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[Two Sessions]

WHEN: October 17 at 9:00 am and 1:30 pm

WHERE: Office of the Federal Register Conference Room, 800 North Capitol Street NW., Washington, DC (3 blocks north of Union Station Metro)

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Presidential Documents

Title 3—

The President

Proclamation 6828 of October 2, 1995

Child Health Day, 1995

By the President of the United States of America

A Proclamation

In hospitals and homes across the country, children begin life free from the burdens of the world. With their eyes and minds open to every influence, they depend on their caregivers to help them take the first, tentative steps toward adulthood. Parents and other family members, communities and churches, educators and the media—all play a role in these crucial early years, providing young people with the direction they need to become happy, productive citizens.

Tragically, far too many children go without this essential love and guidance, living in homes, neighborhoods, and schools where they see and endure violence. One in five pregnant women is abused by her partner; millions of children each year are reported to public social service agencies as being neglected or abused; and in the decade between 1982 and 1992, the number of these reports increased 132 percent. We know that young men and women suffer lasting effects from such experiences—teen suicides have tripled in the last 35 years, and countless youth have grown up to continue the cycle of destructive behavior in their own relationships and families.

In recognition of these heartbreaking realities, the theme of Child Health Day, 1995, is the elimination of violence. As our Nation observes this special day, let us renew our commitment to America's children and rededicate ourselves to ending the physical and emotional mistreatment that damage self-esteem and well-being. Solutions to the plague of violence lie within our own society, and we can find hope in the partnerships forming among public health and mental health professionals, schools, law enforcement officers, religious groups, child care experts, and community leaders. Their efforts, aided by the extensive Federal network already in place, will help to strengthen families and instill in our young people the ambition and spirit that has always driven America forward.

To emphasize the importance of nurturing children's growth and development from birth to maturity, the Congress, by joint resolution approved May 18, 1928, as amended (36 U.S.C. 143), has called for the designation of the first Monday in October as ''Child Health Day'' and has requested the President to issue a proclamation in observance of this day.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim Monday, October 2, 1995, as Child Health Day. On this day, and on every day throughout the year, I call upon my fellow Americans to deepen their commitment to protecting children, taking the necessary steps to meet our obligations to them and to our Nation's future.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of October, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.

William J. Clinton

[FR Doc. 95–24828
Filed 10–2–95; 2:58 pm]
Billing code 3195–01–P

Presidential Documents

Proclamation 6829 of October 2, 1995

National Domestic Violence Awareness Month, 1995

By the President of the United States of America

A Proclamation

Domestic violence disrupts communities, destroys relationships, and harms hundreds of thousands of Americans each year. It is a serious crime that takes many forms and a complex problem with multiple causes. Those abused can be children, siblings, spouses, or parents, and both victims and offenders come from all racial, social, religious, ethnic, and economic backgrounds. Among the most tragic effects of family violence is the cycle of abuse perpetuated by children and teenagers who see and experience brutality at home—these young people often lack crucial guidance to help them form strong, positive bonds of kinship.

Americans are fortunate that knowledge about domestic violence has increased and that public interest in deterrence is stronger than ever. During the past decade, vital partnerships have formed between Federal agencies and private-sector organizations to expand prevention services in urban, rural, and underserved areas across the country. These efforts have helped to coordinate aid for victims and their children—not only providing shelter, but also furnishing alcohol and drug abuse treatment, child care, and counseling. In addition, I am proud that the Violent Crime Control and Law Enforcement Act of 1994 contains tough new sanctions and includes a provision for a national ''hot line'' where victims can receive information and assistance.

But the struggle to end domestic violence is far from over. According to a recent Justice Department study for 1992 and 1993, women were about six times more likely than men to experience violence committed by offenders with whom they had an intimate relationship. And in 1992, nearly 30 percent of all female homicide victims were known to have been killed by husbands, former husbands, or boyfriends. We need more prevention campaigns and public awareness efforts; we must develop and share successful methods of prevention, intervention, and treatment for victims and perpetrators; and we must continue to build alliances among government, community associations, businesses, educators, and religious organizations to strengthen our families and to teach alternatives to violent behavior.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim October 1995, as ''National Domestic Violence Awareness Month.'' I call upon government officials, law enforcement agencies, health professionals, educators, and the people of the United States to join together to end the family violence that threatens so many citizens. I further encourage all Americans to recognize the dedication of those working to end the horrors of abuse. Offering support, guidance, encouragement, and compassion to survivors, these caring individuals exemplify our Nation's highest ideals of service and citizenship.

IN WITNESS WHEREOF, I have hereunto set my hand this second day of October, in the year of our Lord nineteen hundred and ninety-five, and of the Independence of the United States of America the two hundred and twentieth.

William J. Clinton

[FR Doc. 95–24829
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Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AG93

Prevailing Rate Systems; Redefinition of Guaynabo-San Jaun, PR, Nonappropriated Fund Wage Area

AGENCY: Office of Personnel Management.

ACTION: Interim rule with request for comments.

SUMMARY: The Office of Personnel Management is issuing interim regulations to redefine the Guaynabo-San Juan, Puerto Rico, nonappropriated fund Federal Wage System wage area by adding Salinas Municipality as an area of application for pay-setting purposes. No employee's wage rate will be reduced as a result of this change.

DATES: This interim rule becomes effective on October 4, 1995.

Comments must be received by November 3, 1995.

ADDRESSES: Send or deliver comments to Donald J. Winstead, Assistant Director for Compensation Policy, Human Resources Systems Services, U.S. Office of Personnel Management, Room 6H31, 1900 E Street NW., Washington, DC 20415, or FAX: (202) 606–0824.

FOR FURTHER INFORMATION CONTACT: Paul Shields, (202) 606–2848.

SUPPLEMENTARY INFORMATION: The Department of Defense (DOD) notified the Office of Personnel Management (OPM) that the Camp Santiago Army and Air Force Exchange Service employs nine Federal Wage System (FWS) nonappropriated fund (NAF) workers in Salinas Municipality, Puerto Rico. With the consensus approval of the DOD Wage Committee, DOD recommended that Salinas Municipality be added to the area of application of the Guaynabo-San Juan, Puerto Rico, NAF wage area.

Salinas Municipality is not presently defined to a wage area for NAF pay-setting purposes and does not meet the regulatory criteria for establishing a new NAF wage area under 5 CFR 532.219. Thus, Salinas Municipality must be defined as an area of application to an existing wage area.

There is only one NAF wage area for Puerto Rico and the U.S. Virgin Islands—the Guaynabo-San Juan, Puerto Rico, NAF wage area. It currently has two survey municipalities in Puerto Rico and an area of application made up to six Puerto Rico municipalities and two islands of the U.S. Virgin Islands. There are no alternative NAF wage areas to which Salinas Municipality could be defined, given the large separation between the island of Puerto Rico and mainland NAF wage areas. With this change, the wage rates of the nine NAF employees covered would continue to be set using the Guaynabo-San Juan wage schedule.

The Federal Prevailing Rate Advisory Committee reviewed this recommendation and by consensus recommended approval.

Pursuant to 5 U.S.C. 553(b)(3)(B), I find that good cause exists for waiving the general notice of proposed rulemaking. Also, pursuant to section 553(d)(3) of title 5, United States Code, I find that good cause exists for making this rule effective in less than 30 days. The notice is being waived and the regulation is being made effective in less than 30 days so that the positions of these employees will be included within an FWS wage area and appropriate wage rates authorized for their pay.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

U.S. Office of Personnel Management.

Lorraine A. Green,

Deputy Director.

Accordingly, OPM is amending 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Appendix D to Subpart B of Part 532 [Amended]

2. Appendix D to subpart B is amended by revising the list for Guaynabo-San Juan, Puerto Rico, to read as follows:

Appendix D to Subpart B of Part 532—Nonappropriated Fund Wage and Survey Areas

* * * * *

Puerto Rico

Guaynabo-San Juan

Survey area

Puerto Rico: (municipalities)
  Guaynabo
  San Juan

Area of application. Survey area plus:

Puerto Rico: (municipalities)
  Aguadilla
  Isabela
  Ponce
  Salinas
  Toa Baja
  Ceiba
  Vieques
U.S. Virgin Islands:
  St. Croix
  St. Thomas

* * * * *

[FR Doc. 95–24637 Filed 10–3–95; 8:45 am]

BILLING CODE 6325–01–M

5 CFR Parts 870, 871, 872, and 874

RIN 3206–AG68

Federal Employees' Group Life Insurance Program: Assignment of Life Insurance

AGENCY: Office of Personnel Management.

ACTION: Interim regulations with request for comments.

SUMMARY: The Office of Personnel Management (OPM) is issuing interim regulations to implement section 4 of Public Law 103–336, which amended the Federal Employees' Group Life Insurance (FEGLI) law to provide that all Federal employees and former employees could irrevocably assign ownership of their life insurance coverage to someone else. Previously, only judges could assign ownership of their insurance.

DATES: These interim regulations are effective November 3, 1995. Comments must be received on or before November 3, 1995.

ADDRESSES: Send written comments to Lucretia F. Myers, Assistant Director for Insurance Programs, Retirement and Insurance Service, Office of Personnel Management, P.O. Box 57, Washington, DC 20044: or deliver to OPM, Room 3451, 1900 E Street NW., Washington, DC; or FAX to (202) 606–0633.

FOR FURTHER INFORMATION CONTACT: Margaret Sears (202) 606–0004.

SUPPLEMENTARY INFORMATION: Public Law 103–336, enacted October 3, 1994, amended the FEGLI law to provide that all insured Federal employees and former employees may irrevocably assign ownership of their FEGLI coverage to someone else. Previously, the right to assign ownership was limited to judges. These interim regulations amend current regulations to expand their application to all insured Federal employees, annuitants, and compensationers. In addition, the interim regulations address issues that affect employees, annuitants, or compensationers, but do not affect judges.

Under these interim regulations, insured persons may irrevocably assign their life insurance coverage, except for accidental dismemberment insurance and family optional insurance, to one or more individuals, corporations, or trustees. When a person has more than one type of assignable insurance (for example, basic life insurance, standard optional insurance, and additional optional insurance) he or she must assign all of the insurance, not just a portion of it. The insured person may assign ownership to more than one individual, corporation, or trustee. In making an assignment to multiple assignees, the insured person must specify the percentage of the total value of the insurance that is to be owned by each assignee.

An insured person who elects a Living Benefit cannot assign the balance of his or her insurance, nor can an insured person who assigns his or her insurance elect a Living Benefit.

When the assignment is made, the assignee assumes most of the rights related to the insurance, including the right to cancel all insurance, to cancel or reduce optional insurance, to designate beneficiaries, and to convert the insurance to a private policy when the FEGLI coverage terminates for a reason other than cancellation. The insured person retains the right to increase coverage, but cannot reduce or cancel it.

An assignment automatically cancels any designation of beneficiary the insured person might have made, and the insured person no longer has the right to designate a beneficiary. Instead, the assignee assumes the right to designate beneficiaries. Although the assignee is automatically the beneficiary if he or she does not designate a beneficiary, the assignee may designate himself or herself as beneficiary and name another person as contingent beneficiary to receive the insurance benefits if the assignee dies before the insured person. If the assignee does not designate a contingent beneficiary and dies before the insured person, the life insurance is payable to the deceased assignee's estate when the insured person dies. Reopening the deceased assignee's estate years after the assignee's death can cause difficulties for the heirs. By naming a contingent beneficiary, the assignee can simplify payment of the life insurance.

Previously, the regulations permitted legally appointed guardians of assignees to designate beneficiaries on behalf of the assignee. We have discontinued this provision in the interim regulations in order to conform to the regulations applicable to designations of beneficiary made by Federal employees and annuitants (5 CFR 870.902). These regulations do not provide for designations of beneficiary made by legally appointed guardians on behalf of Federal employees and annuitants.

Under the FEGLI law, an employee who retires or receives compensation from the Office of Workers' Compensation Programs and meets certain length-of-participation requirements may continue life insurance coverage as an annuitant or compensationer unless he or she converts it to a private policy. These interim regulations provide that, if the employee had assigned the insurance, the assignee assumes the right to convert the insurance when the insured employee becomes an annuitant or compensationer. If there are multiple assignees, some may choose to convert and some may choose to allow the insurance to continue while the insured person is receiving annuity or compensation payments. In this case, the amount each assignee can convert is determined by the assignee's share of the total value of the insurance. However, the amount of each type of insurance continued is determined by the total percentage of the shares of the assignees who choose continued coverage. For example, if two assignees, each having a 25 percent share in the ownership of the total insurance amount consisting of basic life and standard optional, chose to continue coverage while the other assignees chose to convert, 50 percent of the value of the basic life and 50 percent of the value of the standard optional would be continued. Although the assignees own a share of the total value of the insurance, it is necessary to distinguish between the types of insurance in order to apply premiums and reduction factors during retirement.

An insured person who retires or receives compensation under circumstances that allow continued life insurance coverage retains the right, at the time of retirement, to choose to maintain more than the minimum post-retirement basic life insurance coverage than is provided through the 75 percent reduction after age 65. That is, when a retiree reaches age 65, basic life insurance begins to reduce at a rate of 2 percent per month until it reaches 25 percent of its value at the time the person retired (a 75 percent reduction) unless, at the time of retirement, the person chose to pay an extra premium for a reduction of only 50 percent or no reduction at all. Compensationers' basic life insurance is affected in the same way and they have the same opportunity to elect more that the minimum post-retirement basic life insurance coverage. Assignees cannot make the initial election of a lesser reduction, but if the insured person elects 50 percent or no reduction, the assignee can later cancel that election. When an election of 50 percent or no reduction is cancelled, the reduction percentage reverts to 75 percent.

After making an assignment, the insured person continues to pay the premiums for the insurance through withholdings from pay, annuity, or compensation. However, if the insured person is retired under the Federal Employees Retirement System and the annuity is too small to cover the premiums, either the insured person or the assignee(s) may pay the premiums directly to the retirement system.

FEGLI insurance terminates when an employee separates from his or her position, at the end of 12 months in nonpay status, or when the employee is transferred to a position in which he or

she is not eligible for life insurance coverage. The employee then has a 31-day temporary extension of coverage during which he or she can convert to an individual policy. If the employee has assigned ownership of the insurance, the assignee, not the employee, has the right to convert the insurance to an individual policy on the employee's life. When there are multiple assignees, each assignee can independently convert his or her share of the total insurance amount.

The assignment itself terminates 31 days after the insurance terminates unless the employee returns to a position in which the life insurance resumes before the 31-day period expires. If the employee returns to such a position after the 31-day period, the assignment does not resume. To assign ownership of the life insurance acquired with the new employment, the employee must again execute an assignment form.

In the FEGLI Program, when an annuitant is reemployed in the Federal service in a position in which he or she continues to receive the annuity and is eligible for life insurance coverage, any basic life insurance, standard optional insurance, and family optional insurance the person has as an annuitant is suspended and the person becomes covered as an employee. The additional optional insurance the person has as an annuitant remains in force unless the person chooses to have the coverage as an employee instead. The interim regulations provide that a reemployed annuitant who had previously assigned ownership of his or her life insurance retains the right to make the election concerning the additional optional insurance; however, all insurance the person has, whether as an annuitant or as an employee, is subject to the existing assignment.

Waiver of Notice of Proposed Rulemaking

Pursuant to section 553(b)(3)(B) of title 5 of the U.S. Code, I find that good cause exists for waiving the general notice of rulemaking because these regulations implement Section 4 of Public Law 103–336, which was effective October 3, 1994. Employees and employing offices need to have these regulations in place as soon as possible. Therefore, it is in the public interest not to issue proposed regulations.

Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because they primarily affect Federal employees, annuitants, and compensationers.

List of Subjects

5 CFR Part 870

Administrative practice and procedure, Government employees, Hostages, Iraq, Kuwait, Lebanon, Life insurance, Retirement.

5 CFR Parts 871 and 872

Administrative practice and procedure, Government employees, Life insurance, Retirement.

5 CFR Part 874

Government employees, Life insurance, Retirement.

Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM is amending 5 CFR parts 870, 871, 872, and 874 as follows:

PART 870—BASIC LIFE INSURANCE

1. The authority citation for part 870 continues to read as follows:

Authority: 5 U.S.C. 8716; § 870.202(c) also issued under 5 U.S.C. 7701(b)(2); subpart J also issued under sec. 599C of Pub. L. 101–513, 104 Stat. 2064, as amended.

2. In § 870.601, paragraph (g) is added to read as follows:

§ 870.601 Eligibility for life insurance.

* * * * *

(g) Judges retiring under 28 U.S.C. 371 (a) and (b), 28 U.S.C. 372(a), and 26 U.S.C. 7447 are considered employees under the Federal Employees' Group Life Insurance law. Insurance for these judges continues without interruption or diminution upon retirement.

3. In § 870.701, paragraph (e) is added to read as follows:

§ 870.701 Eligibility for life insurance.

* * * * *

(e) Judges retiring under 28 U.S.C. 371 (a) and (b), 28 U.S.C. 372(a), and 26 U.S.C. 7447 are considered employees under the Federal Employees' Group Life Insurance law. Insurance for these judges continues without interruption or diminution upon retirement. The amount of basic insurance for a judge who elects to receive compensation in lieu of annuity is computed in accordance with § 870.702 of this part.

4. In § 870.801, paragraph (a) is revised to read as follows:

§ 870.801 Assignments.

(a) An insured individual may irrevocably assign ownership of his or her life insurance coverage to one or more individuals, corporations, or trustees. Part 874 of this chapter describes how an insured individual may assign all incidents of ownership (except family optional insurance and accidental dismemberment insurance) to another person, corporation, or trustee. Part 874 also describes the effects of such assignment, procedures for making an assignment, and related matters.

* * * * *

PART 871—STANDARD OPTIONAL LIFE INSURANCE

1. The authority citation for part 871 continues to read as follows:

Authority: 5 U.S.C. 8716.

2. Section 871.701 is revised to read as follows:

§ 871.701 Assignments.

An insured individual may irrevocably assign ownership of his or her life insurance coverage to one or more individuals, corporations, or trustees. Part 874 of this chapter describes how an insured individual may assign all incidents of ownership (except family optional insurance and accidental dismemberment insurance) to another person, corporation, or trustee. Part 874 also describes the effects of such assignment, procedures for making an assignment, and related matters.

PART 872—ADDITIONAL OPTIONAL LIFE INSURANCE

1. The authority citation for part 872 continues to read as follows:

Authority: 5 U.S.C. 8716.

2. Section § 872.701 is revised to read as follows:

§ 872.701 Assignments.

An insured individual may irrevocably assign ownership of his or her life insurance coverage to one or more individuals, corporations, or trustees. Part 874 of this chapter describes how an insured individual may assign all incidents of ownership (except family optional insurance and accidental dismemberment insurance) to another person, corporation, or trustee. Part 874 also describes the effects of such assignment, procedures for making an assignment, and related matters.

PART 874—ASSIGNMENT OF LIFE INSURANCE

Part 874 is revised to read as follows:

Subpart A—Definitions of Terms

Sec.
874.101 Definitions.

Subpart B—Coverage

874.201 Assignments permitted.
874.202 Rights of the assignee.
874.203 Rights of the insured individual after assignment.

Subpart C—Assignment Procedures

874.301 Making an assignment.
874.302 Effective date of the assignment.
874.303 Notification of current address.
874.304 Reconsideration.

Subpart D—Amount of Insurance and Withholdings and Contributions

874.401 Amount of Insurance.
874.402 Withholdings and contributions.

Subpart E—Termination and Conversion

874.501 Termination.
874.502 Eligibility to convert.
874.503 Rates for converted insurance.
874.504 Notification of conversion rights.

Subpart F—Designations of Beneficiary

874.601 Designations and changes of beneficiary.

Subpart G—Annuitants and Compensationers

874.701 Annuitants and compensationers.
874.702 Reemployed annuitants.

Authority: 5 U.S.C. 8716.

Subpart A—Definitions of Terms

§ 874.101 Definitions.

The terms defined under § 870.104 of this chapter have the same meanings in this part.

Subpart B—Coverage

§ 874.201 Assignments permitted.

(a) An insured individual may irrevocably assign ownership of life insurance coverage to one or more individuals, corporations, or trustees. An insured individual may assign ownership of basic life insurance, standard optional life insurance, and additional optional life insurance coverage, but may not assign ownership of family optional insurance or accidental dismemberment coverage. If an insured individual owns more than one assignable type of insurance, he or she must assign all the assignable insurance. An insured individual cannot assign only a portion of assignable insurance.

(b) An insured individual may not name contingent assignees in case the primary assignee dies before the insured individual.

(c) If the insurance is assigned to two or more individuals, corporations, or trustees, the insured individual must specify percentage shares, rather than dollar amounts or types of insurance, to go to each assignee.

(d) Once assigned, the value of the insurance increases or decreases according to any automatic increase or decrease in the value of the coverage as provided for in parts 870, 871, and 872 of this chapter.

(e) An insured individual who has elected a Living Benefit under subpart K of part 870 of this chapter may not assign his or her insurance coverage and an insured individual who has assigned his or her insurance coverage may not elect a Living Benefit.

§ 874.202 Rights of the assignee.

(a) An insured individual who assigns ownership of insurance continues to be the insured individual, but the assignee assumes the rights of an insured individual, except as provided in § 874.203 of this part.

(b) The assignee assumes all rights to waive or decline insurance under this chapter according to the provisions of §§ 870.204, 871.204, and 872.204 of this chapter. When the insurance is assigned to two or more individuals, corporations, or trustees, all assignees must agree to waive or decline the insurance. A waiver of the basic insurance in accordance with the provisions of § 870.204 of this chapter terminates all insurance under this chapter and terminates the assignment under this part.

(c) The assignee may not elect a Living Benefit under subpart K of part 870 of this chapter.

(d) The right of the assignee to designate beneficiaries is set forth in subpart F of this part.

(e) The rights of the assignee when the insured individual retires or becomes a compensationer are set forth in subpart G of this part.

§ 874.203 Rights of the insured individual after assignment.

(a) The right to increase insurance coverage remains with the insured individual and does not transfer to the assignee. If the insured individual who has made an assignment later elects increased insurance under § 871.205 or § 872.205 of this chapter, or during an open enrollment period, the increased insurance is considered covered by the existing assignment.

(b) The rights of an insured individual who assigns his or her life insurance and later retires are set forth in subpart G of this part.

Subpart C—Assignment Procedures

§ 874.301 Making an assignment.

To assign insurance, the insured individual must complete and submit to the employing office a signed and witnessed assignment form (RI 76–10) indicating the intent to irrevocably assign all assignable incidents of ownership in the insurance.

§ 874.302 Effective date of the assignment.

An assignment under this part is effective on the date the employing office receives the properly completed, signed, and witnessed assignment form.

§ 874.303 Notification of current address.

Each assignee is responsible for keeping the insured individual's employing office advised of his or her current address.

§ 874.304 Reconsideration.

An insured individual or an assignee may request the employing agency to reconsider an employing office's initial determination denying an entitlement related to assignments. The rules and procedures under §§ 870.102 and 870.103 are applicable to this part, subject to the withholdings and contributions under § 874.402 of this part.

Subpart D—Amount of Insurance and Withholdings and Contributions

§ 874.401 Amount of insurance.

The amount of insurance is based on the insured individual's basic pay as specified in subpart C of parts 870, 871, and 872 of this chapter.

§ 874.402 Withholdings and contributions.

(a) Subject to the provisions of subpart D of parts 870, 871, and 872 of this chapter, premium payments for assigned insurance are withheld from the pay, annuity, or compensation of the covered individual.

(b) Assignees of insured individuals who are retired under the Federal Employees Retirement System and whose annuities are too low to cover the life insurance premiums may make the direct premium payments described in §§ 870.401(j), 871.401(i), and 872.401(i) of this chapter if the annuitant declines to make direct payment. In such cases, the retirement system must notify the assignees. In the case of multiple assignees, each assignee who chooses to make direct payment is responsible for the percentage of the total premium representing his or her portion of the insurance.

(c) When the amount of insurance continued under § 874.701(d) is not an even multiple of $1,000, withholding is based on the amount of insurance rounded to the next lower thousand.

Subpart E—Termination and Conversion

§ 874.501 Termination.

(a) Assigned insurance terminates under the conditions stated in subpart E of parts 870, 871, and 872 of this chapter.

(b) The assignment terminates 31 days after the insurance terminates, unless the covered individual is reemployed in or returns to a position in which he or she is entitled to coverage under this chapter before the expiration of the 31-day period following termination of insurance.

§ 874.502 Eligibility to convert.

(a) When an insured individual's insurance terminates under the conditions set forth in subpart E of parts 870, 871, and 872 of this chapter, an assignee has the right to convert all or a portion of his or her group life insurance to an individual policy on the insured individual. The conditions specified in subpart E of those parts apply to assignees who elect to convert.

(b) When insurance is assigned to more than one assignee, each assignee has the right to convert all or part of his or her share of the insurance. Except as provided in § 874.701 of this part, any assignee who does not convert loses all interest in the insurance.

(c) When multiple assignees convert the assigned insurance to individual policies on the insured individual in accordance with this subpart, the maximum amount of insurance each assignee can convert is determined by the assignee's share of total insurance under this chapter. If such amount is not a multiple of $1,000, it is rounded up to the next thousand dollars.

§ 874.503 Rates for converted insurance.

Rates for converted life insurance are based on the insured individual's age and class of risk at the time the conversion policy is issued.

§ 874.504 Notification of conversion rights.

The employing office must notify each assignee of his or her conversion right at the time the assigned group insurance terminates.

Subpart F—Designations of Beneficiary

§ 874.601 Designations and changes of beneficiary.

(a) An assignment automatically cancels an insured individual's prior designation of beneficiary.

(b) Each assignee may designate a beneficiary or beneficiaries to receive insurance proceeds upon the death of the insured individual. An assignee may designate himself or herself as the primary beneficiary and name some other person(s) as contingent beneficiary(ies) to receive insurance benefits in the event that the assignee predeceases the insured individual.

(c) Assigned insurance is paid to an assignee's estate if the assignee predeceases the insured individual and—

(1) The assignee did not reassign the insurance,

(2) The assignee did not designate a beneficiary, or

(3) The assignee's designated beneficiary predeceased the insured individual.

(d) The provisions of § 870.902 of this chapter apply to designations of beneficiary filed by assignees.

Subpart G—Annuitants and Compensationers

§ 874.701 Annuitants and compensationers.

(a) If an insured individual assigns basic insurance coverage under this chapter and later becomes eligible to continue such coverage while receiving annuity or workers' compensation as provided under § 870.601(a) or § 870.701(a) of this chapter, the insured individual may, at the time he or she becomes eligible to continue such insurance as an annuitant or compensationer, elect increased lifetime basic insurance coverage as provided in § 870.601(c) (3) and (4) or § 870.701(c) (3) and (4) of this chapter.

(b) After the insured individual has made an election as described in paragraph (a) of this section, the assignee (or, in cases of multiple assignees, all of the assignees acting together) may, at any time, elect to cancel the annuitant's or compensationer's election of increased lifetime basic insurance as provided in § 870.601(c) or § 870.701(c) of this chapter.

(c) When multiple assignees have been named and, at the time the insured individual becomes eligible for continued coverage as an annuitant under §§ 870.601, 871.501, and/or 872.501 of this chapter, some assignees choose to convert their portions and others choose to have their portions of insurance continued during the insured individual's retirement, the amount of each type of continued insurance is the total percentage of the shares of the assignees who choose to continue the coverage.

(d) When multiple assignees have been named and, at the time the insured individual becomes eligible for continued coverage as a compensationer under §§ 870.701, 871.501, and/or 872.501 of this chapter, some assignees choose to convert their portions of the insurance and others choose to have their portions continued while the insured individual is receiving compensation, the amount of each type of continued insurance is determined by the total percentage of the shares of the assignees who choose to continue the coverage.

§ 874.702 Reemployed annuitants.

(a) The right of a reemployed annuitant to elect additional optional coverage as an employee rather than as an annuitant under § 872.604 remains with the insured individual and does not transfer to the assignee.

(b) When an annuitant who has assigned his or her insurance is reemployed in a position in which he or she is entitled to life insurance coverage, the coverage he or she acquires as a reemployed annuitant is subject to the existing assignment.

[FR Doc. 95–24666 Filed 10–3–95; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1443

RIN 0560–AE39

Cottonseed Purchase Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This final rule removes obsolete regulations pertaining to the cottonseed purchase program. The cottonseed purchase program has not been in effect since 1969. This action is being taken as part of the National Performance Review program to eliminate unnecessary regulations and improve those that remain in force.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Bradley Karmen, Consolidated Farm Service Agency, United States Department of Agriculture, room 3746–S, P.O. Box 2415, Washington, DC 20013–2415 or call 202–720–7923.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be not significant for the purposes of Executive Order 12866 and therefore has not been reviewed by the Office of Management and Budget (OMB).

Regulatory Flexibility Act

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since the CCC is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of final rulemaking with respect to the subject matter of these determinations.

Environmental Evaluation

It has been determined by an environmental evaluation that this action will not have a significant impact on the quality of the human environment. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Executive Order 12778

This final rule has been reviewed in accordance with Executive Order 12778. The provisions of the final rule do not preempt State laws, are not retroactive, and do not involve administrative appeals.

Executive Order 12372

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

Paperwork Reduction Act

The amendments to 7 CFR part 1443 set forth in this final rule do not contain information collections that require clearance by the Office of Management and Budget under the provisions of 44 U.S.C. 35.

Background

This final rule removes 7 CFR part 1443 pertaining to the cottonseed purchase program. The cottonseed purchase program has not been in effect since 1969 and the regulations are obsolete.

List of Subjects in 7 CFR Part 1443

Cottonseed, Price support and purchase programs, Cotton ginners, Reporting and recordkeeping requirements, Warehouses.

Accordingly, under the authority of 7 U.S.C. 2202 and 7 CFR 2.65 (a)(14), 7 CFR part 1443 is removed:

Signed at Washington, DC, on September 28, 1995.

Bruce R. Weber,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 95–24625 Filed 10–3–95; 8:45 am]

BILLING CODE 3410–05–P

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

Organization and Operations of Federal Credit Unions

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final rule

SUMMARY: Currently, NCUA Rules and Regulations prohibit officials and certain employees of federally insured credit unions from receiving either incentive pay or outside compensation for certain activities related to credit union lending. To reduce regulatory burden, the NCUA Board is amending the regulations to give member-elected credit union boards more flexibility to determine compensation policies, including the use of incentive pay.

EFFECTIVE DATE: October 4, 1995.

ADDRESSES: National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428.

FOR FURTHER INFORMATION CONTACT: Lisa Henderson, Staff Attorney, (703) 518–6561, at the above address.

SUPPLEMENTARY INFORMATION:

Background

Section 701.21(c)(8) of the NCUA Rules and Regulations, 12 CFR 701.21(c)(8), prohibits federal credit unions from making a loan if, either directly or indirectly, any commission, fee, or other compensation is to be received by the credit union's directors, committee members, senior management employees, loan officers, or any immediate family members of such individuals, in connection with underwriting, insuring, servicing, or collecting the loan. However, non-commission salary may be paid to employees. As a condition of federal insurance pursuant to § 741.3(a) of the Regulations, 12 CFR 741.3(a), the prohibition applies to federally insured state-chartered credit unions. As a consequence of the regulation, federally insured credit unions may not provide incentive compensation to officials and loan officers.

Noting that credit union management had become increasingly interested in implementing lending-related incentive pay programs, the NCUA Board, on March 9, 1994, issued a Request for Comment on whether § 701.21(c)(8) should be amended to permit loan officers and/or senior management to receive incentive pay for underwriting and insuring loans. 59 FR 11937 (March 15, 1994). A total of 252 comments was received, 177 of which expressed support for allowing incentive pay for loan officers.

On April 13, 1995, the Board issued a proposed regulation which would amend § 701.21(c)(8) to authorize lending-related compensation in certain situations where it is currently prohibited. 60 FR 19690 (April 20, 1995). A total of 105 comments was received, 48 from federal credit unions, 29 from state-chartered credit unions, 19 from national and state credit union leagues, 3 from insurance companies, 2 from state credit union regulators, and 1 each from a banking trade association, Member of Congress, law firm, and individual.

Seventy-four commenters felt that the proposed regulation was too restrictive. Seven commenters expressed unqualified support for the proposed regulation and nine expressed qualified support. Seven commenters stated that credit unions should not be permitted to pay incentives, period. Six commenters urged that the current regulation be retained, expressing concern that additional authority to pay incentives could create safety and soundness problems.

