would be removed.

Section 176.410. In § 176.410, the section heading and paragraphs (d) and (e) would be revised to reflect the U.N. hazard classes and divisions for oxidizers (5.1) and for blasting agents (1.5). Editorial revisions would also change all measurements to their metric system equivalents. In addition, the names of materials listed in paragraph (a) would be changed to their proper shipping names as listed in the § 172.101 Table proposed in Docket HM–181, Notice 87–4.

Section 176.415. In § 176.415, the section title and paragraphs (a)(2) and (c)(5) would be revised to read Division 1.5 for blasting agents. The names of the materials to which this section applies would be revised throughout to be consistent with proper shipping names as listed in the § 172.101 Hazardous Materials Table of Docket HM–181, Notice 87–4. These changes will align this section with the proposals of Docket HM–181, Notice 87–4.

Section 176.419. Section 176.419 would be revised to align the section with the classifications proposed in Docket HM–181, Notice 87–4. Flammable solids would be referred to as Class 4 materials, and oxidizers and organic peroxides would be referred to as Class 5 materials. In addition, new provisions would be added that would require packages of Class 4 and Class 5 materials bearing CORROSIVE or KEEP AWAY FROM FOOD labels to be stowed away from foodstuffs.

Subpart L—Section 176.600 and 176.605. The two sections of subpart L and the subpart heading would be revised to align the subpart with the classifications proposed in Docket HM–181, 87–4. Editorial changes in the two sections of subpart L would modify the text to read Division 2.3 for Poison A and 6.1 for Poison B. In addition, § 176.600 paragraphs (c) and (d) would be added stating the requirement that materials labeled with the KEEP AWAY FROM FOOD label must be stowed away from foodstuffs and packages bearing the FLAMMABLE LIQUID or FLAMMABLE GAS label must be stowed away from sources of heat and ignition.

Subpart N—Sections 176.800 through 176.805. The heading and sections of subpart N would be revised to correspond with the classifications proposed in Docket HM–181, Notice 87–4. All references to corrosive materials

would be changed to read Class 8 (corrosive material) material. In addition, § 176.800 would be revised to align the section with the IMDG Code by specifying the stowage requirements for packages of Class 8 (corrosive material) material which also bear POISON or FLAMMABLE LIQUID labels.

Subpart O Heading. The heading of subpart O would be revised to read "Detailed Requirements for Cotton and Vegetable Fibers, Motor Vehicles, and Asbestos" to more adequately describe the requirements found in subpart O. Under the IMDG Code and the classifications proposed in Docket HM-181, Notice 87-4, cotton and other fibers are in either Division 4.1 or 4.2. In a future rulemaking, the rules applying to cotton and other fibers would be relocated to subpart J of part 176.

Section 176.900. In § 176.900, the section heading would be changed to show that this section contains packaging as well as stowage requirements for cotton and other vegetable fibers. Paragraphs (i) and (l) are not consistent with the segregation requirements of proposed § 176.83 and would be removed. In addition, measurements in paragraphs (a), (c)(4), and (j) would be converted to the metric system.

Section 176.901. In § 176.901, the words "1 inch" would be replaced with the metric system equivalent of 2.54 centimeters (cm).

Section 176.902. This section is not consistent with the stowage and segregation requirements for cotton in the § 172.101 Table and proposed § 176.83 and would be removed.

Section 176.903. In § 176.903, the words "2 inches" would be replaced with the metric equivalent of 5 cm.

Section 176.904. The requirements of this section are not consistent with the segregation requirements in proposed § 176.83 for cotton (Division 4.1 or 4.2) and sodium nitrate (Division 5.1). This section would be removed.

Section 176.905. Section 176.905 would be revised to align the section with the proposed classifications in Docket HM-181, Notice 87-4. Flammable gas would be referred to as Division 2.1 materials and all measurements would be converted to the metric system. In addition, current requirements of paragraph (l) regarding the stowage of hazardous materials in holds with motor vehicles are overly restrictive and are not consistent with the international segregation system found in the IMDG Code and would be removed.

Section 176.906. In § 176.906, the reference to § 173.1090 would be revised to refer to § 173.231.

III. Related Rulemakings

A. Docket HM-181A, Notice 90-5, Requirements for Explosives

As part of the effort to align the Hazardous Materials Regulations with international standards, RSPA proposed in Docket HM-181A, Notice 90-5 (55 FR 18438, May 2, 1990) to amend the HMR by incorporating various requirements for explosives found in the U.N. Recommendations. The explosives classifications in this NPRM are aligned with the U.N. classifications for Class 1 (explosive) materials as proposed in Docket HM-181A, Notice 90-5. Throughout this NPRM, Class 1 (explosive) materials have been referred to as shown by the following list:

Present DOT classification	Proposed U.N. classification
Class A Explosives	1.1 or 1.2.
Class B Explosives	1.2 or 1.3.
Class C Explosives	1.4.
Blasting Agents	1.5.
None	1.6.

In addition to the classifications outlined above, Class 1 (explosive) materials would also have compatibility groups assigned. The class and division number for Class 1 (explosive) materials would be followed by a compatibility group letter. These compatibility group letters are used to regulate the storage and transportation of Class 1 (explosive) materials to prevent an increase in hazard that might result if certain types of Class 1 (explosive) materials are transported together. Compatibility group letters proposed in Docket HM-181A, Notice 90-5, and used in this NPRM are defined in the following table:

Description of substances or article to be classified	Compatibility group letter
Primary explosive substance	A
Article containing a primary explosive substance and not containing two or more effective protective features.	B
Propellant explosive substance or other deflagrating explosive substance or article containing such explosive substance.	C
Secondary detonating explosive substance or black powder or article containing a secondary detonating explosive substance, in each case without means of initiation and without a propelling charge, or article containing a primary explosive substance and containing two or more effective features.	D
Article containing a secondary detonating explosive substance, without means of initiation, with a propelling charge (other than one containing flammable or hypergolic liquid).	E
Article containing a secondary detonating explosive substance with its means of initiation, with a propelling charge (other than one containing flammable or hypergolic liquid) or without a propelling charge.	F
Pyrotechnic substance or article containing a pyrotechnic substance, or article containing both an explosive substance and an illuminating, incendiary, lachrymatory or smoke-producing article or one containing white phosphorus, phosphide or flammable liquid or gel).	G
Article containing both an explosive substance and white phosphorous.	H
Article containing both an explosive substance and flammable liquid or gel.	J
Article containing both an explosive substance and a toxic chemical agent.	K
Explosive substance or article containing an explosive substance and presenting a special risk needing isolation of each type.	L
Substance or article so packed or designed that any hazardous effects arising from accidental functioning are limited to the extent that they do not significantly hinder or prohibit fire fighting or other emergency response efforts in the immediate vicinity of the package.	S

B. Docket HM-181B, Notice 90-4, Editorial Revisions to Modal Regulations

In order to align all modal sections of the HMR with the classifications and packaging requirements proposed in Docket HM-181, Notice 87-4, RSPA published a notice of proposed rulemaking on May 2, 1990 (55 FR 18546) that proposed various editorial revisions to the modal hazardous materials transportation requirements in part 174-Rail, part 175-Air, and part 177-Highway. Docket HM-181B, Notice 90-4, together with the editorial revisions contained in this NPRM for water transportation, should effectively align all modal parts of the HMR with the classification scheme proposed in Docket HM-181, Notice 87-4.

C. Docket HM-126C, Emergency Response Communication Standards

On June 27, 1989, RSPA issued a final rule (54 FR 27138) to impose new requirements for emergency response information on shipping papers, and placement of emergency response on vehicles and at transportation facilities. The final rule was followed by a corrections docket issued on January 10, 1990 (55 FR 870) in response to several petitions for reconsideration. The rulemaking is designed to improve the emergency response information requirements in the HMR in order to

enhance communication pertaining to the safe handling and identification of hazardous materials involved in transportation.

The proposals in this docket add no new requirements. However, several sections in part 176 have been revised to specifically refer to the new emergency response requirements of part 172, subpart G. The revisions proposed in this notice are intended to clarify the HMR and direct the reader to applicable sections whenever emergency response information is required.

D. HM–166W, Transportation of Hazardous Materials; Miscellaneous Amendments

On September 20, 1989, RSPA issued a final rule to make miscellaneous amendments to the HMR. Docket HM–166W (54 FR 38790) was promulgated to update the regulations, to eliminate the need for certain DOT approvals, and to reduce RSPA's backlog of rulemaking petitions.

Docket HM–166W revised the requirements of § 176.340 for combustible liquids in portable tanks and § 176.905(k) for motor vehicles on ships. To aid the reader, §§ 176.340 and 176.905(k) have been reprinted as they appeared in Docket HM–166W.

IV. Administrative Notices

A. Executive Order 12291

RSPA has determined that this rulemaking is (1) not "major" under Executive Order 12291; (2) is not "significant" under DOT's regulatory policies and procedures (44 FR 11034); (3) will not affect not-for-profit enterprises or small governmental jurisdictions; and (4) does not require an environmental statement under the National Environmental Policy Act (40 U.S.C. et seq.). The preliminary regulatory evaluation developed by RSPA suggests that the benefits of this rule exceed the costs. However, the analysis presented is more qualitative rather than quantitative. RSPA seeks comments on the benefits and costs associated with this rulemaking. In particular, we seek comments in the following areas:

1. Do the benefits of consolidating the duplicative explosive regulations in 46 CFR part 146 and 49 CFR part 176 exceed the costs? If so, by how much?

2. What are the costs and benefits associated with eliminating the need for dual compliance with U.S. domestic regulations and the IMDG Code by making the U.S. domestic explosives transportation regulations consistent with the international requirements?

3. Currently, all Class A explosives may be transported by freight containers on vessels only after specific approval for the operation has been granted by the Commandant, USCG. Coast Guard approvals are based on freight container inspection criteria found in the IMDG Code. This proposal would eliminate the requirements for special Commandant, USCG approval by adding the serviceability criteria of the IMDG Code directly to part 176. Will the benefits of this approach outweigh the costs?

4. What are the costs and benefits of removing outdated requirements such as those permitting the use of asbestos insulation?

5. RSPA believes that the vast majority of current commercial explosives shipments by vessel are done in accordance with the requirements of the IMDG Code. In order to align 49 CFR part 176 with the IMDG Code, RSPA has proposed to add current IMDG Code requirements regarding handling, fire, and electrical safety for Division 1.1 and 1.2 explosives directly to part 176. What are the costs and benefits of these new requirements for shippers of commercial explosives.

Comments provided on these questions will be incorporated into the final regulatory analysis.

B. Paperwork Reduction Act

The collection of information in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, attention: Desk Officer for the Department of Transportation. All comments must reference the title of this notice, "Transportation of Explosives by Vessel and Miscellaneous Amendments".

The collection of information requirements of this notice are found in § 176.172(c), Structural serviceability of freight containers and vehicles carrying Class 1 (explosive) materials on ships. A statement would be required to accompany freight containers or vehicles transporting Class 1 (explosive) materials on vessels certifying that the freight container or vehicle met the structural serviceability requirements of § 176.172. The likely respondents for this collection of information are hazardous materials shippers who use freight containers or motor vehicles to transport Class 1 (explosive) materials aboard vessels.

C. Impact on Small Entities

RSPA is aware that amendments of such broad applicability may produce an economic impact on various industry segments, a substantial number of which may be small enterprises. The proposals in this notice may affect shippers, carriers, terminal operators, vessel operators, and other transportation organizations that ship hazardous materials by vessel and have small numbers of employees and gross revenues. Based on limited information concerning the size and nature of entities likely to be affected by this notice, I certify this regulation will not have a significant economic impact on a substantial number of small entities under criteria of the Regulatory Flexibility Act.

D. Executive Order 12612

This proposed action has been analyzed in accordance with the principles and criteria in Executive Order 12612 and, based on the information available to it at this time, RSPA does not believe that the proposed rule would have a substantial direct effect on the states, on the Federal-State relationship, or the distribution of power and responsibilities among levels of government. Thus, this regulation contains no policies that have Federalism implications, as defined in Executive Order 12612.

List of Subjects

49 CFR Part 107

Administrative practice and procedure, Hazardous materials transportation, Packaging and containers, Penalties, Reporting and recordkeeping requirements.

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 176

Hazardous materials transportation, Maritime carriers, Radioactive materials, Reporting and recordkeeping requirements.

In consideration of the foregoing, 49 CFR parts 107, 171, and 176 would be amended to read as follows (Note: The proposals in this notice are presented in a manner consistent with the format and recodification changes proposed in Docket HM–181, Notice 87–4 (52 FR 42772; November 6, 1987). Where a proposal is a modification to Notice 87–

4, the appropriate Federal Register page number of Volume 52 is provided):

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

1. The authority citation for part 107 would continue to read as follows:

Authority: 49 App. U.S.C. 1421(c); 49 App. U.S.C. 1802, 1806, 1808–1811; 49 CFR 1.45 and 1.53 and App. A of Part 1, Pub. L. 89–670 (49 U.S.C. 1653(d), 1655)

§ 107.101 [Amended]

2. Section 107.101 would be amended by removing the reference "chapter, 46 CFR part 64 or part 146" and inserting in its place the reference "chapter, or 46 CFR part 64".

§ 107.103 [Amended]

3. In § 107.103, paragraph (a) would be amended by removing the reference "46 CFR 64 or part 146" and inserting in its place the reference "or 46 CFR part 64".

§ 107.113 [Amended]

4. In § 107.113, paragraph (a) would be amended by removing the reference "46 CFR part 64 or part 146" and inserting in its place the reference "or 46 CFR part 64".

§ 107.201 [Amended]

5. In § 107.201, paragraph (c) would be amended by removing the words "and 46 CFR part 146".

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

6. The authority citation for part 171 would be revised to read as follows:

Authority: 49 App. U.S.C. 1802, 1803, 1804, 1805, 1808; 49 CFR part 1.

7. In § 171.7(c), as proposed at 52 FR 42778 on November 6, 1987, in the table a reference would be added under the entry for the Association of American Railroads and the entry for the International Maritime Organization would be revised to read as follows:

§ 171.7 Matter incorporated by reference.

* * * * *

(c) * * *

Source and name of Material	49 CFR Reference
* * * * *	
Association of American Railroads * * *	
Appendix B of AAR Specification M–931 Highway Trailers, All Types, for TOFC Service, 1985 edition.	176.168.
* * * * *	
International Maritime Organization (IMO), Albert Embankment, London, SE1 7SR, United Kingdom. International Maritime Dangerous Goods (IMDG) Code, 1990 Consolidated Edition.	176.2, 176.5, 176.11, 176.27, 176.30, and 176.140.
* * * * *	

8. In § 171.8, the definitions of "Away from", "Separated by a complete hold or compartment from", "Separated from", and "Separated longitudinally by a complete hold or compartment from" would be removed; the definitions of "Captain of the Port", and "trailership" and "competent authority" would be revised; and paragraph (1) of the definition "passenger vessel" would be revised to read as follows:

§ 171.8 Definitions and abbreviations.

* * * * *

Captain of the Port (COTP) means the officer of the Coast Guard, under the command of a District Commander, so designated by the Commandant for the purpose of giving immediate direction to Coast Guard law enforcement activities within an assigned area. As used in this subchapter, the term "Captain of the Port" includes an authorized representative of the Captain of the Port.

* * * * *

Competent authority means a national agency responsible under its national law for the control or regulation of a particular aspect of the transportation of hazardous materials (dangerous goods). The term "Appropriate authority", as used in the ICAO Technical Instructions, has the same meaning as "Competent Authority" For purposes of this subchapter, the Director, Office of Hazardous Materials Transportation, Research and Special Programs Administration, is the Competent Authority for the United States.

* * * * *

Passenger Vessel means—(1) A vessel subject to any of the requirements of the International Convention for the Safety of Life at Sea, 1974, which carries more than 12 passengers;

* * * * *

Trailership means a vessel, other than a carfloat, specifically equipped to carry motor transport vehicles and fitted with installed securing devices to tie down each vehicle. The term "trailership" includes "Roll-on/Roll-off" (RO/RO) vessels.

* * * * *

PART 176—CARRIAGE BY VESSEL

9. The table of sections for part 176 would be amended to read as follows:

Sec.

* * * * *

176.2 Definitions.

* * * * *

176.4 Port security and safety regulations.

* * * * *

176.54 Repairs involving welding, burning and power-actuated tools and appliances.

176.76 Transport vehicles, freight containers, and portable tanks containing hazardous materials.

* * * * *

176.83 Segregation.

SUBPART G—Detailed Requirements for Class 1 (Explosive) Materials

176.100 Permit for Division 1.1. and 1.2 (Class A and B explosive) materials.
176.102 Supervisory detail.
176.104 Loading and unloading Class 1 (explosive) materials.
176.108 Supervision of Class 1 (explosive) materials handling and stowage.

Stowage

176.112 Application of stowage provisions.
176.116 General stowage conditions for Class 1 (explosive) materials.
176.118 Electrical requirements.
176.120 Lightning protection.
176.122 Stowage arrangements under deck.
176.124 Ordinary stowage.
176.128 Magazine stowage' general.
176.130 Magazine stowage type A.
176.132 Magazine stowage type B.
176.133 Magazine stowage type C.
176.134 Vehicles.
176.136 Special stowage.
176.137 Portable magazine.
176.138 Deck stowage.

Segregation

176.140 Segregation from other classes of hazardous materials.
176.142 Hazardous materials of extreme flammability.
176.144 Segregation of Class 1 (explosive) materials.
176.145 Segregation in single-hold vessels.
176.146 Segregation from non-hazardous materials.

Precautions During Loading and Unloading

176.148 Artificial lighting.
176.150 Radio and radar.
176.154 Fueling (Bunkering).
176.156 Defective packages.
176.160 Protection against weather.
176.162 Security.
176.164 Fire precautions and firefighting.

Passenger Vessels

176.166 Transport of Class 1 (explosive) materials on passenger vessels.

Transport Units and Shipborne Barges

176.168 Transport of Class 1 (explosive) materials in vehicle spaces.

176.170 Transport of Class 1 (explosive) materials in freight containers.
176.172 Structural serviceability of freight containers and vehicles carrying Class 1 (explosive) materials on ships.
176.174 Transport of Class 1 (explosive) materials in shipborne barges.

Handling Class 1 (Explosive) Materials in Port

176.176 Signals.
176.178 Mooring lines.
176.180 Watchkeeping.
176.182 Conditions for handling on board ship.
176.184 Class 1 (explosive) materials of Compatibility Group L.
176.190 Departure of vessel.
176.192 Cargo handling equipment for freight containers carrying Class 1 (explosive) materials.

Magazine Vessels

176.194 Stowage of Class 1 (explosive) materials on magazine vessels.

Subpart H—Detailed Requirements for Class 2 (Compressed Gas) Materials

176.200 General stowage requirements.
176.205 Under deck stowage requirements.
176.210 On deck stowage requirements.
176.220 Smoking or open flame and posting of warning signs.
176.225 Stowage of chlorine.
176.230 Stowage of Division 2.1 (flammable gases) materials.

Subpart I—Detailed Requirements for Class 3 (Flammable and Combustible Liquid) Materials

176.305 General stowage requirements.
176.315 Fire protection requirements.
176.320 Use of hand flashlights.
176.325 Smoking or open flame and posting of warning signs.
176.331 Transportation of flammable liquids with foodstuffs.
176.340 Combustible liquids in portable tanks.

Subpart J—Detailed Requirements for Class 4 (Flammable Solids), Class 5 (Oxidizers and Organic Peroxides), and Division 1.5 (Blasting Agents) Materials

176.400 Stowage of Division 1.5 (blasting agents) and Class 5 (oxidizers and organic peroxides) materials.
176.405 Stowage of charcoal.
176.410 Division 1.5 (blasting agents) materials, ammonium nitrate and ammonium nitrate mixtures.
176.415 Permit requirements for Division 1.5 (blasting agents), ammonium nitrates, and certain ammonium nitrate fertilizers.
176.419 Class 4 (flammable solids) or Class 5 (oxidizers and organic peroxides) materials transported with foodstuffs.

Subpart L—Detailed Requirements for Division 2.3 (Poison A) and Division 6.1 (Poison B) Materials

176.600 General stowage requirement.
176.605 Care following leakage or sifting of Division 2.3 and 6.1 poisons (Poisons A or B).

Subpart N—Detailed Requirements for Class 8 (Corrosive Materials) Materials

176.800 General stowage requirements.
176.805 On deck stowage.

Subpart O—Detailed Requirements for Cotton and Vegetable Fibers, Motor Vehicles, and Asbestos

176.900 Packaging and stowage of cotton and vegetable fibers; general.
176.901 Stowage of cotton or vegetable fibers with rosin or pitch.
176.903 Stowage of cotton or vegetable fibers with coal.
176.905 Motor vehicles or mechanical equipment powered by internal combustion engines.
176.906 Stowage and handling of asbestos.

10. The authority citation for part 176 would be revised to read as follows:

Authority: 49 app. U.S.C. 1803, 1804, 1805, 1808; 49 CFR part 1.53, app. A to part 1.

11. Section 176.2 would be added to read as follows:

§ 176.2 Definitions.

As used in this part—

Cantiline means the v-shaped groove between two abutting, parallel horizontal cylinders.

Cargo net means a net made of fiber or wire used to provide convenience in handling loose or packaged cargo to and from a vessel.

Closed freight container means a freight container which totally encloses its contents by permanent structures. A freight container formed partly by a tarpaulin, plastic sheet, or similar material is not a closed freight container.

Commandant (G–MTH) means the Chief, Marine Technical and Hazardous Materials Division, Office of Marine Safety, Security and Environmental Protection, United States Coast Guard, Washington, DC 20593–0001.

Compartment means any space on a vessel that is enclosed by the vessel's decks and its sides or permanent steel bulkheads.

CSC safety approval plate means the safety approval plate specified in Annex I of the International Convention for Safe Containers (1972) and conforming to the specifications in 49 CFR 451.23 and 451.25. The plate is evidence that a freight container was designed, constructed, and tested under international rules incorporated into U.S. regulations in 49 CFR parts 450 through 453. The plate is found in the door area of the container.

Deck structure means a structure of substantial weight and size located on the weather deck of a vessel and integral with the deck. This term includes superstructures, deck houses, mast houses, and bridge structures.

Draft means a load or combination of loads capable of being hoisted into or out of a vessel in a single lift.

Dunnage means lumber of not less than 25 mm (1 inch) commercial thickness or equivalent material laid over or against structures such as tanktops, decks, bulkheads, frames, plating, or ladders, or used for filling voids or fitting around cargo, to prevent damage during transportation.

Explosives anchorage means an anchorage so designated under 33 CFR part 110, subpart B.

Explosive article means an article or device which contains one or more explosive substances. Individual explosive articles are identified in the schedules for Class 1 (explosive) articles found in the IMDG Code.

Explosives handling facility means—

(1) A "designated waterfront facility" designated under 33 CFR part 126 when loading, handling, and unloading Class 1 (explosive) materials; or

(2) A facility for loading, unloading, and handling military Class 1 (explosive) materials which is operated or controlled by an agency of the Department of Defense.

Explosive substance means a solid or liquid material, or a mixture of materials, which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to its surroundings. Individual explosive substances are identified in the schedules for Class 1 (explosive) substances in the IMDG Code.

Handling means the operation of loading and unloading a vessel; transfer to, from, or within a vessel, and any ancillary operations.

Hold means a compartment below deck that is used exclusively for the carriage of cargo.

In containers or the like means in any clean, substantial, weatherproof box structure which can be secured to the vessel's structure, including a portable magazine or a closed transport unit. Whenever this stowage is specified, stowage in deckhouses, mast lockers and oversized weatherproof packages (overpacks) is also acceptable.

Incompatible materials means two materials whose stowage together may result in undue hazards in the case of leakage, spillage, or other accident.

Landing mat means a shock absorbing pad used in loading Class 1 (explosive) materials on vessels.

Machinery Spaces of Category A are those spaces, and trunks to such spaces, which contain:

(1) Internal combustion machinery used for main propulsion:

(2) Internal combustion machinery used for purposes other than main propulsion where such machinery has in the aggregate a total power output of not less than 375 kw; or

(3) Any oil-fired boiler or fuel unit.

Magazine means an enclosure designed to protect certain goods of Class 1 (explosive) materials from damage by other cargo and adverse weather conditions during loading, unloading, and when in transit; and to prevent unauthorized access. A magazine may be a fixed structure in the vessel, a closed freight container, a closed transport vehicle, or a portable magazine.

Master of the Vessel, as used in this part, includes the person in charge of an unmanned vessel or barge.

Open freight container means a freight container that does not totally enclose its contents by permanent structures.

Overstowed means a package or container that is stowed directly on top of another. However, with regard to Class 1 (explosive) stowage, such goods may themselves be stacked to a safe level but other goods should not be stowed directly on top of them.

Pallet means a portable platform for stowing, handling, and moving cargo.

Palletized unit means packages or unpackaged objects stacked on a pallet, banded and secured to the pallet by metal, fabric, or plastic straps for the purpose of handling as a single unit.

Pie plate means a round, oval, or hexagonal pallet without sideboards, used in conjunction with a cargo net to handle loose cargo on board a vessel.

Portable magazine means a strong, closed, prefabricated, steel or wooden, closed box or container, other than a freight container, designed and used to handle Class 1 (explosive) materials either by hand or mechanical means.

Readily combustible material means a material which may or may not be classed as a hazardous material but which is easily ignited and supports combustion. Examples of readily combustible materials include wood, paper, straw, vegetable fibers, products made from such materials, coal, lubricants, and oils. This definition does not apply to packaging material or dunnage

Responsible person means a person empowered to take all decisions relating to his or her specific task, and having the necessary knowledge and experience for that purpose.

Safe working load means the maximum gross weight that cargo handling equipment is approved to lift.

Skilled person means a person having the knowledge and experience to perform a certain duty.

Skipboard means a square or rectangular pallet without sideboards, usually used in conjunction with a cargo net to handle loose cargo on board a vessel.

Splice as used in § 176.172 of this part, means any repair of a freight container main structural member which replaces material, other than complete replacement of the member.

Transport unit means a transport vehicle or a freight container. A "closed transport unit" means a transport unit in which the contents are totally enclosed by permanent structures. An "open transport unit" means a transport unit which is not a closed transport unit. Transport units with fabric sides or tops are not closed transport units for the purposes of this part.

Tray means a type of pallet constructed to specific dimensions for handling a particular load.

12. In § 176.3, paragraph (b) would be revised to read as follows:

§ 176.3 Unacceptable hazardous materials shipments.

* * * * *

(b) A carrier may not transport by vessel any explosive or explosive composition described in § 173.54 of this subchapter.

13. Section 176.4 would be added to read as follows:

§ 176.4 Port security and safety regulations.

(a) Each carrier, master, agent, and charterer of a vessel and all other persons engaged in handling hazardous materials on board vessels shall comply with the applicable provisions of 33 CFR parts 6, 109, 110, 125, 126, and 160.

(b) Division 1.1 and 1.2 (Class A and B explosive) materials may only be loaded on and unloaded from a vessel at—

(1) A facility of particular hazard as defined in 33 CFR 126.05(b);

(2) An explosives anchorage listed in 33 CFR part 110; or

(3) A facility operated or controlled by the Department of Defense.

(c) With the concurrence of the COTP, Division 1.1 and 1.2 (Class A and B explosive) materials may be loaded on or unloaded from a vessel in any location acceptable to the COTP.

14. In § 176.5, paragraph (e) would be removed and paragraph (b)(6) would be revised to read as follows:

§ 176.5 Application to vessels.

* * * * *

(b) * * *

(6) A tug or towing vessel except when towing another vessel having Class 1 (explosive) materials, flammable liquids, or Division 2.1 (flammable gas) materials on board on deck in which case the tug or towing vessel shall make such provisions to guard against and extinguish fire as the Coast Guard may prescribe;

* * * * *

15. In § 176.9, paragraph (a) introductory text would be revised to read as follows:

§ 176.9 "Order-Notify" or "C.O.D." shipments.

(a) A carrier may not transport Division 1.1 or 1.2 (Class A explosive) materials, detonators, or boosters with detonators which are:

* * * * *

16. In § 176.11, paragraphs (a)(1) and (a)(2) would be removed and paragraphs (a), (c), and (f) would be revised to read as follows:

§ 176.11 Exceptions.

(a) A hazardous material may be offered and accepted for transportation by vessel when in conformance with the requirements of the IMDG Code, subject to the conditions and limitations set forth in § 171.12(b) of this subchapter.

* * * * *

(c) The requirements of this subchapter governing the transportation of combustible liquids do not apply to the transportation of combustible liquids in non-bulk (see definitions in § 171.8) packages on board vessels.

* * * * *

(f) Paragraph (a) of this section does not apply to hazardous materials, including certain hazardous wastes and hazardous substances as defined in § 171.8 of this subchapter, which are not subject to the requirements of the IMDG Code.

17. In § 176.30, paragraphs (a)(3) and (a)(5) would be revised to read as follows:

§ 176.30 Dangerous cargo manifest.

(a) * * *

(3) Shipping name and identification number of each hazardous material on board as listed in § 172.101 of this subchapter or as listed in the IMDG Code.

(i) An emergency response telephone number as prescribed in subpart G of part 172 of this subchapter.

(ii) [Reserved]

(4) * * *

(5) Classification of the hazardous material in accordance with either:

(i) The Hazardous Materials Table, § 172.101 of this subchapter; or

(ii) The International Maritime Organization's IMDG Code.

(6) * * *

* * * * *

18. In § 176.54, the section heading and paragraphs (b)(1) and (b)(2) would be revised to read as follows:

§ 176.54 Repairs involving welding, burning, and power-actuated tools and appliances.

* * * * *

(b) * * *

(1) The repairs or work are approved by the COTP under 33 CFR 162.15(c); or

(2) Emergency repairs to the vessel's main propelling or boiler plant or auxiliaries are necessary for the safety of the vessel. If such repairs are performed, the master of the vessel must immediately notify the nearest COTP.

19. Section 176.57 would be revised to read as follows:

§ 176.57 Supervision of handling and stowage.

(a) Hazardous materials may be handled or stowed on board a vessel only under the direction and observation of a responsible person assigned this duty.

(b) For a vessel engaged in coastwise voyages, or on rivers, bays, sounds or lakes, including the Great Lakes when the voyage is not foreign-going, the responsible person may be an employee of the carrier and assigned this duty by the carrier, or a licensed officer attached to the vessel and assigned by the master of the vessel.

(c) For a domestic vessel engaged in a foreign-going or intercoastal voyage, the responsible person must be an officer possessing an unexpired license issued by the USCG and assigned this duty by the master of the vessel.

(d) For a foreign vessel, the responsible person must be an officer of the vessel assigned this duty by the master of the vessel.

20. Section 176.58 would be revised to read as follows:

§ 176.58 Preparation of the vessel.

(a) Each hold or compartment in which hazardous materials are to be stowed must be free of all debris before the hazardous materials are stowed. Bilges must be examined and all residue of previous cargo removed.

(b) All decks, gangways, hatches, and cargo ports over or through which hazardous materials must be passed or handled in loading or unloading must be free of all loose materials before cargo handling operations begin.

(c) No debris that creates a fire hazard or a hazardous condition for persons engaged in handling hazardous materials may be on the weather deck of a vessel during loading or unloading operations.

(d) Hatch beams and hatch covers may not be stowed in a location that would interfere with cargo handling.

21. In § 176.69, paragraph (a) would be revised and paragraphs (d) and (e) would be added to read as follows:

§ 176.69 General stowage requirements for hazardous materials.

(a) Hazardous materials (except as provided in paragraph (c) of this section and Class 9 (miscellaneous hazardous materials) materials must be stowed in a manner that will facilitate inspection during the voyage, its removal from a potentially dangerous situation, and the removal of packages in case of fire.

* * * * *

(d) Packages of hazardous materials must be secured and dunnaged to prevent movement in any direction. Vertical restraints are not required if the shape of the package and the stuffing pattern preclude shifting of the load.

(e) Packages of hazardous materials must be braced and dunnaged so that it is not likely to be pierced by the dunnage or crushed by a superimposed load.

§ 176.74 [Amended]

22. In § 176.74 paragraph (c), the words "ORM material" would be replaced with the words "Class 9 (miscellaneous hazardous materials) materials".

23. In § 176.76, paragraphs (a)(9) and (c) would be removed and reserved, and the section heading and paragraphs (a) introductory text, (a)(2), and (b) would be revised to read as follows:

§ 176.76 Transport vehicles, freight containers, and portable tanks containing hazardous materials.

(a) Except as provided in paragraphs (b) through (f) of this section, hazardous materials authorized to be transported by vessel may be carried on board a vessel in a transport vehicle or freight container, subject to the following conditions (see additional requirements concerning the transport of Class 1 (explosive) materials in §§ 176.168 through 176.172 of this subchapter):

(1) * * *

(2) All packages in the transport vehicle or freight container must be secured to prevent movement in any direction. Restraint is not required if the shape of the packages, loading pattern, and horizontal restraint preclude vertical movement of the load within the freight container or transport vehicle;

* * * * *

(9) [Removed and reserved]

* * * * *

(b) A transport vehicle containing hazardous materials may be carried only on board a trailership, trainship, ferry vessel or car float.

(c) [Removed and reserved]

* * * * *

24. In § 176.78, paragraphs (a), (d), (e)(1), (f)(3), and (l) would be revised to read as follows:

§ 176.78 Use of power-operated industrial trucks on board vessels.

(a) *Power-operated trucks.* A power-operated truck (including a power-operated tractor, forklift, or other specialized truck used for cargo handling) may not be used on board a vessel in a space containing a hazardous material unless the truck conforms with the requirements of this section. The COTP may suspend or prohibit the use of cargo handling vehicles or equipment when that use constitutes a safety hazard.

* * * * *

(d) *Class 1 (explosive) materials.* No power-operated truck may be used to handle Class 1 (explosive) materials or other cargo in an area near Class 1 (explosive) materials on board a vessel except:

(1) A power-operated truck designated EE or EX.

(2) A power-operated truck designated LPS, GS, D, or DS may be used under conditions acceptable to the COTP.

(e) *Other hazardous materials.* (1) Only an "EX", "EE", "GS", "LPA", or "DS" truck may be used in a hold or compartment containing Class 2.1 (flammable gas) materials, flammable liquids, Class 4 (flammable solids) materials, or Class 5 (oxidizers or organic peroxides) materials, cottons or other vegetable fibers, or bulk sulfur.

* * * * *

(f) * * *

(3) A forklift truck used to handle small objects or unstable loads must be equipped with a load backrest extension having height,width, and strength sufficient to prevent any load, or part of it, from falling toward the mast when the mast is in a position of maximum backward tilt. The load backrest extension must be constructed in a manner that does not interfere with good visibility.

* * * * *

(l) *Packaging and stowage of fuel on board a vessel.* Division 2.1 (flammable gas) materials and flammable liquids as fuel for industrial trucks must be packaged and stowed as authorized in 46 CFR 147.60 or 46 CFR 147.45, respectively.

25. Section 176.83 would be revised to read as follows:

§ 176.83 Segregation.

(a) *General.* (1) This section applies to all cargo spaces on deck and under deck on all types of vessels.

(2) Segregation is obtained by maintaining certain distances between incompatible hazardous materials or by requiring the presence of one or more steel bulkheads or decks between them or a combination thereof. Intervening spaces between such hazardous materials may be filled with other cargo which is not incompatible with the hazardous materials.

(3) In addition to general segregation between classes of hazardous materials, there may be a need to segregate a particular material from other materials which would contribute to its hazard. Such segregation requirements are indicated by code numbers in Column 10(c) of the § 172.101 Table.

(4) Segregation is not required between hazardous materials of different classes which comprise the same substance but vary only in their water content (e.g., sodium sulphide in Division 4.2 or Class 8).

(5) Whenever hazardous materials are stowed together, whether or not in a transport unit, the segregation of such hazardous materials from others must always be in accordance with the most restrictive requirements for any of the hazardous materials concerned.

(6) When the § 172.101 Table or § 172.402 requires packages to bear a subsidiary hazard label or labels, the segregation appropriate to the subsidiary hazards must be applied when that segregation is more restrictive than that required by the primary hazard. For the purposes of paragraph (a)(6) of this section, the segregation requirements corresponding to an explosive subsidiary hazard are those for Division 1.4 (Class C explosive) materials.

(7) Where, for the purposes of segregation, terms such as "away from" a particular hazard class are used in the § 172.101 Table, the segregation requirement applies to:

(i) All hazardous materials within the hazard class; and

(ii) All hazardous materials for which a secondary hazard label of that class is required.

(8) Notwithstanding paragraphs (a)(6) and (a)(7) of this section, hazardous materials of the same class may be stowed together without regard to segregation required by secondary hazards if the materials are not incompatible.

(9) Stowage in a shelter-'tween deck cargo space is not considered to be "on deck" stowage.

(b) *General Segregation Table:* The following table sets forth the general requirements for segregation between the various classes of hazardous materials. The properties of materials within each class may vary greatly and may require greater segregation than is reflected in this table. If the § 172.101 Table sets forth particular requirements for segregation, they take precedence over these general requirements.

TABLE 176.83(b).—GENERAL SEGREGATION REQUIREMENTS FOR HAZARDOUS MATERIALS

[Segregation must also take account of a single secondary hazard label, as required by paragraph (a)(6) of this section.]

Class		1.1 1.2 1.5	1.3	1.4 1.6	2.1	2.2	2.3	3	4.1	4.2	4.3	5.1	5.2	6.1	6.2	7	8	9
Explosives	1.1, 1.2, 1.5	*	*	*	4	2	2	4	4	4	4	4	4	2	4	2	4	X
Explosives	1.3	*	*	*	4	2	2	4	3	3	4	4	4	2	4	2	2	X
Explosives	1.4, 1.6	*	*	*	2	1	1	2	2	2	2	2	2	X	4	2	2	X
Flammable gases	2.1	4	4	2	X	X	X	2	1	2	X	2	2	X	4	2	1	X
Non-toxic, non-flammable gases	2.2	2	2	1	X	X	X	1	X	1	X	X	1	X	2	1	X	X
Poisonous gases	2.3	2	2	1	X	X	X	2	X	2	X	X	2	X	2	1	X	X
Flammable liquids	3	4	4	2	2	1	2	X	X	2	1	2	2	X	3	2	X	X
Flammable solids	4.1	4	3	2	1	X	X	X	X	1	X	1	2	X	3	2	1	X
Spontaneously combustible substances	4.2	4	3	2	2	1	2	2	1	X	1	2	2	1	3	2	1	X
Substances which are dangerous when wet	4.3	4	4	2	X	X	X	1	X	1	X	2	2	X	2	2	1	X
Oxidizing substances	5.1	4	4	2	2	X	X	2	1	2	2	X	2	1	3	1	2	X
Organic peroxides	5.2	4	4	2	2	1	2	2	2	2	2	2	X	1	3	2	2	X
Poisons	6.1	2	2	X	X	X	X	X	X	1	X	1	1	X	1	X	X	X
Infectious substances	6.2	4	4	4	4	2	2	3	3	3	2	3	3	1	X	3	3	X
Radioactive materials	7	2	2	2	2	1	1	2	2	2	2	1	2	X	3	X	2	X
Corrosives	8	4	2	2	1	X	X	X	1	1	1	2	2	X	3	2	X	X
Miscellaneous dangerous substances	9	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Numbers and symbols relate to the following terms as defined in paragraph (c) of this section:
1—"Away from."
2—"Separated from."
3—"Separated by a complete compartment or hold from."
4—"Separated longitudinally by an intervening complete compartment or hold from."
x—The segregation, if any, is shown in the § 172.101 Table.
*—See § 176.144 of this Part for segregaton within Class 1.