Final Rule

In response to the comments, and to reduce regulatory burden, the Board has determined to give member-elected boards of directors more flexibility in determining compensation policies for lending-related activities, including the use of incentive pay. Accordingly, the final rule will allow federal credit unions to pay: (1) To any employee, *including* a senior management employee, an incentive or bonus based on the overall financial performance of the credit union; and (2) to any employee, *except* a senior management employee, an incentive based on a loan made by the credit union, provided that the board of the credit union has established written policies and internal controls in connection with the incentive or bonus and monitors compliance with them at least annually. In addition, the final rule will allow a credit union's volunteer officials and non senior management employees, and family members of officials and all employees, to receive compensation from an outside party for a service or activity performed outside the credit union, provided that neither the credit union nor the official, employee, or family member has ''steered'' anyone to the other party. This will allow for ''incidental'' situations resulting from the fact that volunteer officials, non senior management employees, such as part-time employees, and family members of employees, may have jobs

outside the credit union in areas such as insurance or real estate, where customers of the outside business choose to obtain loans from the credit union.

The Board wishes to make clear that this action is not intended to encourage lending-related incentives. In the preamble to the proposed rule, the Board expressed some of its concerns regarding incentive pay, particularly for lending activities. However, this liberalization and deregulation reflects the recognition that there are good arguments and strongly held beliefs on both sides of the incentive pay issue. It is the Board's determination, in light of those considerations and the comments received, that NCUA should structure a rule that involves basic controls and safety and soundness standards and that, beyond that, allows a member-elected board of directors to decide whether to use incentives. Of course, NCUA reserves the right to take exception to any compensation plan for safety and soundness reasons.

Analysis

The supplementary information section of the preamble stated that the structure of the regulation had been changed to make it easier to interpret and administer. The preamble noted that it had been difficult to determine, in the current regulation, whether an activity was part of ''underwriting, insuring, servicing, or collecting'' a loan. The proposed regulation only required that an activity be ''in connection with'' a loan. The preamble stated that NCUA would take a reasonableness approach to that determination.

In an effort to illustrate the distinction between activities in connection and not in connection with lending, the preamble provided examples. The following were presented as being not in connection with lending: (1) Purchasing loan application forms from a company owned by an official; and (2) Financing a home (already) built by a construction company owned by an official. In contrast, the following were presented as being in connection with lending: (1) Obtaining a credit report from a credit bureau owned by an official; and (2) Referring a member to a construction company owned by an official to have a home built and financing the construction of the home.

Eleven commenters stated that the phrase ''in connection with'' was too broad or too vague. Two commenters stated that the examples provided did little to clarify the scope of coverage of the regulation.

The Board continues to believe that the proposed prohibition would be easier to administer than the current regulation and has therefore retained it in the final rule. The Board acknowledges, however, that the examples provided were not helpful. Rather than trying to determine whether an activity is significant enough to be considered ''in connection with'' a loan, the Board has concluded that any activity that is directly linked to lending should be considered to be ''in connection with'' a loan. Under that analysis, each of the four examples discussed above involves an activity that is in connection with a loan.

Proposed paragraph (8)(ii) set forth definitions, only three of which elicited comment. The proposed regulation defined ''compensation'' as including non monetary items, and a few commenters stated that items of nominal value should be excluded. The Board agrees, and has changed the definition accordingly. Items of nominal value are those with a value so small as to make accounting for them unreasonable or administratively impracticable. The board of directors of a credit union may look to Internal Revenue Service law regarding income and de minimus fringe benefits, 26 USC 132, for guidance in this area.

The proposed regulation defined ''employee'' to include independent contractor. The intent was to prevent credit unions from evading the rule by calling an individual who is essentially an employee an independent contractor. Several commenters objected to including independent contractors in the definition of employee. They said that it would have the effect of prohibiting any lending-related compensation to any independent contractors or third parties. The Board agrees and has deleted the term ''independent contractor'' from the final rule. The Board notes, however, that NCUA will treat an individual functioning as an employee as such for the purposes of § 701.21(c)(8).

The proposed regulation defined ''senior management employee'' as it is defined elsewhere in the NCUA regulations (the chief executive officer, any assistant chief executive officers, and the chief financial officer) but added the phrase, ''and any other employee who sets policy for the credit union.'' Several commenters objected to this addition, arguing that it was too broad and muddied the distinction between senior management and other employees. The Board agrees and has deleted the phrase from the final rule.

Finally, in the final rule the Board has deleted the definition of ''workout loan'' as unnecessary and added a definition for ''volunteer official.'' A volunteer official is a director or committee member who is not compensated as such. Federal credit unions are permitted to compensate one director solely for his or her service on the board, and many state-chartered credit unions are permitted by state law to compensate one or more directors for such service. Under the final rule, a director so compensated would not be considered a volunteer official.

Paragraph (8)(iii) of the proposed regulation set forth five exceptions to the prohibition against lending-related compensation. Exception (A), salary for employees, was met with universal approval from the commenters. Exception (B) was an incentive or bonus to an employee, including a senior management employee, based on the credit unions overall financial performance. This codified a position that had been taken in an opinion letter from NCUA and also was supported by the commenters. Accordingly, exceptions (A) and (B) have been retained in the final rule.

Exceptions (C), (D), and (E) authorized payment of an incentive to an employee in connection with processing a loan, making a decision to approve or disapprove a loan, and collecting a loan, respectively, provided that no incentive or bonus was paid to a supervisor of the employee, a senior management employee, or an immediate family member of a supervisor or senior management employee. Exception (D) additionally required that an incentive paid in connection with making a loan decision not be based on the number or dollar amount of loans approved and be structured in a manner that demonstrably protected against an increase in problem loans.

Sixteen commenters said that non senior management should be permitted to receive incentives. Many said that the prohibition against payment of incentives to supervisors would disproportionately affect large credit unions. They argued that lower level supervisors would be caught between senior management, who receive bonuses based on overall performance, and front-line employees, who are eligible for incentive pay. In response to the comments, the Board has removed the prohibition against supervisors receiving incentive pay from the final rule.

Thirty-eight commenters objected to the prohibition against basing incentives on the number or dollar amount of loans approved. Most said there were no other reasonable measures on which to base incentives for loan officers. As

discussed above, the Board has determined to deregulate this issue and allow credit unions to structure their own incentive plans. This is provided for in Exception (C) in the final rule, which simply provides that a federal credit union may pay an incentive or bonus to a non senior management employee in connection with a loan made by the credit union. This includes incentives for any activity connected with lending, including processing and collecting loans, making credit decisions, and selling credit life, credit disability, and mechanical breakdown insurance. The only limitation is that the board of directors of the credit union must have established written policies and internal controls in connection with the incentive or bonus and must monitor those policies and controls annually.

The final rule's requirement of annual monitoring of policies and controls is a change from paragraph (8)(iv) of the proposed regulation, which required quarterly monitoring. Thirteen commenters said that quarterly review was too frequent, arguing that it would put the board of the credit union in the role of micro-managing the credit union. In response to the comments, the change was made. The Board notes, however, that the supervisory committee, or internal auditor in larger credit unions, should consider reviewing the effectiveness of incentive pay policies and controls more frequently than annually.

Paragraph 8(iv) of the proposed rule also required that documentation of the monitoring be made available to the supervisory committee and NCUA. There was some confusion about this requirement. Several commenters asked whether documentation should be made available to examiners during exams or sent to NCUA. There also was a question as to whether state-chartered credit unions should provide documentation to the state regulator. The Board has deleted this requirement as unnecessary. Under the final rule, a credit union wishing to provide incentive pay must establish written policies. These are by definition part of the books and records of the credit union, which are open to the supervisory committee of the credit union and to NCUA examiners.

The preamble to the proposed rule discussed a number of policy changes the regulation would make. It first noted that the current regulation had been interpreted to permit a credit union official or employee to receive compensation for acting as an agent in the sale of property securing a loan made by a credit union, on the rationale that listing or selling a property on which a loan is granted is not included in underwriting, insuring, servicing, or collecting the loan. Since listing or selling property financed by the credit union *is* ''in connection with'' the loan, however, the proposed rule would prohibit compensation for such activity.

The preamble also noted that the current regulation had been interpreted to prohibit a credit union official or employee from, for example, owning an insurance company that sells car insurance to members who finance their cars at the credit union. An argument had been made, however, that the regulatory language prohibited the receipt of compensation in connection with insuring the loan but not in connection with insuring collateral securing the loan. The preamble stated that NCUA was concerned about the opportunity for credit union officials and employees to steer members to a particular insurance agency and that the proposed regulation therefore would prohibit all officials and employees from receiving compensation for insuring collateral securing a loan made by the credit union.

A number of commenters stated that the prohibition against receiving compensation for outside activities might restrict members from volunteering to serve on a credit unions board. The NCUA Board shares that concern and has determined to permit volunteer officials and non senior management employees of a federal credit union, and the family members of officials and all employees, to receive compensation from an outside party for an activity performed outside the credit union, as long as neither the credit union nor the official, employee, or family member refers any person to the other party. Thus, the borrower's receipt of a loan from the credit union should be unconnected to his or her participation in the outside activity of the official, employee, or family member. The Board believes the prohibition should remain in effect for senior management employees in order to prevent situations where subordinate employees feel pressure to make loans to customers of the outside business interest of the senior management employee. The exception will ensure, at the same time, that NCUA's rules do not interfere with the livelihoods of volunteer officials, non senior management employees, such as part-time employees, and the family members of officials and employees. This is set forth in Exception (D) of the final rule.

Regulatory Procedures

Regulatory Flexibility Act

The NCUA Board certifies that this rule will not have a significant impact on a substantial number of small credit unions (those under $1 million in assets). Accordingly, a Regulatory Flexibility Analysis is not required.

Paperwork Reduction Act

NCUA has determined that the requirement to establish a written policy in connection with the payment of lending-related incentives does constitute a collection of information under the Paperwork Reduction Act. The Paperwork Reduction Act of 1995 and regulations of the Office of Management and Budget (OMB) require that the public be provided an opportunity to comment on information collection requirements, including an agency's estimate of the burden of the collection of information. NCUA estimates that no more than 1000 federally insured credit unions will seek to implement lending-related incentive compensation policies. It is NCUA's view that the time a credit union spends developing a responsible policy is not a burden created by this regulation but rather is necessary to the safe and sound payment of lending-related incentives. The paperwork burden created by this rule is the requirement that such policy be put in writing. NCUA estimates that it should take at most one hour to put an incentive policy in written form. Therefore, 1000 total burden hours are required to comply with the collection requirement.

The NCUA Board invites comment on: (1) Whether the collection of information is necessary for the proper performance of the functions of NCUA, including whether the information will have practical utility; (2) The accuracy of NCUA's estimate of the burden of the collection of information; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information. Send comments to Suzanne Beauchesne, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428. Comments should be postmarked by December 4, 1995.

After 60 days, NCUA will submit the paperwork requirement to OMB for review under the Paperwork Reduction Act and will publish a notice to that effect in the Federal Register. NCUA will also publish a notice in the Federal Register once OMB takes action on the submitted request. Until NCUA receives an OMB control number indicating approval of the requirement that

incentive policies be put in writing, a credit union is not required to comply with that requirement.

Regulatory Burden

Section 302 of the Riegle Community Development and Regulatory Improvement Act of 1994 requires the federal regulators of banks and savings associations to make all regulations that impose new requirements take effect on the first date of the calendar quarter following publication of the rule unless good reason exists for some other effective date. Although NCUA is not formally subject to this requirement, Letter to Credit Unions #158 stated that the requirement would be beneficial to credit unions and that NCUA planned to implement it whenever practicable. NCUA believes that an immediate effective date is appropriate since the final rule relieves a regulatory burden on credit unions that wish to implement lending-related incentive compensation programs by permitting them to do so. Although the final rule also imposes a recordkeeping requirement, the primary effect of the rule is to relieve regulatory burden.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. The preamble to the proposed rule acknowledged that the proposed rule would impose some requirements on state-chartered, federally insured credit unions but stated that any effect on the distribution of power and responsibilities among the various levels of government was justified by the potential risk to the NCUSIF. Several commenters argued that no risk to the NCUSIF had been demonstrated and that, for state-chartered credit unions, the matter should be left to state regulators to determine.

The final rule imposes significantly less regulatory burden on credit unions than either the proposed rule or the currently effective rule. Therefore, the effect on state regulatory authority is considerably diminished. The Board continues to believe, however, that any remaining effect on that authority is justified by the potential risk to the NCUSIF without such a rule.

The Board notes that this rule is not intended to expand the authority of state-chartered credit unions. If state law imposes greater restrictions on lending-related compensation than does this rule, state-chartered credit unions must comply with state law.

List of Subjects in 12 CFR Part 701

Federal credit unions, Organization and operations.

By the National Credit Union Administration Board on September 28, 1995.

Becky Baker,

Secretary of the Board.

For the reasons set forth in the preamble, NCUA amends 12 CFR part 701 as follows:

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 USC 1752(5), 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, 1789, and Pub. L. 101–73. Section 701.6 is also authorized by 31 USC 3717. Section 701.31 is also authorized by 15 USC 1601, *et seq.*, 42 USC 1981, and 42 USC 3601–3610. Section 701.35 is also authorized by 12 USC 4311–4312.

§ 701.21 [Amended]

2. Section 701.21(c)(8) is revised to read as follows:

* * * * *

(c) * * *

(8)(i) Except as otherwise provided herein, no official or employee of a Federal credit union, or immediate family member of an official or employee of a Federal credit union, may receive, directly or indirectly, any commission, fee, or other compensation in connection with any loan made by the credit union.

(ii) For the purposes of this section:

Compensation includes non monetary items, except those of nominal value.

Immediate family member means a spouse or other family member living in the same household.

Loan includes line of credit.

Official means any member of the board of directors or a volunteer committee.

Person means an individual or an organization.

Senior management employee means the credit union's chief executive officer (typically, this individual holds the title of President or Treasurer/Manager), any assistant chief executive officers (e.g., Assistant President, Vice President, or Assistant Treasurer/Manager), and the chief financial officer (Comptroller).

Volunteer official means an official of a credit union who does not receive compensation from the credit union solely for his or her service as an official.

(iii) This section does not prohibit:

(A) Payment, by a Federal credit union, of salary to employees;

(B) Payment, by a Federal credit union, of an incentive or bonus to an employee based on the credit union's overall financial performance;

(C) Payment, by a Federal credit union, of an incentive or bonus to an employee, other than a senior management employee, in connection with a loan or loans made by the credit union, provided that the board of directors of the credit union establishes written policies and internal controls in connection with such incentive or bonus and monitors compliance with such policies and controls at least annually.

(D) Receipt of compensation from a person outside a Federal credit union by a volunteer official or non senior management employee of the credit union, or an immediate family member of a volunteer official or employee of the credit union, for a service or activity performed outside the credit union, provided that no referral has been made by the credit union or the official, employee, or family member.

* * * * *

[FR Doc. 95–24688 Filed 10–3–95; 8:45 am]

BILLING CODE 7535–01–P

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12 CFR Part 722

Appraisals

AGENCY: National Credit Union Administration (NCUA).

ACTION: Final amendments.

SUMMARY: The NCUA Board is issuing final amendments to its regulation regarding the appraisal of real estate, adopted pursuant to Title XI of the Financial Institutions Reform, Recovery and Enforcement Act of 1989. The final amendments simplify compliance with regulatory requirements for credit unions by changing provisions of the appraisal regulation that govern: the publication of the Uniform Standards of Professional Appraisal Practice (USPAP); minimum appraisal standards; appraisals to address safety and soundness concerns; unavailable information; additional appraisal standards developed by credit unions; and appraiser independence. The final amendments should reduce costs without affecting the reliability of appraisals used in connection with federally related transactions.

EFFECTIVE DATE: October 1, 1995.

FOR FURTHER INFORMATION CONTACT: Herbert Yolles, Director, Department of Risk Management, Office of Examination and Insurance, (703) 518–6360 or Michael McKenna, Staff

Attorney, Office of General Counsel, (703) 518–6540.

SUPPLEMENTARY INFORMATION:

A. Background

Title XI of the Financial Institutions Reform, Recovery and Enforcement Act of 1989 (FIRREA) directed NCUA and the other financial institution regulatory agencies to publish appraisal rules for federally related real estate transactions within the jurisdiction of each agency. In accordance with statutory requirements, NCUA's final rule sets minimum standards for appraisals used in connection with federally related real estate transactions and identified those transactions that require a state certified appraiser and those that require either a state certified or licensed appraiser.

While in most cases an appraisal is an essential part of a sound underwriting decision, the Board believes that NCUA should not require Title XI appraisals where they impose costs without significantly promoting the safety and soundness of credit unions or furthering the purpose of Title XI of FIRREA. Furthermore, it has been the Board's experience that some requirements are no longer necessary. Accordingly, on March 1, 1995, the Board issued proposed amendments to part 722, the appraisal regulation. *See* 60 FR 13388 (March 13, 1995). The proposed amendments were intended to simplify compliance for credit unions by changing provisions in the appraisal regulation that govern: (i) The publication of the USPAP; (ii) minimum appraisal standards; (iii) appraisals to address safety and soundness concerns; (iv) unavailable information; (v) additional appraisal standards developed by credit unions; and (vi) appraiser independence.

B. Comments

Twenty-nine comments were received. Two commenters fully supported the amendments. The remaining twenty-seven comments were generally positive and consistently supported most of the proposed amendments. The issues that generated the most comments were the de minimus amount and appraiser independence.

Dollar Threshold for Obtaining an Appraisal (the De Minimus Amount)

The current appraisal regulation requires a credit union to obtain an appraisal by a certified and licensed appraiser if the transaction value is in excess of $100,000 for residential real estate and $50,000 for commercial property. *See* 12 CFR 722.3(a). The other federal financial institution regulatory agencies [1] have increased the threshold to $250,000. See 59 FR 29482, June 7, 1994. The Board considered whether the de minimus level should be increased for federally-insured credit unions. Although credit unions are well capitalized, they are generally much smaller than other financial institutions. As a result, the relative size of an average real estate loan in comparison to capital is generally much higher for a credit union, which translates to much greater relative risk. A major portion of the losses to the National Credit Union Share Insurance Fund in the past ten years were associated with real estate lending. Consequently, the Board did not propose to increase either threshold.

Twelve commenters supported the Board's position. One commenter specifically concurred with NCUA's rationale for not increasing the de minimus level. Two commenters believed that increasing the dollar threshold may cause safety and soundness problems. Eight commenters recommended increasing the de minimus level to $250,000 for residential real estate. Most of these commenters believed that retaining the current threshold will make credit union loans more expensive and place credit unions at a competitive disadvantage. Two commenters recommended increasing the de minimus level to $150,000. One commenter suggested increasing the de minimus level to $250,000 for business loans. The Board does not believe the minimal effects on competition outweigh safety and soundness concerns. For credit unions that engage in real estate lending, their greatest single risk protection is to obtain a licensed or certified appraisal to support the loan-to-value ratio. The current thresholds of $100,000 for residential real estate and $50,000 for commercial property are sufficiently high to preclude most home equity or second trust lending from the appraisal requirement, but are low enough to ensure that appraisals are obtained for higher dollar value real estate lending.

Valuation Requirement

The Board did not propose any change to the requirement that any real estate transaction under the de minimus level, and not otherwise exempt, receive a valuation. Three commenters recommended eliminating the valuation requirement if the value of the loan was below a certain dollar threshold. Two commenters would set the dollar threshold for a valuation at $20,000 and one commenter would set the dollar threshold at $50,000.

The Board continues to believe that there should be no de minimus level on the valuation requirement. Loans which are secured by real estate are often made at substantially lower interest rates than noncollateralized loans. The value of the real estate secured as collateral reduces the potential risk of the loan, thereby enabling the credit union to lend at a lower interest rate or smaller spread. Unless a valuation is performed that meets the requirements of part 722, the credit union has no assurance that the real estate offered as collateral is of sufficient value to provide the necessary risk protection to justify the reduced interest rate. However, the Board is exempting from the valuation requirement those real estate loans that are insured by a third party. In this case, there is virtually no risk to the credit union and the valuation requirement serves no practical purpose.

One commenter recommended that the agency define the term ''valuation'' in the preamble of the final regulation. The term was defined in the preamble to the original final rule. See 55 FR 30199 (July 25, 1990). The term was broadly defined to allow credit unions the flexibility to use various methods to measure market value. Any further refinement of the definition would reduce that flexibility. The Board does not believe that would be in the best interests of credit unions.

Some credit unions have established programs in which minimal valuation procedures are used for real estate loans which are below certain dollar thresholds and/or are below certain loan-to-value ratios. These minimal procedures do not involve a physical inspection of the property or ''drive by'', but instead may rely on other written evidence such as a recent tax assessment. The Board has no objection to such alternative valuation procedures, as long as the credit union has fully documented how the alternate procedures will work and demonstrated that the procedures do not impose an unacceptable risk by not performing a physical inspection. The credit union must also demonstrate how the other written evidence correlates to the value of the collateral. What constitutes an unacceptable level of risk will vary for each credit union and each loan based on such factors as the credit union's size, capital level and experience with real estate lending, and the borrower's debt level and credit history. For this reason, the Board believes that it would be inappropriate for it to attempt to set

[1] The Board of Governors of the Federal Reserve System, the Federal Deposit Insurance Corporation, the Office of the Comptroller of the Currency and the Office of Thrift Supervision.

specific parameters on the valuation procedures that credit unions may employ.

1. Exemptions

The Board proposed amendments to clarify and expand the circumstances in which a Title XI appraisal is not required. The Board addressed the following areas: (1) The ''abundance of caution'' provision; (2) liens for purposes other than the real estate's value; (3) requirements for renewals, refinancings and other subsequent transactions; (4) transactions involving real estate notes; (5) transactions insured or guaranteed by a United States Government Agency or United States Government Sponsored Agency; and (6) transactions that meet the qualification for sale to a United States Government Agency or United States Government Sponsored Agency.

The ''Abundance of Caution'' Provision

NCUA's appraisal regulation currently provides that an appraisal is not required when a lien on real estate has been taken as collateral ''solely'' through an abundance of caution and where the terms of the transaction as a consequence have not been made more favorable than they would have been in the absence of a lien. See 12 CFR 722.3(a)(2). To emphasize the broader scope of the abundance of caution exemption, the Board proposed to delete the word ''solely'' from the current exemption. Seven commenters supported and one opposed this amendment. The supporters believed it would add flexibility to credit union's lending policies. One of these commenters suggested that the final regulation also eliminate the requirement that ''the terms of the transaction have not been made more favorable than they would have been in the absence of the lien.'' This commenter stated that if this requirement is not eliminated credit unions would be at a competitive disadvantage with banks and thrifts.

The Board is unwilling to further expand the abundance of caution provision. When the terms of a loan are more favorable than they would have been in the absence of a lien, the more favorable terms are warranted because of the value of the collateral. Without a certified or licensed appraisal (or a valuation if the transaction is below the de minimus level) the credit union has no assurance that the collateral is of sufficient value to provide the necessary risk protection.

The opposing commenter believes this amendment may lead to unwarranted risk. However, this amendment will only affect a small number of transactions and cannot be used when the terms of the transaction have been made more favorable than they would have been in the absence of the lien. A loan falling into this category will not carry any additional risk. Therefore, the Board is adopting this amendment as proposed.

Liens for Purposes Other Than the Real Estate's Value

The Board proposed a new exemption for transactions in which a credit union takes a lien on real estate for purposes other than the value of the real estate, such as when it takes a lien on real estate to protect the legal rights to other collateral. In such cases an appraisal would not be required. Seven commenters supported this amendment. One of these commenters stated that this new exemption would benefit credit unions since it would allow them to take additional security without adding the burden of obtaining an appraisal. Accordingly, the Board is adopting the amendment as proposed.

Requirements for Renewals, Refinancing and Other Subsequent Transactions

The Board proposed exempting from the appraisal requirement subsequent transactions provided no new monies were advanced other than funds necessary to cover reasonable closing costs and where there has been no obvious and material change in the market conditions or physical aspects of the property which would threaten the credit union's collateral protection. Fifteen commenters supported this proposal. One of these commenters stated that this amendment would be beneficial to credit unions and members who wish to refinance an existing mortgage with the same credit union, in order to take advantage of a lower interest rate, but not incur the added expenses of another appraisal.

One commenter recommended even greater flexibility to situations in which an appraisal is not required for renewals, refinancings, and other subsequent transactions. This commenter would exempt a transaction which involves an existing extension of credit provided it meets one of two criteria: (i) There is no advancement of new money except to cover reasonable closing costs or (ii) there has been no obvious and material change in market conditions or physical aspects of the property that threatens the adequacy of the credit union's real estate collateral protection after the transaction, even with the advancement of new monies. This commenter stated that banks and thrifts have this exemption and credit unions would be at a competitive disadvantage without it. The Board believes that an appraisal is necessary if new funds are advanced. The Board believes that safety and soundness concerns outweigh the possible minimal affects on competition.

One commenter supports the proposal but would also require a drive-by appraisal to confirm there had been no material change in the collateral. The Board believes that credit unions should retain the flexibility on how best to determine whether there has been any material change in the collateral. Three commenters objected to this amendment believing an appraisal is necessary because market conditions may have changed since the loan was originally granted. The Board disagrees. If the credit union has made the loan being refinanced and no additional funds are advanced, the risk is only associated with the extension of the repayment period. The Board believes that in most cases this risk will be minimal. In addition, the Board believes that the credit unions will be aware of the deteriorating market trends and will seek a new appraisal if they believe it is necessary. The Board is adopting in final the amendment as proposed. This exemption is not applicable if a member refinances a mortgage with a new lender.

Transactions Involving Real Estate Notes

The Board proposed to allow credit unions to purchase, sell, invest in, exchange, or extend credit secured by real estate notes or interests in real estate notes or interests in real estate without obtaining a new Title XI appraisal if each note or real estate interest is supported by an appraisal that meets the regulatory appraisal requirements for the institution at the time the real estate-secured note was originated. (The transaction would, of course, have to meet other statutory and regulatory requirements applicable to federally-insured credit unions.) The Board believes that this amendment will serve federal public policy interests by helping to ensure that the appraisal regulation does not unnecessarily inhibit secondary mortgage market transactions that involve real estate-secured loans and real estate interests. Six commenters supported this proposal. Most of these commenters believe that this change would permit credit unions to buy or sell loans more easily on the secondary market. Consequently, the Board is adopting this amendment as proposed.

Transactions Insured or Guaranteed by a United States Government Agency or United States Government Sponsored Agency

NCUA's appraisal regulation currently provides that loans insured or guaranteed by an agency of the United States government are exempt from NCUA's appraisal requirements. The Board proposed to delete the requirement that the transaction be supported by an appraisal that conforms to the requirements of the insuring or guaranteeing agency. Five commenters supported this amendment. One commenter objected to it on safety and soundness grounds. The Board believes that loan program standards sufficiently protect credit unions since in order to receive the insurance or guarantee, the transaction must meet all underwriting requirements of the insurer or guarantor, including real estate appraisal or valuation requirements. It is unnecessary to require these transactions to also meet the overlapping requirements of NCUA. Moreover, this exemption will eliminate the confusion among credit unions that two separate appraisals are required; one meeting NCUA's Regulations and another meeting the federal loan program standards. Accordingly, the Board is adopting the proposed amendment in final.

Transactions That Meet the Qualifications for Sale to a United States Government Agency or Government Sponsored Agency

NCUA proposed to permit credit unions to originate, hold, buy or sell transactions that meet the qualifications for sale to any U.S. government agency and certain government sponsored agencies without obtaining a separate appraisal conforming to NCUA's Regulations. The Board believes that permitting credit unions to follow these standardized appraisal requirements, without the necessity of obtaining an appraisal or appraisal supplement will increase a credit union's ability to buy and sell these loans. Also, it may help a credit union with liquidity problems. Four commenters supported this amendment. One commenter suggested that the list of the government sponsored agencies that was in the proposed rule's preamble be included in the preamble of the final regulation so that credit unions would be able to identify those agencies more easily. The Board agrees. These government sponsored agencies are:

* Banks for Cooperatives.
* Federal Agricultural Mortgage Corporation (Farmer Mac).
* Federal Farm Credit Banks.
* Federal Home Loan Banks (FHLBs).
* Federal Home Loan Mortgage Corporation (Freddie Mac).
* Federal National Mortgage Association (Fannie Mae).
* Student Loan Marketing Association (Sallie Mae).
* Tennessee Valley Authority (TVA).

The Board believes the appraisal standards of the U.S. government agencies established to maintain a secondary market in various types of loans are appropriate for these exempt transactions. Furthermore, the Board believes that compliance with these standards will protect the safety and soundness of regulated financial institutions. Accordingly, the Board is adopting the proposed amendments in final.

2. Appraisals to Address Safety and Soundness Concerns

The Board proposed to clarify that NCUA may require Title XI appraisals to address safety and soundness concerns where real estate-related financial transactions present greater-than-normal risk to individual credit unions. For example, NCUA may require a troubled credit union to obtain an appraisal for transactions below the threshold level. Two commenters supported this amendment. One commenter objected stating that USPAP standards already provide sufficient safeguards. In general, the Board believes that the USPAP standards are sufficient but as the above example demonstrates there may be occasions where additional standards are necessary. Accordingly, the Board is adopting this amendment as proposed.

3. Minimum Appraisal Standards

The Board proposed to reduce the number of minimum appraisal standards applicable to Title XI appraisals for federally-related transactions from the thirteen standards found in § 722.4(a) of NCUA's Regulations (12 CFR 722.4(a)) to five and eliminate the current prohibition on the use of the USPAP Departure Provision in connection with federally-related transactions. The Board proposed to require all appraisals for federally-related transactions to: (i) Conform to generally accepted appraisal standards as evidenced by the USPAP; (ii) be written and contain sufficient information and analysis to support the credit union's decision to engage in the transaction; (iii) analyze and report appropriate deductions and discounts for proposed construction or renovation, partially leased buildings, no-market lease terms and tract developments with unsold units (iv) be based upon the definition of market value as set forth in the regulation; and (v) be performed by State licensed or certified appraisers.

The Board also proposed deleting Appendix A from the regulation since USPAP would be referenced in the regulation.

Nine commenters supported the modification and believe that eliminating the parallel USPAP standards will ease regulatory burden. Most of these commenters believed that this amendment will eliminate any confusion on what standards to follow. One commenter specifically stated that the elimination of Appendix A will make it clear to credit unions that any reference to USPAP is the current edition. Ten commenters did not believe this change will ease regulatory burden but they did not object to the change. One of these commenters stated that all the proposed changes are the responsibility of the appraiser and not the credit union. One commenter objected to the amendment because he does not believe the current standards impose any sort of regulatory burden. Two commenters believe the proposed amendments will affect the usefulness of an appraisal. The Board does not believe an appraisal will be less useful by eliminating these standards since an appraiser must still follow the parallel USPAP standards. By eliminating the regulatory standards that parallel USPAP standards the Board is simply reducing the confusion on what standards need to be followed in the preparation of appraisals for federally related transactions.

Departure Provision

The Board proposed to permit credit unions to use appraisals prepared in accordance with the USPAP Departure Provision for federally-related transactions. The Departure Provision permits limited exceptions to specific guidelines in the USPAP. The Board believes that credit unions should be allowed to determine, with the assistance of the appraiser, whether an appraisal to be prepared in accordance with the Departure Provision is appropriate for a particular transaction and consistent with principles of safe and sound lending. Thirteen commenters supported the ability of a credit union to use USPAP's Departure Provision. Most of these commenters do not believe this change would affect the reliability of an appraisal report. They believe this change would provide credit unions with added flexibility which will result in decreased appraisal costs. Five commenters believe the use of the Departure Provision may affect an appraisal's reliability and two of these

commenters stated that the interpretation of the data given by the appraiser may be misleading and not acceptable. The Board believes that appraisal data is always subject to some interpretation. A credit union can minimize this risk by carefully selecting an appraiser. Furthermore, appraisers preparing appraisals using the Departure Provision must still comply with all binding requirements of the USPAP and must be sure that the resulting appraisal is not misleading. The amendment also makes clear that the written appraisal must contain sufficient information and analysis to support the credit union's decision to engage in the transaction. This puts the credit union on notice of their responsibility to have appraisals that are appropriate for the particular federally related transaction.

Deductions and Discounts

The Board proposed to retain the current standard in the appraisal regulation regarding deductions and discounts. See 12 CFR 722.4(a)(8). The USPAP provision on this subject requires the appraiser to include a discussion of deductions and discounts when it is necessary to prevent an appraisal from being misleading. The Board believes it is appropriate to emphasize the need to include an appropriate discussion of deductions and discounts applicable to the estimate of value in Title XI appraisals for federally related transactions. For example, in order to properly underwrite a loan, a credit union may need to know a prospective value of a property, in addition to the market value as the date of the appraisal. A prospective value of a property is based upon events yet to occur, such as completion of construction or renovation, reaching a stabilized occupancy level, or some other event to be determined. Thus, more than one value may be reported in an appraisal as long as all values are clearly described and reflect the projected dates when future events could occur.

The standard on deductions and discounts emphasize the need for appraisers to analyze, apply and report appropriate discounts and deductions when providing values based on future events. In financing the purchase of an existing home in a long-standing community, there typically would be no need to apply any discounts or deductions to arrive at the market value of the property since the credit union's financing of the project does not depend on events such as further development of the property or the sale of units in a tract development. Therefore, the Board is adopting in final the amendment as proposed.

Remaining Standards

The Board also proposed to retain the current market value standard in the appraisal regulation which requires the appraisal to be based on the definition of market value in NCUA's Regulations. See 12 CFR 722.4(a)(2). Finally, the Board proposed a new standard that all appraisals for federally related transactions must be prepared by licensed or certified appraisers. This requirement is mandated by Title XI of FIRREA and is repeated in other parts of the appraisal regulation.

The Board is adopting the minimum appraisal standards as proposed. The Board believes these five standards will simplify compliance with the appraisal regulation without diminishing the usefulness of Title XI appraisals prepared for federally related transactions. Under these standards, the USPAP is referenced but is no longer part of NCUA's Regulations. This approach no longer requires NCUA to republish changes to the USPAP adopted by the Appraisal Standards Board in Appendix A of this rule. The appendix is deleted from NCUA's appraisal regulation.

4. Elimination of the Provision on Unavailable Information

The Board proposed to delete the current provision that requires appraisers to disclose and explain when information necessary to the completion of an appraisal is unavailable. See 12 CFR 722.4(b). The USPAP currently requires appraisers to disclose and explain the absence of information necessary to complete an appraisal that is not misleading. See USPAP Standard Rule 2–2(k). Moreover, when information that may materially affect the estimate of the value is unavailable, the Board believes that generally accepted appraisal standards require appraisers to explain the absence of that information and its effect on the reliability of the appraisal. Therefore, to streamline the regulation the Board is adopting the amendment as proposed.

5. Elimination of the Provision on Additional Appraisal Standards

The Board proposed to delete the current provision that merely confirms the authority of credit unions to require appraisers to comply with additional standards. See 12 CFR 722.4(c). As the regulation's minimum appraisal standards for federally related transactions do not prevent a credit union from requiring additional appraisal standards or information to meet the credit union's business needs. It is unnecessary to keep this provision in the appraisal regulation. Consequently, the Board is adopting the proposed amendment in final.

6. Appraiser Independence

The Board proposed to permit a credit union to use an appraisal that was prepared for any financial service institution including mortgage bankers. Twenty commenters supported this amendment. One of these commenters added a caveat that it should be permissible only if the appraisal is ordered by a lending establishment and the appraiser is one that has been approved by the lender. Three of these commenters believed the appraiser should be certified or licensed. Two commenters say the appraisal should be recent. Three commenters objected to this provision. One of these commenters stated that relying on an appraisal commissioned by another financial institution may lead to a faulty credit decision. A credit union need not rely on an appraisal if it does not have confidence in the report or the appraiser. The Board believes that these are all business decisions that should be made by the credit union and need not be regulated. However, it is incumbent on the credit union to ensure that the appraisal conforms to the requirements of the regulation and is otherwise acceptable. Furthermore, the appraiser would not be allowed to have a direct or indirect interest, financial or otherwise, in the property or the transaction, and must have been directly engaged by the non-regulated institution.

Age of Appraisal

In the preamble to the proposed amendments, the Board addressed the maximum age for an acceptable appraisal. The Board believed that there should be a maximum age (time from date of the appraisal to date of the application of the loan) for an appraisal, but that the age should not be so short as to unnecessarily require a new appraisal in the unlikely event that a mortgage is refinanced within a reasonably short time or a credit union is using an appraisal prepared for another financial service institution. The Board realized that setting a specific time period would not be appropriate in all situations. The Board proposed allowing credit unions to determine the period for an appraisal but recommending that any appraisal over six months not be used. Ten commenters supported the six month recommendation and nine commenters objected. Most of these commenters

would prefer that NCUA allow the determination to be made on a case by case basis or continue with the current one year recommendation. They also believed that in many locations an appraisal that is one year old is still an accurate reflection of market value.

The Board does not have any empirical evidence to demonstrate that an appraisal older than six months is inherently unreliable. The Board believes that while any specific time period will not be appropriate in all situations, appraisals generally can be relied upon for up to one year. During periods of stable real estate market conditions, appraisals that are one year old may be fairly accurate. However, because of the uncertain nature of real estate market conditions, older appraisals may be unreliable. It is the responsibility of the credit union to be aware of market conditions. The ultimate judgment on whether to use an appraisal rests with the credit union. This approach provides guidance while permitting credit unions the flexibility to use their best judgment in this matter.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires NCUA to prepare an analysis to describe any significant economic impact a proposed regulation may have on a substantial number of small credit unions (primarily those under $1 million in assets). The final amendments reduce regulatory burden and are less restrictive than current requirements. Overall, the Board expects the changes to benefit members and federally-insured credit unions regardless of size by reducing costs without substantially increasing the risk of loss. In addition, most small credit unions do not offer real estate loans. Accordingly, the Board determines and certifies that the final rule is not expected to have a significant economic impact on a substantial number of small credit unions and that a Regulatory Flexibility Analysis is not required.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. The final rule will apply to all federally-insured credit unions and reduce regulatory requirements. The Board has determined that the final amendments would not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

Paperwork Reduction Act

The final rule decreases paperwork requirements for a credit union. The paperwork requirements were submitted to the Office of Management and Budget (OMB) for approval under the Paperwork Reduction Act. A notice will be published in the Federal Register once approval is received from OMB.

List of Subjects in 12 CFR Part 722

Appraisals, Credit unions, State-certified and State-licensed appraisers

By the National Credit Union Administration Board on September 28, 1995.

Becky Baker,

Secretary to the Board.

Accordingly, NCUA amends 12 CFR part 722 as follows:

PART 722—APPRAISALS

1. The authority citation for part 722 continues to read as follows:

Authority: 12 U.S.C. 1766, 1789 and Pub. L. No. 101–73.

2. Section 722.3 is amended by revising the section headings, revising paragraphs (a) and (d) and adding a new paragraph (e) to read as follows:

§ 722.3 Appraisals required; transactions requiring a State certified or licensed appraiser.

(a) *Appraisals required.* An appraisal performed by a State certified or licensed appraiser is required for all real estate-related financial transactions except those in which:

(1) The transaction value is $100,000 or less except if it is a business loan and then the transaction value is $50,000 or less;

(2) A lien on real property has been taken as collateral through an abundance of caution and where the terms of the transaction as a consequence have not been made more favorable than they would have been in the absence of a lien;

(3) A lien on real estate has been taken for purposes other than the real estate's value;

(4) A lease of real estate is entered into, unless the lease is the economic equivalent of a purchase or sale of the leased real estate;

(5) The transaction involves an existing extension of credit at the credit union, provided that:

(i) There is no advancement of new monies, other than funds necessary to cover reasonable closing costs; and

(ii) There has been no obvious and material change in market conditions or physical aspects of the property that threatens the adequacy of the credit union's real estate collateral protection after the transaction;

(6) The transaction involves the purchase, sale, investment in, exchange of, or extension of credit secured by, a loan or interest in a loan, pooled loans, or interests in real property, including mortgage-backed securities, and each loan or interest in a loan, pooled loan, or real property interest met the requirements of this regulation, if applicable, at the time of origination;

(7) The transaction is wholly or partially insured or guaranteed by a United States government agency or United States government sponsored agency; or

(8) The transaction either:

(i) Qualifies for sale to a United States government agency or United States government sponsored agency; or

(ii) Involves a residential real estate transaction in which the appraisal conforms to the Federal National Mortgage Association or Federal Home Loan Mortgage Corporation appraisal standards applicable to that category of real estate.

* * * * *

(d) Valuation requirement. Secured transactions exempted from appraisal requirements pursuant to paragraphs (a)(1) of this section and not otherwise exempted from this regulation or fully insured shall be supported by a written estimate of market value, as defined in this regulation, performed by an individual having no direct or indirect interest in the property, and qualified and experienced to perform such estimates of value for the type and amount of credit being considered.

(e) Appraisals to address safety and soundness concerns. NCUA reserves the right to require an appraisal under this subpart whenever the agency believes it is necessary to address safety and soundness concerns.

3. Section 722.4 is revised to read as follows:

§ 722.4 Minimum appraisal standards.

For federally related transactions, all appraisals shall, at a minimum:

(a) Conform to generally accepted appraisal standards as evidenced by the Uniform Standards of Professional Appraisal Practice (USPAP) promulgated by the Appraisal Standards Board of the Appraisal Foundation, 1029 Vermont Ave., NW., Washington, DC 20005;

(b) Be written and contain sufficient information and analysis to support the institution's decision to engage in the transaction;

(c) Analyze and report appropriate deductions and discounts for proposed construction or renovation, partially

leased buildings, non-market lease terms, and tract developments with unsold units;

(d) Be based upon the definition of market value as set forth in § 722.2(f); and

(e) Be performed by State licensed or certified appraisers in accordance with requirements set forth in this subpart.

4. Section 722.5 is amended by revising paragraph (b) to read as follows:

§ 722.5 Appraiser independence.

* * * * *

(b) *Fee Appraisers.* (1) If an appraisal is prepared by a fee appraiser, the appraiser shall be engaged directly by the credit union or its agent and have no direct or indirect interest, financial or otherwise, in the property or the transaction.

(2) A credit union also may accept an appraisal that was prepared by an appraiser engaged directly by another financial services institution; if:

(i) the appraiser has no direct or indirect interest, financial or otherwise, in the property or transaction; and

(ii) the credit union determines that the appraisal conforms to the requirement of this regulation and is otherwise acceptable.

Appendix A—[Removed]

5. Appendix A to Part 722 is removed.

[FR Doc. 95–24690 Filed 10–3–95; 8:45 am]

BILLING CODE 7535–01–U

FEDERAL TRADE COMMISSION

16 CFR Part 436

Trade Regulation Rule: Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures

AGENCY: Federal Trade Commission.

ACTION: Revocation of authorization to use disclosures prepared in compliance with the 1986 Uniform Franchise Offering Circular Guidelines in lieu of disclosures required by the Commission's Franchise Rule.

SUMMARY: On January 1, 1996, the Commission will revoke acceptance of disclosures prepared in accordance with the 1986 Uniform Franchise Offering Circular Guidelines (''UFOC''), adopted by the North American Securities Administrators Association (''NASAA'') on November 21, 1986, for compliance with the pre-sale disclosure requirements of the Commission's Franchise Rule (16 CFR 436.1(a)–(e)).

DATES: Authorization to prepare disclosures that comply with the 1986 UFOC Guidelines is revoked on January 1, 1996. UFOC disclosures required to be prepared, amended, revised, or filed on and after the revocation date by the Rule or state law must satisfy the requirements of the UFOC Guidelines as amended by NASAA on April 25, 1993, and approved by the FTC on December 30, 1993, (58 FR 69,224) for use in compliance with the Franchise Rule.

ADDRESSES: Questions about Franchise Rule compliance obligations arising from this notice should be addressed to Franchise Rule Staff, Division of Marketing Practices, Federal Trade Commission, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Steven Toporoff, Division of Marketing Practices, Room 238, Federal Trade Commission, Washington, D.C. 20580 (202) 326–3135.

SUPPLEMENTARY INFORMATION: The Commission's trade regulation rule entitled ''Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures'' (''Franchise Rule'' or ''Rule'') (16 CFR Part 436) requires franchisors to provide pre-sale disclosures of material information to prospective franchisees. The form and content of the required disclosures is prescribed by §§ 436.1(a)–(e) of the Rule.

When the Rule was issued, the Commission authorized the use of an alternative disclosure format, known as the Uniform Franchise Offering Circular (''UFOC''), in lieu of the disclosures required by §§ 436.1(a)–(e) of the Rule (43 FR 59,614, 59,722). The UFOC had been prepared by state franchise law administrators to enable franchisors to use a single document to comply with the differing pre-sale disclosure requirements of the franchise registration and disclosure laws in their jurisdictions.

The Commission's initial approval of the UFOC extended only to disclosures that complied with the UFOC Guidelines as adopted by the Midwest Securities Commissioners Association (''MSCA'') on September 2, 1975 (43 FR 69,614, 59,722). The Commission subsequently granted a petition from the MSCA's successor, the North American Securities Administrators Association (''NASAA''), for approval of amendments to the UFOC Guidelines that NASAA had adopted on November 21, 1986 (52 FR 22,686).

In a request filed July 2, 1993, NASAA asked the Commission to approve new amendments to the UFOC Guidelines, adopted on April 25, 1993 (Extra Edition, Bus. Fran. Guide (CCH), Rpt. No. 161 (May 25, 1993)). The Commission approved the amendments to the UFOC on December 30, 1993 (58 FR 69,224). The new amendments include significant changes and additions to the present Guidelines, most notably the requirement that UFOC disclosure documents use ''plain English.'' After analyzing the differences between the amended UFOC and the Commission's Rule, the Commission found that, viewed as a whole, the amendments to the UFOC provide prospective franchisees with protection equal to or greater than that provided by the Franchise Rule.

In approving the amendments to the UFOC, the Commission authorized the use, as of January 1, 1994, of disclosures prepared in accordance with the amended UFOC Guidelines. At the same time, the Commission stated that it would revoke its prior authorization for preparation of disclosures in accordance with the 1986 UFOC Guidelines ''effective six months to the day after the date on which the last state requiring pre-sale registration of a franchise adopts the amended UFOC Guidelines.'' The Commission added that ''UFOC disclosures required to be prepared, amended, revised, or filed on and after the revocation date by the Rule or state law must satisfy the requirements of the UFOC Guidelines as amended by NASAA on April 25, 1993, for use in compliance with the Franchise Rule.'' 58 FR at 69,225.

On July 28, 1995, the State of New York became the final franchise registration state to adopt the amendments to the UFOC. Accordingly, the revocation date for the Commission's acceptance of disclosure documents prepared according to the 1986 UFOC Guidelines should be January 28, 1996. The Commission, however, adopts January 1, 1996, as the revocation date of the 1986 UFOC Guidelines. A January 1, 1996, revocation date creates a brightline that would comport with the practice of many franchisors who use a calendar fiscal year. Moreover, a January 1, 1996, revocation date would be easier for franchise regulators to administer. The Commission notes that if it adopted a January 28, 1996, revocation date, then some franchisors would be able to delay converting to the amended UFOC until January 1997. This would delay the phase-in period of the amended UFOC unnecessarily and would deny many prospective franchisees the benefit of the significant improvements set forth in the new UFOC format. Finally, the Commission notes that a January 1, 1996, revocation date likely would cause minimal harm to franchisors. Franchisors have been on notice since December 30, 1993, that the

Commission would revoke acceptance of the 1986 UFOC Guidelines in the near future. Indeed, Section 265 of the amended UFOC Guidelines states NASAA's view that the amended UFOC should take effect ''no later than January 1, 1995.'' Although the Commission did not adopt the January 1, 1995, due date set out in the amended UFOC Guidelines, franchisors were clearly on notice that the franchise registration states preferred an early conversion from the 1986 UFOC to the amended UFOC Guidelines.

For these reasons, the Commission adopts January 1, 1996, as the revocation date for acceptance of disclosures prepared under the 1986 UFOC Guidelines. UFOC disclosures required to be prepared, amended, revised, or filed on and after January 1, 1996, must satisfy the requirements of the 1993 UFOC Guidelines as adopted by NASAA on April 25, 1993, and approved by the Commission on December 30, 1993 (58 FR 69,224) for use in compliance with the Franchise Rule.

List of Subjects in 16 CFR Part 436

Advertising, Business and industry, Franchising, Trade practices.

Authority: 15 U.S.C. 42–58.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 95–24678 Filed 10–3–95; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[TD ATF–368 ; Re: Notice No. 812]

RIN: 1512–AA07

Puget Sound Viticultural Area (94F–019P)

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Final rule, Treasury decision.

SUMMARY: This final rule establishes a viticultural area in the State of Washington to be known as ''Puget Sound.'' The petition for this viticultural area was filed by Gerard and Jo Ann Bentryn, Owners-Winemakers of Bainbridge Island Vineyards.

ATF believes that the establishment of viticultural areas and the subsequent use of viticultural area names as appellations of origin in wine labeling and advertising allows wineries to designate the specific areas where the grapes used to make the wine were grown and enables consumers to better identify the wines they purchase.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: David W. Brokaw, Wine, Beer and Spirits Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226, (202) 927–8230.

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF–53 (43 FR 37672, 54624) revising regulations in 27 CFR Part 4. These regulations allow the establishment of definitive viticultural areas. The regulations allow the name of an approved viticultural area to be used as an appellation of origin on wine labels and in wine advertisements. On October 2, 1979, ATF published Treasury Decision ATF–60 (44 FR 56692) which added a new Part 9 to 27 CFR, providing for the listing of approved American viticultural areas, the names of which may be used as appellations of origin.

Section 4.25a(e)(l), Title 27, CFR, defines an American viticultural area as a delimited grape-growing region distinguishable by geographic features, the boundaries of which have been delineated in Subpart C of Part 9.

Section 4.25a(e)(2), Title 27, CFR, outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area. The petition should include:

(a) Evidence that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical characteristics (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundaries of the viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale, and;

(e) A copy (or copies) of the appropriate U.S.G.S. map(s) with the proposed boundaries prominently marked.

Petition

ATF received a petition from Gerard and Jo Ann Bentryn of Bainbridge Island Vineyards & Winery in Bainbridge Island, Washington, proposing to establish a new viticultural area within the State of Washington to be known as ''Puget Sound.'' Puget Sound (or the ''Sound'') is an inlet of the Pacific Ocean in Northwestern Washington, extending about 100 miles south from Admiralty Inlet and Juan de Fuca Strait to Olympia. The viticultural area lies within the land basin surrounding the Sound. Eight letters of support from wineries and vineyards located within the area were included with the petition. These letters of support were from: Mount Baker Vineyards, Whidbey Island Winery, Lopez Island Vineyards, Inc., E.B. Foote Winery, Blue Apple Vineyard, Molly's Vineyard, Coolen Wine Cellar, and Johnson Creek Winery/Alice's Restaurant.

The Puget Sound viticultural area is located in the Northwestern portion of Washington State. The entire Puget Sound watershed contains 13,100 square miles of land, 150 square miles of fresh water, and 2,500 square miles of saltwater. The Puget Sound viticultural area contains approximately 55% of the watershed's land area and water or 7,150 square miles of land and 1,500 square miles of water for a total area of 8,650 square miles. It has a maximum length of 190 miles from north to south and 60 miles from east to west, although it is most often less than 45 miles wide.

Notice of Proposed Rulemaking

In response to Gerard and Jo Anne Bentryn's petition, ATF published a notice of proposed rulemaking, Notice No. 812, in the Federal Register on May 22, 1995 [60 FR 27060], proposing the establishment of the Puget Sound viticultural area. The notice requested comments from all interested persons by July 6, 1995.

Comments on Notice of Proposed Rulemaking

ATF did not receive any letters of comment in response to Notice No. 812. Eight letters of support from wineries and vineyards located within the area were included with the petition as discussed above. Accordingly, this final rule establishes a Puget Sound viticultural area with boundaries identical to those proposed in Notice No. 812.

Evidence That the Name of the Area is Locally or Nationally Known

The name ''Puget Sound'' was established in 1791 by Captain George

Vancouver when he named, explored, and mapped the area while in service to the British Admiralty. His maps and those of subsequent explorers, settlers and government agencies show the Puget Sound area with the countryside drained by rivers flowing into Puget Sound. Numerous references exist indicating the general use of the name ''Puget Sound'' to refer to the area. The petitioners included copies of title pages of various publications, guide and tour book references, public telephone book listings, and Federal and State agency maps, to illustrate the use of the name. They also submitted an excerpt from, ''Touring the Washington Wine Country,'' 1993, published by the Washington Wine Commission. This publication discusses grape growing in western Washington and states that, ''[t]he expansive Puget Sound basin offers a temperate climate that rarely suffers from prolonged freezing weather in the winter and quite often enjoys a long and warm summer growing season.''

Historical or Current Evidence That the Boundaries of the Viticultural Area Are as Specified in the Petition

The viticultural area is located on the land mass surrounding Puget Sound and known as the Puget Sound basin. The petitioners explained that there are no exacting and commonly understood boundaries for the basin. The basin boundaries, for example, can extend up to the crests of the Olympic and Cascade mountain ranges to include the entire watershed. However, individuals in western Washington State commonly refer to the lowland areas surrounding the Sound as the Puget Sound basin. It is these lowland areas that the petitioners feel are suited for viticulture.

The petitioners stated that, ''Puget Sound has boundaries determined absolutely by the forces of nature, and recognized by common cultural use. We merely used those public roads that most closely fit within those natural boundaries of terminal moraine [accumulation of boulders, stones, or other debris carried and deposited at the edges of the farthest reaches of a glacier's advance], rainfall lines (isohyets), and temperature to draw enforceable borders.'' [Definition added.] The petitioners also state that, ''[t]he * * * viticultural area is smaller than the basin because not all of the basin is suitable for viticulture. Areas with elevations greater than 600 feet are generally too wet or too cold in this region so they have been excluded.''

Evidence Relating to the Geographical Features (Climate, Soil, Elevation, Physical Features, Etc.) Which Distinguish Viticultural Features of the Area From Surrounding Areas

Climate

The climate of Puget Sound is well differentiated from that of surrounding areas. The Olympic Mountains to the west and the Cascade Mountains to the east protect the region from the cool wet influence of the Pacific Ocean and the extreme summer and winter temperatures of eastern Washington. The Strait of Juan de Fuca and associated waterways separate Puget Sound from the cooler summer areas to the north. Foothills to the south of the Puget Sound viticultural area are the limit of the area influenced by the moderating effect of the waters of the Sound. Both summer and winter temperatures are significantly cooler in the hills and mountains to the west, south, and east.

The western, eastern and southern boundaries of the Puget Sound viticultural area closely follow the line formed by a growing season of 180 days and the 60 inch isohyet of annual precipitation. All areas within the viticultural area below 600 feet in elevation have a 180 day or longer growing season with 60 inches or less of annual rainfall, and 15 inches or less of rainfall in the months of April to October (inclusive).

Areas outside of, but adjacent to, the viticultural area to the west, south, and east have a growing season of generally less than 180 days, with more than 60 inches of annual rainfall, and more than 15 inches of rainfall in the months of April to October (inclusive). Examples of weather recording stations surrounding the Puget Sound region are as follows: To the west is Forks, with a growing season of 175 days and an annual precipitation of 118 inches (38 inches April to October). To the southeast is Paradise Ranger Station (Mount Rainier National Park), with a growing season of 50 days and an annual precipitation of 106 inches (39 inches April to October). To the east is Diablo Dam with a growing season of 170 days and an annual precipitation of 72 inches (23 inches from April to October). To the northeast is Heather Meadows Recreational Area (Mt. Baker National Forest) with a growing season of 150 days and an annual precipitation of 110 inches (44 inches from April to October).

The northerly border of the viticultural area closely conforms to the temperature boundary of areas experiencing a mean high temperature in the warmest month (July) of 72 degrees Fahrenheit or greater. Cool air from the Pacific Ocean moves east through the Strait of Juan de Fuca during the growing season limiting the reliable ripening of winegrapes in the areas west of the Elwha River and outside the line formed by the western boundaries of Clallam, San Juan, and Whatcom Counties and the northern boundary of Whatcom County.

Examples of areas to the northwest of the viticultural area with mean high temperatures in the warmest month which are lower than 72 degrees Fahrenheit are: Forks, Washington, 71 degrees F; Clallum Bay, Washington, 67 degrees F; Victoria, British Columbia, 68 degrees F; and Sidney, British Columbia, 67 degrees F.

Degree Days

Total degree days as measured by the scale developed by Winkler and Amerine of the University of California (Davis) range between 1300 at the northern border, to 2200 in the south. Typical readings are: Friday Harbor 1380, Blaine 1480, Sequim 1310, Port Townsend 1480, Mt. Vernon 1530, Coupeville 1360, Monroe 1820, Bothell 1520, Kent 1940, Seattle (U of W) 2160, Bremerton 1810, Vashon 1730, Grapeview 2010, Puyallup 1770, Tacoma 1940, and Olympia 2160. There is a significant temperature variation from north to south. According to the petitioner, this temperature variation is within a range that will allow the same types of grapes to be grown throughout the area.

Rainfall

Rainfall in the Puget Sound viticultural area is substantially less than in surrounding areas. It ranges from 17 inches annually in the north to 60 inches in the south. Typical amounts are: Friday Harbor 28″ Blaine 34″, Sequim 17″, Port Townsend 18″, Mt. Vernon 32″, Coupeville 18″, Monroe 47″, Bothell 40″, Kent 38″, Seattle (U of W) 35″, Bremerton 39″, Vashon 47″, Grapeview 53″, Puyallup 41″, Tacoma 37″, and Olympia 52″. Growing season rainfall ranges from 8 inches in the north to 15 inches in the south. Outside of the boundaries, the rainfall ranges from 70 to 220 inches annually.

Overall, the Puget Sound viticultural area can be characterized as having a growing season of over 180 days, annual degree day averages between 1300 and 2200, and annual rainfall of 60 inches or less.

Soils

Soils in the Puget Sound viticultural area are completely unlike those of the

surrounding upland areas in that they are the result of the advance and withdrawal of the Vashon glaciation. This most recent glaciation (10,000 years ago) coincided at its limits with the eastern, southern, and southwestern boundaries of the viticultural area. The resultant soils are primarily silty to sandy topsoils with scattered small to moderate rounded stones. This is typical of post glacial soils in lowland areas. Areas outside the viticultural area to the west, south and east, were not covered by ice during the Vashon glaciation. Consequently, soils in surrounding areas have entirely different origins and genesis. The primary impact on viticultural conditions by the glaciation of the Puget Sound viticultural area was the development of a semi-permeable cemented subsoil at depths generally from one to ten feet. This subsoil was created by the pressure of one to three thousand feet of overlying ice. The subsoil acts as a storage vehicle for winter rains and allows deep rooted vines to survive the late-summer soil water deficit without irrigation. The surrounding areas which were not glaciated do not share this comparative advantage. The semi-permeable cemented subsoil is the most significant soil factor relative to viticulture in the area.

Topography and Geographical Features

The Puget Sound basin is a large lowland surrounding bodies of salt water called in government reports ''Puget Sound'' or ''Puget Sound and Adjacent Waters.'' These waters comprise Puget Sound, a long, wide ocean inlet. The basin is cut by many rivers flowing into the Sound. Low rolling hills formed by the deposit and erosion of advancing and retreating glaciers are cut by ravines and stream channels. The dominating natural features are the sound itself and the surrounding mountains. The Olympic mountain range forms the western boundary of the Puget Sound basin. These mountains intercept moist maritime Pacific air and account for the relatively low annual precipitation. The Cascade mountain range forms the eastern boundary of the Puget Sound basin. These mountains protect the basin from the extremely cold winters and hot summers of eastern Washington. Elevations in the basin are primarily between sea-level and 1,000 feet. Isolated hills of up to 4,000 feet occur primarily in the northeast but none of the existing vineyards is above 600 feet in elevation.

Viticulture

The petitioners state that neither vinifera nor labrusca vines are native to the area; however, they are now grown throughout the basin. In 1872, Lambert Evans established a vineyard on Stretch Island in southern Puget Sound. He sold the fruit in Seattle. In the 1890's a viticulturalist from the east coast named Adam Eckert brought new grape varieties and planted more vineyards on the island. The first bonded winery in Washington State was established there in 1933 by Charles Somers. Known as the St. Charles Winery, it reached a capacity of 100,000 gallons. Viticulture spread throughout the Puget Sound basin as evidenced by the annual reports of the Washington State Department of Agriculture. These primarily labrusca plantings were gradually supplanted in most of the basin by vinifera plantings from the 1950's to the present. The Washington State Department of Agriculture report entitled, ''Washington Agriculture,'' 1960, reported 2 small areas of grape cultivation outside of Yakima Valley; one of them being ''in western Washington in Kitsap county. There along the shores of Puget Sound, grapes have grown satisfactorily for many years.'' The 1993 publication, ''Touring the Washington Wine Country,'' which is published by the Washington Wine Commission states that, ''Small vineyards flourish on Puget Sound's islands * * *'' There are now over 50 acres of vineyards in the basin and 25 bonded wineries.

Boundaries

The boundaries of the Puget Sound viticultural area may be found on four 1:250,000 scale U.S.G.S. maps titled: Hoquiam, Washington (1974); Seattle, Washington (1974); Wenatchee, Washington (1971); Victoria, B.C., Can., Wash., U.S. (1974); one 1:25,000 scale map titled: Auburn, Washington (1983); and three 1:24,000 scale maps titled: Buckley, Washington (1993); Cumberland, Washington (1993); and Enumclaw, Washington (1993).

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Public Law 96–511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this rule because no requirement to collect information is proposed.

Regulatory Flexibility Act

It is hereby certified that this regulation will not have a significant impact on a substantial number of small entities. The establishment of a viticultural area is neither an endorsement nor approval by ATF of the quality of wine produced in the area, but rather an identification of an area that is distinct from surrounding areas. ATF believes that the establishment of viticultural areas merely allows wineries to more accurately describe the origin of their wines to consumers, and helps consumers identify the wines they purchase. Thus, any benefit derived from the use of a viticultural area name is the result of the proprietor's own efforts and consumer acceptance of wines from that region.

Accordingly, a regulatory flexibility analysis is not required because this final rule is not expected (1) to have significant secondary, or incidental effects on a substantial number of small entities; or (2) to impose, or otherwise cause a significant increase in the reporting, recordkeeping, or other compliance burdens on a substantial number of small entities.

Executive Order 12866

It has been determined that this regulation is not a significant regulatory action because:

(1) It will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866.

Drafting Information

The principal author of this document is David W. Brokaw, Wine, Beer, and Spirits Regulations Branch, Bureau of Alcohol, Tobacco, and Firearms.

List of Subjects in 27 CFR Part 9

Administrative practices and procedures, Consumer protection, Viticultural areas, and Wine

Authority and Issuance

Title 27, Code of Federal Regulations, Part 9, American Viticultural Areas, is to be amended as follows:

PART 9—AMERICAN VITICULTURAL AREAS

Paragraph 1. The authority citation for Part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

Par. 2. Subpart C is amended by adding § 9.151 to read as follows:

§ 9.151 Puget Sound

(a) *Name.* The name of the viticultural area described in this section is ''Puget Sound.''

(b) *Approved maps.* The appropriate maps for determining the boundary of the Puget Sound viticultural area are four 1:250,000 scale U.S.G.S. topographical maps, one 1:25,000 scale topographic map, and three 1:24,000 scale topographic maps. They are titled:

(1) Hoquiam, Washington, 1958 revised 1974 (1:250,000)

(2) Seattle, Washington, 1958 revised 1974 (1:250,000)

(3) Wenatchee, Washington, 1957 revised 1971 (1:250,000)

(4) Victoria, B.C., Can., Wash., U.S., 1957 revised (U.S. area) 1974 (1:250,000)

(5) Auburn, Washington, 1983 (1:25,000)

(6) Buckley, Washington, 1993 (1:24,000)

(7) Cumberland, Washington, 1993 (1:24,000)

(8) Enumclaw, Washington, 1993 (1:24,000)

(c) *Boundary.* The Puget Sound viticultural area is located in the State of Washington. The boundaries of the Puget Sound viticultural area, using landmarks and points of reference found on appropriate U.S.G.S. maps, follow.