(c) *Segregation requirements for breakbulk cargo.* (1) The requirements of this paragraph apply to the segregation of packages containing hazardous materials and stowed as breakbulk cargo;

(2) Definition of the segregation terms:

(i) Legend:

(A) Reference package.



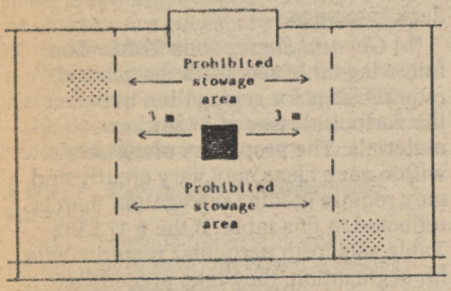
(B) Package containing incompatible goods.



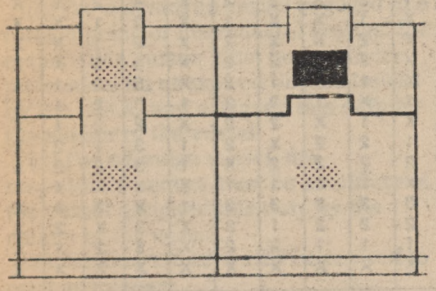
(C) Deck resistant to fire and liquid.

Note: Full vertical lines represent transverse bulkheads between compartments or holds resistant to fire and liquid.

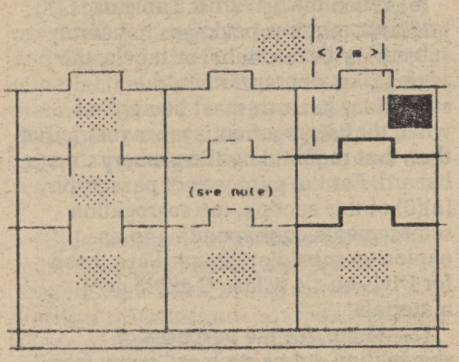
(ii) *"Away from":* Effectively segregated so that the incompatible materials cannot interact dangerously in the event of an accident but may be carried in the same compartment or hold or on deck provided a minimum horizontal separation of 3 meters (10 feet) projected vertically is obtained.



(iii) *"Separated From":* In different compartments or holds when stowed under deck. If the intervening deck is resistant to fire and liquid, a vertical separation (i.e., in different compartments) may be accepted as equivalent to this segregation. For "on deck" stowage, this segregation means a separation by a distance of at least 6 meters (20 feet) horizontally.

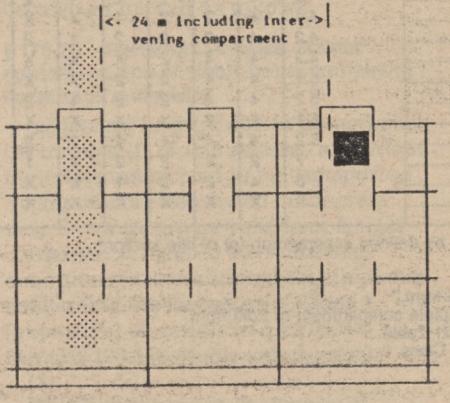


(iv) *"Separated by a complete compartment or hold from":* Either a vertical or horizontal separation. If the intervening decks are not resistant to fire and liquid, then only a longitudinal separation (i.e., by an intervening complete compartment or hold) is acceptable. For "on deck" stowage, this segregation means a separation by a distance of at least 12 meters (39 feet) horizontally. The same distance must be applied if one package is stowed "on deck" and the other one in an upper compartment.



Note: One of the two decks must be resistant to fire and liquid.

(v) *"Separated longitudinally by an intervening complete compartment or hold from":* Vertical separation alone does not meet this requirement. Between a package "under deck" and one "on deck" a minimum distance of 24 meters (79 feet) including a complete compartment must be maintained longitudinally. For "on deck" stowage, this segregation means a separation by a distance of at least 24 meters (79 feet) longitudinally.



(d) *Segregation in transport units:* Two hazardous materials for which any segregation is required may not be stowed in the same transport unit.

(e) *Segregation of hazardous materials stowed as breakbulk cargo from those packed in transport units:*

(1) Hazardous materials stowed as breakbulk cargo must be segregated from materials packed in open transport units in accordance with paragraph (c) of this section.

(2) Hazardous materials stowed as breakbulk cargo must be segregated from materials packed in closed freight containers in accordance with paragraph (c) of this section, except that:

(i) Where "away from" is required, no segregation between packages and the close transport units is required; and

(ii) Where "separated from" is required, the segregation between the packages and the closed transport units may be the same as for "away from".

(f) *Segregation of containers on board container vessels:*

(1) This paragraph applies to the segregation of freight containers which are carried on board container vessels, or on other types of vessels provided these cargo spaces are properly fitted for permanent stowage of freight containers during transport.

(2) For container vessels which have cargo spaces used for breakbulk cargo or any other method of stowage, the appropriate paragraph of this section applies to the relevant cargo space.

(3) *Segregation Table:* The Segregation for Freight Containers Table sets forth the general requirements for segregation between freight containers on board container vessels.

(4) In the Segregation for Freight Containers Table, a "container space" means a distance of not less than 6 meters (20 feet) fore and aft or not less than 2.5 meters (8 feet) athwartship.

TABLE 176.83(f).—SEGREGATION FOR FREIGHT CONTAINERS TABLE

Segregaton requirement	Vertical			Horizontal							
					Closed versus closed		Closed versus open		Open versus open	
	Closed versus closed	Closed versus open	Open versus open		On deck	Under deck	On deck	Under deck	On deck	Under deck
1 "Away from"	One on top of the other permitted.	Open on top of closed permitted.	Not in the same vertical line unless segregated by a deck.	Fore and Aft.	No restriction.	No restriction.	No restriction.	No restriction.	One container space.	One container space or one bulkhead.
		Otherwise as for open versus open.		Athwartships.	No restriction.	No restriction.	No restriction.	No restriction.	One container space.	One container space.
2 "Separated from".		As for open versus open.	Not in the same vertical line unless segregated by a deck.	Fore and aft.	One container space.	One container space or one bulkhead.	One container space.	One container space or one bulkhead.	One container space.	One container space.
				Athwartships.	One container space.	One container space.	One container space.	Two container spaces.	Two container spaces.	One bulkhead.
3 "Separated by a complete compartment or hold from".				Fore and aft.	One container space.	One bulkhead.	One container space.	One bulkhead.	Two container spaces.	Two bulkheads.
				Athwartships.	Two container spaces.	One bulkhead..	Two container spaces.	One bulkhead.	Three container spaces.	Two bulkheads.
4 "Separated longitudinally by an intervening complete compartment or hold from".	Prohibited	Prohibited	Prohibited	Fore and aft.	Four container spaces.	One bulkhead and four container spaces *.	Four container spaces.	Two bulkheads.	Four container spaces.	Two bulkheads.
				Athwartships.	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited.

* Containers not less than 6 meters (20 feet) from intervening bulkhead.
NOTE: All bulkheads and decks must be resistent to fire and liquid.

(g) *Segregation of transport units on board trailerships:*

(1) The requirements of this paragraph apply to the segregation of transport units which are carried on board trailerships or in "roll-on/roll-off" cargo spaces.

(2) For trailerships which have spaces suitable for breakbulk cargo, containers, or any other method of stowage, the appropriate paragraph of this section applies to the relevant cargo space.

(3) *Segregation Table:* The Segregation of Transport Units on Board Trailerships and Trainships table sets forth the general requirements for segregation between transport units on board trailerships.

TABLE 176.83(g).—SEGREGATION OF TRANSPORT UNITES ON BOARD TRAILERSHIPS AND TRAINSHIPS

Segregation requirement		Closed versus closed		Closed versus open		Open versus open	
		On deck	Under deck	On deck	Under deck	On deck	Under deck
1 "Away from"	Fore and aft	No restriction	No restriction	No restriction	No restriction	At least 3 meters.	At least 3 meters
	Athwart-ships	No restriction	No restriction	No restriction	No restriction	At least 3 meters.	At least 3 meters
2 "Separated from"	Fore and aft	At least 6 meters.	At least 6 meters or one bulkhead.	At least 6 meters.	At least 6 meters or one bulkhead.	At least 6 meters.	At least 12 meters or one bulkhead
	Athwart-ships	At least 3 meters.	At least 3 meters or one bulkhead.	At least 3 meters.	At least 6 meters or one bulkhead.	At least 6 meters.	At least 12 meters or one bulkhead
3 "Separated by a complete compartment or hold from".	Fore and aft	At least 12 meters.	At least 24 meters + deck.	At least 24 meters.	At least 24 meters + deck.	At least 36 meters.	Two decks or two bulkheads
	Athwart-ships	At least 12 meters.	At least 24 meters + deck.	At least 24 meters.	At least 24 meters + deck.	At least 36 meters.	Prohibited

TABLE 176.83(g).—SEGREGATION OF TRANSPORT UNITES ON BOARD TRAILERSHIPS AND TRAINSHIPS—Continued

Segregation requirement		Closed versus closed		Closed versus open		Open versus open	
		On deck	Under deck	On deck	Under deck	On deck	Under deck
4 "Separated longitudinally by an intervening complete compartment or hold from".	Fore and aft	At least 36 meters.	Two bulkheads or at least 36 meters + two decks.	At least 36 meters.	At least 48 meters including two bulkheads.	At least 48 meters.	Prohibited
	Athwart-ships	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited	Prohibited

NOTE: All bulkheads and decks must be resistant to fire and liquid.

(h) *Segregation on board barge-carrying vessels:*

(1) The requirements of this section apply to the segregation in shipborne barges as well as to the segregation between shipborne barges carried on board vessels specially designed and equipped to carry such barges.

(2) On barge-carrying vessels which incorporate other stowage spaces or any other method of stowage, barges containing hazardous materials must be segregated from hazardous materials not stowed in barges as prescribed in paragraphs (b) and (j) of this section.

(i) *Segregation in shipborne barges:* Hazardous materials transported in shipborne barges must be segregated as prescribed in paragraphs (a), (b), and (c) of this section.

(j) *Segregation between shipborne barges on barge-carrying vessels:*

(1) When a shipborne barge is loaded with two or more hazardous materials with different requirements for segregation, the most stringent applicable segregation requirement must be applied.

(2) "Away from" and "separated from" require no segregation between shipborne barges.

(3) For barge-carrying vessels with vertical holds, "Separated by a complete compartment or hold from" means that separate holds are required. On barge-carrying vessels having horizontal barge levels, separate barge levels are required and the barges may not be in the same vertical line.

(4) "Separated longitudinally by an intervening complete compartment or hold from" means, for barge-carrying vessels with vertical holds, that separation by an intervening hold or engine room is required. On barge-carrying vessels having horizontal barge levels, separate barge levels and a longitudinal separation by at least two intervening barge spaces are required.

(k) *Segregation requirements for ferry vessels.* A ferry vessel (when operating either as a passenger or cargo vessel) that cannot provide the separation required in this section may carry incompatible hazardous materials in separate transport vehicles if they are stowed to give the maximum possible separation.

26. In § 176.84, as proposed at 52 FR 42989 on November 6, 1987, paragraph (c) would be added to read as follows:

§ 176.84 Other requirements for stowage and segregation for cargo vessels and passenger vessels.

* * * * *

(c) *Provisions for the stowage of Class 1 (explosive) materials:*

(1) The stowage provisions of § 172.101 Table notwithstanding, small quantities of prohibited Class 1 (explosive) materials, except Class 1 (explosive) materials in compatibility groups A, H, J, K, and L, may be transported on passenger vessels in accordance with § 176.166 of this part. Where so permitted, these Class 1 (explosive) materials must be stowed in the same manner as is required for cargo vessels.

(2) Unless specified otherwise in column 10(c) of the § 172.101 Table, explosive substances and articles which require magazine stowage ("6" in column 10(a) of the Table) must be stowed as follows:

(i) *On deck:* in containers or the like.

(ii) *Under deck:* in magazines, Type B.

(3) Unless otherwise specified in column 10(c) of the § 172.101 Table, explosive substances and explosive articles which are not required to be stowed in magazines ("1, 2" in column 10(a) of the Table) must be stowed as follows:

(i) *On deck:* in containers or the like.

(ii) *Under deck:* ordinary stowage.

(4) The following notes in column 10(c) of the § 172.101 Table apply to the transport of Class 1 (explosive) materials by vessel:

Note	Provision
1E	Cargo vessel, on deck, in containers or the like.
2E	Cargo vessel, on deck, in portable magazines.
3E	Cargo vessel, on deck, secured to the vessel's structure.
4E	Cargo vessel, under deck, Magazine, Type A.
5E	Cargo vessel, under deck, Magazine, Type B.
6E	Cargo vessel, under deck, Magazine, Type C.
7E	Cargo vessel, under deck, Ordinary Stowage.
8E	Cargo vessel, under deck, Special Stowage.
9E	Passenger vessel, stowage as for cargo vessel.
10E	Magazine, Type B, if in effectively sealed dust-tight packages; otherwise, Magazine, Type A.
11E	On-deck portable magazine must be steel.
12E	Stowage as specified by Competent Authority.
13E	On deck, in containers not exceeding 2.5t gross per container or group. There may not be more than 2 such containers or groups; they must be separated from each other, and from any other explosive substance or article by at least 9 m. Containers or groups must be at least 9 m from the bridge or accommodation.
14E	On deck, in steel portable magazines or steel freight containers.
15E	On-deck, containers must be leak-proof.
16E	On deck, in containers or sheeted stacks. The gross weight of each stack or group of containers may not exceed 2.5t. There may not be more than 2 stacks or groups of containers; they must be separated from each other, and from any other explosive substances or articles by at least 9m. Stacks or containers must be at least 9 m from the bridge or accommodation.
17E	On deck stowage is recommended.
18E	For international shipments, stow in the same manner as is required for "cartridges for weapons' inert projectile" UN0012, Class 1.4S.
19E	Substances which contain ammonium nitrate or other ammonium salts must be stowed "away from" Explosives, Blasting. Type C, UN 0083.
20E	Stow in accordance with § 172.84(c)(5).
21E	Cargo space ventilation must be carefully controlled to avoid excessive condensation.
22E	May not be stowed together with explosive substances containing ammonium nitrate or other ammonium salts.
23E	Segregate from other Class 1 (explosive) materials in the same manner as is required for flammable liquids.

(5) Explosive articles designated by special provision "20E" in column

10(c) of the § 172.101 Table must be stowed as follows:

(i) Projectiles for guns, cannon, or mortars:

(A) *On deck:* in containers or the like.

(B) *Under deck:* ordinary stowage.

(ii) All other types:

(A) *On deck:* in steel portable magazines or steel portable magazines which are capable of preventing leakage of their contents.

(B) *Under deck:* Special stowage.

§ 176.90 [Amended]

27. In § 176.90, the word "explosive" would be revised to read "Class 1 (explosive) material" both places it appears.

§ 176.91 [Amended]

28. In § 176.91, the words "six gallons" would be revised to read "23 liters (six gallons)".

§ 176.92 [Amended]

29. In § 176.92, the words "compressed gas" would be revised to read "Class 2 (compressed gas) material".

30. In § 176.93, paragraph (a) introductory text would be revised to read as follows:

§ 176.93 Vehicles having refrigerating or heating equipment.

(a) A transport vehicle fitted with refrigerating or heating equipment using a flammable liquid or Division 2.1 (flammable gas) material, or diesel oil as fuel, may be transported on a ferry vessel. However, the refrigerating or heating equipment may not be operated while the vehicle is on the vessel, unless the equipment complies with the following requirements:

* * * * *

31. Section 176.96 would be revised to read as follows:

§ 176.96 Materials of construction.

Barges used to transport hazardous materials must be constructed of steel.

§ 176.98 [Amended]

32. In § 176.98, the words "Column (7)" would be changed to "Column (10)".

33. Section 176.99 would be revised to read as follows:

§ 176.99 Permit requirements for certain hazardous materials.

The permits required by §§ 176.100 and 176.415 for loading, unloading, and handling Division 1.1 and 1.2 (Class A explosive) materials, Division 1.5 (blasting agents) materials, ammonium nitrate and certain ammonium nitrate mixtures and fertilizers must be obtained before these materials may be loaded on, unloaded from, or handled on board a barge or barge carrying vessel. However, a barge loaded with these materials being placed on, removed from, or handled on board a barge carrying vessel is not subject to these permit requirements.

34. Subpart G would be revised to read as follows:

Subpart G—Detailed Requirements for Class 1 (Explosive) Materials

§ 176.100 Permit for Division 1.1 and 1.2 (Class A and B explosive) materials.

Before Division 1.1 and 1.2 (Class A and B explosive) materials may be discharged from, loaded on, handled or restowed on board a vessel at any place in the United States, the carrier must obtain a permit from the COTP. Exceptions to this permit requirement may be authorized by the COTP.

§ 176.102 Supervisory detail.

(a) Except as provided in paragraph (c) of this section, the COTP may assign a USCG supervisory detail to any vessel to supervise the loading, handling or unloading of Class l (explosive) materials.

(b) The owner, agent, charterer, master or person in charge of the vessel, and all persons engaged in the handling, loading, unloading, and stowage of Class 1 (explosive) materials shall obey all orders that are given by the officer in charge of the supervisory detail.

(c) If Class 1 (explosive) materials are loaded onto or unloaded from a vessel at a facility operated or controlled by the Department of Defense, the Commanding Officer of that facility may decline the USCG supervisory detail. Whenever the supervisory detail is declined, the Commanding Officer of the facility shall ensure compliance with the regulations in this part.

§ 176.104 Loading and unloading Class 1 (explosive) materials.

(a) Packages of Class 1 (explosive) materials may not be thrown, dropped, rolled, dragged, or slid over each other or over a deck.

(b) When Class 1 (explosive) materials are stowed in a hold below one in which any cargo is being handled, the hatch in the deck dividing the two holds must have all covers securely in place.

(c) Drafts of Class 1 (explosive) materials must be handled in accordance with the following:

(1) A draft may not be raised, lowered, or stopped by sudden application of power or brake.

(2) A draft may not be released by tripping or freeing one side of the cargo-handling equipment and tumbling the Class 1 (explosive) materials off.

(3) All drafts, beams, shackles, bridles, slings, and hoods must be manually freed before the winch takes control.

(4) Slings may not be dragged from under a draft by winching except for the topmost layer in the hold when power removal is the only practical method and when the cargo cannot be toppled.

(5) Handles or brackets on packages in a draft may not be used for slinging purposes.

(d) A combination woven rope and wire sling or a sling that is formed by use of an open hook may not be used in handling Class 1 (explosive) materials.

(e) Only a safety hook or a hook that has been closed by wire may be used in handling drafts of Class 1 (explosive) materials.

(f) Wire rope or wire rope assemblies, including splices and fittings, used in handling Class 1 (explosive) materials must be unpainted and kept bare to permit inspection of their safe working condition. A mechanical end fitting (pressed fitting) may be used in place of an eye splice, if the efficiency of the mechanical end fitting is at least equal to the efficiency of an eye splice prepared as prescribed in 29 CFR 1918.51(c)(1).

(g) Packages of Division 1.1 and 1.2 (Class A and B explosive) materials which are not part of a palletized unit must be loaded and unloaded from a vessel using a chute or conveyor as described in § 176.163, or a mechanical hoist and a pallet, skipboard, tray, or pie plate fitted with a cargo net or sideboards.

(h) Packages of Division 1.1 and 1.2 (Class A and B explosive) materials must be loaded or unloaded in accordance with the following:

(1) A cargo net with a pallet, skipboard, tray, or pie plate, must be loaded so that a minimum displacement of packages occurs when it is lifted.

(2) A cargo net must completely encompass the bottom and sides of the draft. The mesh of the cargo net must be of a size and strength that will prevent a package in the draft from passing through the net.

(3) When a tray is used in handling packages, no package may extend more than one-third its vertical dimension above the sideboard of the tray.

(i) A landing mat must be used when a draft of Division 1.1 or 1.2 (Class A and B explosive) materials is deposited on deck. The landing mat must have dimensions of at least 1 meter (3 feet) wide, 2 meters (6 feet) long, and 10 cm (4 inches) thick, and be made of woven hemp, sisal, or similar fiber, or foam

rubber, polyurethane or similar resilient material.

(j) In addition to the other requirements of this section, packages of Division 1.1 and 1.2 (Class A and B explosive) materials must be handled in accordance with the following:

(1) Packages may not be loaded or unloaded through a hatch at the same time that other cargo is being handled in any hold served by that hatch.

(2) Packages may not be loaded or unloaded from the same hatch by using two pieces of cargo equipment unless the equipment is positioned at the forward and aft ends of the hatch.

(3) Packages may not be lifted over Class 1 (explosive) materials or other hazardous materials.

(4) The height of any structure, equipment, or load on a deck over which packages must be lifted may not be higher than the hatch coaming or bulwark, or 1 meter (3 feet), whichever is greater.

(k) Unpackaged explosive devices may not be handled by their lifting lugs or suspension lugs.

(l) A chute may not be used when loading or unloading Class 1 (explosive) materials in compatibility group A or B.

§ 176.108 Supervision of Class 1 (explosive) materials handling and stowage.

(a) During the handling and stowage of Class 1 (explosive) materials, a responsible person shall be in constant attendance during the entire operation to direct the handling and stowage of Class 1 (explosive) materials, including the preparation of the holds. The responsible person must be aware of the hazards involved and the steps to be taken in an emergency, and must maintain sufficient contact with the master to ensure proper steps are taken in an emergency.

(b) Each person involved in the handling of Class 1 (explosive) materials on a vessel shall obey the orders of the responsible person.

Stowage

§ 176.112 Application of stowage provisions.

(a) The provisions of §§ 176.116(e), 176.118, and 176.120 of this subpart do not apply to Division 1.4 (Class C explosive) materials, compatibility group S. Such materials may be stowed together with all other Class 1 (explosive) materials except those of compatibility group A or L. They must be segregated from other hazardous materials in accordance with Table 176.83(b) of this part.

§ 176.116 General stowage conditions for Class 1 (explosive) materials.

(a) *Heat and sources of ignition:* (1) Class 1 (explosive) materials must be stowed in a cool part of the ship and must be kept as cool as practicable while on board. Stowage must be well away from all sources of heat, including steam pipes, heating coils, sparks, and flame.

(2) Except where Class 1 (explosive) materials are transported in closed freight containers or portable steel units, compartments containing Class 1 (explosive) materials must be provided with suitable means of arresting a flash. All ventilation shafts must be protected by single metallic gauze not less than 140 mesh per sq cm (30 x 30 mesh), or double gauze not less than 62 mesh per sq cm (20 x 20 mesh) at the end remote from the compartment. The screen must be positively attached to ensure secure fitting.

(3) Except where the consignment of Class 1 (explosive) materials consists only of explosive *articles,* the wearing of shoes or boots with unprotected metal nails, heels, or tips of any kind is prohibited.

(b) *Wetness:* (1) Spaces where Class 1 (explosive) materials are stowed below deck must be dry. In the event of the contents of packages being affected by water when on board immediate advice must be sought from the shippers; pending this advice handling of the packages must be avoided.

(2) Bilges and bilge sections must be examined and any residue of previous cargo removed before Class 1 materials (explosive) are loaded onto the vessel.

(c) *Security:* All compartments, magazines, and transport units containing Class 1 (explosive) materials must be locked or suitably secured in order to prevent unauthorized access.

(d) *Secure stowage:* Class 1 (explosive) materials must be securely stowed to prevent movement in transit; where necessary, precautions must be taken to prevent cargo sliding down between the frames at the ship's sides.

(e) *Separation from Accommodation Spaces and Machinery Spaces:*

Class 1 (explosive) materials must be stowed as far away as practicable from any accommodation spaces or any machinery space and may not be stowed directly above or below such a space. The requirements in paragraphs (e)(2) through (e)(4) of this section are minimum requirements in addition to the applicable requirements of 46 CFR chapter I. Where the requirements of this subpart are less stringent than those of 46 CFR chapter I, the 46 CFR chapter I requirements must be satisfied for ships to which they are applicable.

(2) There must be a permanent A Class steel bulkhead between any accommodation space and any compartment containing Class 1 (explosive) materials. Divisions 1.1 and 1.2 (Class A and B explosive) materials, 1.3 (Class B explosive) materials, or 1.5 (blasting agents) materials may not be stowed within 3 meters (10 feet) of this bulkhead; in the decks immediately above or below an accommodation space they must be stowed at least 3 meters (10 feet) from the line of this bulkhead projected vertically.

(3) There must be a permanent A Class steel bulkhead between a compartment containing Class 1 (explosive) materials and any machinery space. Class 1 (explosive) materials, except those in Division 1.4 (Class C explosive), may not be stowed within 3 meters (10 feet) of this bulkhead; and in the decks above or below the machinery space they must be stowed at least 3 meters (10 feet) from the line of this bulkhead projected vertically. In addition to this separation, there must be insulation to Class A60 standard as defined in 46 CFR 72.05–10(a)(1) if the machinery space is one of Category 'A' unless the only Class 1 (explosive) materials carried are in Division 1.4S (Class C explosive).

(4) Where Class 1 (explosive) materials are stowed away from bulkheads bounding any accommodation space or machinery space, the intervening space may be filled with cargo that is not readily combustible.

§ 176.118 Electrical requirements.

(a) Electrical equipment and cables installed in compartments in which Class 1 (explosive) materials are stowed which do not need to be energized during the voyage must be isolated from the supply so that no part of the circuit within the compartment is energized. The method of isolation may be by withdrawal of fuses, opening of switches or circuit breakers, or disconnection from bus bars. The means, or access to the means, of disconnection/reconnection must be secured by a locked padlock under the control of a responsible person.

(b) Electrical equipment and cables in a cargo space in which Class 1 (explosive) materials are stowed which are energized during the voyage for the safe operation of the ship must meet the requirements of Subchapter J of 46 CFR chapter I. Before Class 1 (explosive) materials are loaded aboard a vessel, all cables must be tested by a skilled person to ensure that they are safe and to determine satisfactory grouping,

insulation resistance, and continuity of the cable cores, metal sheathing or armoring.

(c) All Class 1 (explosive) materials must be stowed in a safe position relative to electrical equipment and cables. Additional physical protection must be provided where necessary to minimize possible damage to the electrical equipment or cables, especially during loading and unloading.

(d) Cable joints in the compartments must be enclosed in metal-clad junction boxes.

(e) All lighting equipment and cables must be of the fixed type and must meet the relevant inspection, test, and installation standards of 46 CFR chapter I, subchapter J.

§ 176.120 Lightning protection.

A lightning conductor grounded to the sea must be provided on any mast or similar structure unless effective electrical bonding is provided between the sea and the mast or structure from its extremity and throughout to the main body of the hull structure. Steel masts in ships of all welded construction comply with this requirement.

§ 176.122 Stowage arrangements under deck.

When stowed under deck, Class 1 (explosive) materials must be in conformance with one of the three stowage arrangements described in §§ 176.124 through 176.136 of this subpart.

§ 176.124 Ordinary stowage.

(a) Ordinary stowage is authorized for most explosive articles carried by vessels. The exceptions are those for which this subpart prescribes "magazine" or "special" stowage.

(b) Class 1 (explosive) materials requiring ordinary stowage must be stowed in accordance with § 176.116 of this subpart.

§ 176.128 Magazine stowage, general.

(a) Magazine stowage is sub-divided into three different types of magazines designated by the letters A, B, and C. A magazine may be a fixed structure in the vessel, a closed freight container, or a portable magazine unit. Freight containers, portable magazines, and vehicles must be properly secured in position. Magazines may be positioned in any part of the vessel conforming to the general stowage conditions for Class 1 (explosive) materials, except magazines which are fixed structures must be constructed in a location in which their doors, where fitted, are easily accessible.

(b) Magazine stowage is required for all explosive substances, except "Explosive Substances, n.o.s." in compatibility groups G, L, or S. Magazine stowage type A is required for those substances which must be kept clear of steelwork. All other explosive substances must be given magazine stowage type B, except those in compatibility group A for which magazine stowage type C is prescribed.

(c) Magazine stowage type B is required for Charges, propelling, for cannon, UN0279, UN0414, and UN0242, and Charges, supplemental, explosive, UN0600, in compatibility group C or D; and magazine stowage type C is required for detonators and similar articles in divisions and compatibility group 1.1B and 1.2B (Class A and B explosive).

§ 176.130 Magazine stowage type A.

(a) In addition to protecting the Class 1 (explosive) materials and preventing unauthorized access, magazine stowage type A guards against friction between any spilled contents of packages and the vessel's sides and bulkheads.

(b) Class 1 (explosive) materials requiring magazine stowage type A must be stowed in a magazine which is tightly sheathed with wood on its inner sides and floor.

(c) When utilized as part of the magazine structure, the vessel's sides and bulkheads must be clean, free from rust or scale, and protected by battening or sweatboards spaced not more than 150 mm (6 inches) apart. All stanchions and other unprotected structural members must be similarly clean and battened. The underside of the deck above the magazine must be clean and free of rust and scale, but need not be battened.

(d) The top of the stow within the magazine must be at least 30 cm (12 inches) from the underside of the deck above.

(e) A type A magazine constructed in the square of a cargo space may not be loaded from the top.

(f) When other Class 1 (explosive) materials are stowed with Class 1 (explosive) materials for which magazine stowage type A is required, they or their packagings may have no exposed external parts made of ferrous metal or aluminum alloy.

§ 176.132 Magazine stowage type B.

(a) Magazine stowage type B is the same as magazine stowage type A as prescribed in § 176.130 of this subpart, except:

(1) The floor need not be tightly sheathed with wood but must be sparred or protected by wooden pallets, or dunnage; and

(2) Battening of the vessel's sides, bulkheads, and stanchions is not required.

(b) A compartment may be used for magazine stowage type B without a magazine structure provided that:

(1) The Class 1 (explosive) materials are stowed on wooden gratings, pallets, or dunnage, directly on the deck and not on other cargo;

(2) Other cargo stowed in the same compartment is not readily combustible material; and

(3) The position of the stowage is such that there is direct access to the hatchway.

(c) Class 1 (explosive) materials and other cargo in the same compartment must be secured to eliminate the possibility of significant movement. Where an entire deck is used as a magazine, the stowage must be so arranged that the Class 1 (explosive) materials stowed therein will be removed from the ship before working any cargo in any decks above or below the space in the same hatch.

§ 176.133 Magazine stowage type C.

The construction requirements for magazine stowage type C are the same as for magazine stowage Type B as prescribed in § 176.132 of this subpart, except that the magazine must be located as near as practicable to the centerline of the vessel and must not be closer to the vessel's side than a distance equal to one-eighth of the vessel's beam or 2.5 meters (8 feet) whichever is less.

§ 176.134 Vehicles.

Closed vehicles may be used to transport Class 1 (explosive) materials requiring magazine stowage by vessel if they meet the requirements of the appropriate magazine stowage type. See § 176.168 of this subpart for additional requirements relating to the transport of Class 1 (explosive) materials in vehicles.

§ 176.136 Special stowage.

(a) Special stowage is required for certain articles presenting both explosive and chemical hazards, such as smoke or lachrymatory (compatibility group G or H), toxic (compatibility group K), or substances and articles which present a special risk (compatibility group L). Class 1 (explosive) materials requiring special stowage must be stowed on deck unless such stowage is impracticable and the COTP authorizes special stowage below deck.

(b) Class 1 (explosive) materials for which special stowage is required must be stowed as far away as practicable from living, accommodation, and

working areas, and may not be overstowed. Steel portable magazines and freight containers in which such Class 1 (explosive) materials are stowed may not be located closer to the vessel's side than a distance equal to one-eighth of the vessel's beam or 2.5 meters (8 feet) whichever is less.

(c) Explosive articles having U.N. number 0015, 0016, 0018, 0019, 0301, or 0303 may be given ordinary stowage in a lower hold or 'tween deck. Other Class 1 (explosive) materials in compatibility groups G and H may be in open stowage out to the ship's side on a floodable lower hold or deep tank in such a position that other cargo cannot be contaminated by leakage; in all other cases such Class 1 (explosive) materials must be stowed in steel portable magazines or in freight containers. If a freight container is used for this purpose, the floor of the freight container must be leakproof; for example, an all-metal container may be used and a fillet of cement or other material worked across the bottom of the door opening.

(d) Class 1 (explosive) materials stowed in one compartment may not be of more than one compatibility group, except the COTP may allow Class 1 (explosive) materials of compatibility groups G and H in separate steel portable magazines to be stowed in the same compartment, not less than 3 meters (10 feet) apart.

(e) Class 1 (explosive) materials in compatibility groups K and L must be stowed in a steel portable magazine regardless of the stowage position in the vessel.

§ 176.137 Portable magazine.

(a) Each portable magazine used for the stowage of Class 1 (explosive) materials on board vessels must meet the following requirements:

(1) It must be weather tight, constructed of wood or metal lined with wood at least 2 cm (3/4 inch) thick, and with a capacity of no more than 3.1 cubic meters (110 cubic feet).

(2) All inner surfaces must be smooth and free of any protruding nails, screws or other projections.

(3) If constructed of wood, a portable magazine must be framed of nominal 5 cm X 10 cm (2 X 4 inch) lumber, and sheathed with nominal 2 cm (3/4 inch) thick boards or plywood.

(4) When constructed of metal, the metal must be not less than 3.2 mm (1/8 inch) thick.

(5) Runners, bearers, or skids must be provided to elevate the magazine at least 10 cm (4 inches) from the deck. Padeyes, ring bolts, or other suitable means must be provided for securing.

(6) If the portable magazine has a door or hinged cover, the door or cover must have a strong hasp and padlock or equally effective means of securing.

(7) The portable magazine must be marked on its top and four sides, in letters at least 8 cm (3 inches) high, as follows: "EXPLOSIVES—HANDLE CAREFULLY—KEEP LIGHTS AND FIRE AWAY"

(b) A portable magazine which meets the requirements for a type 2 or type 3 magazine under 27 CFR Part 55 subpart K may be used for the stowage of Class 1 (explosive) materials on board vessels.

(c) A portable magazine with a capacity exceeding 3.1 cubic meters (110 cubic feet) may be used for the stowage of Class 1 (explosive) materials under such construction, handling, and stowage requirements as the COTP approves.

§ 176.138 Deck stowage.

(a) Class 1 (explosive) materials stowed on deck must be carried as close to the vessel's centerline as practicable.

(b) Class 1 (explosive) materials may not be stowed within a horizontal distance of 6 meters (20 feet) from any fire, machinery exhaust, galley uptake, locker used for combustible stores, or other potential sources of ignition. They must be clear of walkways and cargo working areas, fire hydrants, steam pipes, and means of access, away from all other facilities necessary for the safe working of the vessel, and not less than a horizontal distance of 8 meters (26 feet) from the bridge, accommodation areas, and lifesaving appliances.

(c) Where vessels are fitted with container fastening arrangements, freight containers containing Class 1 (explosive) materials may be overstowed by containers of compatible Class 1 (explosive) materials or non-hazardous cargo. Where vessels are not fitted with container fastening arrangements, freight containers loaded with Class 1 (explosive) materials may be stowed only on the bottom tier of the stowage.

Segregation

§ 176.140 Segregation from other classes of hazardous materials.

(a) Class 1 (explosive) materials must be segregated from other packaged hazardous materials in accordance with § 176.83.

(b) Class 1 (explosive) must be segregated from bulk solid dangerous cargoes in accordance with the General Introduction to the IMDG Code. Notwithstanding § 176.83(b), ammonium nitrate and sodium nitrate may be stowed together with blasting explosives, except those containing chlorates, provided the mixed stowage is treated as blasting explosives (see § 176.410(e)).

§ 176.142 Hazardous materials of extreme flammability.

(a) Except as allowed by paragraph (b) of this section, certain hazardous materials of extreme flammability may not be transported in a vessel carrying Class 1 (explosive) materials. This prohibition applies to the following hazardous materials:

Carbon disulfide	UN 1131	Class 3.1
Diethyl Zinc	UN 1366	Class 4.2
Dimethyl Zinc	UN 1370	Class 4.2
Magnesium Alkyls	UN 3053	Class 4.2
Nickel Carbonyl	UN 1259	Class 6.1
Pyrophoric Liquids, n.o.s.	UN 2845	Class 4.2

(b) The hazardous materials listed in paragraph (a) of this section may be transported in a vessel carrying the following Class 1 (explosive) materials as cargo:

(1) Division 1.4 (Class C explosive) materials, compatibility group S.

(2) Explosive articles having the following proper shipping names and identification numbers (see column (4) of the § 172.101 Table) if designed for lifesaving purposes and their total net explosive mass (weight) does not exceed 50 kg (112 lbs) per vessel:

(i) ARTICLES, PYROTECHNIC: U.N. Nos. 0428, 0429, 0430, 0431.

(ii) CARTRIDGES, FLASH: U.N. Nos. 0049, 0050.

(iii) CARTRIDGES, SIGNAL: U.N. Nos. 0054, 0312.

(iv) SIGNAL DEVICES, HAND: U.N. No. 0191.

(v) SIGNALS, DISTRESS: U.N. Nos. 0194, 0195.

(vi) SIGNALS, SMOKE: U.N. Nos. 0196, 0197, 0313.

(3) Class 1 (explosive) materials in compatibility groups C, D, and E if the total net explosive mass (weight) does not exceed 10 kg (22 pounds) per vessel.

(4) Explosive articles in compatibility group G, except fireworks and Class 1 (explosive) materials requiring special stowage if the total net explosive mass (weight) does not exceed 10 kg (22 pounds) per vessel.

(c) When a vessel carrying Class 1 (explosive) materials allowed under paragraph (b) of this section also carries a hazardous material of extreme flammability, that hazardous material must be stowed in a part of the vessel as remote as practicable from the Class 1 (explosive) materials.

§ 176.144 Segregation of Class 1 (explosive) materials.

(a) Class 1 (explosive) materials may be stowed within the same compartment, magazine, portable magazine, or transport unit as indicated in Table 176.144(a).

(b) Where Class 1 (explosive) materials of different compatibility groups are allowed to be stowed in the same compartment, magazine, portable magazine, or transport unit, the stowage arrangements must conform to the most stringent requirements for the entire load.