(1) Beginning where the Whatcom county line comes closest to an unnamed secondary road (referred to in the petition as Silver Lake Road) on the U.S.G.S. map ''Victoria,'' T41N/R6E;

(2) Then south along Silver Lake Road approximately 5.5 miles to its intersection with State Highway 542, T39N/R5E;

(3) Then west and then southwest along State Highway 542 approximately 11 miles to its intersection with State Highway 9, T38N/R5E;

(4) Then south along State Highway 9 approximately 44 miles to its intersection with an unnamed secondary road (referred to in the petition as Burn Road) at the town of Arlington, T31N/R5E;

(5) Then south, southeast along Burn Road approximately 11 miles to its intersection with State Highway 92, T30N/R6E;

(6) Then south along State Highway 92 approximately 3 miles to its intersection with an unnamed light duty road (referred to in the petition as Machias Hartford Road), T29N/R6E;

(7) Then south along Machias Hartford Road approximately 4 miles to its intersection with an unnamed secondary road (referred to in the petition as Lake Roesiger Road), on the U.S.G.S. map ''Wenatchee,'' T29N/R7E;

(8) Then east along Lake Roesiger Road approximately 3.5 miles to its intersection with an unnamed secondary road (referred to in the petition as Woods Creek Road), T29N/R7E;

(9) Then south along Woods Creek Road approximately 10.5 miles to its intersection with U.S. Highway 2 in the town of Monroe, T27N/R7E;

(10) Then west along U.S. Highway 2 approximately ½ mile to its intersection with State Highway 203, T27N/R6E;

(11) Then south along State Highway 203 approximately 24 miles to its intersection with an unnamed secondary road (referred to in the petition as Preston-Fall City Road), at the town of Fall City, T24N/R7E;

(12) Then southwest along Preston-Fall City Road approximately 4 miles to its intersection with Interstate Highway 90 at the town of Preston, T24N/R7E;

(13) Then east along Interstate Highway 90 approximately 3 miles to its intersection with State Highway 18, T23N/R7E;

(14) Then southwest along State Highway 18 approximately 7 miles to its intersection with an unnamed secondary road (referred to in the petition as 276th Avenue SE), T23N/R6E;

(15) Then south along 276th Avenue SE approximately 5 miles to its intersection with State Highway 516 at the town of Georgetown, T22N/R6E;

(16) Then west along State Highway 516 approximately 2 miles to its intersection with State Highway 169 at the town of Summit on the U.S.G.S. map, ''Seattle,'' (shown in greater detail on the U.S.G.S. map, ''Auburn''), T22N/R6E;

(17) Then south along State Highway 169 approximately 11.5 miles to its intersection with State Highway 410 at the town of Enumclaw on the U.S.G.S. map, ''Wenatchee,'' (shown in greater detail on the U.S.G.S. map, ''Enumclaw''), T20N/R6E;

(18) Then southwest approximately 5 miles along State Highway 410 until its intersection with State Highway 165 on the U.S.G.S. map, ''Seattle,'' (shown in greater detail on the U.S.G.S. map, ''Buckley''), T19N/R6E;

(19) Then southwest on State Highway 165 until its intersection with State Highway 162 at the town of Cascade Junction on the U.S.G.S. map, ''Seattle'' (shown in greater detail on the U.S.G.S. Map, ''Buckley''), T19N/R6E;

(20) Then southwest along State Highway 162 approximately 8 miles to its intersection with an unnamed secondary road (referred to in the petition as Orville Road E.), T19N/R5E;

(21) Then south along Orville Road E., approximately 8 miles to its intersection with the CMSTP&P railroad at the town of Kapowsin, on the U.S.G.S. map, ''Hoquiam,'' T17N/R5E;

(22) Then south along the CMSTP&P railroad approximately 17 miles to where it crosses the Pierce County line at the town of Elbe, T15N/R5E;

(23) Then west along the Pierce County line approximately 1 mile to the eastern tip of Thurston County, T15N/R5E;

(24) Then west along the Thurston County line approximately 38 miles to where it crosses Interstate Highway 5, T15N/R2W;

(25) Then north along Interstate Highway 5 approximately 18 miles to its intersection with U.S. Highway 101 at the town of Tumwater on the U.S.G.S. map ''Seattle,'' T18N/R2W;

(26) Then northwest along U.S. Highway 101 approximately 18 miles to its intersection with State Highway 3 at the town of Shelton, T20N/R3W;

(27) Then northeast along State Highway 3 approximately 24 miles to where it crosses the Kitsap County line, T23N/R1W;

(28) Then north along the Kitsap County line approximately 3 miles to the point where it turns west, T23N/R1W;

(29) Then west along the Kitsap County line approximately 11 miles to the point where it turns north, T23N/R3W;

(30) Then continuing west across Hood Canal approximately 1 mile to join with U.S. Highway 101 just south of the mouth of an unnamed creek (referred to in the petition as Jorsted Creek), T23N/R3W;

(31) Then north along U.S. Highway 101 approximately 40 miles to the point where it turns west at the town of Gardiner on the U.S.G.S. map ''Victoria,'' T30N/R2W;

(32) Then west along U.S. Highway 101 approximately 32 miles to where it crosses the Elwha River, T30N/R7W;

(33) Then north along the Elwha River approximately 6 miles to its mouth, T31N/R7W;

(34) Then continuing north across the Strait of Juan de Fuca approximately 5

miles to the Clallam County line, T32N/R7W;

(35) Then northeast along the Clallam County line approximately 14 miles to the southwestern tip of San Juan County, T32N/R4W;

(36) Then northeast along the San Juan County line approximately 51 miles to the northern tip of San Juan County, T38N/R3W;

(37) Then northwest along the Whatcom County line approximately 19 miles to the western tip of Whatcom County, T41N/R5W;

(38) Then east along the Whatcom County line approximately 58 miles to the beginning.

Signed: August 29, 1995.

Daniel R. Black,

Acting Director.

Approved: September 14, 1995.

John P. Simpson,

Deputy Assistant Secretary, (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 95–24660 Filed 10–3–95; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 948

West Virginia Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving, with exceptions, an amendment to the West Virginia permanent regulatory program (hereinafter referred to as the West Virginia program). The amendment revises the State's bonding requirements and the acid mine drainage treatment provisions of the Special Reclamation Fund. The amendment will improve operational efficiency, clarify ambiguities, and revise the West Virginia program to be consistent with the Surface Mining Control and Reclamation Act of 1977 (SMCRA) and the corresponding Federal regulations. Further amendments will be required to being the West Virginia Program into full compliance with SMCRA.

EFFECTIVE DATE: October 4, 1995. Approval dates of regulatory program amendments are listed in § 948.15(o).

FOR FURTHER INFORMATION CONTACT: Mr. James C. Blankenship, Jr., Director, Charleston Field Office, Office of Surface Mining Reclamation and Enforcement, 1027 Virginia Street East, Charleston, West Virginia 25301, Telephone (304) 347–7158.

SUPPLEMENTARY INFORMATION:

I. Background
II. Submission of the Proposed Amendment
III. Director's Findings
IV. Summary and Disposition of Comments
V. Director's Decision
VI. Procedural Determinations

I. Background

SMCRA was passed in 1977 to address environmental and safety problems associated with coal mining. Under SMCRA, OSM works with States to ensure that coal mines are operated in a manner that protects citizens and the environment during mining, that the land is restored to beneficial use following mining, and that the effects of past mining at abandoned coal mines are mitigated.

Many coal-producing States, including West Virginia, have sought and obtained approval from the Secretary of the Interior to carry out SMCRA's requirements within their borders. In becoming the primary enforcers of SMCRA, these ''primacy'' States accept a shared responsibility with OSM to achieve the goals of SMCRA. Such States join with OSM in a shared commitment to the protection of citizens—our primary customers—from abusive mining practices, to be responsive to their concerns, and to allow them full access to information needed to evaluate the effects of mining on their health, safety, general welfare, and property. This commitment also recognizes the need for clear, fair, and consistently applied policies that are not unnecessarily burdensome to the coal industry—producers of an important source of our Nation's energy.

Under SMCRA, OSM sets minimum regulatory and reclamation standards. Each primacy State ensures that coal mines are operated and reclaimed in accordance with the standards in its approved State program. The States serve as the front-line authorities for implementation and enforcement of SMCRA, while OSM maintains a State performance evaluation role and provides funding and technical assistance to States to carry out their approved programs. OSM also is responsible for taking direct enforcement action in a primacy State, if needed, to protect the public in cases of imminent harm or, following appropriate notice to the State, when a State acts in an arbitrary and capricious manner in not taking needed enforcement actions required under its approved regulatory program.

Currently there are 24 primacy States that administer and enforce regulatory programs under SMCRA. These States may amend their programs, with OSM approval, at any time so long as they remain no less effective than Federal regulatory requirements. In addition, whenever SMCRA or implementing Federal regulations are revised, OSM is required to notify the States of the changes so that they can revise their programs accordingly to remain no less effective than the Federal requirements.

A major goal of SMCRA is to ensure adequate reclamation of all areas disturbed by coal mining. To accomplish this, mining is allowed to proceed only after an operator has filed a performance bond of sufficient amount to ensure completion of reclamation. In the event of bond forfeiture, the regulatory authority uses the performance bond money to contract for the necessary reclamation work. SMCRA also allows for the adoption of an alternative bonding system so long as it achieves the purposes and objectives of the conventional bonding system described above. Under an alternative bonding system, rather than posting full-cost reclamation bonds, an operator is allowed to participate in a bond pool or other financial mechanism that is to provide sufficient revenue at any time to complete reclamation in the event of bond forfeiture.

As part of their approved programs, primacy States have adopted procedures consistent with Federal bonding requirements. The Secretary conditionally approved West Virginia's alternative bonding system on January 21, 1981 (46 FR 5326). After receipt of a required actuarial study, the Secretary fully approved the State's alternative bonding system on March 1, 1983 (48 FR 8448).

Background information on the West Virginia program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the January 21, 1981, Federal Register (46 FR 5915). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 948.10, 948.12, 948.13, 948.15, and 948.16.

II. Submission of the Proposed Amendment

On October 1, 1991, OSM notified West Virginia that it needed to amend its alternative bonding system to be in compliance with sections 509(c) and 519(b) and 519(c)(3) of SMCRA (Administrative Record No. WV–878). OSM's annual reviews of the West Virginia program had found that the

State's alternative bonding system no longer met the requirements for such systems because, as of June 30, 1990, liabilities exceeded assets by $6.2 million dollars. OSM also informed the State that its alternative bonding system must provide for the abatement or treatment of polluted water flowing from permanent program bond forfeiture sites unless its approved program included another form of financial guarantee to provide for water treatment. The proposed amendment now under consideration was submitted to OSM in response to this letter and concurrent State initiatives to address bonding and water quality problems.

In a series of three letters dated June 28, 1993, and July 30, 1993 (Administrative Record Nos. WV–888, WV–889 and WV–893), the West Virginia Division of Environmental Protection (WVDEP) submitted an amendment to its approved permanent regulatory program that included numerous revisions to the West Virginia Surface Coal Mining and Reclamation Act (referred to herein as ''the Act,'' WVSCMRA § 22A–3–1 *et seq.*) and the West Virginia Surface Mining Reclamation Regulations (CSR § 38–2–1 *et seq.*). OSM grouped the proposed revisions that concern bonding into one amendment that is the subject of this notice. The main provisions of the amendment will:

- Allow for the selection and prioritization of bond forfeiture sites to be reclaimed;
- Limit administrative expenditures from the Special Reclamation Fund to an amount not to exceed 10 percent of the total annual assets in the Fund;
- Raise the special reclamation tax from one cent to three cents per ton and provide for the collection of the tax whenever liabilities exceed assets;
- Require site-specific bonds that reflect the relative potential cost of reclamation but do not exceed $5,000 per acre;
- Allow for the use of incremental and open-acre bonds;
- Require penal bonds instead of performance bonds; and
- Require bond forfeiture sites to be reclaimed in accordance with the approved reclamation plan or modifications thereof.

OSM announced receipt of the proposed amendment in the August 12, 1993, Federal Register (58 FR 42903) and invited public comment on its adequacy. Following this initial comment period, WVDEP revised the amendment on August 18, 1994, September 1, 1994, and May 16, 1995 (Administrative Record Nos. WV–933, WV–937, and WV–979B). OSM reopened the comment period on August 31, 1994 (59 FR 44953), September 29, 1994 (59 FR 49619), and May 19, 1995 (60 FR 26855), and held public meetings in Charleston, West Virginia on September 7, 1993, October 27, 1994, and May 30, 1995.

III. Director's Findings

A. Proposed Revisions to the West Virginia Surface Coal Mining and Reclamation Act (WVSCMRA)

1. § 22–3–11: Bonds; Amount and Method of Bonding; Bonding Requirements; Special Reclamation Tax and Fund; Prohibited Acts; Period of Bond Liability

a. *§ 22–3–11(a): Penal Bonds.* West Virginia proposes to revise its Code to require that penal bonds payable to the State of West Virginia be furnished by each operator before a permit is issued. The reference to ''performance bond'' has been changed to either ''penal bond'' or ''bond'' throughout § 22–3–11 to reflect this proposed revision. Section 509(a) of SMCRA and 30 CFR 800.11(a) require that a performance bond be furnished by each operator before a permit is issued. A penal bond differs from a performance bond in that, in the event of forfeiture, the State retains the entire amount of the bond without regard to the cost of reclamation. Under a performance bond, any funds not used to reclaim the site for which the bond was forfeited must be returned to the operator.

West Virginia's proposed requirement that the total bond or collateral amount be forfeited and deposited in the State's reclamation fund lies within the discretion provided to the States by section 509(c) of SMCRA. SMCRA authorizes States to establish alternative bonding systems that will achieve the objectives and purposes of the bonding program otherwise required by SMCRA. The penal bond provisions provide substantial economic incentive for the operator to complete the required reclamation of the permitted area. This is consistent with 30 CFR 800.11(e)(2) which provides that an alternative bonding system must include a substantial economic incentive for the permittee to comply with all reclamation provisions. Also, while the court in *In re Permanent Surface Mining Regulation Litigation* held that OSM cannot approve penal bonds in a State program under SMCRA in a conventional bonding system, this decision does not prohibit the approval of penal bonds when the State independently authorizes them by statute, not by a rule promulgated under the authority of SMCRA. *In re Permanent Surface Mining Regulation Litigation,* 14 ERC 1083, 1100–01 (D.D.C., 1980) and Civ. No. 79–1144, mem. op. at 48–49 (D.D.C., May 16, 1980) as stayed in part on August 15, 1980. Therefore, the Director finds the proposed amendment is not inconsistent with SMCRA or the Federal regulations and is hereby approved.

b. *§ 22–3–11(g): Special Reclamation Fund.* The West Virginia alternative bonding system was conditionally approved by the Secretary on January 21, 1981, and the condition on the approval was removed on March 1, 1983 (46 FR 5954 and 48 FR 8448). This approval was granted under section 509(c) of SMCRA, which allows for the approval of an alternative bonding system that will achieve the objectives and purposes of section 509. In drafting section 509(c), Congress was not specific on how alternative bonding programs such as West Virginia's should be financed. The only test applicable is whether the proposed alternative system achieves the objectives and purposes of a conventional bonding system as expressed in section 509 of SMCRA and as implemented by 30 CFR 800.11(e).

(1) West Virginia is revising § 22–3–11(g) to allow development of a long-range planning process for selection and prioritization of sites to be reclaimed so as to avoid inordinate short-term obligations of the fund's assets of such magnitude that the solvency of the fund is jeopardized.

Section 509(a) of SMCRA requires the operator to post a reclamation bond that is sufficient to assure completion of the reclamation plan for that permitted site if the work must be performed by the regulatory authority. In addition, 30 CFR 800.50(b)(2) requires the regulatory authority to use funds collected from bond forfeiture to complete the reclamation plan for the site to which bond coverage applies. Section 509(c) of SMCRA and 30 CFR 800.11(e) are silent on the question of prioritizing sites for reclamation, but both imply that the funds necessary for adequate reclamation must be readily available. Specifically, 30 CFR 800.11(e)(1) specifies that an alternative bonding system must ensure that ''the regulatory authority will have sufficient money to complete the reclamation plan for any areas which may be in default at any time.''

However, since the State's regulations at CSR 38–2–12.4(c) provide that reclamation operations must be initiated within 180 days following final forfeiture notice, a planning process for selection and prioritization of sites to be reclaimed should not adversely impact the requirement that all sites for which

bonds are posted be reclaimed in accordance with their reclamation plans.

Therefore, to the extent that the proposed provision provides only for a ranking of sites for reclamation without compromising the requirement that all sites for which bonds were posted be properly and timely reclaimed, this provision is not inconsistent with the bond forfeiture provisions at section 509(a) of SMCRA and 30 CFR 800.50(b)(2), or the alternative bonding system criteria of 30 CFR 800.11(e). The proposed provision on the selection and prioritizing of forfeiture sites is hereby approved.

(2) West Virginia proposes to revise § 22–3–11(g) to specify that the Director of WVDEP may expend up to 25 percent of the annual amount of fee collections of the special reclamation fund to design, construct, and maintain water treatment systems when they are required to complete reclamation of bond forfeiture sites.

For conventional bonds, 30 CFR 800.14(b) provides that ''the amount of the bond shall be sufficient to assure the completion of the reclamation plan if the work had to be performed by the regulatory authority in the event of forfeiture.'' Under 30 CFR 780.18(b)(9), 780.21(h), 784.13(b)(9), and 784.14(g), the reclamation plan must include the steps to be taken to comply with all applicable effluent limitations and State and Federal water quality laws and regulations. These steps include treatment. Therefore, when the mining and reclamation plan indicates that treatment will be needed on a temporary basis during mining and the early stages of reclamation, the bond must be calculated to include an amount adequate to provide for continued temporary treatment in the event forfeiture occurs within the timeframe during which treatment is needed.

Also, under 30 CFR 800.15(a), the regulatory authority is required to adjust the amount and terms of a conventional bond whenever the cost of future reclamation changes. Therefore, if an unanticipated treatment need arises, the regulatory authority has an obligation to order an increase in the minimum bond required for the site. This amount must be adequate to cover all foreseeable treatment costs. This interpretation is consistent with the preamble to 30 CFR 800.17, which under the heading ''Section 800.17(c)'' states that:

> Performance bonding continues to be required at § 800.17(a) for surface disturbances incident to underground mining to ensure that the reclamation plan is completed for those areas. Completion of the reclamation plan as it relates to mine drainage and protection of the hydrologic balance would continue to be covered by the bond with respect to requirements included in § 784.14. 48 FR 32948, July 19, 1983.

Sections 780.21(h) and 784.14(g) require a hydrologic reclamation plan showing how surface and underground mining operations will comply with applicable State and Federal water quality laws and regulations. Furthermore, section 519(b) of SMCRA requires the regulatory authority, when evaluating bond release requests, to consider whether pollution of surface and ground water is occurring, the probability of any continuing pollution, and the estimated cost of abating such pollution. Section 519(c)(3) of SMCRA and the implementing regulations at 30 CFR 800.40(c)(3) provide that no bond shall be fully released until all the reclamation requirements of the Act, the regulatory program, and the permit have been met. These requirements include abatement of surface and ground water pollution resulting from the operation.

The preamble to 30 CFR 700.11(d) clarifies that the regulatory authority may release the bond and terminate jurisdiction over a site with ongoing treatment needs, but only if an enforceable mechanism such as a contract or a trust fund of sufficient duration and with adequate resources exists to ensure that treatment continues once jurisdiction is terminated. See 53 FR 44361–62, November 2, 1988.

Section 509(c) of SMCRA authorizes the Secretary to approve an alternative bonding system if it will achieve the objectives and purposes of the otherwise mandatory conventional bonding program. As noted previously in this preamble, Section 519(c)(3) of SMCRA provides final bond release shall not occur ''until all reclamation requirements of this Act are fully met.'' The Federal regulations at 30 CFR 800.11(e)(1) require that this system ensure that the regulatory authority has sufficient funds to assure completion of the reclamation plan, which includes treatment to meet State and Federal water quality requirements.

Therefore, to be in accordance with the above-referenced sections of SMCRA and the Federal regulations, an alternative bonding system must provide for complete abatement or treatment of water pollution from bond forfeiture sites. If particular sites were bonded with conventional bonds, such bonds would have to be sufficient to address all reclamation obligations on site, and none of these site-specific bonds could be ''fully released until all reclamation requirements of this Act are fully met.'' *See* SMCRA Section 519(c)(3). Similarly, OSM cannot allow States to set a predetermined limit on the amount of funds expended on any aspect of bond forfeiture reclamation, including water treatment. Such a limit, whether it be 25 percent of total annual revenues or any other predetermined amount, arbitrarily restricts expenditures for water treatment purposes, without regard to the amount needed to adequately treat each site so that it meets applicable effluent limits and water quality standards. In effect, such a limit means that sites covered by the alternative bonding system would be covered by bonds which are not ''sufficient to assure the completion of the reclamation plan if the work had to be performed by the regulatory authority in the event of forfeiture.'' *See* SMCRA Section 509(a). In other words, the State cannot be certain, in advance, that only 25 percent of the total annual revenues of the special reclamation fund will be needed to accomplish the water treatment objectives for all bond forfeiture sites, since the alternative bonding system must assume all reclamation-related responsibilities, including water treatment, for a participant who defaults on his or her reclamation obligations.

Therefore, the Director is not approving the proposed revision to the extent that water treatment on bond forfeiture sites is made discretionary (use of the word ''may'' instead of ''shall''). Similarly, the Director is not approving this proposed revision to the extent that it limits expenditures for water treatment to 25 percent of the fees collected annually for the special reclamation fund. The Director is requiring West Virginia to amend its program to remove the 25 percent limitation or to otherwise provide for the treatment of polluted water discharged from all bond forfeiture sites. The cost of water treatment at existing bond forfeiture sites may be addressed by program amendments that increase the special reclamation tax or provide additional funding from other sources. The cost of water treatment at future bond forfeiture sites may be addressed by adjusting site-specific bonds for water treatment at future bond forfeiture sites may be addressed by adjusting site-specific bonds for water treatment where necessary, or by implementing the environmental security account envisioned in CSR § 38–2–11.7, or by increasing the special reclamation tax to cover the additional cost of water treatment.

(3) West Virginia proposes to revise § 22–3–11(g) to require that monies accrued in the special reclamation fund, including interest, be used solely and exclusively for the purposes set forth in

subsection (g). This provision clarifies that the fund can only be used for specific purposes and cannot be used to finance other State programs. Furthermore, West Virginia proposes to revise § 22–3–11(g) by limiting the amount the Director of the WVDEP may expend on administrative expenses to an amount not to exceed 10 percent of the total annual assets in the special reclamation fund. Such administrative funds can only be used to implement and administer the provisions of articles 2, 3, and 4 of chapter 22 of the West Virginia Code and, as they apply to the surface mine board, articles 1 and 4 of chapter 22b of the West Virginia Code. This revision gives the Director of WVDEP discretionary power to allocate 10 percent of the total annual assets in the special reclamation fund to administrative costs incurred under the abandoned mine land program, the mining and reclamation program, the minerals other than coal program, and the Surface Mine Board.

OSM expressed concern about the State using money from the fund for any expense not related to bond forfeiture reclamation since the fund's liabilities now exceed its assets. In response, the State indicated that the 10 percent amount generally is expended exclusively for administration of the bond forfeiture/special reclamation program (Administrative Record No. WV–916).

While there is no direct Federal counterpart authorizing expenditures of bond forfeiture funds for the purpose of administrative expenses, the Director finds that this provision is not inconsistent with the objectives and purposes of section 509 of SMCRA. The Director is approving this revision to § 22–3–11(g) to the extent that the special reclamation fund can withstand administrative cost withdrawals without hampering the State's ability to complete reclamation of bond forfeiture a sites.

(4) Special Reclamation Tax

(a) West Virginia proposes to revise § 22–3–11(g) to increase the fee paid into the special reclamation fund from one cent to three cents per ton of clean coal mined and to clarify how the fee is to be collected. Section 509(c) of SMCRA and 30 CFR 800.11(e) of the Federal regulations do not specify the types of revenue-raising mechanisms. The Director is therefore approving these revisions because, under SMCRA, States have discretion in how to collect revenue to support alternative bonding systems and because the proposed tax increase will improve the financial condition of the fund.

(b) West Virginia proposes to add a provision to § 22–3–11(g) to require that every person liable for payment of the special reclamation tax pay the amount due without notice or demand for payment. The Tax Commissioner must provide the Director of the WVDEP a quarterly listing of all persons known to be delinquent in payment of the special tax. The Director of the WVDEP may take such delinquencies into account in making determinations on the issuance, renewal, or revision of any permit. Although there are no direct Federal counterparts to these provisions, the Director finds that they are a reasonable means of enforcing fee payment requirements and are hereby approved.

(c) West Virginia also proposes to revise § 22–3–11(g) by adding a requirement that the special reclamation tax be collected from every person conducting coal surface mining operations whenever the liabilities of the State for bond forfeiture reclamation exceed the accrued amount in the special reclamation fund. In conjunction with this new provision, the State is proposing to remove the requirement for a one million dollar cash reserve.

Existing State law requires that the special reclamation tax be collected whenever the assets in the fund fall below one million dollars and to continue to be collected until assets exceeded two million dollars. This provision under normal circumstances enables the fund to maintain a cash balance to reclaim sites as they were forfeited.

Section 509(c) of SMCRA requires that, under an alternative bonding system, the regulatory authority must have available sufficient money to complete the reclamation plan for any site that may be in default at any time. An alternative bonding system cannot be allowed to incur a deficit if it is to have available adequate revenues to complete the reclamation of all outstanding bond forfeiture sites. Under a conventional bonding system, an operator must post a full-cost reclamation bond that is sufficient to cover the cost of reclamation during the life of the operation. Periodic adjustments in bond amounts are required to ensure that the bond is adequate to cover the cost of reclamation, including water treatment, at any time. Under an alternative bonding system, the sit-specific bond does not have to be sufficient to cover the cost of reclamation. However, alternative bonding systems must include reserves and revenue-raising mechanisms adequate to ensure completion of the reclamation plan and fulfillment of the permittee's obligations, including any treatment needs.

Although the proposed site-specific bonding rates are significantly higher than the State's existing flat rate bond of $1,000 per acre and the State is proposing to increase its special reclamation tax from one cent to three cents per ton of mined coal to generate more revenue for the fund, State records indicate that the proposed bonding rates and the increase in revenues are still insufficient to ensure complete reclamation, including water treatment, at all bond forfeiture sites.

Therefore, the Director is disapproving the proposal to the extent that it would allow the special reclamation fund to incur a deficit. He is requiring West Virginia to remove the provision that allows collection of the special reclamation tax only when the bond forfeiture liabilities of the State exceed the fund's assets.

(d) West Virginia proposed new provisions to require the Tax Commissioner to deposit the fees collected with the State Treasurer to the credit of the special reclamation fund. Monies in the fund must be placed in an interest-bearing account with interest being returned to the fund on an annual basis. This proposed revision will improve the financial condition of the fund and is hereby approved.

2. § 22–3–12: Site-Specific Bonding

West Virginia proposes to develop and implement a site specific bonding system. Under the proposed system, the amount of the penal bond can not be less that $1,000 nor more than $5,000 per acre, and the bond must reflect the relative cost of reclamation associated with the activities to be permitted. The types of mining, mining techniques, mining methods, equipment, support facilities, topography, geology, and effect on water quality are among the factors that must be considered in determining the amount of site-specific bond. In addition, type of application, environmental enhancement, mining experience of the applicant, and compliance history of the applicant are among the factors that the Director of WVDEP may consider in determining the amount of site-specific bond.

The State's development of site-specific bonding requirements should provide greater assurance that reclamation will be completed by the permittee and will improve the financial stability of the special reclamation fund. The increase in bond should also provide a substantial economic incentive for the permittee to comply with all reclamation requirements to avoid the economic loss in case of bond

forfeiture. Therefore, the Director finds this provision is not inconsistent with the requirements of section 509(c) of SMCRA and 30 CFR 800.11(e) of the Federal regulations. Subsection 12 is hereby approved.

B. Proposed Revisions to the West Virginia Surface Mining Reclamation Regulations

1. CSR § 38–2–11.2: All Bonds

a. The State proposes to delete old subsection 11.2(c), which required a written notification to a permittee who is without bond coverage and required the cessation of mining until bond replacement. The State proposes to revise subsection 11.2(d), which requires the Director of the WVDEP to issue a notice of violation against any operator who is without bond coverage. The notice of violation now must provide that bond coverage be replaced within 15 days instead of 90 days. Mining cannot resume until an acceptable form of bond has been posted.

The Federal regulation at 30 CFR 800.16(e)(2) has provisions which require the regulatory authority, upon notification that an operator is without bond coverage, to notify the operator, in writing, to replace bond coverage within a reasonable period, not to exceed 90 days. Section 800.16(e)(2) does not specify the form of written notification and only specifies the maximum period for bond replacement. The Director considers West Virginia's proposed requirement for replacement of bond coverage within 15 days of a notice of violation to be a reasonable period of time as required by 30 CFR 800.16(e)(2). Section 800.16(e)(2) also requires that mining operations shall not resume until the regulatory authority has determined that an acceptable bond has been posted. Therefore, the Director finds the deletion of old subsection 11.2(c) and the resultant revision of CSR § 38–2–11.2(d) do not render the revised provisions less effective than 30 CFR 800.16(e)(2).

However, the Director notes that new subsection 11.3(b)(1)(G)(vii)(III), in its provision for issuance of a notice of violation against any operator who is without bond coverage, still retains the requirement that a notice of violation specify a reasonable period to replace bond coverage, not to exceed 90 days. The Director suggests that retention of the 90 day period for replacement of bond coverage in this provision was probably an oversight by the State, and it, therefore, should be removed.

b. The State also proposes to add subsection 11.2(e) to allow the Director of WVDEP to require a showing that the bond is sufficient or the assignee has the capability or financial resources to assume the liability for bonds and permits which are transferred, assigned, or sold and which have significant long-term environmental liability. Although there is no direct Federal counterpart to this provision in 30 CFR Part 800, the Federal regulations at 30 CFR 774.17(b)(3) require that an applicant for transfer, assignment, or sale of permit rights obtain appropriate performance bond coverage in an amount sufficient to cover the proposed operations. Therefore, the Director finds that CSR § 38–2–11.2(e) is not inconsistent with the Federal bonding requirements at 30 CFR Part 800 or the Federal permitting requirements at 30 CFR 774.17(b)(3). Subsection 11.2(e) is hereby approved.

c. The Director notes that West Virginia needs to amend its regulations at CSR § 38–2–11.2(b) to delete the word ''performance'' in order to remain consistent with its new penal bond requirements.

2. CSR § 39–2–11.3: Bond Instruments

The State proposes to revise and reorganize its surety bonding, collateral bonding, escrow bonding, self-bonding, and combined surety/escrow bonding requirements into new subsection 11.3, entitled ''Bond Instruments.'' The provisions for surety bonds at old subsection 11.3 are now located at subsection 11.3(a); the provisions for collateral bond at old subsection 11.4 were reorganized at subsection 11.3(b); the provisions for escrow bonding at old subsection 11.5 were relocated to subsection 11.3(c); the provisions for self-bonding at old subsection 11.6 are now at subsection 11.3(d); and the provisions for combined surety/escrow bonding at old subsection 11.7 were reorganized at subsection 11.3(e). The substantive revisions proposed for the various types of bonding instruments are discussed below.

a. Subsection 11.3(a): Surety Bonds

(1) At subsection 11.3(a)(1), West Virginia added the requirement that a surety bond be approved by the Director of WVDEP. Although the Federal counterpart regulation at 30 CFR 800.20(a) does not contain this provision, the Federal regulations at 30 CFR 800.11 do require that before a permit is issued the operator file a bond which is acceptable to the regulatory authority. Therefore, the Director finds that CSR § 38–2–11.3(a)(1) is consistent with 30 CFR 800.20(a) and is hereby approved.