(c) Where a mixed load of Class 1 (explosive) materials of different hazard divisions and/or stowage arrangements is carried within a compartment, magazine, or transport unit, the entire load must be treated as belonging to the hazard division having the greatest hazard (for example, if a load of Division 1.1 (Class A explosive) materials is mixed with Division 1.3 (Class B explosive) materials, the load would be treated as a Division 1.1 (Class A explosive)) material as defined in § 173.50(b) of this subchapter and the stowage must conform to the most stringent requirements for the entire load.

(d) If some of the Class 1 (explosive) materials in a stowage mixture require magazine stowage, Class 1 (explosive) materials requiring ordinary stowage may be stowed in the same magazine. When the magazine is used for substances requiring Type A stowage, the other Class 1 (explosive) materials stowed therein must have no exposed parts of ferrous metals or aluminum alloy, unless separated by a partition.

(e) *Segregation on deck:* When Class 1 (explosive) materials in different compatibility groups are carried on deck, they must be stored not less than 6 meters (20 feet) apart unless they are allowed under Table 176.144(a) to be stowed in the same compartment, magazine, or transport unit.

TABLE 176.144(a)—AUTHORIZED MIXED STOWAGE FOR EXPLOSIVES

[An "X" indicates that explosives in the two different compatibility groups reflected by the location of the "X" may not be stowed in the same or an adjacent compartment, portable magazine, or transport unit]

Compatibility groups	A	B	C	D	E	F	G	H	J	K	L	N	S
A		X	X	X	X	X	X	X	X	X	X	X	X
B	X		X	X	X	X	X	X	X	X	X	X	
C	X	X				X	1	X	X	X	X		
D	X	X				X	1	X	X	X	X		
E	X	X				X	1	X	X	X	X		
F	X	X	X	X	X		X	X	X	X	X	X	
G	X	X	1	1	1	X		X	X	X	X	X	
H	X	X	X	X	X	X	X		X	X	X	X	
J	X	X	X	X	X	X	X	X		X	X	X	
K	X	X	X	X	X	X	X	X	X		X	X	
L	X	X	X	X	X	X	X	X	X	X	2	X	X
N	X	X				X	X	X	X	X	X		
S	X										X		

Notes:

1. Explosive articles in compatibility group G, other than fireworks and those requiring special stowage, may be stowed with articles of compatibility groups C, D, and E, provided no explosive substances are carried in the same compartment, portable magazine or transport unit.
2. Explosives in compatibility group L may only be stowed in the same compartment, magazine or transport unit with identical explosives within compatibility group L.

§ 176.145 Segregation in single hold vessels.

(a) On board a vessel having a single cargo hold, Class 1 (explosive) materials in hazard division/compatibility group 1.1B and 1.2B may be stowed in the same compartment with substances of compatibility group D, provided:

(1) The net explosive weight of the compatibility group B explosive does not exceed 50 kg (110 pounds); and

(2) The compatibility group B explosives are stowed in a steel portable magazine that is stowed at least 6 meters (20 feet) from the compatibility group D substances.

(b) Division/compatibility group 1.4B (Class C explosive) materials may be stowed in the same compartment with substances of compatibility group D provided the Class 1 (explosive) materials of different compatibility groups are separated by either a distance of at least 6 meters (20 feet) or by a steel partition.

§ 176.146 Segregation from non-hazardous materials.

(a) Except as required by paragraphs (b) and (c) of this section, Class 1 (explosive) materials need not be segregated from other cargo of a non-dangerous nature.

(b) Mail, baggage, and personal and household effects may not be stowed in the same compartment as, or in compartments immediately above or below, Class 1 (explosive) materials other than those in compatibility group S.

(c) Where Class 1 (explosive) materials are stowed against an intervening bulkhead, any mail on the other side of the bulkhead must be stowed away from it.

(d) *In order to avoid contamination:*

(1) an explosive substance or article which has a secondary POISON hazard label must be stowed "separated from" all foodstuffs, except when such materials are stowed in separate closed transport units, the requirements for "away from" segregation apply.

(2) An explosive substance or article which has a secondary CORROSIVE hazard label must be stowed "away from" foodstuffs.

Precautions During Loading and Unloading

§ 176.148 Artificial lighting.

Electric lights, except arc lights, are the only form of artificial lighting permitted when loading and unloading Class 1 (explosive) materials.

§ 176.150 Radio and radar.

(a) Except as provided in paragraph (b) of this section, when Class 1 (explosive) materials (other than explosive articles in Division 1.4 (Class C explosive) or any explosive substance) are loaded, unloaded, or handled, the responsible person must ensure that all sources of electromagnetic radiation such as radio and radar transmitters are deenergized by opening the main switches controlling the sources and tagging them to warn that the devices are to be energized until loading or unloading has ceased.

(b) During the loading or unloading of all explosive articles (except those in Division 1.4 (Class C explosive)), no radio or radar transmitter may be used within 50 meters (164 feet) of such articles except for VHF transmitters the power output of which does not exceed 25 watts and of which no part of the antenna system is within 2.0 meters (6.6 feet) of the Class 1 (explosive) materials.

(c) Explosive articles which are sensitive to electromagnetic radiation from external sources must be stowed at a safe distance from the vessel's radio cabin, receiving and transmitting apparatus radio antenna or lead-in, and radar installation, with due regard to the character of the vessel and the degree of screening-off of the explosive articles.

§ 176.154 Fueling (bunkering).

(a) Class 1 (explosive) materials, except those in compatibility group S, may not be loaded or unloaded when fueling (bunkering) is in progress except with the prior authorization of the COTP, and under conditions prescribed by that officer.

(b) Vessels containing Class 1 (explosive) materials may not be fueled (bunkered) with the hatches open unless authorized by the COTP.

§ 176.156 Defective packages.

(a) No leaking, broken, or otherwise defective package containing Class 1 (explosive) materials, including packages which have been adversely affected by moisture, may be accepted for shipment. The master or person in charge of a vessel on which there is a defective package containing Class 1 (explosive) materials must seek advice from the shipper concerning withdrawal, repair, or replacement. No repair of damaged or defective package containing Class 1 (explosive) materials may be performed on board a vessel.

(b) No Class 1 (explosive) material, which for any reason has deteriorated or undergone a change of condition that increases the hazard attendant upon its conveyance or handling, may be moved in the port area, except as directed by the COTP.

(c) If any package of Class 1 (explosive) materials, or seal of a package of Class 1 (explosive) materials, appears to be damaged, that package must be set aside for examination and repair or otherwise disposed of as directed by the shipper.

(d) If any Class 1 (explosive) materials are spilled or released from a package, the responsible person must ensure that an appropriate emergency response is undertaken in accordance with the emergency response information required under § 172.602 of this subchapter. The master of the vessel must report each incident involving spillage or release of Class 1 (explosive) materials to the COTP as soon as practicable.

§ 176.160 Protection against weather.

Any person loading or unloading packages containing Class 1 (explosive) materials shall take adequate measures to prevent these packages from becoming wet.

§ 176.162 Security.

(a) A responsible person must be present at all times when the hatches of spaces containing Class 1 (explosive) materials are open. No unauthorized person may be permitted to access spaces in which Class 1 (explosive) materials are stowed. Magazines must be secured against unauthorized entry when loading has been completed, or when loading or unloading is stopped. Packages containing Class 1 (explosive) materials may not be opened on board ship.

§ 176.164 Fire precautions and firefighting.

(a) Matches, lighters, fire, and other ignition sources are prohibited on and near any vessel on which Class 1 (explosive) materials are being loaded, unloaded, or handled except in places designated by the master or the COTP.

(b) A fire hose of sufficient length to reach every part of the loading area with an effective stream of water must be laid and connected to the water main, ready for immediate use.

(c) No repair work may be carried out in a cargo space containing Class 1 (explosive) materials other than those of Division 1.4 (Class C explosive). No welding, burning, cutting, or riveting operations involving the use of fire, flame, spark, or arc-producing equipment may be conducted on board except in an emergency; and, if in port, with the consent of the COTP.

(d) Each compartment, including a closed vehicle deck space, which contains Class 1 (explosive) materials must be provided with a fixed fire extinguishing system. Each adjacent cargo compartment must be either protected by a fixed fire extinguishing installation or must be accessible for firefighting operations.

(e) A vessel must have a power-operated fire pump, which together with its source of power and sea connections must be located outside the machinery space, and two sets of breathing apparatus.

Passenger Vessels

§ 176.166 Transport of Class 1 (explosive) materials on passenger vessels.

(a) The following Class 1 (explosive) materials may be transported as cargo on passenger vessels:

(1) Division 1.4 (Class C explosive) materials, compatibility group S.

(2) Explosive articles designed for lifesaving purposes as identified in § 176.143(b)(2), if the total net explosive mass (weight) does not exceed 50 kg (110 pounds).

(3) Class 1 (explosive) materials in compatibility groups C, D, and E, if the total net explosive mass (weight) does not exceed 10 kg (22 pounds) per vessel.

(4) Articles in compatibility group G other than those requiring special stowage, if the total net explosive mass (weight) does not exceed 10 kg (22 pounds) per vessel.

(5) Articles in compatibility group B, if the total net explosive mass (weight) does not exceed 5 kg (11 pounds).

(b) Class 1 (explosive) materials which may be carried on passenger vessels are identified in column (10) of the § 172.101 Table. They must be stowed in accordance with Table 176.166(b).

TABLE 176.166(b).—STOWAGE ARRANGEMENTS IN PASSENGER VESSELS

Class/division	Samples, explosive	Goods, N.O.S. class 1	Goods shipped under a specific proper shipping name												
			Compatability group												
			A	B	C	D	E	F	G	H	J	K	L	N	S
1.1	d	d	c	e	e	e	e	c	e	-	c	-	c	-	-
1.2	d	d	-	e	e	e	e	c	e	c	c	c	c	-	-
1.3	d	d	-	-	e	e	-	c	e	c	c	c	c	-	-
1.4	d	d	-	b	b	b	b	c	b	-	-	-	-	-	a
1.5	d	d	-	-	-	e	-	-	-	-	-	-	-	-	-
1.6	d	d	-	-	-	-	-	-	-	-	-	-	-	e	-

a—As for cargo ships, on deck or under deck.
b—As for cargo ships, on deck or under deck, in portable magazines only.
c—Prohibited.
d—As specified by the Director, OHMT, or competent authority of the country in which the Class 1 (explosive) materials are loaded on the vessel.
e—In containers or the like, on deck only.

(c) Notwithstanding the provisions of paragraph (a) of this section, a combination of the substances and articles listed in paragraphs (a)(1) through (a)(5) of this section may be transported on the same passenger vessel provided the total net explosive mass (weight) of the combination of Class 1 (explosive) materials carried does not exceed the smallest quantity specified for any one of the substances or articles in the combination.

Transport Units and Shipborne Barges

§ 176.168 Transport of Class 1 (explosive) materials in vehicle spaces.

(a) All transport vehicles and cargo must be properly secured.

(b) All transport vehicles used for the carriage of Class 1 (explosive) materials must be structurally serviceable as defined in § 176.172(a)(2) of this subpart.

(c) Vehicles used to transport Class 1 (explosive) materials must conform to the requirements in §§ 177.834 and 177.835 of this subchapter.

(d) Class 1 (explosive) materials which require special stowage must be transported in transport vehicles approved for the purpose by the Director, Office of Hazardous Materials Transportation; except Class 1 (explosive) materials in compatibility group G or H may be carried in steel portable magazines or freight containers. Closed transport vehicles may be used as magazines; transport vehicles of other types may be used to transport Class 1 (explosive) materials which require ordinary stowage.

(e) Class 1 (explosive) materials of different compatibility groups may not be stowed in the same vehicle except as allowed in § 176.144 of this subpart.

(f) Vehicles containing different Class 1 (explosive) materials require no segregation from each other provided these materials may be carried together under the provisions of § 176.144 of this subpart. In all other instances, the vehicles must be "separated from" one another.

(g) All transport vehicles used for the transport of Class 1 (explosive) materials must have lashing arrangements for securing the vehicle on the ship and preventing the movement of the vehicle on its springs during the sea passage.

(h) Where a portable magazine or closed freight container is carried on a chassis, twist locks or other suitable securing arrangements must be provided and made secure.

§ 176.170 Transport of Class 1 (explosive) materials in freight containers.

(a) When Class 1 (explosive) materials are stowed in a freight container, the freight container may be regarded as a magazine but not as a separate compartment.

(b) Freight containers exceeding 6 meters (20 feet) in length may not carry more than 5000 kg (11,000 pounds) net explosive weight of explosive substances, except explosive substances in Division 1.4.

(c) Freight containers used to transport Class 1 (explosive) materials for which magazine stowage type A is required must be fitted with a close-boarded floor and must have a non-metallic lining.

(d) Class 1 (explosive) materials of different compatibility groups may not be stowed within the same freight container except as allowed in § 176.144 of this subpart.

(e) On vessels other than specially fitted container ships, freight containers containing Class 1 (explosive) materials must be stowed only in the lowest tier.

(f) Freight containers carrying different Class 1 (explosive) materials require no segregation from each other, provided the provisions of § 176.144 of this subpart allow the Class 1

(explosive) materials to be carried together in the same compartment. In all other instances, the containers must be "separated from" one another in accordance with 176.83(f) of this part.

(g) Freight containers carrying Class 1 (explosive) materials may not be handled on board a vessel with fork lift trucks unless approved by the COTP. This does not preclude the use of front loading trucks using side-frame lifting equipment.

§ 176.172 Structural serviceability of freight containers and vehicles carrying Class 1 (explosive) materials on ships.

(a) A freight container may not be offered for the carriage of Class 1 (explosive) materials unless the container is structurally serviceable as evidenced by a current CSC (International Convention for Safe Containers) approval plate and verified by a detailed visual examination as follows:

(1) Before a freight container or transport vehicle is packed with Class 1 (explosive) materials, it must be visually examined by the shipper to ensure it is structurally serviceable, free of any residue of previous cargo, and its interior walls and floors are free from protrusions.

(2) "Structurally serviceable" means the freight container or the vehicle cannot have major defects in its structural components, such as top and bottom side rails, top and bottom end rails, door sill and header, floor cross members, corner posts, and corner fittings in a freight container. Major defects include—

(i) Dents or bends in the structural members greater than 19 mm (¾ inch) in depth, regardless of length;

(ii) Cracks or breaks in structural members;

(iii) More than one splice or an improper splice (such as a lapped splice) in top or bottom end rails or door headers;

(iv) More than two splices in any one top or bottom side rail;

(v) Any splice in a door sill or corner post;

(vi) Door hinges and hardware that are seized, twisted, broken, missing, or otherwise inoperative;

(vii) Gaskets and seals that do not seal; or

(viii) For freight containers, any distortion of the overall configuration great enough to prevent proper alignment of handling equipment, mounting and securing chassis or vehicle, or insertion into ships' cells.

(3) In addition, deterioration in any component of the freight container or vehicle, regardless of the material of construction, such as rusted-out metal in sidewalls or disintegrated fiberglass, is prohibited. Normal wear, however, including oxidation (rust), slight dents and scratches and other damage that does not affect serviceability, or the weather-tight integrity of the units, is not prohibited.

(b) As used in paragraph (a) of this section, "splice" means any repair of a freight container main structural member which replaces material, except complete replacement of the member.

(c) All shipments of Class 1 (explosive) materials except those in Division 1.4 (Class C explosive) must be accompanied by a statement, which may appear on the shipping paper, certifying that the freight container or the vehicle is structurally serviceable as defined in paragraph (a)(2) of this section.

§ 176.174 Transport of Class 1 (explosive) materials in shipborne barges.

(a) Fixed magazines may be built within a shipboard barge. Portable magazines and freight containers may be used as magazines with a barge.

(b) Shipborne barges may be used for the carriage of all types of Class 1 (explosive) materials. When carrying Class 1 (explosive) materials requiring special stowage, the following requirements apply:

(1) Class 1 (explosive) materials in compatibility group G or H must be stowed in steel portable magazines or freight containers.

(2) Class 1 (explosive) materials in compatibility group K or L must be stowed in steel portable magazines.

(c) Class 1 (explosive) materials of different compatibility groups may not be stowed within the same shipborne barge unless under § 176.144(b) of this subpart they are authorized to be stowed in the same compartment.

Handling Class 1 (Explosive) Materials in Port

§ 176.176 Signals.

(a) When Class 1 (explosive) materials are being loaded, handled, or unloaded on a vessel, the vessel must exhibit the following signals:

(1) By day, flag "B" (Bravo) of the international code of signals; and

(2) By night, an all-round fixed red light.

§ 176.178 Mooring lines.

(a) All lines used in mooring the vessel must be of sufficient strength, type, and number for the size of the vessel and local conditions.

(b) While the vessel is moored or anchored in a port area, towing wires of adequate size and length must be properly secured to mooring bits at the bow and stern ready for immediate use with the towing eyes passed outboard and kept at about water level.

(c) The mooring arrangements must be such that the vessel can be released quickly in an emergency.

§ 176.180 Watchkeening.

Whenever Class 1 (explosive) materials are on board a vessel in port, there must be sufficient crew on board to maintain a proper watch and to operate the propulsion and firefighting equipment in case of an emergency.

§ 176.182 Conditions for handling on board ship.

(a) *Weather conditions.* Class 1 (explosive) materials may not be handled in weather conditions which may seriously increase the hazards presented by the Class 1 (explosive) materials. During electrical storms, cargo operations must be halted and all hatches containing Class 1 (explosive) materials must be closed.

(b) *Darkness.* Class 1 (explosive) materials may not be handled on board a vessel during the hours of darkness unless prior consent has been obtained from the COTP.

(c) *Lighting.* The area where Class 1 (explosive) materials are handled or where preparations are being made to handle Class 1 (explosive) materials must be illuminated with lighting that is sufficient to perform the handling operation.

(d) *Protective equipment.* (1) A sufficient quantity of appropriate protective equipment must be provided for the personnel involved in handling Class 1 (explosive) materials.

(2) The protective equipment must provide adequate protection against the hazards specific to the Class 1 (explosive) materials handled.

(e) *Intoxicated persons.* No person under the influence of alcohol or drugs to such an extent that the person's judgment or behavior is impaired may participate in any operation involving the handling of Class 1 (explosive) materials. The master of the vessel must keep any such person clear of any areas where Class 1 (explosive) materials are being handled.

(f) *Smoking.* (1) Smoking is prohibited on the vessel while Class 1 (explosive) materials are being handled or stowed except in places designated by the master of the vessel.

(2) Conspicuous notices prohibiting smoking must be posted and clearly visible at all locations where Class 1 (explosive) materials are handled or stored.

(g) All hatches and cargo ports opening into a compartment in which Class 1 (explosive) materials are stowed must be kept closed except during loading and unloading of the compartment. After loading, hatches must be securely closed.

§ 176.184 Class 1 (explosive) materials of Compatibility Group L.

Class 1 (explosive) materials in compatibility group L may not be handled in a port area without the special permission of, and subject to any special precautions required by, the COTP.

§ 176.190 Departure of vessel.

When loading of Class 1 (explosive) materials is completed, the vessel must depart from the port area as soon as is reasonably practicable.

§ 176.192 Cargo handling equipment for freight containers carrying Class 1 (explosive) materials.

(a) Except in an emergency, only cargo handling equipment that has been specifically designed or modified for the handling of freight containers may be used to load, unload, or handle freight containers containing Division 1.1 or 1.2 (Class A and B explosive) materials.

(b) The gross weight of a freight container containing Class 1 (explosive) materials may not exceed the safe working load of the cargo handling equipment by which it is handled.

Magazine Vessels

§ 176.194 Stowage of Class 1 (explosive) materials on magazine vessels.

(a) *General.* The requirements of this section are applicable to magazine vessels and are in addition to any other requirements in this subchapter.

(b) *Type vessel authorized.* A single deck vessel with or without a house on deck is the only type vessel that may be used as a magazine vessel. A magazine vessel may not be moved while Class 1 (explosive) materials are on board.

(c) *Location of explosives.* Division 1.1, 1.2, or 1.3 (Class A and B explosive) materials, in excess of 2268 kg (5000 pounds), stored in any magazine vessel must be stowed below deck. No Class 1 (explosive) materials may be stowed on deck unless the vessel is fitted with a deck house having a stowage area which meets the requirements in this subpart for the stowage of Class 1 (explosive) materials. Detonators, Division 1.1 (Class A explosive), and detonating primers, Division 1.1 (Class A explosive), may not be stored on the same magazine vessel with other Division 1.1, 1.2, and 1.3 (Class A or B explosive) materials.

(d) *Class 1 (explosive) materials storage spaces.* Any compartment on a magazine vessel used for the stowage of Class 1 (explosive) materials must be completely ceiled with wood so as to provide a smooth interior surface. Each metal stanchion in the compartment must be boxed in the same manner. An overhead ceiling is not required when the overdeck is weather tight. All nail and bolt heads must be countersunk and any exposed metal must be covered with wood.

(e) *Initiating explosives, detonators and boosters with detonators.* No explosive substance in Division 1.1, compatibility group A may be stowed in the same compartment with any other Class 1 (explosive) materials when there is any explosive substances in Division 1.1 or 1.2 (Class A explosive) on the same magazine vessel. Detonators and detonating primers must be stowed at least 8 meters (26 feet) from any bulkhead forming a boundary of a compartment containing any other Class 1 (explosive) materials.

(f) *Dry storage spaces.* A magazine vessel having a dry storage space capable of being used for any purpose whatsoever must have a cofferdam at least 61 cm (24 inches) wide fitted between the dry storage space and each adjacent compartment containing Class 1 (explosive) materials. The cofferdam must be constructed of wood or steel, formed by two tight athwartship bulkheads extending from the skin of the vessel to the overdeck. If the cofferdam extends to the weather deck, a watertight hatch must be fitted in the deck to provide access to the cofferdam.

(g) *Lighting.* Non-sparking, battery-powered, self-contained electric lanterns or non-sparking hand flashlights are the only means of artificial light authorized.

(h) *Living quarters.* Living quarters must be fitted on the inside with a non-combustible material approved by the Commandant, USCG. Bracketed ship's lamps are the only lighting fixtures authorized to be used in the living quarters. Any stove used for heating or cooking must be securely fastened and may not be mounted closer than 15 cm (6 inches) to the deck or sides of the house. Any smoke pipe for the stove which passes through the roof of the house must be kept at least 8 cm (3 inches) away from any woodwork. Each smoke pipe must be protected by a layer of non-combustible material approved by the Commandant, USCG, an air space of at least 2.54 cm (1 inch), and a metal collar of at least 1.5 mm (16 gauge) sheet secured only on the weather side of the roof. There may be no opening from any living quarters into any stowage compartment.

(i) *Storage of other hazardous materials.* Magazine vessels having Class 1 (explosive) materials on board may not be used for the storage of any other hazardous material.

(j) *Magazine vessel's stores.* Hazardous materials used as stores on board any magazine vessel must comply with the requirements of 46 CFR part 147.

(k) *Matches.* Safety matches requiring a prepared surface for ignition are the only type of matches authorized to be possessed or used on board a magazine vessel. They must be kept in a metal box or can with a metal cover and stored in the custodian's living quarters.

(l) *Firearms.* Firearms and ammunition (other than cargo) are not permitted on board a magazine vessel.

(m) *Fire extinguishing equipment.* No Class 1 (explosive) materials may be loaded or stowed in, unloaded from, or handled on any magazine vessel unless four fire extinguishers that meet the requirements for Type A Size II or Type B Size III in 46 CFR subpart 95.50 are near and accessible to the magazines.

(n) *Supervision.* A magazine vessel containing Class 1 (explosive) materials must be continuously attended by a custodian employed for that purpose by the vessel's owner.

(o) *Unauthorized persons on magazine vessels.* The custodian of a magazine vessel shall prevent unauthorized persons from coming on board unless it is necessary to abate a hazard to human life or a substantial hazard to property.

(p) *Repacking of Class 1 (explosive) materials on board.* No Class 1 (explosive) materials may be repacked on board a magazine vessel. Broken or damaged packages must be handled in accordance with the requirements of § 176.156 of this subpart. Packages requiring an emergency response must be handled in accordance with the emergency response information required under § 172.602 of this subchapter.

(q) *Work boat.* Each magazine vessel must be equipped with a work boat.

(r) *Life preservers.* One approved personal flotation device must be available for each person employed on a magazine vessel.

(s) *Fenders.* Each magazine vessel must be fitted with fenders in sufficient number and size to prevent any vessel tying up alongside from coming in contact with the hull.

35. Subpart H would be revised to read as follows:

Subpart H—Detailed Requirements for Class 2 (Compressed Gas) Materials

§ 176.200 General stowage requirements.

(a) Each package of Class 2 (compressed gas) material being transported by vessel must be prevented from making direct contact with the vessel's deck, side, or bulwark by dunnage, shoring, or other effective means.

(b) When cylinders of Class 2 (compressed gas) materials being transported by vessel are stowed in a horizontal position, each tier must be stowed in the cantlines of the tier below it, and the valves on cylinders in adjacent tiers must be at alternate ends of the stow. Each tier may be stepped back and the ends alternated in order to clear the flange. Lashing must be provided to prevent any movement.

(c) When cylinders of Class 2 (compressed gas) materials being transported by vessel are stowed in a vertical position they must be stowed upright in a block and cribbed or boxed in with suitable dunnage. The box or crib must be dunnaged at least 10 cm (4 inches) off any metal deck. The cylinders in the box or crib must be braced to prevent any movement. The box or crib must be securely chocked and lashed to prevent any movement.

(d) Any package containing Division 2.3 (poison gas) materials must be stowed separate from all foodstuffs.

(e) Class 2 (compressed gas) materials may not be stowed "on deck" over a hold or compartment containing coal.

(f) Class 2 (compressed gas) material must be kept as cool as practicable and be stowed away from all sources of heat and ignition.

§ 176.205 Under deck stowage requirements.

(a) When a Class 2 (compressed gas) material is stowed below deck, it must be stowed in a mechanically ventilated cargo space capable of being ventilated with no source of artificial heat and clear of living quarters. No bulkhead or deck of that hold or compartment may be a common boundary with any boiler room, engine room, coal bunker, galley or boiler room uptake.

(b) When Division 2.1 (flammable gas) materials are stowed below deck, it must be stowed in a hold or compartment which complies with paragraph (a) of this section and the following requirements:

(1) Each hold or compartment must be ventilated.

(2) Each hold or compartment must be equipped with an overhead water sprinkler system or fixed fire extinguishing system.

(3) Each electrical power line in the hold or compartment must be protected by a strong metal covering to prevent crushing by cargo being stowed against it.

(4) Except when fitted with electrical fixtures of the explosion-proof type, each electrical circuit serving the hold or compartment must be disconnected from all sources of power. No circuit may be energized until the Division 2.1 (flammable gas) cargo and any vapors have been removed from the hold or compartment. Explosion-proof portable lighting may be used if the source of power is from electrical outlets outside the hold or compartment and above the weather deck.

(5) Any opening in a common bulkhead of an adjacent hold or compartment must be securely closed off and made gas-tight, unless the adjacent hold or compartment is also used for the stowage of Division 2.1 (flammable gas) materials.

(6) Full and efficient hatch covers must be used. Tarpaulins, if fitted, must be protected by dunnaging before overstowing with any cargo. Each tarpaulin must be in one piece and free of rents, tears, and holes.

(7) A fire screen must be fitted at the weather end of each vent duct leading from the hold or compartment. The fire screen must completely cover the open area. It must consist of two layers of fine brass wire screen at least 50 × 50 cm (20 × 20 inches) mesh or finer, spaced not less than 1 cm (½ inch) or more than 4 cm (1½ inches) apart. The screen may be removable if means for securing it in place when in service are provided.

(8) The hold or compartment may not be fitted with any gooseneck type vent trunk head.

(9) All electrical apparatus located in the hold or compartment must have a positive means for disconnecting it from power outside the hold or compartment containing any Division 2.1 (flammable gas) materials.

§ 176.210 On deck stowage requirements.

Cylinders of Class 2 (compressed gas) materials being transported by vessel must be protected from radiant heat which includes the direct rays of the sun by structural erections or awnings. A tarpaulin covering the cylinders is not acceptable if it comes in contact with them.

§ 176.220 Smoking or open flame and posting of warning signs.

(a) Smoking or the use of open flame is prohibited in any hold or compartment containing a Division 2.1 (flammable gas) material, near any Division 2.1 (flammable gas) material stowed on deck, or near any ventilator leading to a hold containing this material.

(b) A sign carrying the legend:

FLAMMABLE VAPORS
KEEP LIGHTS AND FIRE AWAY
NO SMOKING

must be conspicuously posted at each approach to an "on deck" Division 2.1 (flammable gas) material stowage area and near each cargo hold ventilator leading to a hold containing this material. The sign must be painted on a white background using red letters. The letters may not be less than 8 cm (3 inches) high.

§ 176.225 Stowage of chlorine.

Chlorine (UN1017) must be stowed separate from copper or brass leaf sheets and finely divided organic material.

§ 176.230 Stowage of Division 2.1 (flammable gases) materials.

Division 2.1 (flammable gases) materials transported in Specifications 106A and 110A multi-unit car tanks must be stowed on deck only, and must be shaded from radiant heat.

36. Subpart I would be revised to read as follows:

Subpart I—Detailed Requirements for Class 3 (Flammable and Combustible Liquid) Materials

§ 176.305 General stowage requirements.

(a) Flammable and combustible liquids must be kept as cool as reasonably practicable and be stowed away from all sources of heat and ignition.

(b) Except as otherwise provided in § 176.76(g), a package containing a flammable liquid and equipped with a vent or safety relief device must be stowed "on deck" only.

(c) The following requirements apply to each hold or compartment in which flammable and combustible liquids are being transported:

(1) The hold or compartment must be ventilated except that the stowage of non-bulk packages of combustible liquids (see § 171.8 definitions) may be in non-ventilated holds.

(2) Stowage of flammable or combustible liquids within 6 meters (20 feet) of a bulkhead which forms a boundary or deck of a boiler room, engine room, coal bunker, galley, or boiler room uptake is not permitted. If the amount of the liquid to be stowed in a hold will not permit compliance with

the requirement for a 6 meter (20 foot) separation, less separation distance is authorized if at least one of the following conditions exists:

(i) The bulkhead or deck is covered with at least 8 cm (3 inches) of insulation on the entire area subject to heat:

(ii) A temporary wooden bulkhead at least 5 cm (2 inches) thick is constructed in the hold at least 8 cm (3 inches) off an engine room or 15 cm (6 inches) off a boiler room bulkhead, covering the entire area of the bulkhead that is subject to heat and the space between the permanent bulkhead and the temporary wooden bulkhead is filled with mineral wool or equivalent bulk noncombustible insulating material or

(iii) A temporary wooden bulkhead is constructed of at least 2.5 cm (1 inch) thick tongue and groove sheathing, located 1 meter (3 feet) from the boiler room or engine room bulkhead, and filled with sand to a height of 2 meters (6 feet) above the tank top, or, if the cargo compartment is located between decks, 1 meter (3 feet) of sand.

(3) Combustible liquids may not be stowed in a hold within 6 meters (20 feet) of a common bulkhead with the engine room unless the means of vessel propulsion is internal combustion engines.

(4) Each cargo opening in a bulkhead of an adjacent hold must be securely closed off and made gas-tight, unless the adjacent hold is also used for the stowage of a flammable or combustible liquid.

(d) In addition to the requirements specified in paragraph (b) of this section, the following requirements apply to each hold or compartment in which a flammable liquid is transported:

(1) Full and effective hatch covers must be used. Tarpaulins, if fitted, must be protected by dunnaging before overstowing with any cargo. Each tarpaulin must be in one piece and free of rents, tears, and holes;

(2) If flammable liquids in excess of 1016 kg (2240 pounds) are stowed under deck in any one hold or compartment, a fire screen must be fitted at the weather end of each vent duct leading from that hold or compartment. The fire screen must completely cover the open area. It must consist of two layers of fine brass wire screen at least 20×20 mesh or finer spaced not less than 1 cm (½ inch) or more than 1 cm (½ inch) apart. The screen may be removable only if means for securing it in place when in service are provided;

(3) Each electrical power line in the hold or compartment must be protected by a strong metal covering to prevent crushing by cargo being stowed against it;

(4) Except when fitted with explosion-proof type electrical fixtures, each electrical circuit serving the hold or compartment must be disconnected from all sources of power from a point outside the hold or compartment containing flammable liquids. No circuit may be energized until the flammable liquids and any vapors have been removed from the hold or compartment. Explosion-proof type portable lighting may be used if the source of power is from electrical outlets outside the hold or compartment and above the weather deck; and

(5) Flammable liquids in excess of 1016 kg (2240 pounds), may not be transported in any hold or compartment that is fitted with a gooseneck type of vent head.

(e) On a passenger vessel, each hold or compartment used to transport flammable liquids must be equipped with an overhead water sprinkler system or fixed fire-extinguishing system.

(f) On a passenger vessel, each hold or compartment used to transport flammable liquids under a passenger space must have an overdeck of an A–60 type construction (see 46 CFR 72.05–10(c)(1)) or equivalent or have its underside covered with at least 8 cm (3 inches) of noncombustible insulation.

(g) No flammable liquid in a drum or wooden case, having inside packagings of more than one liter (one quart) capacity each, may be stowed as a beam filler. A wooden barrel, a wooden box or a fiberboard box, with any flammable liquid material in inside packagings of not more than one liter (one quart) capacity each, may not be stowed as a beam filler unless it is possible to stow and observe any "THIS SIDE UP" marking.

§ 176.315 Fire protection requirements.

(a) For each 79,800 liters (21,000 U.S. gallons) or part thereof of any flammable and combustible liquids being transported on board a vessel in a portable tank, rail tank car, or a motor vehicle cargo tank, there must be provided at least one B–V semiportable foam (152 liter/40 gallon capacity)(see 46 CFR 95.50), dry chemical (100 lbs./45 kg minimum capacity) or equivalent fire extinguisher, or a fire hose fitted with an approved portable mechanical foam nozzle with pick-up tube and two 19 liter (5 gallon) cans of foam liquid concentrate. Each foam system must be suitable for use with each flammable or combustible liquid it is intended to cover. Each fire extinguisher must be accessible to the tank it is intended to cover.

(b) The fire hose at each fire hydrant in the vicinity of flammable and combustible liquids stowage areas must be fitted with an approved combination spray nozzle.

(c) The pressure must be maintained in the vessel's fire mains during the loading and unloading of the flammable and combustible liquids.

(d) Two 7 kg (15 pound) capacity hand portable dry chemical or two portable 10 liter (2½ gallon) foam-type extinguishers must be accessible to any packaged flammable or combustible liquid and suitable for use with the lading.

(e) The requirements of this section do not apply to portable tanks and their contents authorized under 46 CFR part 93 or 46 CFR part 64.

§ 176.320 Use of hand flashlights.

Each hand flashlight used on deck near or in any hold or compartment containing a flammable liquid, must be of the nonsparking type.

§ 176.325 Smoking or open flame and posting of warning signs.

(a) Smoking or the use of open flame is prohibited in any hold or compartment containing a flammable or combustible liquid, near any flammable or combustible liquid stowed on deck, or near any ventilator leading to a hold containing such material.

(b) A sign carrying the legend:

FLAMMABLE VAPORS

KEEP LIGHTS AND FIRE AWAY

NO SMOKING

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must be conspicuously posted at each approach to a flammable or combustible liquid stowed "on deck" and near each cargo hold ventilator leading to a hold or compartment containing this material. This sign must be painted on a white background using red letters. The letters may not be less than 8 cm (3 inches) high.

§ 176.331 Transportation of flammable liquids with foodstuffs.

Each package containing a flammable liquid which bears a POISON label must be stowed separate from foodstuffs. Each package containing a flammable liquid which bears a CORROSIVE or KEEP AWAY FROM FOOD label must be stowed away from foodstuffs.

§ 176.340 Combustible liquids in portable tanks.

(a) Combustible liquids, having a flashpoint of 37.8 °C (100 °F) or higher,

may be transported by vessel only in one of the portable tanks as specified below:

(1) Portable tanks authorized in § 173.241 of this subchapter.

(2) In nonspecification portable tanks, subject to the following conditions:

(i) Each portable tank must conform to §§ 178.251 and 178.253 of this subchapter, except as otherwise provided in this paragraph;

(ii) The rated capacity of the tank may not exceed 4542 liters (1,200 gallons), and the rated gross weight may not exceed 13.608 kg (30,000 pounds);

(iii) The vibration test in § 178.253–5 need not be performed;

(iv) When the total surface area of the tank exceeds 14.9 square meters (160 square feet), the total emergency venting capacity must be determined in accordance with Table III in § 178.341–4 of this subchapter;

(v) In place of a specification identification marking required by § 178.251–7 of this subchapter, the tank must be marked, on two sides in letters at least 5 cm (2 inches) high on contrasting background: "FOR COMBUSTIBLE LIQUIDS ONLY" and "49 CFR 176.340". This latter marking is the certification of the person offering the combustible liquid materials for transportation that the portable tank conforms to this paragraph;

(vi) Each tank must be made of steel;

(vii) The design pressure of the tank must be not less than 62 KPa (9 psig);

(viii) No pressure relief device may open at less than 34.4 KPa (5 psig);

(ix) Each tank must be retested and marked at least once every 2 years in accordance with the requirements applicable to a DOT specification 57 portable tank in § 173.32 (e)(2), (e)(3), and (e)(4) of this subchapter; and

(x) Each tank must conform to the provisions of § 173.24 of this subchapter and paragraphs (g), (h), (i), and (k) of § 173.32 of this subchapter.

(3) Portable tanks approved by the Commandant, USCG (G–MTH).

37. Subpart J would be revised to read as follows:

Subpart J—Detailed Requirements for Class 4 (Flammable Solids), Class 5 (Oxidizers and Organic Peroxides), and Division 1.5 (Blasting Agents) Materials

§ 176.400 Stowage of Division 1.5 (blasting agents) and Class 5 (oxidizers and organic peroxides) materials.

(a) Class 4 (flammable solid) material and Division 5.2 (organic peroxide) material must be kept as cool as reasonably practicable and be stowed away from all sources of heat and ignition.

(b) Division 5.2 (organic peroxide) material must be stowed away from living quarters or access to them. Division 5.2 (organic peroxide) material not requiring temperature control should be protected from radiant heat which includes direct rays of the sun and stowed in a cool, well-ventilated area.

(c) No Division 1.5 (blasting agents) or Class 5 (oxidizers and organic peroxides) materials being transported by vessel may be stowed in the same hold or compartment with any readily combustible material such as a combustible liquid, a textile product, or with a finely divided substance, such as an organic powder.

(d) No Division 1.5 (blasting agents) or Class 5 (oxidizers and organic (peroxides) being transported by vessel may be stowed in a hold or compartment containing sulfur in bulk, or in any hold or compartment above, below, or adjacent to one containing sulfur in bulk.

§ 176.405 Stowage of charcoal.