(2) At subsection 11.3(a)(2), the State proposes to delete the requirement that the surety be notified within 30 days after receipt of a request for bond adjustment. This provision is duplicative of a provision for notification to the surety in the State's regulations at subsection 12.3. Therefore, since subsection 12.3 is referenced in subsection 11.3(a)(2), the Director finds this deletion does not render the surety bond regulation at CSR § 38–2–11.3(a)(2) less effective than the Federal counterpart at 30 CFR 800.20(b), and he is, therefore, approving it.

b. Subsection 11.3(b): Collateral Bonds

(1) West Virginia proposed a revision to subsection 11.3(b) to clarify that collateral bonds ''will be negotiable and guaranteed.'' Although the Federal regulations at 30 CFR 800.21 do not contain this clarifying language, the collateral bond definition at § 800.5(b) does require all forms of collateral bond to be negotiable and guaranteed. Therefore, the Director finds that subsection 11.3(b) does not render the collateral bond provisions of CSR § 38–2–11.3 less effective than the counterpart provisions of 30 CFR 800.21. Subsection 11.3(b) is hereby approved.

(2) West Virginia proposes to revise subsection 11.3(b)(1)(A) by requiring that bonds used as collateral shall be bonds of the United States or its possessions. These forms of bond satisfy the definition of ''collateral bond'' at 30 CFR 800.5. The Director therefore finds the revision of CSR § 38–2–11.3(b)(1)(A) is no less effective than 30 CFR 800.5 and is hereby approved.

The Director notes, however, that § 22–3–11(c)(1) of WVSCMRA still allows bonds of the Federal Land Bank or of the homeowners' loan corporation to be used as collateral bond. He is advising West Virginia that this provision should be removed to eliminate the inconsistency between the State's statute and regulations. Furthermore, it is the Director's understanding that such financial institutions no longer exist in the State.

(3) West Virginia is proposing to add full faith and credit general obligation bonds of the State of West Virginia, or other States, and any county, district municipality of the State of West Virginia or other States as acceptable forms of collateral bond. Since the definition of ''collateral bond'' at 30 CFR 800.5 includes negotiable bonds of a State or a municipality, the Director finds West Virginia's provision for these forms of bond at CSR § 38–2–11.3(b)(1)(B) is no less effective than the collateral bond provisions at 30 CFR

800.21. This revision of subsection 11.3(b)(1)(B) is hereby approved.

(4) West Virginia proposes to delete subsection 11.4(a)(2), which requires the regulatory authority to value collateral at its current market value, not at face value. West Virginia's Code and regulations consistently refer to market value in relation to collateral bond. The State's Code at § 22–3–11(c)(1) requires the market value of collateral bond to be equal to or greater than the sum of the bond. This is consistent with 30 CFR 800.21(e)(2), which requires that at no time can the bond value of collateral exceed the market value. Also, West Virginia's regulations at CSR § 38–2–11.3(b)(8) require that bond value be evaluated relative to market value for all collateral posted. For these reasons, the Director finds that this deletion does not render West Virginia's collateral bond provisions at CSR § 38–2–11.3(b) less effective than the Federal provisions at 30 CFR 800.21.

(5) West Virginia proposes to revise CSR § 38–2–11.3(b)(1)(G)(ii) by changing the phrase ''if not replaced by other suitable evidence of financial responsibility'' with the phrase ''if not replaced by other suitable bond or letter of credit.'' This revised language is substantively identical to 30 CFR 800.21(b)(2) which requires that letters of credit utilized as securities in areas requiring continuous bond coverage shall be forfeited and collected, if not replaced by other suitable bonds or letters of credit. Therefore, the Director finds West Virginia's revised regulation is no less effective than the Federal regulation and is hereby approved.

(6) At subsection 11.3(b)(4), the State is requiring the maximum insurable amount for individual certificates to be determined only by the Federal Deposit Insurance Corporation (FDIC) by removing its reference to the Federal Savings and Loan Insurance Corporation (FSLIC). Because the functions of the FSLIC were transferred to FDIC in 1989, the Director finds West Virginia's revised regulation at CSR § 38–2–11.3(b)(4) is no less effective than the Federal regulation at 30 CFR 800.21(a)(4) and is hereby approved.

(7) West Virginia proposes to delete 11.4(a)(7) which required the applicant to deposit sufficient amounts of certificates of deposit to assure that the WVDEP could liquidate them prior to maturity, upon forfeiture, for the amount of the bond required. Neither SMCRA nor the Federal regulations at 30 CFR 800.21 include a similar provision. Therefore, the Director finds the deletion of this provision does not render the West Virginia program less effective than SMCRA or the Federal regulations.

(8) West Virginia proposed to amend subsection 11.3(b)(8) by rewording the requirement that ''in no case shall the bond value exceed the market value'' to ''in no case shall the market value be less than the required bond value.'' Although the Federal regulation at 30 CFR 800.21(e)(2) retains the replaced language, West Virginia's rewording does not change the meaning of the requirement. Both require that the market value of collateral be equal to or greater than the required bond value. Therefore, the Director finds the revision at CSR § 38–2–11.3(b)(8) does not render it less effective than 30 CFR 800.21(e) and is hereby approved.

(9) The State is proposing to add a new provision at subsection 11.3(b)(9) which allows certain collateral bonds for permits issued prior to January 1, 1993, to remain in effect unless the bond is determined to be insufficient or otherwise invalid. The West Virginia program at subsection 2.26 specifically identifies the types of collateral that could be used as a collateral bond prior to January 1, 1993. Therefore, the Director finds that the new provision at subsection 11.3(b)(9) does not render West Virginia's collateral bond provisions at CSR § 38–2–11.3(b) less effective than the Federal collateral bond provisions at 30 CFR 800.21. Subsection 11.3(b)(9) is hereby approved.

c. Subsection 11.3(c): Escrow Bonding

At subsection 11.3(c)(2), West Virginia is removing the FSLIC as an example of a Federal insurance program. This subsection still requires that escrow funds in Federally insured accounts are not to exceed the maximum insured amount under applicable Federal insurance programs such as FDIC. The revised Federal regulations no longer contain separate provisions governing escrow bonds, as they are now considered to be cash accounts. Since the FSLIC no longer exists, the Director finds this deletion does not render CSR 38–2–11.3(c)(2) less effective than 30 CFR 800.21(d)(4) for cash accounts.

d. Subsection 11.3(d): Self-Bonding

(1) West Virginia proposes to revise subsection 11.3(d)(5)(E) by deleting the phrase ''if permitted under State law.'' The deletion would clarify that indemnity agreements may operate as judgments under forfeiture conditions. Since revised subsection 11.3(d)(5)(E) contains self-bonding provisions which are substantively the same as that of the Federal counterpart regulation, the Director finds the State's regulation is no less effective than the Federal regulation at 30 CFR 800.23(e)(4). Subsection 11.3(d)(5)(E) is hereby approved.

(2) The State proposes to delete existing CSR § 38–2–11.6(h) which requires the issuance of a notice of violation for failure to have adequate bond coverage. This provision is duplicative of a provision in subsection 11.2(d) under the general requirements for all bonds. Therefore, the Director finds this proposed deletion does not render West Virginia's regulations at new CSR 38–2–11.3(d) less effective than the Federal regulations at 30 CFR 800.23.

3. CSR § 38–2–11.4: Incremental Bonding

a. West Virginia proposed to revise subsection 11.4(a)(1) to require a bond in the appropriate amount be filed for the initial increment and each succeeding increment of land to be mined within the permit area prior to any land disturbance. Also, existing subsection 11.8(a)(3) was deleted as its substantive requirements are contained in subsection 11.4(a)(1). The incremental bonding provisions at subsection 11.4(a)(1) are substantively the same as those in the counterpart Federal regulations at 30 CFR 800.11 (b) and (c). The Federal regulations at 30 CFR 800.11(b)(1) require that a bond be filed for the initial increment, at 30 CFR 800.11(b)(2) that additional bond be filed for succeeding increments as surface coal mining and reclamation operations are initiated, and at 30 CFR 800.11(c) that an operator not disturb any surface areas or succeeding increments prior to acceptance of the bond. Therefore, the Director finds West Virginia's proposed incremental bonding provisions at CSR § 38–2–11.4(a)(1) are no less effective than the counterpart Federal provisions at 30 CFR 800.11 (b) and (c). Subsection 11.4(a)(1) is hereby approved.

b. The State also proposes to revise subsection 11.4(a)(2) to require that an operator who has chosen to bond either the entire permit area or in increments must continue the same manner of bonding during the term of the permit. The minimum amount of bond is $10,000.

While section 509(a) of SMCRA and 30 CFR Part 800 of the Federal regulations require that the minimum amount of bond for the entire area under one permit be $10,000, they do not specifically require that the operator's manner of binding, entire permit area or increments of the permit area, be continued for the term of the permit.

Nonetheless, there is nothing in the State's proposal that would conflict with any Federal requirement or result in less stringent bonding of disturbed areas. Therefore, the Director finds West Virginia's proposed regulation at CSR § 38–2–11.4(a)(2) is not inconsistent with SMCRA or the Federal regulations and is hereby approved.

c. The State proposes to revise subsection 11.4(a)(3), by adding a new provision that requires independent increments to be of sufficient size and configuration so as to provide for efficient and contemporaneous reclamation operations. Because this provision is substantively identical to the Federal regulation, the Director finds that West Virginia's proposed revision is no less effective than 30 CFR 800.11(b)(4) and is hereby approved.

d. The Director notes that West Virginia needs to amend its regulations at CSR § 38–2–11.4(a)(1) and 11.4(a)(4) to delete the word ''performance'' in order to remain consistent with its new penal bond requirements.

4. SCR § 38–2–11.5: Open-Acre Limit Bonding

West Virginia proposes to add new provisions in this subsection allowing for elective open-acre limit bonding for surface extraction operations only. These provisions would provide an alternative to bonding either the entire permit area or bonding the permit area in increments. Open-acre limit bonding is a mechanism whereby the operator bonds a designated portion of the total permit area. Only that portion of the permit area which is bonded may be disturbed. After surface extraction and reclamation has taken place on this ''open-acre limit'' portion of the permit, the operator is required to verify that that portion of the permit has been backfilled, graded and revegetated in accordance with the reclamation plan and the applicable statutory and regulatory provisions. At that point, the operator may apply the already established ''open-acre limit'' bond amount to another portion of the permit. The acreage of the next succeeding portion must not exceed the acreage of the previous portion. Mining and reclamation continue in this manner until the entire permit area has been reclaimed.

Subsection 11.5(a)(1) requires a permittee to post a general bond in the amount of $750 per acre to ensure successful revegetation of the entire permitted area. Subsection 11.5(a)(2) requires the permittee to post an open-acre limit bond in accordance with the site-specific bonding requirements of subsection 11.6, which require a bond of not less than $1,000 nor more than $5,000 per acre based on specified criteria. The minimum amount of the open-acre limit bond will be $10,000. This subsection also requires the permittee to post an ancillary facility bond for haulroads, sediment control systems and other permanent or semi-permanent control systems and other permanent or semi-permanent ancillary facilities at a rate of $1,000 per acre for the total proposed disturbed acreage of such facilities.

The general and ancillary facility bonds are to remain in place until released in accordance with CSR § 38–2–12.2 of the State's regulations. The open-acre limit bond can be reapplied to an undisturbed portion of the permit area after the initial open-acre limit area has been backfilled, regraded, and vegetated in accordance with the approved reclamation plan and the provisions of CSR § 38–2–14.15 of the State's regulations.

Subsection 11.5(b) contains permit application requirements for open-acre limit bonding. The permit application must contain a separate bonding section which includes: (1) An overlay outline map which depicts the location and extent of the initial open-acre limit, remaining permit area for which no initial bond is to be posted, and ancillary facilities; (2) a description of the bonding instruments for the three types of bond; and (3) a narrative description for the timing and sequence of mining and reclamation operations.

Subsection 11.5(c) provides that when mining and reclamation of the initial or succeeding open-acre limit is nearing completion, the permittee must submit a request to advance the open-acre limit into the undisturbed portions of the permit area by an amount of acreage not to exceed the acreage reclaimed within the existing open-acre limit area. An overlay map depicting the reclaimed open-acre limit area and the undisturbed area to which the bond is being transferred and a copy of the bond release advertisement must accompany the request. Subsection 11.5(d) provides that approval for transfer of the open-acre limit bond may not be granted until a review of the request and site is made and verified by the Director of WVDEP.

Subsection 11.5(e) provides that the permittee must apply for bond release in the same manner as described in section 23 of the Act and subsection 12.2 of these regulations when all mining and reclamation on the permit area are completed. As discussed in finding B.7., no portion of the open-acre bond can be released until all coal extraction operations are completed and the entire disturbed area is backfilled and regraded. Therefore, the proposal will not allow for final release of any open-acre limit bonded area without public notice and opportunity for comment.

While the Federal conventional bonding regulations do not contain a counterpart form of West Virginia's proposed open-acre-limit bonding, section 509(c) of SMCRA and 30 CFR 800.11(e) of the Federal regulations allow the States wide latitude in establishing alternative bonding systems. Nothing in the State's proposal is inconsistent with these requirements since the open-acre bond would replace only the site-specific component of the alternative bonding system.

The permittee would still have to pay the special reclamation fee and the alternative bonding system would still remain responsible for completion of reclamation in the event the permittee defaulted. The open-acre limit bonding rules at CSR § 38–2–11.5 are hereby approved.

5. CSR § 38–2–11.6: Site-Specific Bonding

West Virginia proposes adding CSR § 38–2–11.6 to implement the site-specific bonding provisions of § 22–3–12 of the West Virginia Code. The proposed rules establish separate requirements for four major categories of mining permits: surface mines, underground mines, coal refuse disposal sites, and coal preparation plants. Under the proposed rules, the site-specific bonds cannot be less than $1,000 nor more than $5,000 per acre or fraction thereof. This subsection includes tables to be used to calculate the per-acre bond for each category of mining included in a permit.

Subsection 11.6(a) provides that the site-specific bond criteria shall not apply where active or inactive operations are in compliance with the provisions of subsection 14.15 and where coal extraction operations are nearly completed, or when the operations are eligible for or have received Phase I bond release. In its September 1, 1994, submittal, the State proposed to exempt from the site-specific bonding criteria only those sites where coal extraction operations were ''completed'' and which met the other above-referenced criteria. However, this proposed subsection was revised in the May 16, 1995, submittal to exempt sites from the site-specific bonding requirements where coal extraction operations are nearly but not totally complete. Subsection 11.6(a)(1) provides that surface mine permits shall be reviewed at the time of renewal or midterm review and a determination made in accordance with specified

criteria as to whether the site-specific bond will apply. Subsections 11.6(a) (2), (3), and (4) provide that existing permits for underground mines, preparation plants, and coal refuse sites, respectively, shall be subject to the site-specific bond criteria at the time of application for renewal or midterm review and shall not be renewed by the Director of WVDEP until the appropriate amount of bond is posted.

Subsection 11.6(b) explains the major criteria that will apply to the four categories of mining permits. The criteria consists of relative cost factors associated with reclamation of a forfeited site, the risk of bond forfeiture, the operator's history of performance, and environmental enhancement potential. Subsections 11.6 (c), (d), (e) and (f) specify the subcriteria to be considered for computing the bond for surface mines, underground mines, coal preparation plants, and coal refuse sites. In the May 16, 1995, submittal, the State proposed to limit the period of consideration of an applicant's violation history and acts of environmental enhancement to within five years of the date of surface mine application approval instead of ten years as first proposed. Also, coal loading facilities will not be subject to site-specific bonding criteria applicable to coal preparation plants. Subsection 11.6(g) provides for an informal conference if the applicant contests the per-acre amount of the bond. The final decision may be appealed by the operator in accordance with § 22–5–21 of the West Virginia Code.

Since participation in West Virginia's alternative bonding system is mandatory, the requirement of 30 CFR 800.14(b) that the amount of the bond be sufficient to assure the completion of the reclamation plan in event of forfeiture is not applicable to the State's site-specific bonds. The State's development of more detailed site-specific bonding requirements should result in better reclamation of the mined lands by providing incentives to design and conduct mining operations in a more environmentally sound manner.

These bonding requirements should improve the financial condition of the special reclamation fund. To the extent that the new system results in an increase in bond amounts, it will provide greater incentive for the permittee to comply with all reclamation requirements to avoid the economic loss associated with bond forfeiture, in keeping with the requirements for alternative bonding systems at 30 CFR 800.11(e)(2). Therefore, the Director finds that the State's site-specific bonding provisions are not inconsistent with the requirements of section 509(c) of SMCRA and 30 CFR 800.11(e) for alternative bonding systems. The site-specific bonding rules at CSR § 38–2–11.6 are hereby approved.

However, the Director's approval is subject to the stipulation that nothing in these regulations or this approval may be construed as altering or authorizing a variance or deviation from the permitting requirements and performance standards of West Virginia's approved program.

For example, subsection 11.6(c)(4)(A) could be read to be inconsistent with the West Virginia program regulations at CSR § 38–2–14.15 for timely backfilling and grading because the conversion factor at subsection 11.6(c)(4)(A)(iii) applies in part if the reclamation plan contains unspecified ''vague'' time and distance criteria. Subsection 14.15(b) requires that the permit include specific time, distance, or acreage standards for each type of surface mining operation. There is no provision anywhere in section 14.15 for ''vague'' time and distance criteria. Hence, the reference to ''vague criteria'' in subsection 11.6 may not be interpreted as authorizing the approval of such criteria.

The Director notes that the text of subsection 11.6(c)(1)(B)(ii) refers to a factor of ''0.5'' while the referenced table identifies a factor of ''0.6.'' Also, for consistency, subsection 11.6(c)(1)(B)(ii) and Table 1 probably should be revised to read ''three to six fills''; otherwise a plan calling for two fills is covered by both subparts (i) and (ii). Similarly, subsection 11.6(c)(2)(B)(i) and (ii) both apply to mining plans where two seams of coal are to be mined. To lend consistency to its regulations, subpart (ii) and Table 1 should probably be revised to read ''three or four seams of coal.''

6. CSR § 38–2–11.7: Environmental Security Account

Proposed subsection 11.7 requires the WVDEP to study the feasibility of developing an environmental security account for water quality. The study is to include: (1) a screening process for determining which sites have the potential for producing acid mine drainage, (2) a process for predicting the rate and duration of acid mine drainage, (3) a method for estimating water treatment costs, (4) a system to ensure that sufficient monies will be placed in an escrow account to provide financial assurance that treatment will be accomplished and maintained, and (5) procedures to ensure the expenditure of funds from the escrow account in the event of default will provide water treatment. Furthermore, subsection 11.7(f) provides that after the study is completed, the Director of WVDEP may propose regulations to implement the environmental security account for water quality, but the regulations will not become effective until approved by the legislature. Subsection 11.7(g) provides that the Director of WVDEP shall inform the legislature if statutory changes are necessary to implement an effective system for financial assurances. Subsection 11.7(h) provides that nothing in this subsection authorizes the issuance of a permit that will violate applicable effluent limitations or water quality standards without treatment.

Development of an environmental security account for water quality could enhance the financial status of the State's special reclamation fund. Therefore, the Director finds the provisions at CSR § 38–2–11.7, which provides for a feasibility study, are not inconsistent with 509(c) of SMCRA or 30 CFR 800.11(e) of the Federal regulations. The Director notes that pursuant to 30 CFR 732.17(g), any regulations proposed to implement the environmental security account as a bonding mechanism for water quality or to otherwise incorporate it into the coal regulatory program must also be approved by OSM.

7. CSR § 38–2–12.2: Requirement To Release Bonds

West Virginia proposes to revise subsection 12.2(c) to provide for the release of all or part of the bond for the permit area or increment thereof. The State also proposes to revise subsection 12.2(c)(2) to delete the provision relating to chemical treatment of water at Phase II bond release and to add a provision at subsection 12.2(c)(2)(B) to require that the terms and conditions of the NPDES permit be met. Subsection 12.2(c)(2)(E) now requires that the amount of the remaining bond must be sufficient to reestablish vegetation and maintain permanent drainage control structures. These revised provisions are substantively the same as the Federal counterpart provisions at 30 CFR 800.40(c)(2) and are hereby approved.

The State proposes to add new subsection 12.2(d) to prohibit the release of any portion of the bonds posted in accordance with subsection 11.5 (open-acre limit bonding) until all coal extraction operations are completed and the entire disturbed area has been completely backfilled and regraded. Because of the floating nature of this type of bond, this restriction is needed to provide a degree of protection consistent with other types of site-

specific bond authorized under the alternative bonding system.

The State proposes to revise newly designated subsection 12.2(e) by deleting the provision for a qualified exemption to the requirement that no bond release or reduction be granted if, at the time, water discharged from or affected by the operation requires chemical treatment to comply with applicable effluent limitations or water quality standards.

The Director finds that the revised bond release provisions either remain substantively the same as the Federal regulations at 30 CFR 800.40 for conventional full-cost bonds or do not conflict with any Federal requirements or adversely impact other aspects of the West Virginia program. The changes will not negatively impact the solvency of the alternative bonding system. Therefore, the proposed revisions are not inconsistent with section 509(c) of SMCRA or the Federal regulations at 30 CFR 800.11(e). CSR § 38–2–12.2 is hereby approved.

8. CSR § 38–2–12.3: Bond Adjustments

a. West Virginia proposes to revise subsection 12.3 to provide for bond adjustments for an overbonded permit area. An overbonded permit area is an area that was originally bonded by one operator for one permit, but has subsequently been bonded again for a second permit, while the original bond remains in effect. Subsection 12.3(a) of the proposed regulations provides that where a permittee demonstrates on the basis of a sworn statement and a progress map that a portion of the permit area will remain undisturbed or has been overbonded, the Director of WVDEP may adjust the amount of the bond corresponding to the number of undisturbed or overbonded acres, provided that a minimum $10,000 bond remains for the disturbed portion of the permit. The Director of WVDEP must make a decision on the request within 30 days. If the request is denied, the Director of WVDEP must provide the permittee with an opportunity for an informal conference. Subsection 12.3(c) now contains the previously approved provision which specifies that the provisions of subsection 12.3 are not subject to the provisions of subsection 12.2.

On April 1, 1994 (Administrative Record No. WV–916), OSM requested the State to explain the term ''overbonded.'' The State replied that this provision means that when any part of an existing permit is covered by a new permit, the amount of bond for the ''double bonded area'' of the existing permit can be terminated and returned to the existing permittee. Since 30 CFR 800.15(c) provides that a permittee may request reduction of the amount of bond by submitting evidence that proves the permittee's method of operation or other circumstances reduces the estimated cost of reclamation, OSM accepted this clarification of the proposed revision. The revised State regulations at subsections 12.3 (a) and (c) are substantively the same as and therefore no less effective than the corresponding Federal regulations at 30 CFR 800.15 (b) and (c).

b. West Virginia proposes to revise subsection 12.3(b) by adding a provision that, upon receipt of a permit revision, the Director of WVDEP may review the bond adequacy and if necessary increase the amount of the bond.

Under the Federal counterpart regulation at 30 CFR 800.15(d), the regulatory authority has a mandatory duty rather than the discretionary authority to review the bond for adequacy whenever a permit is revised. However, this mandatory requirement does not apply to bonds under an alternative bonding system since the alternative bonding system provides a source of funds other than the site-specific bond for completion of the reclamation plan in the event of forfeiture. West Virginia has an alternative bonding system in which participation is mandatory. Therefore, the Director finds CSR § 38–2–12.3(b), as revised, is not inconsistent with SMCRA or the Federal regulations, and he is approving this new provision as proposed.

9. CSR § 38–2–12.4: Bond Forfeiture

a. The State is proposing to revise subsection 12.4(a) to provide that, when necessary, the Director of WVDEP must forfeit the entire bond, not just an amount based on the estimated total cost of achieving the reclamation plan requirements as specified in the current regulation. These proposed revisions to subsection 12.4(a) are in accordance with the proposed revision to WV Code § 22–3–11(a), which requires that all reclamation bonds be penal in nature. For the reasons discussed in finding A.1.a., the Director finds that the proposed revisions will not render the State program less stringent than SMCRA or less effective than the Federal rules.

b. The State also proposes to revise subsection 12.4(a)(2)(B) to provide that when a surety completes the reclamation, ''no surety liability shall be released until successful completion of all reclamation under the terms of the permit and in accordance with the Act and these regulations to include the revegetation liability period.'' OSM questioned West Virginia about the meaning of the phrase ''to include the revegetation liability period.'' West Virginia responded that this phrase merely provides an example and is not intended to exclude other types of reclamation responsibilities (Administrative Record No. WV–929).

The Federal regulations at 30 CFR 800.50(a)(2)(ii) provide that, when the regulatory authority allows a surety to complete the reclamation plan, no surety liability shall be released until successful completion of all reclamation under the terms of the permit, including applicable liability periods of § 800.13. The liability periods of § 800.13 include the extended responsibility period for successful revegetation and achievement of the reclamation requirements of the Act, the permanent regulatory program, and the permit. Therefore, the Director finds the revised provision of CSR § 38–2–12.4(a)(2)(B), is substantively identical to and no less effective than the counterpart Federal provision at 30 CFR 800.50(a)(2)(ii).

c. At CSR § 38–2–12.4(b), West Virginia proposes combining the provisions of existing subsections 12.4(b) and 12.4(c). West Virginia revised the provision in new subsection 12.4(b) that provides for the use of the proceeds to accomplish completion of reclamation by changing the citation reference of the regulations governing water quality from subsection 14.5 to subsection 12.5. Subsection 12.5 requires the establishment of an inventory of bond forfeiture sites and a priority listing of such sites for water treatment while subsection 14.5 contains general water quality standards for active mining operations.

The Federal regulations at 30 CFR 800.50(b)(2) require the regulatory authority to use funds collected from bond forfeiture to complete the reclamation plan. The amended reference pertains to only one of the requirements for completion of reclamation at a bond forfeiture site (water quality), however, new subsection 12.4(c) requires that a bond forfeiture site be reclaimed in accordance with the reclamation plan. Therefore, the proposed revision will not render CSR § 38–2–12.4 less effective than the counterpart Federal regulations at 30 CFR 800.50(b). Furthermore, as discussed in finding A.1.b(2), the Director is requiring the State to revise its program to provide for the treatment of polluted water discharging from all bond forfeiture sites.

d. West Virginia reorganized the provisions of existing paragraph (d) of

subsection 12.4 into new paragraphs (c), (d), and (e).

(1) In the June 28, 1993, version of the proposed amendment, as revised by letter dated July 30, 1993 (Administrative Record Nos. WV–889 and WV–893), new subsection 12.4(c) [previously 12.4(d)(2)] required the Director of WVDEP to initiate operations to reclaim a bond forfeiture site within 180 days after the notice of forfeiture is served. It also required remediation of acid mine drainage, including chemical treatment where appropriate.

On April 1, 1994, OSM advised West Virginia that to be no less effective than 30 CFR 800.50(b)(2), bond forfeiture sites must ''be reclaimed in accordance with the approved reclamation plans or modifications thereof.'' (Administrative Record No. WV–916). The Federal regulations at 30 CFR 800.50(b)(2) and 800.11(e) require bond forfeiture sites to be reclaimed in accordance with the reclamation plans of the revoked or suspended permits, including any modifications approved by the regulatory authority.

In its submission of September 1, 1994, West Virginia revised its regulations at CSR § 38–2–12.4(c) to clarify that bond forfeiture sites will be reclaimed in accordance with approved reclamation plans or modifications thereof (Administrative Record No. WV–937). This proposal satisfies the requirements at 30 CFR 948.15(k)(8) and 948.16(ww) that reclamation on bond forfeiture sites be completed in accordance with the approved reclamation plan. Therefore, the Director is approving this proposed revision, and he is removing the required amendment at 30 CFR 948.16(ww).

(2) New subsection 12.4(d) retains the provision from existing subsection 12.4(d)(2) that requires the Director of WVDEP to make expenditures from the special reclamation fund to complete reclamation when the proceeds of bond forfeiture are less than the actual cost of reclamation. New subsection 12.4(d) also includes the new provision requiring the Director of WVDEP to take the most effective actions possible to remediate acid mine drainage, including chemical treatment where appropriate.

Since this revised provision still makes it mandatory that West Virginia use the special reclamation fund to complete reclamation at bond forfeiture sites, the Director finds that subsection 12.4(d), as revised, is consistent with the requirements of section 509(c) of SMCRA and 30 CFR 800.11(e) of the Federal regulations and is hereby approved.

(3) At subsection 12.4(e) [previously 12.4(d)(1)], the State proposes to provide that the operator, permittee, or other responsible party be liable for all costs in excess of the amount forfeited. The Director of WVDEP may commence civil, criminal, or other appropriate action to collect such costs.

The Federal regulations at 30 CFR 800.50(d)(1) require that the operator be liable for costs in excess of the amount forfeited. They allow the regulatory authority to recover from the operator all costs of reclamation in excess of the amount forfeited. Although West Virginia does not define ''other responsible party,'' it is commonly understood that it would include any other person who may be responsible for the mining operation.

West Virginia's proposed requirement is neither specifically authorized nor prohibited by SMCRA. However, it is consistent with the principles and purposes of SMCRA to ensure the reclamation of surface areas disturbed by coal mining. *See* SMCRA section 102(e). Therefore, since the proposed provision does not conflict with any Federal requirements under SMCRA, the Director finds that the proposed revision does not render subsection 12.4(e) inconsistent with SMCRA or the Federal regulations, and he is approving it.

e. West Virginia deleted existing subsection 12.4(e) pertaining to the effective date of the provisions within subsection 12.4 relating to water quality. Because the date has long since passed, the Director finds this deletion will not render the West Virginia program less effective than the Federal regulations.

10. CSR § 38–2–12.5: Water Quality Enhancement

a. Prioritization of Forfeited Sites

West Virginia proposes to add a new subsection 12.5 to implement that portion of § 22–3–11(g) of the West Virginia Code which authorizes WVDEP to prioritize bond forfeiture sites for reclamation purposes. Subsection 12.5(a) requires the Director of WVDEP to establish an inventory of all sites for which bonds have been forfeited. The inventory is to include data relating to the quality of water being discharged from the sites. Subsection 12.5(b) requires a priority listing of these sites based upon the severity of the discharges, the quality of the receiving stream, effects on downstream water users, and other factors determined to affect the priority ranking.

Subsection 12.5(c) provides that, until the legislature supplements or adjusts the special reclamation fund, the Director of WVDEP can selectively choose sites from the inventory for water quality enhancement projects. Subsection 12.5(d) provides that, in selecting sites for water improvement projects, the Director must consider relative benefits and costs of the projects.

Subsection 12.5(e) required the Director of WVDEP to submit to the legislature, a detailed report and inventory of acid mine drainage from bond forfeiture sites. The report, which was submitted on December 31, 1993, includes cost estimates for long-term chemical treatment of drainage from each site and proposals for supplementing and adjusting the special reclamation fund to pay for this treatment (Administrative Record No. 952).

For the reasons set forth in finding A.1.b.(1), and subject to the same stipulations, subsection 12.5 is not inconsistent with the reclamation requirements of 30 CFR 800.50(b)(2) and 800.11(e), except as discussed in finding B.10.b. below. Subsections 12.5 (a), (b), (c) and (e) are hereby approved.

b. Limitation on Water Treatment at Bond Forfeiture Sites

Subsection 12.5(d) also provides that expenditures from the special reclamation fund for water quality enhancement projects may not exceed 25 percent of the fund's gross annual revenue. For the reasons set forth in finding A.1.b.(2), the Director finds that this limitation is inconsistent with 30 CFR 800.11(e) and is hereby disapproved. Also, the Director is requiring that the State revise subsection 12.5(d) to remove the 25 percent limitation or to otherwise provide for the treatment of polluted water discharged from all existing and future bond forfeiture sites.

C. The West Virginia Alternative Bonding System

On October 1, 1991 (Administrative Record No. WV–878), OSM notified West Virginia in accordance with 30 CFR 732.17 that its regulatory program no longer met all Federal requirements. Since 1989, OSM's annual reviews of West Virginia's alternative bonding system had found the system to be incapable of meeting the Federal requirements at 30 CFR 800.11(e) since its alternative bonding system liabilities exceeded assets. As of June 30, 1990, the special reclamation fund liabilities exceeded assets by $6.2 million. Also, a 1993 actuarial study by the accounting firm of Deloitte and Touche estimated that, by 1997, the State's special reclamation fund would have a deficit

of $13.8 million (Administrative Record No. 952). This estimate did not include the cost of water treatment on bond forfeiture sites.

In addition, on December 31, 1993, the WVDEP submitted an ''Acid Mine Drainage Bond Forfeiture Report'' to the West Virginia legislature, as required by CSR § 38–2–12.5(e) (Administrative Record No. WV–952). The report identified acidic discharges from 89 bond forfeiture sites, which produce approximately 10 percent of the acid mine drainage in the State. Under the best-case scenario, the WVDEP estimated that treatment to neutralize only the discharges from bond forfeiture sites that are affecting receiving streams would require approximately $2 million annually. Treatment of all discharges from all sites to meet Federal and State effluent limitations and water quality standards would cost approximately $4.7 million annually.