(a) Before stowing charcoal Division 4.2 (flammable solid), UN1361, NA1361, or UN1362 on a vessel for transportation, the hold or compartment in which it is to be stowed must be swept as clean as practicable. All residue of any former cargo, including a petroleum product, a vegetable or animal oil, nitrate, or sulfur, must be removed.

(b) Charcoal packed in bags and offered for transportation on board a vessel in a quantity over 1016 kg (2240 pounds) must be loaded so that the bags are laid horizontally and stacked with space for efficient air circulation. If the bags are not compactly filled and closed to avoid free space within, vertical and horizontal dunnage strips must be laid between the bags. Space for ventilating must be maintained near bulkheads, the shell of the vessel, the deck, and the overhead. No more than 40.6 metric tons (40 long tons) of charcoal may be stowed in a hold or compartment when other stowage space is available. If the unavailability of hold or compartment space requires the stowage of a larger amount, the arrangement of the stow for ventilation must be adjusted to ensure a sufficient venting effect.

(c) Any loose material from bags broken during loading must be removed. Broken bags may be repacked or have the closures repaired and the repaired bags restowed.

(d) Charcoal "screenings" packed in bags must be stowed to provide spaces for air circulation between tiers regardless of the quantity stowed.

§ 176.410 Division 1.5 (blasting agents) materials, ammonium nitrate and ammonium nitrate mixtures.

(a) This section prescribes requirements to be observed with respect to transportation of each of the following hazardous materials by vessel:

(1) Explosives, blasting, type E, and Explosives, blasting, type B, Division 1.5 (blasting agent) compatibility group D, UN0331 and UN0332.

(2) Ammonium nitrate fertilizer, Division 1.1 (Class A explosive) compatibility group D, UN0222 or UN0223.

(3) Ammonium nitrate fertilizer, Division 5.1 (oxidizer), UN1942.

(4) Ammonium nitrate fertilizer, Division 5.1 (oxidizer), UN2068.

(5) Ammonium nitrate fertilizer, Division 5.1 (oxidizer), UN2067.

(6) Ammonium nitrate fertilizer, Division 5.1 (oxidizer), UN2069 or UN2072.

(7) Ammonium nitrate fertilizer, Division 5.1 (oxidizer), UN2070.

(b) This section does not apply to Ammonium nitrate fertilizer, Class 9 (miscellaneous hazardous materials), UN2071 or to any non-acidic ammonium nitrate mixed fertilizer containing 13 percent or less ammonium nitrate, less than 5 percent organic material, and no other oxidizing material, and which does not meet the criteria for any other hazard set forth in part 173 of this subchapter.

(c) When Division 1.5 (blasting agents) compatibility group D materials, ammonium nitrate, or any of the ammonium nitrate fertilizers listed in paragraph (a) of this section are transported by vessel:

(1) They must be stowed well away from any steam pipe, electric circuit, or other source of heat;

(2) Smoking may not be permitted except in designated areas away for the material and "No-Smoking" signs must be posted in accordance with § 176.60;

(3) Fire hoses must be connected, laid out, and tested before loading or unloading commences; and

(4) A fire watch must be posted in the hold or compartment where the material is being loaded or unloaded.

(d) When any of the hazardous materials listed in paragraph (a) of this section is transported in bags by vessel:

(1) The requirements specified in paragraph (c) of this section must be complied with;

(2) The temperature of the bagged material may not exceed 54 °C (130 °F);

(3) Minimum dunnage and sweatboards must be used to prevent any friction or abrasion of bags, and to

allow for the circulation of air and access of water in the event of fire;

(4) The bags must be stowed from side to side, out to the sweatboards;

(5) A space of 46 cm (18 inches) must be provided between any transverse bulkhead and the bags;

(6) The bags must be stowed so as to provide a 46 cm (18 inch) athwartship trench along the centerline of the compartment, continuous from top to bottom;

(7) The bags must be stowed so as to provide a 46 cm (18 inch) amidship trench running fore and aft from bulkhead to bulkhead;

(8) The bags may not be stowed less than 46 cm (18 inches) from any overhead deck beam;

(9) The bags must be stowed so as to provide vent flues 36 cm (14 inches) square at each corner of the hatch continuous from top to bottom;

(10) Trenching must be accomplished by alternating the direction of the bags in each tier (bulkheading); and

(11) The bags must be blocked and braced as necessary to prevent shifting of the bagged cargo adjacent to any trench area.

(e) Notwithstanding § 176.83(b) of this part, ammonium nitrate and ammonium nitrate fertilizers classed as Division 5.1 (oxidizers) materials, may be stowed in the same hold, compartment, magazine, or freight container with Class 1 materials (explosive), except those containing chlorates, in accordance with the segregation and separation requirements of § 176.144 of this Part applying to Explosives, blasting, type B, and Explosives, blasting, type E, Division 1.5 compatibility group D.

(f) No mixture containing ammonium nitrate and any ingredient which would accelerate the decomposition of ammonium nitrate under conditions incident to transportation may be transported by vessel.

§ 176.415 Permit requirements for Division 1.5 (blasting agents), ammonium nitrates, and certain ammonium nitrate fertilizers.

(a) Except as provided in paragraph (b) of this section, before any of the following material is loaded on or unloaded from a vessel at any waterfront facility, the carrier concerned must obtain written permission from the nearest COTP:

(1) Ammonium nitrate fertilizer, Division 1.1 (Class A explosive) compatibility group D, UN0222 or UN0223.

(2) Ammonium nitrate UN1942, ammonium nitrate fertilizers containing more than 60 percent ammonium nitrate, ammonium nitrate fertilizer, Division 5.1 (oxidizer) UN2070, or Division 1.5 (blasting agent) compatibility group D materials packaged in a paper bag, burlap bag, or other nonrigid combustible packaging, or any rigid container with combustible inside packagings.

(3) Any other ammonium nitrate or ammonium nitrate fertilizer not listed in § 176.410(a) or (b) of this subpart except ammonium nitrate fertilizer Class 9 (miscellaneous hazardous materials) material, UN2071.

(b) Any of the following may be loaded on or unloaded from a vessel at any waterfront facility without a permit:

(1) Ammonium nitrate fertilizer, Division 5.1 (oxidizer) UN1942, in a rigid container with noncombustible inside packaging.

(2) Ammonium nitrate fertilizer, Division 5.1 (oxidizer) UN2067, if the nearest COTP is notified at least 24 hours in advance of any loading or unloading or unloading in excess of 454 kg (1,000 pounds).

(3) Ammonium nitrate fertilizer, n.o.s., Division 5.1 (oxidizer) UN2072, containing 40 percent or more fine calcium carbonate or dolomite.

(4) Non-acidic ammonium nitrate fertilizer, n.o.s., Division 5.1 (oxidizer) UN2072, containing less than 5 percent organic material and 60 percent or less ammonium nitrate.

(5) Division 1.5 (blasting agents) compatibility group D materials in a rigid container with non-combustible inside packaging.

(6) Ammonium nitrate fertilizers, Class 9 (miscellaneous hazardous materials), UN2071.

(c) Before a permit may be issued, the following requirements must be met in addition to any others the COTP may require:

(1) If the material is ammonium nitrate fertilizer Division 1.1 (Class A explosive) compatibility group D, UN0222 or UN0223; ammonium nitrate fertilizer Division 5.1 (oxidizer), UN2070; or Explosives, blasting, type E, Division 1.5 (blasting agents) compatibility group D, UN0332 in combustible packaging or in a rigid container with combustible inside packaging, it must be loaded or unloaded at a facility remote from populous areas or high value or high hazard industrial facilities so that in the event of fire or explosion loss of lives and property may be minimized;

(2) If the material is ammonium nitrate fertilizer Division 1.1 (Class A explosive) compatibility group D, UN0222 or UN0223 in rigid metal drums with non-combustible inside packagings; an ammonium nitrate fertilizer, Division 5.1 (oxidizer) UN2070, containing more than 60 percent ammonium nitrate; or ammonium nitrate fertilizer, Division 5.1 (oxidizer), UN2070 in rigid containers with combustible inside packagings, it must be loaded or unloaded at a facility removed from congested areas or high value or high hazard industrial facilities;

(3) Each facility at which the material is to be loaded or unloaded must conform with the requirements of the port security and local regulations and must have an abundance of water readily available for fire fighting; and

(4) Each facility at which the material is to be loaded or unloaded must be located so that each vessel to be loaded or unloaded has an unrestricted passage to open water. Each vessel must be moored bow to seaward, and must be maintained in a mobile status during loading, unloading, or handling operations by the presence of tugs or the readiness of engines. Each vessel must have two wire towing hawsers, each having an eye splice, lowered to the water's edge, one at the bow and the other at the stern.

(5) If the material is ammonium nitrate fertilizer, Division 1.1 (Class A explosive) compatibility group D, UN0222 or UN0223; ammonium nitrate fertilizer, Division 5.1 (oxidizer) UN2070; an ammonium nitrate fertilizer, Division 5.1 (oxidizer) containing more than 60 percent ammonium nitrate; or Division 1.5 (blasting agents) compatibility group D materials in non-rigid combustible packaging and loaded in freight containers or transport vehicles, it may be loaded or unloaded at a non-isolated facility provided that facility meets the approval of the COTP.

§ 176.419 Class 4 (flammable solids) or Class 5 (oxidizers and organic peroxides) materials transported with foodstuffs.

Each package containing Class 4 (flammable solids) or Class 5 (oxidizers and organic peroxides) materials, bearing a POISON label and being transported on a vessel must be stowed separate from foodstuffs. Each package containing Class 4 (flammable solids) or Class 5 (oxidizers or organic peroxides) materials which bears a CORROSIVE or KEEP AWAY FROM FOOD label must be stowed away from foodstuffs.

38. Subpart L would be revised to read as follows:

Subpart L—Detailed Requirements for Division 2.3 (Poison A) and Division 6.1 (Poison B) Materials

§ 176.600 General stowage requirement.

(a) Each package required to have a POISON GAS or POISON label thereon being transported on a vessel must be stowed clear of living quarters and any ventilation ducts serving living quarters and separate from foodstuffs.

(b) Each package required to have both a POISON GAS label and a FLAMMABLE GAS label thereon must be segregated as a Division 2.1 (flammable gas) material.

(c) Each package required to have a KEEP AWAY FROM FOOD label must be stowed away from foodstuffs.

(d) Each package of Division 2.3 (Poison A) material or Division 6.1 (Poison B) material which also bears a FLAMMABLE LIQUID or FLAMMABLE GAS label must be stowed in a mechanically ventilated space, kept as cool as reasonably practicable, and be stowed away from all sources of heat and ignition.

§ 176.605 Care following leakage or sifting of Division 2.3 and 6.1 poisons (Poisons A or B).

A hold or compartment containing a package of Division 2.3 or 6.1 poisons (Poison A or B) which has leaked or sifted must be thoroughly cleaned and decontaminated after the cargo is unloaded and before the hold or compartment is used for the stowage of any other cargo.

39. Subpart N would be revised to read as follows:

Subpart N—Detailed Requirements for Class 8 (Corrosive Materials) Materials

§ 176.800 General stowage requirements.

(a) Each package of a Class 8 (corrosive material) material being transported on a vessel must be stowed clear of living quarters, and away from foodstuffs and cargo of an organic nature. Each package of Class 8 (corrosive material) which bears a POISON label must be stowed separate from foodstuffs.

(b) A package of Class 8 (corrosive material) material may not be stowed over any readily combustible material.

(c) Glass carboys containing Class 8 (corrosive material) material may not be stowed on board any vessel, other than a barge, more than two tiers high unless each carboy is boxed or crated with neck protection extending to the sides of the carboy box. This protective construction must be strong enough to permit stacking one on top of the other.

(d) A Class 8 (corrosive material) material may not be stowed over a hold or compartment containing cotton unless the deck is of steel and the hatch is fitted with a tight coaming. In addition, the deck must be tight against leakage and the Class 8 (corrosive material) material may not be stowed over the square of the hatch.

(e) Each package of Class 8 (corrosive material) which also bears a FLAMMABLE LIQUID label must be stowed away from all sources of heat and ignition.

§ 176.805 On deck stowage.

(a) When break bulk Class 8 (corrosive materials) materials being transported on a vessel are stowed on deck:

(1) Provisions must be made for leakage from any package to drain away from other cargo into an overboard scupper or freeing port. The drainage may not enter an enclosed drainage system other than a direct overboard scupper. If the stowage is not practical, sufficient clean dry sand must be placed under and around the lower tier of packages to absorb any leakage.

(2) Dunnage must be provided on the deck and arranged so that any leakage will be apparent.

(3) Any leakage that occurs must be washed down, using liberal quantities of water.

40. Subpart O would be revised to read as follows:

Subpart O—Detailed Requirements for Cotton and Vegetable Fibers, Motor Vehicles, and Asbestos

§ 176.900 Packaging and stowage of cotton and vegetable fibers: general.

(a) Cotton, Division 4.1, NA1365, Cotton, wet, Division 4.2, UN1365, and other vegetable fibers, Division 4.1, being transported on a vessel must be securely baled and bound. Each bale of cotton or vegetable fibers must be covered with bagging on at least three-fourths of its surface, including both ends. Cut cotton linters may be accepted for transportation by vessel when baled and covered with bagging on the soft sides only if the bale is compressed to a density of at least 512 kg/cubic meter (32 pounds per cubic foot) and it is bound with at least six bands per bale. Any poorly compressed bale or any bale having damaged bindings may not be transported by vessel.

(b) Each bale of Cotton, wet, UN1365 must be stowed separately from any bales of dry cotton or vegetable fibers, in a 'tween deck space and not overstowed. Any bale of cotton or vegetable fibers which is saturated with water may not be transported by vessel.

(c) Bales of cotton or vegetable fibers showing contact with oil or grease may not be accepted for transportation by vessel.

(d) Cotton or vegetable fibers must be stowed in a hold or compartment in accordance with the following requirements:

(1) All traces of oil or residue in the hold or compartment must be removed;

(2) A recently painted hold or compartment may not be used unless it is thoroughly dry;

(3) Each ventilation cowl serving the hold or compartment must be fitted with a spark screen;

(4) When a bulkhead of the hold or compartment is common with a boiler room, engine room, coal bunker, or galley and subjected to heat, a wooden bulkhead must be erected between the bulkhead and any cotton or vegetable fibers. This wooden bulkhead must be at least 15 cm (6 inches) from a boiler room bulkhead, and at least 5 cm (2 inches) from an engine room, coal bunker, or galley bulkhead;

(5) Each 'tween deck hatch must be closed with hatch covers, tarpaulins, and dunnage; however, metal hatch covers which are sealed by other means to provide equivalent protection may be used;

(6) Each hold or compartment must be equipped with a carbon dioxide or overhead water sprinkler system or other approved fixed extinguishing system. Before loading, the extinguishing system must be examined to ensure that it is in good working condition; and

(7) Each hold or compartment must be clear of all debris and swept as clean as practicable before loading.

(e) Naked lights or any fire likely to produce sparks are not permitted on the vessel, dock area, or on any lighters alongside a vessel during loading or unloading of cotton or vegetable fibers.

(f) Upon completion of stowage, each opening must be completely closed. Where required, tarpaulins must be fitted and secured in place to provide a tight hold. During a period of temporary stoppage of loading or unloading, a hatch may be left open. However, during that period, a fire watch, designated by the master or officer-in-charge, must be stationed in the hold or compartment in which the cotton or vegetable fibers are stowed.

(g) At least one fire hose must be connected while cotton or vegetable fibers are being loaded or unloaded. Each fire pump must be operated before any loading or unloading. Pressure must be maintained on each fire main during the loading and the fire hose laid out ready for immediate use. Portable fire extinguishers must be placed to be readily available. The fire hose, fire pumps, and fire extinguishers may be the vessel's equipment or shore equipment.

(h) Smoking is not permitted on a vessel during the loading or unloading of cotton or vegetable fibers except at those times and in those places

designated by the master or officer-in-charge. "NO SMOKING" signs must be conspicuously posted in appropriate places and the responsible person in charge of the loading or unloading (see § 176.57 of this part) must ensure that they are observed.

(i) Cotton or vegetable fibers may be stowed in the same hold over bulk sulfur if the sulfur has been trimmed and leveled and the hold is thoroughly cleaned of sulfur dust. A tight floor of two layers of 2.54 cm (1 inch) crossed clean dunnage boards must be laid on the sulfur before cotton or vegetable fibers are stowed. These substances may be stowed alongside each other in the same hold if they are separated by a tight dustproof wood bulkhead.

(j) Cotton or vegetable fibers may not be stowed in a 'tween deck hold over bulk sulfur in a lower hold unless the 'tween deck hold has been thoroughly cleaned of all sulfur dust and the 'tween deck hatch covers are in place and covered with tarpaulins and dunnage.

§ 176.901 Stowage of cotton or vegetable fibers with rosin or pitch.

(a) Unless impracticable, cotton or vegetable fibers being transported on a vessel may not be stowed in the same hold or compartment with rosin or pitch being transported on the same vessel.

(b) When separate stowage is impracticable, the cotton or vegetable fibers may be stowed in the same hold or compartment with rosin or pitch if they are separated by clean dunnage or a cargo of a non-combustible nature. When such stowage within the same hold or compartment involves large amounts of cotton or fibers or of rosin or pitch, the rosin or pitch must be floored off with at least two layers of 2.54 cm (1 inch) dunnaging and the cotton or vegetable fibers stowed above.

§ 176.903 Stowage of cotton or vegetable fibers with coal.

Cotton or vegetable fibers being transported on a vessel may not be stowed in the same hold with coal. They may be stowed in adjacent holds if the holds are separated by a tight steel bulkhead and the cotton or vegetable fibers are dunnaged at least 5 cm (2 inches) off the bulkhead. Cotton or vegetable fibers may be stowed in a hold above or below one in which coal is stowed if there is a tight steel intervening deck and all hatch covers are in place and covered with tarpaulins.

§ 176.905 Motor vehicles or mechanical equipment powered by internal combustion engines.

(a) A motor vehicle or any mechanized equipment powered by an internal combustion engine is subject to the requirements of this subchapter when carried as cargo on a vessel if the engine or fuel tank contains fuel or if either battery cable is connected. Such vehicles or equipment are excepted from the requirements of this subchapter if the following requirements are met:

(1) For a motor vehicle or mechanical equipment having an internal combustion engine using fuel classed as a flammable liquid material by this subchapter: the fuel tank is empty, the engine is run until it stalls for lack of fuel, both battery cables are disconnected, and no hazardous material is stowed in the vehicle or equipment; or

(2) For motor vehicle or mechanical equipment having an internal combustion engine using liquid fuel classed as a combustible liquid by this subchapter: the fuel tank contains 418 liters (110 gallons) of fuel or less, both battery cables are disconnected and no hazardous material is stowed in the vehicle or equipment.

(b) Before being loaded on a vessel, each vehicle must be inspected for leaks. A vehicle showing any signs of leakage may not be transported.

(c) Each vehicle stowed in a hold or compartment must have the battery cables disconnected and secured away from the battery terminals, unless it is stowed in a hold or compartment designated by the administration of the country in which the vessel is registered to be specially suited for vehicles. See 46 CFR 70.10–44 and 90.10–38 for U.S. vessels.

(d) The fuel tank of a vehicle being transported as cargo on a vessel may not be more than one-fourth full.

(e) All equipment used for handling vehicles must be designed so that the fuel tank and fuel system are protected from stress that might cause rupture or other damage incident to handling.

(f) Whenever possible each vehicle must be stowed to allow for its inspection during transit.

(g) Two hand-held, portable, dry chemical fire extinguishers of at least 4.5 kg (10 pounds) capacity each must be separately located in an accessible compartment in which any motor vehicle is stowed.

(h) "NO SMOKING" signs must be conspicuously posted at each access opening to the hold or compartment.