Furthermore, State records show that, as of June 30, 1994, 243 bond forfeiture sites containing 10,996 acres have not been completely reclaimed. The State estimates that the total liabilities of the fund exceed total assets by $22.2 million. This estimate does not include the cost of treating polluted water discharged from bond forfeiture sites. On July 20, 1994, the West Virginia Supreme Court ruled that the treatment of acid mine drainage is a component of reclamation and that the WVDEP has a mandatory nondiscretionary duty to utilize moneys from the special reclamation fund, up to 25 percent of the annual amount, to treat acid mine drainage at forfeiture sites when the proceeds from forfeited bonds are less than the actual cost of reclamation (*WVHC v. WVDEP*, No. 22233, July 20, 1994).

An alternative bonding system cannot be allowed to incur a deficit if it is to have available adequate revenues to complete the reclamation of all outstanding bond forfeiture sites. Alternative bonding systems must include reserves and revenue-raising mechanisms adequate to ensure completion of the reclamation plan and fulfillment of the permittee's obligations, including any water treatment needs.

Although the proposed site-specific bonding rates are significantly higher than the State's old flat rate bond of $1,000 per acre and the State is proposing to increase its special reclamation tax from one cent to three cents per ton of mined coal to generate more revenue for the fund, State records indicate that the proposed bonding rates and the increase in revenues to the special reclamation fund are still insufficient to ensure complete reclamation, including treatment of polluted water.

Therefore, the Director finds that West Virginia's alternative bonding system no longer meets the requirements of 30 CFR 800.11(e). Furthermore, it is not achieving the objectives and purposes of the conventional bonding program set forth in section 509 of SMCRA since the amount of bond and other guarantees under the West Virginia program are not sufficient to assure the completion of reclamation. Hence, the Director is requiring West Virginia to eliminate the deficit in the State's alternative bonding system and to ensure that sufficient funds will be available to complete reclamation, including the treatment of polluted water, at all existing and future bond forfeiture sites. The Director has taken and will take similar actions in all other states with deficits in alternative bonding systems.

IV. Summary and Disposition of Comments

Public Comments

The Director solicited public comments and provided an opportunity for public meetings on the proposed amendment on three separate occasions. Public meetings were held on September 7, 1993, October 27, 1994, and May 30, 1995 (Administrative Record Nos. WV–906, WV–958, and WV–983). Comments on the special reclamation fund and bonding provisions were received from GAI Consultants, Inc. (GAI); West Virginia Coal Association (WVCA); West Virginia Mining and Reclamation Association (WVMRA); Arch of West Virginia (AWV); Buffalo Coal Company, Inc. (BCC); National Council of Coal Lessors, Inc. (NCCL); West Virginia Highlands Conservancy (WVHC); the West Virginia Chapters of Trout Unlimited (TU) and the Sierra Club (SC); National Citizens Coal Law Project (NCCLP), and the Downstream Alliance (DA).

Following is a summary of the substantive comments received on the proposed amendment. Comments identifying errors of a purely typographical or editorial nature and comments voicing general support or opposition to the proposed amendments but devoid of any specific statements are not discussed. The summarized comments and responses to the comments are organized by the section of the amended statutes and regulations to which they pertain. All citations to the State statutes and regulations in comments and responses have been adjusted to reflect the nomenclature of the August 18, 1994, version of the statutes and the May 16, 1995, version of the regulations.

WVSCMRA § 22–3–11(c)(2): Alternative Bonding System

WVCA, WVMRA, and the WVHC commented on WVSCMRA § 22–3–11(c)(2) which provides that the Director of the WVDEP may approve an alternative bonding system under certain conditions. The State has not proposed any revisions to this section of the West Virginia statute. In acting on State program amendments, OSM only addresses those sections of a State's laws and regulations were revisions are proposed by a State. OSM will take the comments received into consideration when reviewing the State's statute and rules pursuant to 30 CFR 732.17.

WVSCMRA § 22–3–11(g): Special Reclamation Fund

1. *Comment:* WVHC did not generally support the revisions proposed for the special reclamation fund. WVHC stated the belief that ''the state has a mandatory duty to treat water as a part of the approved reclamation plan at all forfeited sites, and that the alternative bonding system/special reclamation fund is to provide the State sufficient money to complete all reclamation, at all times, at any and all forfeited sites, including water treatment where necessary to meet effluent limitations and water quality standards.'' This belief was also expressed by the SC which added that the 25 percent limit applied to expenditures for water treatment explicitly weakens the Federal requirement for full and prompt reclamation.

WVHC commented that the provisions of section 509(c) of SMCRA, the provisions of 30 CFR 800.11(e) of the Federal regulations, and the West Virginia Supreme Court Decision in the Mandamus action (*WVHC* v. *WVDEP*, No. 22233, July 20, 1994) supported its belief [*See* Administrative Record No. WV–930 for a copy of the referenced decision]. WVHC pointed out that the actuarial study of 1993 was not an acceptable assessment of the adequacy of the special reclamation fund since it asserted the State was not liable for water treatment at bond forfeiture sites. WVHC further urged OSM to require the State resolve the issue of inadequate funds, assess additional monies for the special reclamation fund, and expend the monies to reclaim existing bond forfeiture sites.

In general, WVHC believed that the codification language used by OSM left several unanswered questions and that findings contained in the preamble would be forgotten.

Response: As discussed in finding A.1.b.(2), the Director is requiring West Virginia to amend its program to remove the 25 percent limitation or to otherwise provide for treatment of polluted water discharged from all bond forfeiture sites. Also, as discussed in finding A.1.b.(4)(c), the Director is requiring the State to remove the provision that allows collection of the special reclamation tax only when the bond forfeiture liabilities of the State exceed the fund's assets.

This rulemaking does not attempt to answer all potential questions about bonding and the reclamation of bond forfeiture sites but only to address the proposed revisions to the West Virginia program. The findings contained in this preamble should be read in conjunction with the codification section to fully understand the Director's decision.

2. *Comment:* The WVHC commented that OSM should not only disapprove as part of the State program the provision limiting the use of monies for water treatment at bond forfeiture sites but should also require the State to remove the restricting language from its rules and law. WVHC stated that in the eyes of State legislature and State Courts the provision would continue to be implemented until removed from State law and regulations. WVHC added that without clear and decisive direction and actions on the part of OSM, there will be no significant improvement in the West Virginia program.

Response: As discussed in finding A.1.b.(2), the director is requiring West Virginia to remove the 25 percent limitation on the use of special reclamation funds for water treatment at bond forfeiture sites from its statute and regulations or to otherwise provide for the treatment of polluted water discharged from all bond forfeiture sites.

3. *Comment:* WVMRA generally supported the proposed bonding revisions for § 22–3–11(g). WVMRA argued that the special reclamation fund revisions, including the 25 percent set aside for water treatment systems, were not OSM issues since there are no Federal requirements in these areas. The question of water treatment at forfeiture sites was thought to be a Clean Water Act issue which should be handled by the State under the NPDES program. WVMRA pointed out that West Virginia's bonding provisions were more stringent than Federal government bonding requirements and cited the State's requirement for penal bonds as an example. WVMRA commented that ''the bonding program has been consistent with insuring compliance with the State law and all regulations promulgated thereunder for more than the 17 year history since PL 97–87 was passed.''

WVMRA argued that West Virginia has adequate funds to guarantee that the performance standards of the Act are carried out, and referenced two actuarial studies as support for this view. WVMRA stated that any requirements beyond the performance standards of the Act are not germane to the bonding requirements. WVMRA also stated that ''any attempt to burden the State of West Virginia, and more particular (sic) its mining industry, with rules and regulations not supported by Federal or State law, will not be tolerated nor can the State of West Virginia be held to any standard not imposed upon other States, including Tennessee, in which OSM administers the program.'' [WVMRA referenced text in a letter dated January 15, 1993, to David Callaghan from former OSM Director Harry Snyder pertaining to requirements for water treatment as support for its comments. Since this letter was subsequently rescinded by Acting OSM Director W. Hord Tipton by letter dated January 25, 1993, it no longer reflects OSM policy and is, therefore, not being discussed.]

Response: Section 509(c) of SMCRA authorizes the Secretary, acting through OSM, to approve an alternative bonding system if it will achieve the objective and purposes of the otherwise mandatory conventional bonding program. The Federal regulations at 30 CFR 800.11(e)(1) require funds to be sufficient to assure completion of the reclamation plans for all bond forfeiture sites, which includes treatment to meet State and Federal water quality requirements. The Secretary conditionally approved an alternative bonding system as part of the West Virginia program on January 21, 1981 (46 FR 5924), with subsequent final approval on March 1, 1983 (48 FR 8448). West Virginia's approved alternative bonding system includes the special reclamation fund as one source of money for completing the reclamation plan for a bond forfeiture site. Also, 30 CFR 732.17(g) requires changes to laws or regulations that make up the approved State program be submitted to the Director as an amendment. Therefore, the revisions pertaining to West Virginia's special reclamation fund are OSM issues, and OSM is required to make a determination as to whether these revisions are consistent with section 509(c) of SMCRA and the implementing Federal regulations at 30 CFR 800.11(e). The Director disagrees that only performance standards of the Act are germane to bonding requirements. See discussion in findings A.1.b.(2). The Director also disagrees that the West Virginia alternative bonding system has adequate funding. See discussion in finding A.1.b.(4)(c).

4. *Comment:* The WVHC expressed concern that withdrawals from the Special Reclamation Fund for administrative purposes for programs other than bond forfeiture reclamation will deplete the Fund.

Response: As discussed in finding A.1.b(3), the State in § 22–3–11(g) is proposing to limit the use of the Special Reclamation Fund. The Director of the WVDEP will have discretionary power to allocate up to 10 percent of the total annual assets of the Fund to administrative costs incurred under the abandoned mine land program, the mining and reclamation program, the minerals other than coal program, and the Surface Mine Board. While most of these expenditures are unrelated to the reclamation of bond forfeiture sites, the Director of OSM does not have the authority under SMCRA to restrict the use of the Fund to only bond forfeiture reclamation. However, the State is accountable for ensuring that adequate moneys are available in the special reclamation fund to complete the reclamation of all forfeiture sites in a timely manner. Under West Virginia's approved alternative bonding system, any drawdown of the fund for administrative purposes unrelated to bond forfeiture reclamation must be compensated for by higher site-specific bonds, a higher special reclamation tax or both.

5. *Comment:* The WVMRA commented that OSM had overstated the magnitude of the backlog in forfeiture sites that need to be reclaimed by failing to note that of the 243 forfeiture sites, 43 have been granted Phase I release, 17 have been granted Phase II release and 12 of the forfeitures were for technicalities like failure to have proper insurance. Also, the special reclamation fund was believed to be financially sound since as of April 30, 1995, there was a balance of over $8 million with interest accumulating at a rate of $250,000 per quarter. Annual payments into the fund by coal operators was more than $3.7 million. Reclamation costs on forfeiture sites were $2,820 per acre in 1994—the lowest per acre cost in the history of the program.

Response: The Director acknowledges that some sites on the list of bond forfeiture sites have been partially reclaimed, however, there is still a substantial backlog in reclamation work even after allowing for these sites. The State's estimate that, as of June 30, 1994, total liabilities of the special

reclamation fund exceeded assets by $22.2 million takes into account a cash balance in the fund.

WVSCMRA § 22–3–23(c)(3) Colombo Amendment

WVCA, WVMRA, and SC commented on WVSCMRA § 22–3–23(c)(3). The State has not proposed any revisions to this section of the West Virginia statute. In acting on State program amendments, OSM only addresses those sections of a State's laws and regulations where revisions are proposed by a State. OSM and the State met on August 16, 1995, to resolve differences concerning this provision and to address other matters. OSM is conducting a survey of potential Colombo sites to determine the scope and nature of the problem. The WVDEP has agreed to cooperate with OSM by providing information they may have and to not release additional sites under the Colombo provision. The disapproval of WVSCMRA § 22–3–23(c)(3) found at 30 CFR 948.12(e) and the program set aside at 30 CFR 948.13(c) remain in effect.

CSR § 38–2–11.2(e) Bond Liability for Permits Transferred, Assigned, or Sold Under the Provisions of CSR § 38–2–3.25

Comment: AWV pointed out that the provision does not give the Director of WVDEP the authority to increase bond amounts to address deficiencies in permits which are transferred or assigned. AWV further argued that ''this provision should not apply to permits which are assigned pursuant to 38 W.Va. C.S.R. § 3.25(c), since liability under the bond and permit under such an arrangement remains with the original permittee.'' AWV stated that ''the suggestion that bonds, in themselves, can be transferred is misleading and inconsistent with other provisions in the regulations.'' AWV also suggested that the provision should be rewritten to clarify that permits instead of bonds are transferred and to allow the Director of WVDEP to require bond adjustment as an alternative to the proposed requirement for assumption of liability.

Response: The intent of this provision is to ensure that the person who is to receive the permit has adequate financial resources to manage long-term environmental liabilities associated with mining such as water treatment. It is within the State's authority to require such a demonstration prior to permit transfer. Although the Director agrees that the provision could be clarified, as discussed in finding B.1.b, the new provision at CSR § 38–2–11.2(e) is not inconsistent with the Federal bonding requirements at 30 CFR Part 800 or the Federal permitting requirements at § 774.17(b)(3).

CSR § 38–2–11.6 Site-Specific Bonding

Comment: AWV expressed support for West Virginia's efforts to implement site-specific bonding in order to improve its regulatory program. However, AWV stated that ''the regulation should more clearly identify how the bonding changes will be implemented and administered.''

Subsection 11.6(a): AWV commented that the provisions of subsection 11.6 should only apply to permits issued after its effective date. AWV further commented that considering bond is limited to $5,000 per acre, West Virginia should add language to subsection 11.6(a) to clarify the procedures for calculating bond when more than one permit includes the same area. The DA believed that the $5,000 per acre limit on site-specific bonds contradicted SMCRA because such a bond is insufficient to enable the regulatory authority to complete reclamation, especially in the case of underground mines where there is liability for acid mine drainage and subsidence. The WVHC commented that site-specific bonds should be required where coal extraction is complete and for operations that are eligible for or have received Phase I bond release.

Subsection 11.6 (c), (d), (e), and (f): AWV stated that ''a general concern with respect to all of the subsection 11.6 tables is that the factors 0.2, 0.6, and 1.0 produce too many extreme and inequitable results, thereby distorting the significance of some criteria.'' In support of its concern, AWV presented three examples and argued that: (1) factoring under subsection 11.6(c)(1)(B) for three excess spoil disposal fills is three times higher than a plan for two, while six fills is the same as three; (2) the provisions at subsection 11.6(c)(2)(C)(ii) and (iii) differentiate between conventional and highwall auger mining even though the cost per linear foot to reclaim the highwall would not differ and (3) the provisions at subsection 11.6(d)(1)(A) do not consider the vicinity of backfill material when factoring for shaft or slope entry backfills. AWV also noted a typographical error and some inconsistencies in the provisions of subsection 11.6(c).

Subsection 11.6(c)(5)(A): AWV commented that West Virginia should clarify the terms ''active permit'' and ''last full calendar year'' as it relates to this provision. AWV also commented that West Virginia should add a provision to this subsection specifying that violations pending review or appeal would not be considered.

Subsection 11.6(v)(5)(B): AWV pointed out that the percentages used for contemporaneous reclamation were discretionary since they were not defined. AWV also commented that consideration of an operation's ''contemporaneous reclamation'' status should not be limited to the permit application review period.

Subsection 11.6(c)(6)(B): AWV commented that national and local reclamation awards should not be a consideration since they often depend on other factors not related to success of reclamation. AWV further suggested that WVDEP factor in the amount of disturbed land reclaimed in a 24-month period instead of awards.

Subsection 11.6(g): AWV suggested that West Virginia add language in subparagraph (2) to allow the Director of WVDEP to not hold an informal conference if he agreed that ''the amount proposed by the applicant is appropriate.''

Response: Under an alternative bonding system, a State has considerable latitude in setting site-specific bond amounts and administering the program. The State may even choose to place a limit on the per-acre amount of the site-specific bond. The most important factor that has to be considered is whether the alternative bonding system has adequate revenue to cover the cost of reclamation of those sites that may be forfeited and that it provides substantial economic incentive for the operator to comply with all reclamation requirements. As discussed in finding B.5., the Director found the State's provisions for site-specific bonding are not inconsistent with the requirements of section 509(c) of SMCRA and 30 CFR 800.11(e) of the Federal regulations.

CSR § 38–2–11.7 Environmental Security Account for Water Quality

1. *Comment:* WVCA commented that ''OSM appears to mischaracterize the scope and purpose of this proposed rule, which allows WVDEP to create an Environmental Security Account. OSM states that this regulation does not provide any authority for WVDEP to issue permits for discharges that will violate effluent limitations or water quality standards 'without treatment.' *See* 58 Fed. Reg. at 42909. If by the phrase 'without treatment' OSM means to say that this proposed regulation prohibits WVDEP from issuing permits for operations which may generate acid mine drainage, it is simply wrong. Nothing in either § 38–2–11.7 or SMCRA contains any such prohibition.

While both SMCRA and the WVSCMRA require operators to avoid production of acid mine drainage, they both also specifically recognize water treatment as one avoidance technique. *See* 30 U.S.C. §§ 1265(b)(10)(A)(ii); W. Va. Code §§ 22–3–13(b)(10)(A)(ii) &–14(b)(9)(A)(ii).''

Response: West Virginia included this provision in paragraph (h), which reads ''nothing in this subsection shall authorize in any way the issuance of a permit in which acid mine drainage is anticipated, and which would violate applicable effluent limitations or water quality standards without treatment.'' The Federal Register notice stated that this language was part of the proposed State rule. Paragraph (h) of CSR § 38–2–11.7 clarifies the intent of the West Virginia State legislature when it authorized the Director of WVDEP to study the desirability of establishing an environmental security account and in promulgating rules to implement such an account. OSM has not mischaracterized the State's proposed rule since the exact language used by the West Virginia State legislature was repeated in the Federal Register

2. *Comment:* WVHC expressed concern that the language in subsection 11.7(f) would allow statutory changes to become effective without the approval of OSM. WVHC commented that ''while the Supreme Court of W.V. has reiterated the legal requirement of OSM approval of all statutes and regulations pertaining to the approved program in footnote 23 of the Mandamus decision of July 1994 (*WVHC v. WVDEP,* No. 22233, July 20, 1994), there are frequent debates and sometimes heated discussions of this matter in Legislative Committee meetings.''

Response: As discussed in finding B.6., any regulations proposed to implement the environmental security account as a bonding mechanism for water quality or to otherwise incorporate it into the coal regulatory program must be approved by OSM. Also, 30 CFR 732.17(g) prohibits the implementation of any statutory or regulatory changes to a State program without prior OSM approval.

CSR § 38–2–12.2 Requirement to Release Performance Bonds

1. *Comment: Subsection 12.2(a)(1)* AWV commented that ''subsection 11.5(a)(1) of these proposed rules states that a general bond in the amount of seven hundred fifty dollars ($750) per acre will serve as sufficient financial assurance that the revegetation requirements of Section 9 of the regulations will be satisfied. Consistent with this statement, AWV believes that 38 W.V.A. C.S.R. § 12.2(c)(1) should be modified as that upon meeting the requirements for a Phase I bond release, a site-specified reassessment should be conducted. Assuming these requirements are met, the bond amount should be reduced to $750 per acre, as specified in Subsection 11.5(a)(1), instead of the minimum 60 percent bond release now in effect.''

Response: Subsection 11.5(e) provides that the operator will apply for bond release in accordance with section 23 of the Act and subsection 12.2 only after completion of all mining and reclamation on the permit area. In accordance with the State's open-acre limit bonding requirements at subsection 11.5, the State does not plan to release the open-acre bond at the completion of the backfilling and grading of each open-acre unit. This bond will be rolled over to the next increment.

2. *Comment: Subsection 12.2(e)* WVMRA commented that OSM does not have any water quality or chemical treatment requirements for bond releases. BCC and WVMRA both commented that this provision is more stringent than the OSM requirement since bond cannot be reduced or released if chemical treatment is required.

Response: The Director disagrees that the Federal regulations do not have any water quality or chemical treatment requirements for bond releases. Section 519(b) of SMCRA and the implementing Federal regulations at 30 CFR 800.40(b)(1) require the regulatory authority, when evaluating bond release requests, to consider whether pollution of surface and ground water is occurring, the probability of any continuing pollution, and the estimated cost of abating such pollution. Furthermore, section 519(c)(3) of SMCRA and the implementing Federal regulations at 30 CFR 800.40(c)(3) provide that no bond shall be fully released until all the reclamation requirements of SMCRA and the permit are fully met. These requirements include abatement of surface and ground water pollution resulting from the operation. Both SMCRA and the Federal regulations effectively require that discharges from the site be in compliance with all applicable effluent limitations as a prerequisite for bond release. Therefore, as discussed in finding B.7., the revised bond release provisions either remain substantively the same as the Federal regulations at 30 CFR 800.40 or do not conflict with any Federal requirements or adversely impact other aspects of the West Virginia program.

CSR § 38–2–12.3 Bond Adjustments

Comment: WVHC commented that the State's proposed amendment satisfies 30 CFR 800.15(d) by providing for bond adjustment in the case of increased area being added to the permit. However, the amendment should also include language to more adequately reflect compliance with 30 CFR 800.15(a) as well. ''The state must be able to adjust the bond 'from time to time' not only as the area is increased or decreased, but also 'where the cost of future reclamation changes', e.g., at renewal time, or at any time during the life of a permit that some unforeseen or unanticipated complication arises that would cause the cost of reclamation to increase.''

Response: As discussed in finding B.8.b., mandatory review for bond adequacy is limited to the States with conventional bonding programs since those States have no other source of funds other then the bond for completion of the reclamation in the event of forfeiture. Therefore, since West Virginia has an alternative bonding system with mandatory participation, which includes other sources of moneys for reclaiming bond forfeiture sites, the requirement to review bonds for adequacy is not mandatory. However, bond adjustment would be advisable so as to ensure the long-term financial soundness of an alternative bonding system.

CSR § 38–2–12.4 Forfeiture of Bonds

1. Comments: Subsection 12.4(a)

a. GAI stated its opposition to the requirements that all bond amounts be forfeited rather than an amount based on the estimated total cost of achieving the reclamation plan requirements. GAI commented that all bonds not required to reclaim should be returned, since subsection 12.4(e) allows WVDEP to sue for all costs in excess of the amount forfeited.

Response: As discussed in finding A.1.a., West Virginia's proposed requirement that the total bond by forfeited, rather than an amount based on the estimated cost of reclamation, is not inconsistent with any Federal requirements.

b. WVCA commented that OSM should find the provision at subsection 12.4(a), which would require WVDEP to forfeit the entire amount of reclamation bonds irrespective of the actual cost to reclaim mine sites, both unauthorized by the WVSCMRA and inconsistent with SMCRA. WVCA further stated that this regulation was intended to dovetail with a statutory amendment which the WVDEP proposed, but which was

rejected by the West Virginia Legislature in the 1992/1993 legislative session. WVCA explained that the Circuit Court of Kanawha County recently ruled that the WVSCMRA does not allow WVDEP to forfeit the entire amount of a reclamation bond, but only so much as is necessary to cover the estimated costs of reclamation (*Vaco Enterprises, Inc.*, v. *Callaghan*, Civil Action No. 92–Misc–256 (Kanawha County, Nov. 9, 1992).

WVCA further commented that OSM has rejected this form of bond release since 30 CFR 800.50(d)(2) specifically provides that in the event the amount of performance bond forfeited was more than the amount necessary to complete the reclamation, the unused funds would be returned. WVCA then referenced a Federal court decision in *In Re: Permanent Surface Mining Regulation Litigation*, 14 Env't Rep. Cas. (BNA) 1083, 1100–1101 (D.D.C. 1980). WVCA stated that ''based on the court's directive, OSM expressly rejected any notion that reclamation bonds are penal in nature. OSM wrote that: 'OSM views a reclamation bond as one guaranteeing the performance of reclamation work. Therefore, it is not a penal bond. Upon forfeiture, only the amounts necessary to complete the reclamation work can be used by the regulatory authority.' 48 FR 32932, 32957 (July 19, 1983).''

Response: At the time WVCA submitted its comments on September 13, 1993, the referenced Circuit Court ruling was meaningful to the proposed amendment being reviewed by OSM. However, this amendment was revised with West Virginia's submitted dated August 18, 1994. The August 1994 submittal contained House Bill 4065 which was passed by the West Virginia legislature on or before March 12, 1994. In it, the West Virginia legislature approved the use of penal bonds, thereby effectively superseding the Circuit Court ruling. As discussed in finding A.1.a., the legislature's action creating penal bonds is not inconsistent with section 509 of SMCRA and the Federal implementing regulations pertaining to performance bonds.

2. Comments: Subsection 12.4(b)

WVHC commented that the State's duty to meet the requirements of subsection 14.5 when reclaiming bond forfeiture sites had been replaced with meeting the requirements of subsection 12.5. Subsection 12.5 establishes an inventory of all sites where bonds have been forfeited and a priority listing of sites to receive water treatment whereas subsection 14.5 establishes water quality standards for active mining operations.

Response: For the reasons given in finding B.9.c., the Director is approving this revision.

3. Comments: Subsection 12.4(c)

a. GAI argued that instead of West Virginia looking for ''the most effective method to control acid mine drainage'' that they should be looking for ''the most cost effective method.'' GAI explained that one methodology may cost $100,000 and another may cost $3,000,000 with only one-tenth of one percent difference in remediation between the two methods.

Response: The Director agrees with the desirability of seeking the most cost-effective treatment, so long as the site is brought into compliance with applicable effluent limitations and water quality standards. It is noted that subsection 12.5(d) requires the Director of WVDEP to take into consideration the relative benefits and costs of water enhancement projects for bond forfeiture sites.

b. *Comment:* WVHC stated that subsection 12.4(c) limits reclamation and the amount of acid mine drainage treatment to the amount of money available. WVHC commented that SMCRA 509(c) and 30 CFR 800.11(e) require that the amount of money be sufficient to match the problem rather than the other way around as this proposal suggests. WVHC stated that the last sentence of subsection 12.4(c) should be dropped from the rule.

Response: As discussed in finding C., the Director is requiring West Virginia to eliminate the deficit in the State's alternative bonding system and to ensure that sufficient money will be available to complete reclamation, including the treatment of polluted water, of all existing and future bond forfeiture sites.

c. *Comment:* WVMRA also did not support the revision at subsection 12.4(c) which requires the Director of WVDEP to take the most effective actions possible to remediate acid mine drainage, including chemical treatment where appropriate. WVMRA stated that there are no Federal or State programs which require mandatory water treatment.

Response: The Director disagrees with the commenter. See finding A.1.b.(2) for a discussion of this issue.

d. WVHC also commented that in its September 1, 1994, submission, WVDEP has added the phrase to reclaim the site ''in accordance with the approved reclamation plan or modification thereof.'' WVHC commented that this could easily allow changes in reclamation plans after forfeiture to relieve the agency of any undesired expense in land or water reclamation requirements without public notice or involvement. WVHC stated that the words ''or modification thereof'' are inappropriate and should be eliminated. WVHC pointed out that the State must be held responsible through the alternative bonding system for the same reclamation plan that it permitted and bonded. Doubts were also expressed on whether the State would make the proper distinction between significant and insignificant permit revisions.

Response: As discussed in finding B.9.d.(1), the Director is approving West Virginia's proposed amendment revising CSR § 38–2–12.4(c) to require that bond forfeiture sites be reclaimed in accordance with the approved reclamation plan or modifications thereof. The Director believes that regulatory authorities need to have the flexibility to modify reclamation plans for forfeiture sites since existing approved plans may be technically impossible to implement and may not satisfy the changing interests of surface landowners. This most often happens when forfeiture occurs before mining is completed. All modifications to the reclamation plan by the regulatory authority must be consistent with the approved State permanent program.

The remainder of the comment pertaining to public notice and involvement in reclamation plan modifications goes beyond the scope of this proposed change by West Virginia since the proposed revision merely acknowledges that modification of reclamation plans can occur. The amendment is silent as to public participation in the modification process.

4. *Comment: Subsection 12.4(d)* WVHC commented that this section also ends with the sentence that provides for limiting acid mine drainage treatment to the funds available. WVHC also stated that the words ''in accordance with the approved reclamation plan'' should be included, and the last sentence of subsection 12.4(d) should be deleted.

Response: Since subsection 12.4(c) provides that reclamation for bond forfeiture sites will be completed in accordance with the approved reclamation plan, West Virginia does not have to repeat this provision in paragraph (d).

5. *Comment: Subsection 12.4(e)* NCCL expressed concerns pertaining to the insertion of the language ''or other responsible party'' into this subsection. NCCL stated that ''WVDEP proposes to amend the regulation to provide that the 'operator, permittee or other responsible party shall be liable for all costs in excess of the [bond] amount forfeited.'

The term 'other responsible party' is not defined. We believe that this undefined term is either redundant or intended by WVDEP to extend the scope of the surface mining laws to land owners and other persons that SMCRA was intended to protect.''

NCCL stated that ''the term 'operator' is defined in broad terms to include all persons who either should obtain a permit or who engage in surface mining and reclamation. This term thus includes all persons who might be liable for reclamation costs incurred by an operator, including those persons who might individually be liable for the violations of corporations. Accordingly, there is no need to create another category of 'other responsible persons.' We are concerned that in situations where a specific bond is insufficient to cover the cost of reclaiming a site, including potential long term treatment of acid mine drainage, WVDEP will decline to use the State Special Reclamation Fund to treat water and will instead try to impose these costs on landowners pursuant to revised subsection 12.4(e). Whatever its motivation, the WVDEP's actions are absolutely inconsistent with the goals of SMCRA.''

NCCL further stated that ''West Virginia has an alternative bonding system as provided in 30 CFR 800.11(e) funded by a mix of site-specific bond and 'bond pool' (i.e., the State Special Reclamation Fund) monies. Despite the bifurcated funding mechanism of this system, the full costs of reclamation are and must nonetheless be borne exclusively by the operators either through site-specific bonds or the special reclamation fund (which operators alone fund through a severance fee).'' NCCL also commented that ''the incentives to reclaim are absent or diminished when reclamation costs may be transferred from operators to other parties such as area landowners, which Congress intended to protect, nor hold liable for, surface mining operations. See 30 U.S.C. § 1202(b).''

NCCL also stated that ''OSM has even recognized in promulgation of its expansive 'ownership and control' regulations that direct liability for reclamation costs and for compliance with SMCRA belongs solely to the operator or permittee.'' To support this statement, NCCL presented discussions from two Federal Register notices (54 FR 18438–43, April 28, 1989, and 53 FR 38868–85, October 3, 1988).

Response: As discussed in finding B.9.d.(3), the proposed requirement in CSR § 38–2–12.4(e) is not prohibited by SMCRA. Also, under the Federal Clean Water Act, a permittee, operator and/or landowner can be held responsible for the treatment of point source discharges that do not meet NPDES effluent limitations after forfeiture.

CSR § 38–2–12.5 Water Quality Enhancement

1. *Comment subsection 12.5(d):* BCC commented that the proposal for supplementing and adjusting the special reclamation fund to pay for long-term acid mine drainage treatment from forfeiture sites goes far beyond any OSM counterpart.

WVMRA commented that ''this policy sets a priority and inventory and makes some recommendations, but there is no legal guidance from OSM regarding what such a program should include. This makes evaluation of this policy impossible.''

Response: As discussed in finding B.10.a., subsection 12.5 is being approved to the extent that it provides only for a ranking of sites for reclamation without compromising the requirement that all sites be properly reclaimed in a timely manner.

2. *Comment subsection 12.5(d):* WVHC stated that the alternative bonding system fund must be increased to address the liability rather than the liability being adjusted to match the funds available.

Response: As discussed in finding B.10.b., the Director is requiring the State to revise subsection 12.5(d) to remove the 25 percent limitation or to otherwise provide for the treatment of polluted water discharged from bond forfeiture sites.

Retroactive Approval of Amendment

Comment: The WVCA and the WVMRA objected to the proposed provision at 30 CFR 948.15(o)(1) which would make OSM's approval of the State's program amendment retroactive. WVMRA commented that OSM had no authority to retroactively approve the amendment.