(i) Except when being transported in a space specially suited for vehicles, the following additional requirements apply to the stowage of any vehicles containing a flammable or combustible liquid:

(1) Each portable electrical light and hand flashlight used in the stowage area must be an approved, explosion-proof type. All electrical connections for any portable light must be made to outlets outside the space in which any vehicle is stowed:

(2) Each hold or compartment must be ventilated and fitted with an overhead water sprinkler system or fixed fire extinguishing system;

(3) Each hold or compartment must be equipped with a smoke or fire detection system; and

(4) All electrical equipment in the hold or compartment other than fixed explosion-proof lighting must be disconnected from its power source at a location outside the hold or compartment during the handling and transportation of any vehicle. Where the disconnecting means is a switch or circuit breaker, it must be locked in the open position until all vehicles have been discharged.

(j) Motor vehicles may be refueled when necessary in the hold of a vessel in accordance with § 176.78.

(k) Motor vehicles with fuel in their tanks may be stowed in a closed freight container if the battery cables are disconnected and secured away from the battery terminals and the following warning is affixed to the access doors: "WARNING—MAY CONTAIN EXPLOSIVE MIXTURES WITH AIR—KEEP IGNITION SOURCES AWAY WHEN OPENING." The warning must be on a contrasting background and must be readily legible from a distance of 8 meters (26 feet).

§ 176.906 Stowage and handling of asbestos.

Asbestos must be stowed, handled, and unloaded, and any asbestos contamination of vessels removed, in a manner that will minimize exposure of personnel to airborne asbestos particles released incident to transportation.

Issued in Washington, DC, on May 4, 1990, under authority delegated in 49 CFR part 106, appendix A.

Alan I. Roberts,

Director, Office of Hazardous Materials Transportation.

[FR Doc. 90–10974 Filed 5–18–90; 8:45 am]

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federal register

Monday
May 21, 1990

Part IV

Department of Transportation

Coast Guard

Research and Special Programs Administration

46 CFR Part 146

Transportation of Military Explosives by Vessel; Revocation of CFR Part; Notice of Proposed Rulemaking

DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Part 146

Research and Special Programs Administration

[Docket No. HM-204A; Notice No. 90-7]

RIN 2137-AA10

Transportation of Military Explosives by Vessel; Revocation of CFR Part

AGENCY: United States Coast Guard (USCG) and Research and Special Programs Administration (RSPA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The USCG and RSPA propose to revoke 46 CFR part 146 which contains requirements for the transportation and stowage of military explosives on board vessels. This action is being done concurrently with a separate notice of proposed rulemaking under RSPA Docket HM-204, Notice 90-6, which appears elsewhere in today's Federal Register. This revocation would eliminate outdated requirements and requirements which overlap or conflict with the proposals in Docket HM-204.

DATES: Comments must be received on or before July 16, 1990.

ADDRESSES: Written comments should be submitted to the Dockets Unit, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590-0001. Comments should identify the docket number and should be submitted, if possible, in five copies. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the docket number (i.e., Docket HM-204A). The Dockets Unit is located in Room 8421 of the Nassif Building, 400 Seventh Street SW., Washington, DC 20590-0001. The public docket may be reviewed between the hours of 8:30 a.m. and 5 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Carl V. Strombom, Standards Division, Office of Hazardous Materials Transportation, RSPA, Department of Transportation, 400 Seventh Street, SW, Washington, DC 20590-0001, telephone (202) 366-4488, or Mr. Frank K. Thompson, Office of Marine Safety, Security, and Environmental Protection, (G-MTH-1), U.S. Coast Guard Headquarters, 2100 Second Street SW, Washington, DC 20593-0001, telephone (202) 267-1577.

SUPPLEMENTARY INFORMATION:

I. Background Information

In a separate document in this issue of the Federal Register, RSPA has published a notice of proposed rulemaking (NPRM) concerning the carriage of hazardous materials by vessel (Docket No. HM-204; Notice No. 90-6). Docket HM-204 proposes to revise requirements currently found in 46 CFR part 146 concerning the transportation of military explosives by vessel, and to relocate them in 49 CFR part 176. Docket HM-204 also proposes editorial changes to 49 CFR part 176 to align the hazard class nomenclature and units of measure with proposals made under Docket HM-181, Notice 87-4 (52 FR 16482; November 11, 1987). Docket HM-181, Notice 87-4 proposed to revise provisions in the Hazardous Materials Regulations (HMR) pertaining to hazard classification, hazard communication, and packaging to, among other purposes, harmonize requirements of the HMR with international standards based on the United Nations Committee of Experts Recommendations on the Transport of Dangerous Goods (U.N. Recommendations).

At present, two separate sets of Federal regulations govern the transportation of explosives by vessel in U.S. waters. The regulations applying to the transportation of "military" explosives are in 46 CFR part 146, while the regulations for all other types of explosives are in 49 CFR subchapter C. The only significant distinction between "military" and other explosives is in their end-use; the existence of two essentially overlapping sets of regulations is of historical, rather than technical or legal, origin.

The responsibility for regulating the shipment of hazardous materials by all modes of transportation has been delegated to the Administrator of RSPA, except for the authority governing the shipment of bulk hazardous materials by water, which is delegated to the Commandant, U.S. Coast Guard. Military explosives are not shipped as bulk commodities in the same sense of the term " bulk" elsewhere in the title 46 regulations. The term "explosives in bulk" defined in 46 CFR 146.29-11(a)(2) applies only to certain classes of military explosives in any package or container, except "made-up" ammunition devices such as bombs, grenades, and cartridges. With the proposed transfer of the military explosives regulations to title 49, this definition would no longer have any significance and would be removed.

In 1974, hazardous material regulations applying to packaged materials transported by vessel, including those regulations applicable to explosives other than military explosives, were revised and relocated from 46 CFR to 49 CFR, chapter 1, subchapter C (i.e., the HMR). The regulations governing military explosives which remain in 46 overlap and, in some areas, conflict with the explosives regulations in the HMR. The existence of two sets of regulations, either of which could apply to the shipment of military explosives, causes shippers to be confused about which rules they must follow.

RSPA, with the cooperation and assistance of the Hazardous Materials Branch of the Marine Technical and Hazardous Materials Division, USCG, is now proposing to consolidate requirements for military explosives with those applicable to other explosives. The proposed consolidation would make the present military explosives regulations in 46 CFR part 146 unnecessary.

The present USCG stowage classification system set forth in 46 CFR 146.29-100 would not be carried over into the proposed revision of 49 CFR part 176. Under these proposed rules, all explosives and other hazardous materials would be classified according to the classification system proposed in Docket HM-181A, Notice 90-5 (55 FR 18438), which is based on the U.N. Recommendations. When transported by vessel, explosives would be stowed and segregated according to their "hazard class and division" (i.e., Class 1, Division 1.1, 1.2, etc.) and "compatibility group" (i.e., A, B, C, D, etc.). The U.N. system is in nearly universal use outside the United States and has been adopted by the U.S. Department of Defense for the storage of explosives at ammunition depots and for other non-transportation applications.

Docket HM-181A, Notice 90-5 proposed significant changes to the explosive classification system currently in use in the HMR. Because of the proposals in Docket HM-181A, Notice 90-5 and Docket 204, Notice 90-6, the current USCG classification system in 46 CFR part 146 is no longer necessary and would be revoked.

The following table lists each section of present 46 CFR part 146 and the provision(s) of 49 CFR chapter I, subchapter C by which it would be replaced. In the table, "new" preceding a 49 CFR entry indicates that provision does not appear in the HMR at present; "revised" means that a provision in the present HMR would be modified in consequence of the adoption of the new provisions; and "existing" indicates the 46 CFR section would be replaced by a

current section of the HMR that has not been modified by proposals in Docket HM–204 or Docket HM–181A. Certain requirements of part 146 are no longer necessary; these are indicated in the table by "not replaced". Section numbers followed by HM–181A in parentheses indicate that the new section does not appear in the present HMR but is being proposed by Docket HM–181A. As indicated, one provision of Part 46 would be replaced by an existing provision of 33 CFR.

46 CFR	49 CFR
Subpart 146.01	
146.01–1	Existing 176.1
146.01–3	Not replaced
Subpart 146.02	
146.02–1	Existing 176.1
146.02–2	Existing 176.5
146.02–5	Existing 176.13
146.02–6	Existing 176.15
146.02–6a	Existing 176.18
146.02–12	Existing 176.39
146.02–14	Existing 176.50
146.02–15	Existing 176.45
146.02–16	Existing 176.52
146.02–20	Revised 176.54
146.02–22	Existing 176.36
146.02–25	Existing 176.31, Existing 176.65
146.02–35	Existing 176.48
Subpart 146.05	
146.05–1	Existing 171.2
146.05–3	Existing 173.21
146.05–11	Existing 176.27
146.05–12	Existing 176.24
146.05–15	Existing 171.2
Subpart 146.09	
146.09–7	Not replaced
146.09–8	Not replaced
146.09–11	New 176.104
146.09–15	Revised 176.78
146.09–16	Existing 176.79
Subpart 146.20	
146.20–1	New 173.50 (HM–181A)
146.20–3	New 173.54 (HM–181A); formerly existing 173.51
146.20–5	New 173.50 and new 173.52 (HM–181A)
146.20–7	New 173.50 and new 173.52 (HM–181A)
146.20–9	New 173.50 and new 173.52 (HM–181A)
146.20–11	New 173.50 and new 173.52 (HM–181A)
146.20–13	New 173.56 (HM–181A); formerly existing 173.86
146.20–53	New 176.194; formerly existing 173.177
Subpart 146.29	
146.29–1	Not replaced
146.29–3	Not replaced
146.29–7	Revised 176.4, new 176.162
146.29–9	Existing 176.12, revised 176.11
146.29–11	New 173.59 (HM–181A), new 176.2, new 176.172
146.29–13	Revised 176.100
146.29–14	Existing 176.30
146.29–15	33 CFR 126.16
146.29–17	Revised 176.3, new 176.166
146.29–19	New 176.102
146.29–21	New 176.162
146.29–23	New 176.108, new 176.118
146.29–25	New 176.150, new 176.154, new 176.164, new 176.176, new 176.178
146.29–27	New 176.164
146.29–29	Existing 176.60, new 176.182(g)
146.29–31	New 176.182(f)
146.29–33	New 176.104, new 176.192
146.29–35	New 176.148
146.29–37	Not replaced
146.29–39	New 176.104
146.29–41	Not replaced
146.29–42	Revised 176.76, new 176.170, new 176.172
146.29–43	Not replaced
146.29–45	New 176.104
146.29–47	Existing 172.301, new 173.60 (HM–181A)
146.29–49	Existing 176.95 through 176.99, new 176.104
146.29–51	Revised 176.83, new 176.112
146.29–53	New 176.140, new 176.194
146.29–55	New 176.146
146.29–57	New 176.138
146.29–59	Revised 176.83, new 176.140, new 176.142
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146.29–89	New 176.128, new 176.136, new 176.137, new 176.138
146.29–90	New 176.170
146.29–91	Revised 176.84(c)
146.29–93	Revised 176.84(c), new 176.144
146.29–95	New 176.116
146.29–97	Revised 176.53, new 173.59 (HM–181A), new 176.116
146.29–99	New 176.144
146.29–100	New 173.51, revised 176.83

II. Administrative Notices

A. Paperwork Reduction Act

This proposed rulemaking contains no information collection requirements.

B. Regulatory Flexibility Act

RSPA is aware that the amendments proposed in this NPRM may produce an economic impact on industry segments, a number of which may be small enterprises. These enterprises may include hazardous materials shippers, carriers, terminal operators, vessel operators, and other transportation organizations that have small numbers of employees and limited gross revenues. Based on limited information concerning the size and nature of entities likely to be affected by this proposed rule, I certify that the regulations proposed within would not, if promulgated, have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

C. Executive Order 12612

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism assessment. This proposal has no substantial direct impact on the States, on the Federal-State relationship, or on the distribution of power and responsibilities among levels of government. Therefore, this proposed rulemaking contains no policies with Federalism implications as defined in Executive Order 12612.

D. Executive Order 12291

RSPA has determined that this rulemaking: (1) Is not "major" under Executive Order 12291; (2) is not "significant" under DOT's regulatory policies and procedures (44 FR 11034); (3) will not affect not-for-profit enterprises or small governmental jurisdictions; and (4) does not require an environmental impact statement under the National Environmental Policy Act (40 U.S.C. 4321 *et seq.*). Since the only purpose of this proposed rulemaking is to inform interested readers of the revocation of regulations in 46 CFR part 146 and their transfer to 49 CFR part 176, RSPA has determined that a regulatory evaluation is not necessary because the anticipated impact of the proposals in this notice would be minimal.

List of Subjects

46 CFR Part 146

Arms and munitions, Hazardous materials transportation, Labeling, Marine safety, Packaging and containers, Vessels.

In consideration of the foregoing, the U.S. Coast Guard and the Research and Special Programs Administration propose to revoke part 146 of Title 46, Code of Federal Regulations.

Issued in Washington, DC on May 4, 1990, under authority delegated in 49 CFR part 106, appendix A.

Alan I. Roberts,

Director, Office of Hazardous Materials Transportation.

[FR Doc. 90–10973 Filed 5–18–90; 8:45 am]

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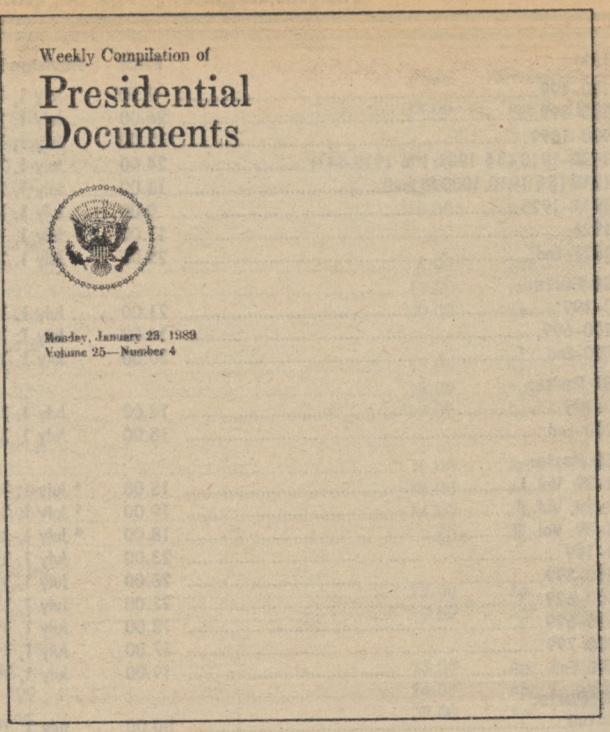
[4] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

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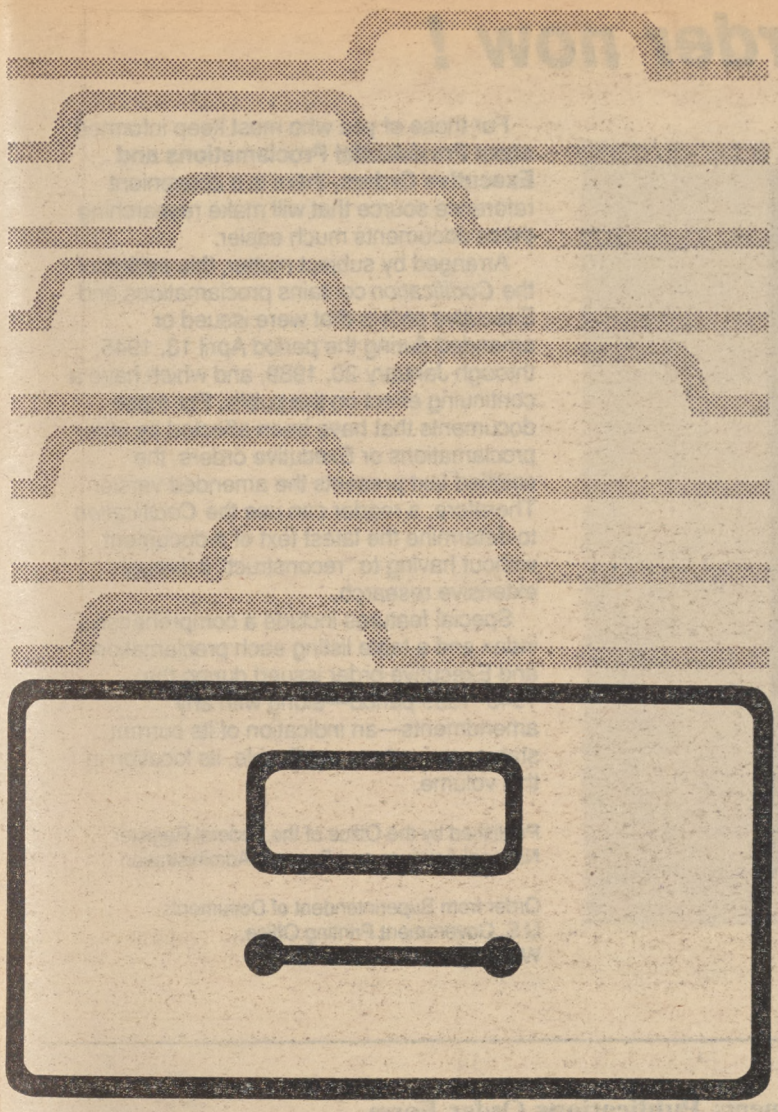
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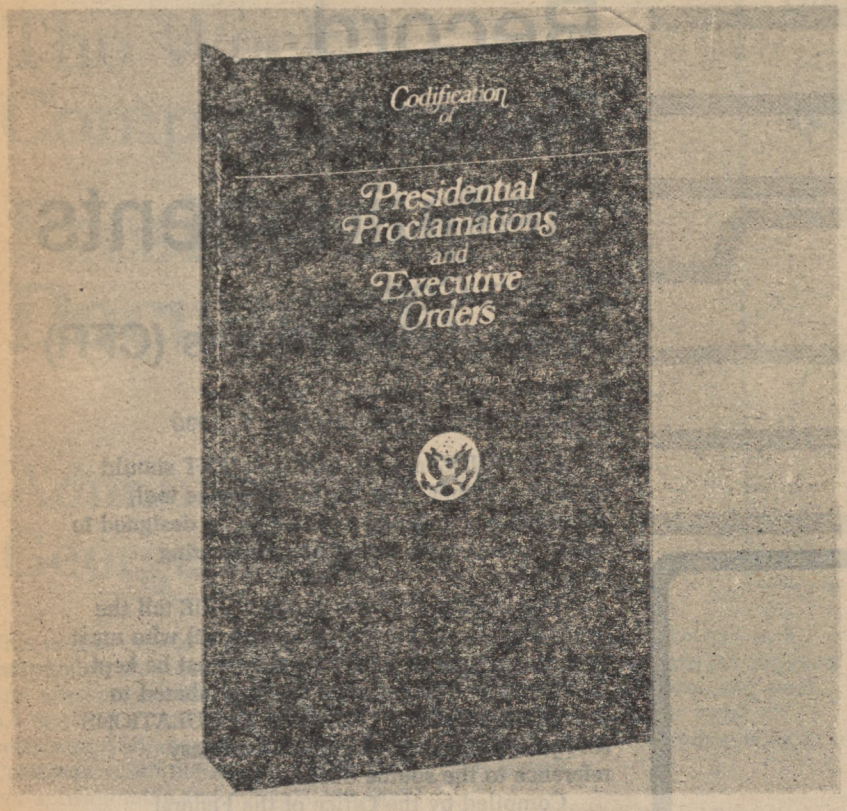
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