Response: As discussed in the Director's Decision (Subsection V), the Director believes he has ample cause and legal basis for making his decision on this amendment retroactive to the dates when the proposed revisions were submitted to OSM.

Federal Agency Comments

Pursuant to section 503(b)(1) of SMCRA and 30 CFR 732.17(h)(11)(i), OSM solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the West Virginia program on four different occasions (Administrative Record Nos. WV–891, WV–897, WV–936, and WV–942). Comments were received from the U.S. Bureau of Land Management, the Mine Safety and Health Administration, the U.S. Bureau of Mines, and the U.S. Army Corps of Engineers. These Federal agencies acknowledged receipt of the amendments, but generally had no comment or acknowledged that the revisions were satisfactory.

Environmental Protection Agency (EPA)

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to obtain the written concurrence of the EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*).

On July 2 and August 3, 1993 (Administrative Record Nos. WV–892 and WV–896), OSM solicited EPA's concurrence with the proposed amendment. On October 17, 1994 (Administrative Record No. WV–949), EPA gave its written concurrence with a condition based on subsection 5.4(b)(4) of West Virginia's regulations. This conditional concurrence does not pertain to the bonding requirements, which are the subject of this rulemaking. Therefore, EPA's concurrence will be discussed in the third and final rulemaking on the proposed amendment.

Pursuant to 30 CFR 732.17(h)(11)(i), the Director solicited comments on the proposed amendment from EPA on four different occasions in 1993 and 1994 (Administrative Record Nos. WV–891, WV–897, WV–936, and WV–942). In its letter dated October 17, 1994 (Administrative Record No. WV–949), EPA submitted the following comments on the proposed amendment provisions pertaining to the bonding requirements.

1. *Comment:* EPA commented that ''the matrices on Tables 1 and 4 [CSR § 38–2–11.6, Site-Specific Bonding] provide a method for determining reclamation bonds with a maximum of $5,000 per acre. It is noted that the maximum portions which can be attributed for water quality concerns are based on overburden/ material analyses and are only $400 for surface mines and $800 for refuse disposal sites. It is also understood that, under current State regulations, a maximum of only 25 percent of the Special Reclamation Fund, or bond pool, can be used for treatment of forfeiture sites. Considering the experience to date for long-term treatment of acid discharges from bond forfeiture sites, the above funding sources are very inadequate. It is apparent that the answer for preventing

future acid mine drainage is to scrutinize proposed mining permits for their acid drainage potentials and deny permits to those with higher potentials. For proposed mines with lower acid drainage potentials, funding from the site-specific bonds, Special Reclamation Fund or other alternative sources should be increased to amounts to provide for the contingency of long-term treatment.''

Response: As discussed in finding A.1.b.(2), the Director is requiring West Virginia to amend its program to provide for the treatment of polluted water discharging from all bond forfeiture sites.

Also, as discussed in finding A.1.b.(4)(c), the Director disapproved the proposal that would allow the special reclamation fund to incur a deficit. Furthermore, as discussed in finding C., the Director found the State's alternative bonding system is not achieving the objectives and purposes of the conventional bonding program as set forth in section 509 SMCRA, and he is requiring the State to eliminate the deficit in the State's alternative bonding system and to ensure that sufficient money will be available to complete reclamation, including treatment of polluted water, at existing and future bond forfeiture sites.

2. *Comment:* EPA also expressed concern about the potential for acid seepage from backfills after Phase I bond is released pursuant to the provisions of section 12.2(c)(1), where 60 percent of the total bond may be released. EPA recommended that ''Phase I bond release for mines with acid potential be delayed for a year or sufficient period after backfilling to determine if acid seepage will occur.'' EPA further recommended withholding of the entire bond if acid seepage did occur after this period.

Response: The Director finds that EPA's recommendations have merit. However, nothing in SMCRA or the Federal regulations require Phase I bond release to be delayed in order to determine if acid seepage will occur. It should be noted that compliance with the State's existing toxic handling and hydrologic reclamation plan requirements should prevent postmining acid seeps from occurring. Further, subsection 14.7(d) provides that after treatment facilities are removed, a one-year history of meeting applicable effluent limitations is required to establish that the hydrologic balance is being preserved.

State Historical Preservation Officer and the Advisory Council on Historic Preservation (ACHP)

Pursuant to 30 CFR 732.17(h)(4), OSM solicited comments on the proposed amendment from the West Virginia Division of Culture and History and the ACHP on four different occasions (Administrative Record Nos. WV–891, WV–897, WV–936, and WV–942). Neither agency commented on the proposed amendment.

V. Director's Decision

Based on the above findings, the Director is approving with certain exceptions and additional requirements the proposed amendment as submitted by West Virginia on June 28, 1993, as modified on July 30, 1993; August 18, 1994; and September 1, 1994, and May 16, 1995. As discussed in the findings, there are some exceptions to this approval. The Director also is requiring the State to make additional changes to certain provisions to ensure that the program is no less stringent than SMCRA and no less effective than the Federal regulations.

As discussed in findings A.1.b.(1) and B.10.a., the Director is approving those portions of § 22–3–11(g) of WVSCMRA and CSR § 39–2–12.5 that concern prioritization of forfeited sites only to the extent that these provisions authorize the ranking and prioritization of bond forfeiture sites for reclamation purposes. Nothing in this decision shall be construed as compromising the requirement that all bond forfeiture sites be properly reclaimed in a timely manner.

In addition, as discussed in findings A.1.b.(2), A.1.b.(4)(c), and B.10.b., the Director is not approving § 22–3–11(g) of WVSCMRA and CSR § 39–2–12.5(d) to the extent that they limit expenditures on water treatment at bond forfeiture sites to 25 percent of the assets of the special reclamation fund and authorize collection of the special reclamation tax only when the fund's liabilities exceed its assets.

As discussed in finding A.1.b.(3), the Director is approving § 22–3–11(g) of WVSCMRA concerning administrative expenses only to the extent that the special reclamation fund can withstand all authorized administrative cost withdrawals without hampering the State's ability to complete the reclamation of bond forfeiture sites in a timely manner and in accordance with their approved reclamation plans.

As discussed in finding B.5., the Director is approving CSR § 38–2–11.6 with the stipulation that nothing in these regulations or this approval may be construed as altering or authorizing a variance or deviation from the permitting requirements and performance standards of the approved West Virginia program.

The Director is amending 30 CFR Part 948 to codify this decision. Under 30 CFR 732.17(g), no changes in State laws or regulations may take effect for purposes of the State program unless and until they are approved as a program amendment. With respect to those changes in State laws and regulations approved in this document, the Director is making the effective date of his approval retroactive to the date upon which they took effect in West Virginia for purposes of State law. He is taking this action in recognition of the extraordinarily complex nature of the review and approval process for this particular amendment, the significance of its provisions to the adequacy of the alternative bonding system, and the need to affirm the validity of State actions taken during the interval between State implementation and the decision being announced today. Retroactive approval of these provisions is in keeping with the purposes of SMCRA relating to State primary and environmental protection.

To assure consistency with 30 CFR 732.17(g), which states that ''[no] * * * change to laws or regulations shall take effect for purposes of a State program until approved as an amendment,'' the Director's approval of the revisions, as noted in the codification below, includes West Virginia's previous and ongoing implementation of these revisions. The changes approved in this rulemaking strengthen the West Virginia program and, as such, are consistent with SMCRA and the Federal regulations at 30 CFR 732.17(g).

Retroactive approval of the revisions is appropriate because no detrimental reliance on the previous West Virginia laws or regulations has occurred for the period involved. OSM is approving these changes back only to the dates from which West Virginia began enforcing them. As support for his decision, the Director cites the rationale employed by the United States Claims Court in *McLean Hosp. Corp.* v. *United States,* 26 Cl. Ct. 1144 (1992). In *McLean,* the Court held that retroactive application of a rule was appropriate where the rule was identical in substance to guidelines which had been in effect anyway during the period in question. Therefore, the Court concluded, the plaintiff could not ''claim that it relied to its detriment on a contrary rule.'' 26 Cl. Ct. at 1148. Likewise, since the Director is approving changes which the State has

been enforcing there can be no claim of detrimental reliance on any contrary West Virginia statutes or regulations in this instance.

Making portions of the approval retroactive does not require reopening of the comment period under section 553(b)(3) of the Administrative Procedure Act (APA), 5 U.S.C. § 553(b)(3). The public, in general, and the coal industry in West Virginia in particular have had sufficient notice of these revised statutory and regulatory revisions to support retroactive OSM approval. Retroactive approval constitutes an acknowledgement of statutory and regulatory revisions which West Virginia has been implementing since the respective approval dates of these revisions at the State level, and would have been expected as a natural outgrowth of the proposal. The retroactive approval does not apply to earlier versions of these provisions to the extent that such provisions were inconsistent with Federal requirements.

Furthermore, ''good cause'' exists both under section 553(b)(3)(B) of the APA, 5 U.S.C. § 553(b)(3)(B), for retroactive approval (if notice were not sufficient) and under section 553(d)(3) of the APA, 5 U.S.C. § 553(d)(3), for not delaying the effective date of the approval for 30 days after the publication of this Federal Register decision document. As noted in the findings above, most of these bonding revisions are needed to improve the efficacy and financial status of West Virginia's bonding program in general, and its alternative bonding system in particular. *See, for example,* findings A.1.a. (penal bonding), A.1.b.(4)(a) (increase in the special reclamation tax), and B.5 (site-specific bonding). Failure to make OSM approval of these salutary provisions retroactive could cause significant disruption to the orderly enforcement and administration by West Virginia of its bonding program, particularly if the funding of the alternative bond system was affected. The Director believes that the desire to avoid such unfortunate consequences, coupled with the lack of any prejudice to the public or to the regulated community, are sufficient bases to constitute ''good cause.''

Effect of Director's Decision

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State submits and obtains the Secretary's approval of a regulatory program. Similarly, 30 CFR 732.17(a) requires that the State submit any alteration of an approved State program to OSM for review as a program amendment. Thus, any changes to the State program are not enforceable until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State programs. In oversight of the West Virginia program, the Director will recognize only the statutes, regulations and other materials approved by OSM, together with any consistent implementing policies, directives and other materials, and will require the enforcement by West Virginia of only such provisions. The provisions that the Director is approving today will take effect on the specified dates for purposes of the West Virginia program.

VI. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 504 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 27, 1995.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 948—WEST VIRGINIA

1. The authority citation for Part 948 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 948.15 is amended by adding paragraph (o) to read:

§ 948.15 Approval of regulatory program amendments.

* * * * *

(o)(1) *General description and effective dates.* Except as noted in paragraph (o)(3) of this section, the amendment submitted by West Virginia to OSM by letter dated June 28, 1993, as revised by submittals dated July 30, 1993; August 18, 1994; September 1, 1994; and May 16, 1995, is approved to the extent set forth in paragraph (o)(2) of this section. These portions of the amendment pertain to bonding requirements; the Director will announce a decision on the other provisions of the amendment at a later time. The effective dates of the Director's approval of the provisions identified in paragraph (o)(2) of this section are set forth below:

(i) March 10, 1990, for the statutory changes submitted to OSM by letter

dated June 28, 1993 (Administrative Record No. WV–888);

(ii) December 1, 1992, for the rule changes submitted to OSM by letter dated June 28, 1993 (Administrative Record No. WV–889);

(iii) May 2, 1993, for the rule changes submitted to OSM by letter dated July 30, 1993 (Administrative Record No. WV–893);

(iv) June 11, 1994, for the statutory changes submitted to OSM by letter dated August 18, 1994 (Administrative Record No. WV–933); and

(v) October 4, 1995, for the rule changes submitted to OSM by letters dated September 1, 1994, and May 16, 1995 (Administrative Record Nos. WV–937 and WV 979B).

(2) *Approved revisions.* Except as noted in paragraph (o)(3) of this section, the following provisions of the amendment described in paragraph (o)(1) of this section are approved:

(i) *Revisions to the West Virginia Surface Coal Mining and Reclamation Act.*

§ 22–3–11(a)	Bond Requirements.
§ 22–3–11(g)	Special Reclamation Fund.

(*The provision authorizing annual diversions of up to 10 percent of the fund's assets for administrative costs associated with various State regulatory and reclamation programs is approved only to the extent that these withdrawals do not hamper the State's ability to complete the reclamation of bond forfeiture sites in a timely manner in accordance with the approved reclamation plans.*)

§ 22–3–12 ...	Site-Specific Bonding.

(ii) *Revisions to the West Virginia Code of State Regulations (CSR).*

§ 38–2–11.2	General Requirements for All Bonds.
§ 38–2–11.3	Collateral Bonds.
§ 38–2–11.4	Incremental Bonding.
§ 38–2–11.5	Open-Acre Limit Bonding.
§ 38–2–11.6	Site-Specific Bonding.

(*These regulations are approved with the stipulation that nothing in CSR § 38–2–11.6 or the Director's approval of this subsection may be construed as altering or authorizing a variance or deviation from the permitting requirements and performance standards of the approved West Virginia program.*)

§ 38–2–11.7	Environmental Security Account.
§ 38–2–12.2	Requirement to Release Bonds.
§ 38–2–12.3	Bond Adjustments.
§ 38–2–12.4(a)	Bond Forfeiture.
§ 38–2–12.4(a)(2)(B).	Bond Forfeiture.
§ 38–2–12.4(c)	Bond Forfeiture.
§ 38–2–12.4(d), (e).	Bond Forfeiture.
§ 38–2–12.5	Water Quality Enhancement.

(*These regulations are approved with the stipulation that nothing in CSR § 38–2–12.5 or the Director's approval of this subsection may be construed as compromising the program requirement that all bond forfeiture sites be fully reclaimed in a timely manner.*)

(3) *Exceptions.*

(i) Section 22–3–11(g) of the Code of West Virginia is not approved to the extent that it limits special reclamation fund expenditures on water treatment at bond forfeiture sites to 25 percent of the fund's annual fee collections and authorizes collection of the special reclamation tax only when the fund's liabilities exceed its assets.

(ii) Subsection 38–2–12.5(d) of the West Virginia Code of State Regulations is not approved to the extent that it limits expenditures on water treatment at bond forfeiture sites to 25 percent of the special reclamation fund's gross annual revenue.

3. Section 948.16 is revised by removing and reserving paragraph (ww) and by adding paragraphs (jjj), (kkk), and (lll) to read:

§ 948.16 Required regulatory program amendments.

* * * * *

(jjj) By December 1, 1995, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption, to revise § 22–3–11(g) of the Code of West Virginia and § 38–2–12.5(d) of the West Virginia Code of State Regulations to remove the limitation on the expenditure of funds for water treatment or to otherwise provide for the treatment of polluted water discharged from all bond forfeiture sites.

(kkk) By December 1, 1995, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption, to remove the provision of § 22–3–11(g) of the Code of West Virginia that allows collection of the special reclamation tax only when the special reclamation fund's liabilities exceed its assets.

(lll) By December 1, 1995, West Virginia must submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption, to eliminate the deficit in the State's alternative bonding system and to ensure that sufficient money will be available to complete reclamation, including the treatment of polluted water, at all existing and future bond forfeiture sites.

[FR Doc. 95–24580 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF DEFENSE

Department of the Army

32 CFR Part 505

Privacy Program

AGENCY: Department of the Army, DOD.

ACTION: Final rule.

SUMMARY: The Department of the Army system of records notice A0381-45cDAMI was deleted October 4, 1995. Therefore, the exemption rule is being deleted with this action.

In addition, the Army is amending three existing exemption rules to reflect the exemptions taken in the system of records notices. The amendments to the existing rules change the system identifiers and provide the provisions of 5 U.S.C. 552a from which the system of records may be exempt, and the reasons therefore. The system identifiers are A0381–20bDAMI, entitled Counterintelligence Operations Files; A0614–115DAMI, entitled Department of the Army Operational Support Activities; and A0318–100aDAMI, entitled Intelligence Collection Files.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Ms. Pat Turner at (602) 538–6856 or DSN 879–6856.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

The Director, Administration and Management, Office of the Secretary of Defense has determined that this proposed Privacy Act rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of $100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866 (1993).

Regulatory Flexibility Act of 1980

The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense.

Paperwork Reduction Act

The Director, Administration and Management, Office of the Secretary of Defense certifies that this Privacy Act proposed rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act of 1974.

The Department of the Army system of records notice A0381–45cDAMI was deleted October 4, 1995. Therefore, the exemption rule is being deleted with this action.

In addition, the Army is amending three existing exemption rules. The amendments to the existing rules change the system identifiers and provide the provisions of 5 U.S.C. 552a from which the system of records may be exempt, and the reasons therefore. The system identifiers are A0381–20bDAMI, entitled Counterintelligence Operations Files; A0614–115DAMI, entitled Department of the Army Operational Support Activities; and A0318–100aDAMI, entitled Intelligence Collection Files.

List of Subjects in 32 CFR Part 505

Privacy.

Accordingly, 32 CFR part 505 is amended as follows:

1. The authority citation for 32 CFR part 505 continues to read as follows:

Authority: Pub. L. 93–579, 88 Stat 1896 (5 U.S.C.552a).

2. Section 505.5, is amended by revising the text of paragraphs (e)ac, (e)ad, and (e)af, and removing and reserving paragraph (e)ae as follows:

§ 505.5 Exemptions.

* * * * *

(e) *Exempt Army records.* * * *

ac. System identifier: A0381–20bDAMI.

(1) System name: Counterintelligence/Security Files.

(2) Exemption: All portions of this system of records may be exempt from the provisions of subsections (c)(3), (d)(1) through (d)(5), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I), and (f) of 5 U.S.C. 552a.

(3) Authority: 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5).

(4) Reasons: (a) From subsection (c)(3) because disclosing the agencies to which information from this system has been released could inform the subject of an investigation of an actual or potential criminal violation, or intelligence operation or investigation; or the existence of that investigation or operation; of the nature and scope of the information and evidence obtained as to his/her activities or of the identify of confidential sources, witnesses, and intelligence personnel and could provide information to enable the subject to avoid detection or apprehension. Granting access to such information could seriously impede or compromise an investigation; endanger the physical safety of confidential sources, witnesses, intelligence personnel, and their families; lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony and disclose investigative techniques and procedures. In addition, granting access to such information could disclose classified and sensitive sources, information, and operational methods and could constitute an unwarranted invasion of the personal privacy of others.

(b) From subsection (d)(1) through (d)(5) because granting access to records in this system of records could inform the subject of a counterintelligence operation or investigation of an actual or potential criminal violation or the existence of that operation or investigation; of the nature and scope of the information and evidence obtained as to his/her activities; or of the identity of confidential sources, witnesses and intelligence personnel and could provide information to enable the subject to avoid detection or apprehension. Granting access to such information could seriously impede or compromise an operation or investigation; endanger the physical safety of confidential sources, witnesses, intelligence personnel and their families; lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony and disclose investigative techniques and procedures. In addition, the agency is required to protect the confidentiality of sources who furnished information to the Government under an expressed promise of confidentiality or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence. This confidentiality is needed to maintain the Government's continued access to information from persons who otherwise might refuse to give it.

(c) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of specific information in the early stages of an investigation or operation. Relevance and necessity are often questions of judgement and timing, an it is only after the information is evaluated that the relevance and necessity of such information can be established. In addition, during the course of the investigation or operation, the investigator may obtain information which is incidental to the main purpose of the investigative jurisdiction of another agency. Such information cannot readily be segregated. Furthermore, during the course of the investigation or operation, the investigator may obtain information concerning violations of laws other than those which are within the scope of his/her jurisdiction. In the interest of effective intelligence operations and law enforcement, military intelligence agents should retain information, since it an aid in establishing patterns of criminal or intelligence activity and provide valuable leads for other law enforcement or intelligence agencies.

(d) From subsection (e)(4)(G), (e)(4)(H), and (f) because this system or records is being exempt from subsections (d) of the Act, concerning access to records. These requirements are inapplicable to the extent that this system of records will be exempt from subsections (d)(1) through (d)(5) of the Act. Although the system would be exempt from these requirements, the Deputy Chief of Staff for Intelligence has published information concerning its notification, access, and contest procedures because under certain circumstances, the Deputy Chief of Staff for Intelligence could decide it is appropriate for an individual to have access to all or a portion of his/her records in this system of records.

(e) From subsection (e)(4)(I) because it is necessary to protect the confidentiality of the sources of information, to protect the privacy and physical safety of confidential sources and witnesses and to avoid the disclosure of investigative techniques and procedures. Although the system will be exempt from this requirement, the Deputy Chief of Staff for Intelligence has published such a notice in broad, generic terms.

ad. System identifier: A0614–115DAMI.

(1) System name: Department of the Army Operational Support Activities.

(2) Exemption: All portions of this system of records that fall within the provisions of 5 U.S.C. 552a(k)(1), (k)(2), or (k)(5) may be exempt from subsections 5 U.S.C. 552a(c)(3), (d)(1) through (d)(5), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I), and (f).

(3) Authority: 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5).

(4) Reasons: (a) From subsection (c)(3)because disclosing the agencies to which information from this system has

been released could reveal the subject's involvement in a sensitive intelligence or counterintelligence operation or investigation of an actual or potential criminal violation, or intelligence operation or investigation; or the existence of that investigation or operation. Granting access to such information could seriously impede or compromise an investigation or operation; endanger the physical safety of participants and their families, confidential sources, witnesses, intelligence personnel, and their families; and lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony and disclose investigative techniques and procedures.

(b) From subsection (d)(1) through (d)(5) because granting access to records could inform the subject of an intelligence or counterintelligence operation or investigation of an actual or potential criminal violation or the existence of that operation or investigation; of the nature and scope of the information and evidence obtained, or of the identity of confidential sources, witnesses and intelligence personnel. Granting access to such information could seriously impede or compromise an operation or investigation; endanger the physical safety of confidential sources, witnesses, intelligence personnel and their families; lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony; disclose investigative techniques and procedures; invade the privacy of those individuals involved in intelligence programs and their families; compromise and thus negate specialized techniques used to support intelligence programs; and interfere with and negate the orderly conduct of intelligence and counterintelligence operations and investigations. In addition, the agency is required to protect the confidentiality of sources who furnished information to the Government under an expressed promise of confidentiality or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence. This confidentiality is needed to maintain the Government's continued access to information from persons who otherwise might refuse to give it.

(c) From subsection (e)(1) because it is not always possible to detect the relevance of specific information in the early stages of an investigation or operation. Relevance and necessity are often questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established. In addition, during the course of the investigation or operation, the investigator or operative may obtain information which is incidental to the main purpose of the investigative jurisdiction of another agency. Such information cannot readily be segregated. Furthermore, during the course of the investigation or operation, the investigator may obtain information concerning violations of law other than those which are within the scope of his/her jurisdiction. In the interest of effective intelligence operations and law enforcement, military intelligence agents should retain information, since it is an aid in establishing patterns of criminal or intelligence activity and provides valuable leads for other law enforcement or intelligence agencies.

(d) From subsection (e)(4)(G), (e)(4)(H), and (f) because this system or records is being exempt from subsections (d) of the Act, concerning access to records. These requirements are inapplicable to the extent that this system of records will be exempt from subsections (d)(1) through (d)(5) of the Act. Although the system would be exempt from these requirements, the Deputy Chief of Staff for Intelligence has published information concerning its notification, access, and contest procedures because under certain circumstances, the Deputy Chief of Staff for Intelligence could decide it is appropriate for an individual to have access to all or a portion os his/her records in this system of records.

(e) From subsection (e)(4)(I) because it is necessary to protect the confidentiality of sources of information, to protectthe privacy and physical safety of participants and their families, confidential sources, and witnesses and to avoid the disclosure of specialized techniques and procedures. Although the system will be exempt from this requirement, the Deputy Chief of Staff for Intelligence has published such a notice in broad, generic terms.

ae. [Reserved.]

af. System identifier: A0381–100aDAMI.

(1) System name: Intelligence/Counterintelligence Source Files.

(2) Exemption: All portions of this system of records that fall within the provisions of 5 U.S.C. 552a(k)(1), (k)(2), or (k)(5) may be exempt from subsections 5 U.S.C. 552a(c)(3), (d)(1) through (d)(5), (e)(1), (e)(4)(G), (e)(4)(H), and (e)(4)(I), and (f).

(3) Authority: 5 U.S.C. 552a(k)(1), (k)(2), and (k)(5).

(4) Reasons: (a) From subsection (c)(3)because disclosing the agencies to which information from this system has been released could reveal the subject's involvement in a sensitive intelligence or counterintelligence operation or investigation of an actual or potential criminal violation, or intelligence operation or investigation; or the existence of that investigation or operation. Granting access to such information could seriously impede or compromise an investigation or operation; endanger the physical safety of participants and their families, confidential sources, witnesses, intelligence personnel, and their families; and lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony and disclose investigative techniques and procedures.

(b) From subsection (d)(1) through (d)(5) because granting access to records could inform the subject of an intelligence or counterintelligence operation or investigation of an actual or potential criminal violation or the existence of that operation or investigation; or the nature and scope of the information and evidence obtained, or of the identity of confidential sources, witnesses and intelligence personnel. Granting access to such information could seriously impede or compromise an operation or investigation; endanger the physical safety of confidential sources, witnesses, intelligence personnel and their families; lead to the improper influencing of witnesses; the destruction of evidence or the fabrication of testimony; disclose investigative techniques and procedures; invade the privacy of those individuals involved in intelligence programs and their families; compromise and thus negate specialized techniques used to support intelligence programs; and interfere with and negate the orderly conduct of intelligence and counterintelligence operations and investigations. In addition, the agency is required to protect the confidentiality of sources who furnished information to the Government under an expressed promise of confidentiality or, prior to September 27, 1975, under an implied promise that the identity of the source would be held in confidence. This confidentiality is needed to maintain the Government's continued access to information from persons who otherwise might refuse to give it.

(c) From subsection (e)(1) because it is not always possible to detect the relevance or necessity of specific information in the early stages of an investigation or operation. Relevance and necessity are often questions of judgment and timing, and it is only after the information is evaluated that the relevance and necessity of such information can be established. In

addition, during the course of the investigation or operation, the investigator or operative may obtain information which is incidental to the main purpose of the investigative jurisdiction of another agency. Such information cannot readily be segregated. Furthermore, during the course of the investigation or operation, the investigator may obtain information concerning violations of law other than those which are within the scope of his/her jurisdiction. In the interest of effective intelligence operations and law enforcement, military intelligence agents should retain information, since it is an aid in establishing patterns of criminal or intelligence activity and provides valuable leads for other law enforcement or intelligence agencies.

(d) From subsection (e)(4)(G), (e)(4)(H), and (f) because this system of records is being exempt from subsection (d) of the Act concerning access to records. These requirements are inapplicable to the extent that this system of records will be exempt from subsections (d)(1) through (d)(5) of the Act. Although the system would be exempt from these requirements, the Deputy Chief of Staff for Intelligence has published information concerning its notification, access, and contest procedures because under certain circumstances, the Deputy Chief of staff for Intelligence could decide it is appropriate for an individual to have access to all or a portion of his/her records in this system of records.

(e) From subsection (e)(4)(I) because it is necessary to protect the confidentiality of sources of information, to protect the privacy and physical safety of participants and their families, confidential sources, and witnesses and to avoid the disclosure of specialized techniques and procedures. Although the system will be exempt from this requirement, the Deputy Chief of Staff for Intelligence has published such a notice in broad generic terms.

* * * * *

Dated: September 28, 1995.

L. M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–24664 Filed 10–3–95; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AH18

Eligibility Reporting Requirements

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations regarding eligibility verification reports (EVRs) for income-based benefits. This amendment implements legislation which eliminated the mandatory requirement for submission of EVRs on an annual basis from recipients of pension or parents' dependency and indemnity compensation (DIC) and gives VA discretionary authority to require such reports where necessary to determine eligibility. This amendment sets forth the guidelines that the Secretary will use in exercising this discretionary authority.

EFFECTIVE DATE: This amendment is effective October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Paul Trowbridge, Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue NW., Washington, DC 20420, telephone (202) 273–7210.

SUPPLEMENTARY INFORMATION: The term ''eligibility verification report'' means a VA form which requests information needed to determine or verify eligibility for VA's income-based benefit programs (pension and parents' DIC). Until recently VA was required by law (38 U.S.C. 1315(e) and 38 U.S.C. 1506(2)) to secure a completed EVR at least once a year from every pension beneficiary and every parents' DIC beneficiary under the age of 72. Public Law 103–271, the Board of Veterans' Appeals Administrative Procedures Improvement Act of 1994, amended 38 U.S.C. 1315 and 1506 to give the Secretary of Veterans Affairs discretionary authority to require submission of income and resource reports by recipients of income-based benefits.

On May 15, 1995, we published a document in the Federal Register (60 FR 25877) proposing criteria for determining which claimants and beneficiaries must complete an EVR. Interested parties were invited to submit written comments on or before July 14, 1995, and we appreciate the one comment that was received.

The commenter, noting that in the past workload backlogs developed when all EVRs fell due at the same time, expressed concern over the possibility of similar backlogs developing if all EVRs are sent at the same time.

While we appreciate the commenter's concern, any potential negative impact from concentrating the EVR workload at one time will be ameliorated by the vast reduction in the total number of EVRs we request. We project that with implementation of this final rule the number of annual EVRs will drop from approximately 850,000 to around 350,000.

The commenter also expressed concern that some beneficiaries who are not required to complete an annual EVR will not advise VA of unreimbursed medical expenses that could reduce countable income for VA purposes, and thereby lose potential entitlement to increased benefits.

Each year VA will remind beneficiaries who are not required to submit EVRs that they might be due an adjustment because of unreimbursed medical expenses paid from their own funds during the previous calendar year. Beneficiaries will therefore be reminded of the opportunity to advise VA of medical expenses as they have been in the past, but the ultimate responsibility for doing so lies with the beneficiary.

Based on the rationale set forth in this document and in the proposed rule, the provisions of the proposed rule are adopted as a final rule without change.

The Secretary certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This amendment will directly affect VA beneficiaries but will not affect small businesses. Therefore, pursuant to 5 U.S.C. 606(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance program numbers are 64.104, 64.105, and 64.110.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Health care, Individuals with disabilities, Pensions, Veterans.

Approved: September 7, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended as follows:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 510(a), unless otherwise noted.

2. Section 3.256 is revised to read as follows:

§ 3.256 Eligibility reporting requirements.

(a) Obligation to report changes in factors affecting entitlement. Any individual who has applied for or receives pension or parents' dependency and indemnity compensation must promptly notify the Secretary in writing of any change affecting entitlement in any of the following:

(1) Income;

(2) Net worth or corpus of estate;

(3) Marital status;

(4) Nursing home patient status;

(5) School enrollment status of a child 18 years of age or older; or

(6) Any other factor that affects entitlement to benefits under the provisions of this Part.

(b) Eligibility verification reports. (1) For purposes of this section the term eligibility verification report means a form prescribed by the Secretary that is used to request income, net worth (if applicable), dependency status, and any other information necessary to determine or verify entitlement to pension or parents' dependency and indemnity compensation.

(2) The Secretary shall require an eligibility verification report under the following circumstances:

(i) If the Social Security Administration has not verified the beneficiary's Social Security number and, if the beneficiary is married, his or her spouse's Social Security number;

(ii) If there is reason to believe that the beneficiary or, if the spouse's income could affect entitlement, his or her spouse may have received income other than Social Security during the current or previous calendar year; or

(iii) If the Secretary determines that an eligibility verification report is necessary to preserve program integrity.

(3) An individual who applies for or receives pension or parents' dependency and indemnity compensation as defined in §§ 3.3 or 3.5 of this part shall, as a condition of receipt or continued receipt of benefits, furnish the Department of Veterans Affairs an eligibility verification report upon request.

(c) If VA requests that a claimant or beneficiary submit an eligibility verification report but he or she fails to do so within 60 days of the date of the VA request, the Secretary shall suspend the award or disallow the claim.

(Authority: 38 U.S.C. 1315(e) and 1506)

3. Section 3.277 is amended by revising the heading and paragraphs (b) and (c); and by adding paragraph (d) as follows:

§ 3.277 Eligibility reporting requirements.

* * * * *

(b) Obligation to report changes in factors affecting entitlement. Any individual who has applied for or receives pension must promptly notify the Secretary in writing of any change affecting entitlement in any of the following:

(1) Income;

(2) Net worth or corpus of estate;

(3) Marital status;

(4) Nursing home patient status;

(5) School enrollment status of a child 18 years of age or older; or

(6) Any other factor that affects entitlement to benefits under the provisions of this Part.

(c) Eligibility verification reports. (1) For purposes of this section the term eligibility verification report means a form prescribed by the Secretary that is used to request income, net worth, dependency status, and any other information necessary to determine or verify entitlement to pension.

(2) The Secretary shall require an eligibility verification report under the following circumstances:

(i) If the Social Security Administration has not verified the beneficiary's Social Security number and, if the beneficiary is married, his or her spouse's Social Security number;

(ii) If there is reason to believe that the beneficiary or his or her spouse may have received income other than Social Security during the current or previous calendar year; or

(iii) If the Secretary determines that an eligibility verification report is necessary to preserve program integrity.

(3) An individual who applies for or receives pension as defined in § 3.3 of this part shall, as a condition of receipt or continued receipt of benefits, furnish the Department of Veterans Affairs an eligibility verification report upon request.

(d) If VA requests that a claimant or beneficiary submit an eligibility verification report but he or she fails to do so within 60 days of the date of the VA request, the Secretary shall suspend the award or disallow the claim.

* * * * *

[FR Doc. 95–24673 Filed 10–3–95; 8:45 am]

BILLING CODE 8320–01–M

38 CFR Part 20

RIN 2900–AH57

Rules of Practice—Advancement on the Docket

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Rules of Practice of the Board of Veterans' Appeals (the Board) to provide that an appeal may be advanced on the Board's docket where administrative error results in significant delay in docketing the appeal. The Board's current Rules of Practice do not address the problem of administrative error with respect to advancement on the docket. The Rules of Practice are also amended to provide that the Board may advance a case on the docket on its own motion, the motion of the appellant, or the motion of the appellant's representative.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Steven L. Keller, Chief Counsel, Board of Veterans' Appeals, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420 (202–565–5978).

SUPPLEMENTARY INFORMATION: The Board of Veterans' Appeals (the Board) decides appeals of claims for veterans' benefits. At the close of Fiscal Year 1994, more than 47,000 appeals were pending at the Board.

Generally, the law requires that the Board consider each case in regular order according to the case's place on the Board's docket. 38 U.S.C. 7107(a)(1). The Board assigns docket numbers. Prior to 1994, docket numbers were assigned when the claims file was physically transferred from the agency of original jurisdiction (typically one of the Department's 58 regional offices) to the Board's offices in Washington, D.C. Beginning in 1994, the Board instituted a new procedure under which docket numbers are assigned as soon as the agency of original jurisdiction forwards a photocopy of the notice of appeal (VA Form 9) to the Board.

The law permits a case to be ''advanced on the docket'' upon motion only if it involves interpretation of law of general application affecting other claims or for other sufficient cause shown. 38 U.S.C. 7107(a)(2). Because of the large numbers of appeals—on average, the Board receives from 35,000 to 40,000 per year—the Board has taken a restrictive view of its authority to advance cases on the docket. The current regulation, 38 CFR 20.900(c), provides just two examples of ''other

sufficient cause shown'' (described in the regulation as ''good cause''): (1) terminal illness and (2) extreme hardship which might be relieved in whole or in part if the benefits sought on appeal were granted.

The current regulation does not deal with the appeals which, due to administrative error, have not been properly processed, resulting in a significant delay in assignment of a docket number which does not, in turn, fairly represent that appeal's true place in the queue of cases waiting to be decided.

Further, with respect to the change in 1994 to the Board's docketing procedures described above, we have learned that some cases which were at regional offices awaiting hearings by traveling members of the Board under former 38 U.S.C. 7110 were not properly identified to the Board at the time of change. As a result, cases that should have numbers reflecting docketing in early 1994 may instead be assigned docket numbers reflecting mid- or late-1995 docketing.

To address these problems, this document amends the Rules of Practice to provide that ''good cause'' for advancing a case on the docket also includes administrative error which results in significant delay in docketing the appeal.

The Rules of Practice are also amended to provide that a motion to advance a case on the docket may be made by the Chairman, the Vice Chairman, the appellant, or the appellant's representative.

Finally, the Rules of Practice are amended to (1) delete the requirement that the Chairman make the decision on the motion to advance and (2) provide that, where a motion is received prior to the assignment of the appeal to an individual member or panel of members, the ruling on the motion will be by the Vice Chairman, who may delegate that authority to a Deputy Vice Chairman. This change is required because (1) 38 U.S.C. 7102(b), as added by Pub. L. No. 103–271, prohibits cases from being assigned to the Chairman as an individual member, and (2) to maintain consistency in the decisions on such motions.

This final rule consists of agency policy, procedure, or practice and, consequently, pursuant to 5 U.S.C. 553, is exempt from notice and comment and effective date provisions.

The Secretary hereby certifies that this final regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The rule would not directly affect any small entities. Only VA beneficiaries would be directly affected. Pursuant to 5 U.S.C. 605(b), this final regulation is therefore exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

There are no Catalog of Federal Domestic Assistance numbers associated with this final rule.

List of Subjects in 38 CFR Part 20

Administrative practice and procedure, Claims, Lawyers, Legal services, Veterans.

Approved: September 25, 1995.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 20 is amended as set forth below:

PART 20—BOARD OF VETERANS' APPEALS: RULES OF PRACTICE

1. The authority citation for part 20 continues to read as follows:

Authority: 38 U.S.C. 501(a).

Subpart J—Action by the Board

2. In § 20.900, the first four sentences in paragraph (c), the seventh sentence in paragraph (c), and the authority citation at the end of the section are revised to read as follows:

§ 20.900 Rule 900. Order of consideration of appeals.

* * * * *

(c) *Advancement on the docket.* A case may be advanced on the docket if it involves an interpretation of law of general application affecting other claims or for other good cause. Examples of such good cause include terminal illness, extreme hardship which might be relieved in whole or in part if the benefits sought on appeal were granted, administrative error which results in significant delay in docketing the appeal, etc. Advancement on the docket may be requested by motion of the Chairman, the Vice Chairman, the appellant, or the appellant's representative. Such motions must be in writing and must identify the law of general application affecting other claims or other good cause involved. * * * Where a motion is received prior to the assignment of the case to an individual member or panel of members, the ruling on the motion will be by the Vice Chairman, who may delegate such authority to a Deputy Vice Chairman. * * *

(Authority: 38 U.S.C. 7107(a))

[FR Doc. 95–24501 Filed 10–3–95; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NC–076–1–7141a; FRL–5291–3]

Approval and Promulgation of Implementation Plans North Carolina: Approval of Revisions to the State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On March 23, 1995, the State of North Carolina, through the North Carolina Department of Environment, Health and Natural Resources, submitted revisions to the North Carolina State Implementation Plan (SIP). EPA is approving these revisions to rules 15A NCAC 2D .0501 Compliance With Emission Control Standards, .0516 Sulfur Dioxide Emissions From Combustion Sources, and .0530 Prevention Of Significant Deterioration. The intended effect of this revision is to clarify certain provisions and ensure consistency with requirements of the Clean Air Act.

DATES: This final rule is effective December 4, 1995 unless notice is received by November 3, 1995 that someone wishes to submit adverse or critical comments. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Written comments should be addressed to: Scott M. Martin, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

North Carolina Department of Environment, Health and Natural Resources, 512 North Salisbury Street, Raleigh, North Carolina 27604.

FOR FURTHER INFORMATION CONTACT: Scott M. Martin, Regulatory Planning

and Development Section, Air Programs Branch, Air, Pesticides & Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, NE., Atlanta, Georgia 30365. The telephone number is 404/347–3555 extension 4216.

SUPPLEMENTARY INFORMATION: On March 23, 1995, the State of North Carolina, through the North Carolina Department of Environment, Health and Natural Resources, submitted revisions covering the adoption of amendments to rules 15A NCAC 2D .0501 Compliance With Emission Control Standards, .0516 Sulfur Dioxide Emissions From Combustion Sources, and .0530 Prevention Of Significant Deterioration.

Rule .0501 was amended to include a description of the sulfur dioxide stack testing compliance methods and to update referenced American Society for Testing and Materials (ASTM) methods. Rule .0516 was amended to clarify that the general sulfur dioxide emissions standard does not apply to spodumene ore roasting. Requirements for spodumene ore roasting are established in Rule .0527. Rule .0530 was amended to establish an increment level for PM–10, as required in 40 CFR 51.166, to replace the increment level for total suspended particulate. EPA is approving the amendments of rules 15A NCAC 2D .0501, .0516, and .0530 because these revisions are consistent with the requirements of the Clean Air Act and EPA guidance.

Final Action

EPA is approving the above referenced revisions to the North Carolina SIP. This action is being taken without prior proposal because the EPA views this as a noncontroversial amendment and anticipates no adverse comments. However, in a separate document in this Federal Register publication, the EPA is proposing to approve the SIP revision should adverse or critical comments be filed. This action will be effective December 4, 1995 unless, by November 3, 1995, adverse or critical comments are received.

If the EPA receives such comments, this action will be withdrawn before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on this action serving as a proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time. If no such comments are received, the public is advised that this action will be effective December 4, 1995.

Under section 307(b)(1) of the Clean Air Act (CAA), 42 U.S.C. 7607(b)(1), petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by December 4, 1995. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2) of the Act, 42 U.S.C. 7607(b)(2)).

The Office of Management and Budget has exempted these actions from review under Executive Order 12866.

Nothing in this action shall be construed as permitting or allowing or establishing a precedent for any future request for a revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

Under the Regulatory Flexibility Act, 5 U.S.C. 600 et seq, EPA must prepare a regulatory flexibility analysis assessing the impact of any proposed or final rule on small entities. 5 U.S.C. 603 and 604. Alternatively, EPA may certify that the rule will not have a significant impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and government entities with jurisdiction over populations of less than 50,000.

SIP approvals under 110 and subchapter I, part D of the CAA do not create any new requirements, but simply approve requirements that the State is already imposing. Therefore, because the Federal SIP-approval does not impose any new requirements, I certify that it does not have a significant impact on any small entities affected. Moreover, due to the nature of the Federal-state relationship under the CAA, preparation of a regulatory flexibility analysis would constitute Federal inquiry into the economic reasonableness of state action. The CAA forbids EPA to base its actions concerning SIPs on such grounds. *Union Electric Co.* v. *USEPA*, 427 U.S. 246, 256–66 (S.Ct. 1976); 42 U.S.C. 7410(a)(2) and 7410 (k)(3).

Unfunded Mandates

Under sections 202, 203 and 205 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must undertake various actions in association with proposed or final rules that include a Federal mandate that may result in estimated costs of $100 million or more to the private sector, or to State, local, or tribal governments in the aggregate.

Through submission of this state implementation plan or plan revision, the State and any affected local or tribal governments have elected to adopt the program provided for under section 110 of the CAA. These rules may bind State, local and tribal governments to perform certain duties. EPA has examined whether the rules being approved by this action will impose any mandate upon the State, local or tribal governments either as the owner or operator of a source or as a regulator, or would impose any mandate upon the private sector. EPA's action will impose no new requirements; such sources are already subject to these regulations under State law. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action. Therefore, this final action does not include a mandate that may result in estimated costs of $100 million or more to State, local, or tribal governments in the aggregate or to the private sector.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 25, 1995.

Patrick M. Tobin,

Acting Regional Administrator.

Part 52 of chapter I, title 40, Code of Federal Regulations, is amended as follows:

PART 52—[AMENDED]

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

Authority: 42.U.S.C. 7401–7671q.

Subpart II—North Carolina

2. Section 52.1770 is amended by adding paragraph (c)(86) to read as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

(86) The PM–10 rules, Stack Testing Methods and other miscellaneous

revisions to the North Carolina State Implementation Plan which were submitted on March 23, 1995.

(i) Incorporation by reference. Addition of new North Carolina rules 15A NCAC 2D .0501, .0516, and .0530 which were state effective on February 1, 1995.

(ii) Other material. None.

[FR Doc. 95–23819 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 271

[FRL–5311–7]

Wyoming; Final Authorization of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of final determination on Wyoming's application for final authorization.

SUMMARY: Wyoming has applied for final authorization under the Resource Conservation and Recovery Act (RCRA). The United States Environmental Protection Agency (EPA) has reviewed Wyoming's application and has reached a final determination that Wyoming's hazardous waste program satisfies all of the requirements necessary to qualify for final authorization. Thus, EPA is granting final authorization to Wyoming to operate its program, subject to the authority retained by EPA in accordance with the Hazardous and Solid Waste Amendments of 1984.

EFFECTIVE DATE: Final authorization for Wyoming shall be effective at 1:00 p.m. on October 18, 1995.

FOR FURTHER INFORMATION CONTACT: Marcella DeVargas, (8HWM–WM) 999 18th Street, Suite 500, Denver, Colorado 80202–2466, phone 303/293–1670.

SUPPLEMENTARY INFORMATION:

A. Background

Section 3006 of the Resource Conservation and Recovery Act (RCRA) allows the Environmental Protection Agency (EPA) to authorize State hazardous waste programs to operate in the State in lieu of the Federal hazardous waste program. To qualify for final authorization, a State's program must (1) be ''equivalent'' to the Federal program, (2) be consistent with the Federal program and other State programs, and (3) provide for adequate enforcement. Section 3006(b) of RCRA, 42 U.S.C. 6926(b).

On July 17, 1995, Wyoming submitted an official application to obtain final authorization to administer the RCRA program. On July 27, 1995, EPA published a tentative decision announcing its intent to grant Wyoming final authorization. Further background on the tentative decision to grant authorization appears at 60 FR 38537, July 27, 1995.

Along with the tentative determination EPA announced the availability of the application for public comment and the date of a public hearing on the application. The public hearing was held on August 29, 1995.

EPA did not receive any written comments. At the public hearing, several oral comments were made expressing support for EPA's tentative determination. One commenter asked if the State had chosen to be more or less stringent than the Federal rules in regard to the RCRA publicly owned treatment works exclusion. The response was the State law requires the State to regulate the same universe of hazardous wastes as is regulated under RCRA, therefore, the State has adopted the federal exclusion for hazardous waste discharged to publicly owned treatment works. The commenter also suggested the Clean Water Act Pretreatment rules also be delegated to the State of Wyoming. Delegation of the pretreatment program is not the subject of this action today.

Because EPA Region VIII and the State worked closely to develop the authorization package, most EPA concerns were addressed before submittal of the application by the State. The State also conducted four (4) public meetings throughout the State, and solicited comments on the draft program description and the draft Memorandum of Agreement from facilities, industry organizations, and environmental groups.

Wyoming's program is ''broader in scope'' than the Federal program in two significant ways. First, Wyoming rules require an applicant for a permit to demonstrate fitness by requiring that the past performance of the applicant or any partners, executive officers, or corporate directors, be reviewed. Second, county commissions must approve certain hazardous waste management facilities, and certain hazardous waste management facilities must also obtain an industrial siting permit. These portions of Wyoming's program, because they are broader in scope, are not a part of the Federally approved program.

EPA will administer the RCRA permits or portion of permits or administrative orders it has issued to facilities in the State until they expire or are terminated. The State may issue comparable State permits in accordance with the procedures found in Chapter 3 of the Wyoming rules. For facilities without RCRA permits, or for facilities where the State makes technical changes prior to federal permits, the State will call in Part B permit applications.

The regulations under Section 7 of the Endangered Species Act (at 50 CFR Part 402) require that EPA consult with the United States Fish and Wildlife Service (the ''Service'') regarding this decision. EPA has done so and the Service has concurred with EPA's determination that this authorization is not likely to adversely affect listed species or critical habitat.

The Agency's general policy in authorizing state programs under various federal authorities has been to develop informal coordination procedures with the Service to ensure protection of listed species and critical habitat, and only to consult under section 7 of the ESA after authorization in those instances where EPA is itself the permitting agency subject to section 7 requirements. In addition, the Agency believes that issues related to protection of endangered species and habitat are most effectively addressed in the context of broader programmatic strategies worked out with the states, and EPA will continue to move in this direction with interested parties.

In the case of this RCRA base program authorization for Wyoming, EPA Region VIII and the State have agreed to work closely with the Service to address impacts to listed species or critical habitat that may result from the issuance of RCRA permits by the State. EPA Region VIII's decision to follow the processes described in the EPA/Wyoming MOA and correspondence with the Service does not subject EPA after authorization to the consultation requirements of the ESA, nor does it create any rights by any person to enforce the provisions of the ESA against EPA.

Today's decision to authorize the Wyoming hazardous waste regulatory program does not extend to ''Indian Country,'' as defined in 18 U.S.C. 1151, including the Wind River Reservation.

Should Wyoming decide in the future to apply for authorization of its hazardous waste program on Indian Country the State would have to provide an appropriate analysis of the State's jurisdiction to enforce in these areas. In order for a state (or Tribe) to satisfy this requirement, it must demonstrate to the EPA's satisfaction that it has authority either pursuant to explicit Congressional authorization or applicable principles of Federal Indian law to enforce its laws against existing

and potential pollution sources within any geographical area for which it seeks program approval.

EPA is not making a determination that the State either has adequate jurisdiction or lacks such jurisdiction. Should the State of Wyoming choose to submit an analysis with regard to jurisdiction of the State over all or part of Indian Country in the State, it may do so without prejudice.

Any future EPA evaluation of whether to approve the Wyoming program for Indian Country to include Indian reservation lands, would be governed by EPA's judgment as to whether the State has demonstrated adequate authority to justify such approval, based upon its understanding of the relevant principles of Federal Indian law and sound administrative practice. The State may wish to consider EPA's discussion of the related issue of Tribal jurisdiction found in the preamble to the Indian Water Quality Standards Regulation (see 56 FR 64876, December 12, 1991).

B. Decision

After reviewing the public comments, I conclude that Wyoming's application for final authorization meets all of the statutory and regulatory requirements established by RCRA. Accordingly, Wyoming is granted final authorization for the Federal RCRA program in effect as of July 8, 1984; Pre-cluster rules, non-HSWA revision clusters I, II, III, IV, V, and VI; and for HSWA clusters I and II; RCRA cluster I, II, III, (except for 279.10 (b)(2)), and IV, and the following RCRA cluster V rules: Recovered Oil Exclusion, 59 FR 38536, July 28, 1994, (Code Rule 135), Removal of the Conditional Exemption for Certain Slag Residuals, 59 FR 43496, August 24, 1994, (Code Rule 136), Universal Treatment Standards and Treatment Standards for Organic Toxicity Characteristic Wastes and Newly Listed Wastes, 59 FR 47482, September 19, 1994, and the Land Disposal Restriction Phase II rules, 60 FR 242, January 3, 1995. Accordingly, Wyoming is granted final authorization to operate its hazardous waste program, subject to the limitations on its authority imposed by the Hazardous and Solid Waste Amendments of 1984 (Public Law 98–616, November 8, 1984) (HSWA). Wyoming now has the responsibility for permitting treatment, storage and disposal facilities within its borders and carrying out the other aspects of the RCRA program, subject to the HSWA. Wyoming also has primary enforcement responsibility, although EPA retains the right to conduct inspections under Section 3007 of RCRA and to take enforcement actions under Sections 3008, 3013 and 7003 of RCRA.

As stated above, Wyoming's authority to operate a hazardous waste program under Subtitle C of RCRA is limited by the HSWA. Prior to that date, a State with final authorization administered its hazardous waste program entirely in lieu of the EPA. The Federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities the State was authorized to permit. When new, more stringent Federal requirements were promulgated or enacted, the State was obligated to enact equivalent authority within specified time frames. New Federal requirements did not take effect in an authorized State until the State adopted the requirements as State law.

In contrast, under Section 3006(g) of RCRA, 42 U.S.C. 6926(g), new requirements and prohibitions imposed by the HSWA take effect in authorized States at the same time as they take effect in non-authorized States. EPA is directed to carry out those requirements and prohibitions in authorized States, including the issuance of full or partial permits, until the State is granted authorization to do so. While States must still adopt HSWA-related provisions as State law to retain final authorization, the HSWA applies in authorized States in the interim.

As a result of the HSWA, there is a dual State/Federal regulatory program in Wyoming. To the extent the authorized State program is unaffected by the HSWA, the State program will operate in lieu of the Federal program. Where HSWA-related requirements apply, however, EPA will administer and enforce these portions of the HSWA in Wyoming until the State receives authorization to do so. Among other things, this may entail the issuance of Federal RCRA permits for those areas in which the State is not yet authorized. Once the State is authorized to implement a HSWA requirement or prohibition, the State program in that area will operate in lieu of the Federal program. Until that time the State will assist EPA's implementation of the HSWA under a Cooperative Agreement.

Any State requirement that is more stringent than a HSWA provision remains in effect; thus, the universe of the more stringent provisions in the HSWA and the approved State program define the applicable Subtitle C requirements in Wyoming.

EPA has published a Federal Register notice that explains in detail the HSWA and its effect on authorized States. That notice was published at 50 FR 28702–28755, July 15, 1985.

Compliance with Executive Order 12826: The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12826.

Unfunded Mandates Reform Act: Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), P.L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments and the private sector. Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures to State, local, and tribal governments, in the aggregate, or to the private sector, of $100 million or more in any one year. When a written statement is needed for an EPA rule, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, giving them meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising them on compliance with the regulatory requirements.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. EPA does not anticipate that the approval of Wyoming's hazardous waste program referenced in today's notice will result in annual costs of $100 million or more.

EPA's approval of state programs generally have a deregulatory effect on the private sector because once it is determined that a state hazardous waste program meets the requirements of RCRA section 3006(b) and the

regulations promulgated thereunder at 40 CFR Part 271, owners and operators of hazardous waste treatment, storage, or disposal facilities (TSDFs) may take advantage of the flexibility that an approved state may exercise. Such flexibility will reduce, not increase, compliance costs for the private sector. Thus, today's rule is not subject to the requirements of sections 202 and 205 of the UMRA.

EPA has determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments. The Agency recognizes that small governments may own and/or operate TSDFs that will become subject to the requirements of an approved state hazardous waste program. However, such small governments which own and/or operate TSDFs are already subject to the requirements in 40 CFR Parts 264, 265 and 270. Once EPA authorizes a state to administer its own hazardous waste program and any revisions to that program, these same small governments will be able to own and operate their TSDFs with increased levels of flexibility provided under the approved State program.

Certification under the Regulatory Flexibility Act: Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of Wyoming's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of Sections 2002(a), 3006, and 7004(b) of RCRA, 42 U.S.C. 6912(a), 6926, 6974(b).

Dated: September 26, 1995.

William P. Yellowtail,

Regional Administrator.

[FR Doc. 95–24657 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 300

[FRL–5311–6]

National Oil and Hazardous Substances Pollution Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency.

ACTION: Notice of deletion of the Stewco, Incorporated Superfund Site (Site) from the National Priorities List.

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Site in Waskom, Texas, from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR Part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), which EPA promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA). EPA and the State of Texas have determined that all appropriate Fund-financed responses under CERCLA have been implemented and that no further cleanup by responsible parties is appropriate. Moreover, EPA and the State of Texas have determined that remedial actions conducted at the Site to date have been protective of public health, welfare, and the environment.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Ernest R. Franke, Remedial Project Manager, US EPA, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8521.

SUPPLEMENTARY INFORMATION: The Site to be deleted from the NPL is the ''STEWCO Superfund Site,'' Waskom, Texas. A Notice of Intent to Delete for this Site was published on July 27, 1995, (60 FR 422). The closing date for public comment was August 25, 1995. EPA received no comments during the comment period.

EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as a list of the most serious of those sites. Sites on the NPL may be the subject of remedial response actions financed using the Hazardous Substance Response Trust Fund (Fund). Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP, provides that in the event of a significant release from a site deleted from the NPL, the site shall be restored to the NPL without application of the Hazard Ranking System. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response actions.

List of Subjects in 40 CFR Part 30

Environmental protection, Hazardous waste.

Dated: July 25, 1995.

Dated: September 20, 1995.

A. Stanley Meiburg,

Acting Regional Administrator, Environmental Protection Agency, Region 6.

For the reasons setout in the preamble, 40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(d); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580; 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B—[Amended]

2. Table 1 of Appendix B to part 300 is amended by removing STEWCO Superfund Site, Waskom, Texas.

[FR Doc. 95–24655 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 76

[CS Docket No. 94–44; DA 95–2024]

Cable Television Service; List of Major Television Markets

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, through this action, amends its rules regarding the listing of major television markets, to change the designation of the Denver, Colorado television market to include the community of Castle Rock, Colorado. This action, taken at the request of LeSea Broadcasting Corporation, licensee of television station KWHD(TV), channel 53 (Independent), Castle Rock, Colorado, and after evaluation of the comments filed in this proceeding, amends the rules to designate the subject market as the Denver-Castle Rock, Colorado television market. With this action, this proceeding is terminated.

EFFECTIVE DATE: November 3, 1995.

FOR FURTHER INFORMATION CONTACT: William H. Johnson, Cable Services Bureau, (202) 416–0800.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Report and Order, Docket 94–44, adopted September 21, 1995 and released September 29, 1995. The full text of this decision is available for inspection and copying during normal business hours in the FCC Reference Center (room 239), 1919 M Street NW., Washington, DC 20554, and may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 1919 M Street NW., Washington, DC 20554.

List of Subjects in 47 CFR Part 76

Cable television.

Part 76 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 76—CABLE TELEVISION SERVICE

1. The authority for Part 76 continues to read as follows:

Authority: 47 U.S.C. 154, 303.

§ 76.51 Major television markets.

2. Section 76.51 is amended by revising paragraph (a)(32) to read as follows:

* * * * *

(a) * * *

(32) Denver-Castle Rock, Colorado

* * * * *

Federal Communications Commission.

William H. Johnson,

Deputy Chief, Cable Services Bureau.

[FR Doc. 95–24643 Filed 10–3–95; 8:45 am]

BILLING CODE 6712–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 227

[I.D. 092895B]

Endangered and Threatened Species; West Coast Pink Salmon Petition Determination

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of determination.

SUMMARY: NMFS has determined that neither Elwha River nor lower Dungeness River pink salmon, as petitioned, constitute a ''species'' under the Endangered Species Act of 1973 (ESA). However, Elwha River and lower Dungeness River pink salmon are part of a larger evolutionarily significant unit (ESU) that includes all odd-year pink salmon stocks in Washington as far west as the Elwha River and in southern British Columbia, Canada (including the Fraser River and eastern Vancouver Island), as far north as Johnstone Strait. Further, NMFS has identified a second pink salmon ESU which includes even-year pink salmon residing in the Snohomish River, WA. NMFS has determined that, at the present time, neither of these ESUs warrant listing as a threatened or endangered species.

ADDRESSES: Environmental and Technical Services Division, NMFS, 525 NE Oregon Street, Suite 500, Portland, OR 97232.

FOR FURTHER INFORMATION CONTACT: Garth Griffin, Environmental and Technical Services Division, 503/231-2005 or Marta Nammack, Protected Species Management Division, 301/713-1401.

SUPPLEMENTARY INFORMATION:

Petition Background

On March 14, 1994, the Secretary of Commerce received a petition from Professional Resources Organization-Salmon (PRO-Salmon), to list as threatened or endangered nine naturally spawning populations of salmon indigenous to northwestern Washington and to designate critical habitat under the ESA (PRO-Salmon, 1994). Two of the petitioned populations included pink salmon (*Oncorhynchus gorbuscha*) stocks residing in the Elwha River and the lower Dungeness River on Washington's Olympic Peninsula. NMFS published a document on September 12, 1994 (59 FR 46808) that the petition presented substantial scientific information indicating that listings may be warranted. Concurrently, NMFS also announced its intention to initiate comprehensive status reviews of all species of Pacific salmon and anadromous trout in Washington, Oregon, Idaho, and California.

In announcing these comprehensive status reviews, NMFS requested comments from any party having relevant information concerning (1) whether any salmon stock qualifies as a ''species'' under the ESA and (2) whether any salmon stock is endangered or threatened based on NMFS' listing criteria. In addition, NMFS specifically solicited information on the petitioned stocks. NMFS also requested information on areas that may qualify as critical habitat for all stocks of pink, chum, sockeye, and chinook salmon, and sea-run cutthroat trout in Washington, Oregon, Idaho, and California. Status reviews for west coast coho salmon and steelhead are nearing completion.

Biological Background

The NMFS' Northwest Fisheries Science Center Biological Review Team (BRT) has reviewed the status of west coast pink salmon (Northwest Fisheries Science Center BRT, 1995), the prominent results of which are summarized below. A copy of the draft BRT report is available upon request (see **ADDRESSES**).

Pink salmon occur in oceanic and freshwater areas around the Pacific rim of Asia and North America. Spawning populations range from Puget Sound, WA to Norton Sound, AK in North America and from North Korea to the Anadyr Gulf, Russia in Asia (Heard, 1991; Mathisen, 1994). In Washington, pink salmon regularly spawn as far south as southern Puget Sound and on the Olympic Peninsula along the Strait of Juan de Fuca (Williams et al., 1975, Washington Department of Fisheries (WDF) et al., 1993), with about 70 percent of the spawning in north Puget Sound (WDF et al., 1993).

Across its natural range, pink salmon spawn in both large and small river systems in the late summer and fall. Spawning occurs in shallow pools and riffles exposed to moderately fast currents. Water temperatures during peak spawning activity range from about 5°–15° C. Pink salmon mature at the smallest average size of any species of Pacific salmon (1.0–2.5 kg) and show marked sexual dimorphism (Davidson, 1935; Pritchard, 1937; Beacham and Murray, 1985). Spawning populations throughout much of the range of pink salmon may be extremely large, often exceeding hundreds of thousands of adults (Heard, 1991; WDF et al., 1993).

Upon emerging from gravel, juvenile pink salmon migrate rapidly downstream, generally in schools. After a few weeks to a few months in estuaries and nearshore habitat, pink salmon migrate to sea where they reside for 12–16 months (Heard, 1991).

In addition to their small size, extreme sexual dimorphism, and short freshwater residence as juveniles, pink salmon differ from other salmonids in that they lack a variable age structure. Almost all pink salmon are 2 years of age at maturity (Gilbert, 1914; Bilton and Ricker, 1965; Turner and Bilton, 1968). The most significant result of this rigid age structure has been the development of two separate, and often distinctive, broodlines of pink salmon. Fish in the broodline that mature in even-numbered years are referred to as ''even-year'' pink salmon while those that mature in alternate, odd-numbered

years are referred to as ''odd-year'' pink salmon (Aspinwall, 1974; Johnson, 1979; McGregor, 1982; Beacham et al., 1985).

The geographic distribution of the two pink salmon broodlines is not random. At the southern extent of the pink salmon range in North America, odd-year pink salmon are most abundant (Atkinson et al., 1967; WDF et al., 1993). Pink salmon populations in British Columbia are dominated by odd-year fish, whereas populations from the northern Queen Charlotte Islands and western Alaska are dominated by even-year fish (Neave, 1952; Aro and Shepard, 1967; Ricker and Manzer, 1974). In Asia and North America, even-year pink salmon generally become more abundant as latitude increases (Heard, 1991). The reasons for this variation in broodline dominance are not well understood (Ricker, 1962; Heard, 1991).

Consideration as a ''Species'' Under the ESA

To qualify for listing as a threatened or endangered species, Elwha River and lower Dungeness River pink salmon must constitute ''species'' under the ESA. The ESA defines a ''species'' to include any ''distinct population segment of any species of vertebrate * * * which interbreeds when mature.'' On November 20, 1991, NMFS published a policy (56 FR 58612) describing how it will apply the ESA definition of ''species'' to Pacific salmonid species. This policy provides that a salmonid population will be considered distinct, and hence a species under the ESA, if it represents an ESU of the biological species. The population must satisfy two criteria to be considered an ESU: (1) It must be reproductively isolated from other conspecific population units, and (2) it must represent an important component in the evolutionary legacy of the biological species. The first criterion, reproductive isolation, need not be absolute, but must be strong enough to permit evolutionarily important differences to accrue in different population units. The second criterion would be met if the population contributed substantially to the ecological/genetic diversity of the species as a whole. Further guidance on the application of this policy is contained in ''Pacific salmon (*Oncorhynchus spp.*) and the Definition of Species under the ESA,'' which is available upon request (see **ADDRESSES**).

Reproductive Isolation

For this criterion, NMFS has considered available information regarding geographic and life-history factors that may isolate pink salmon, as well as genetic factors which indicate reproductive isolation. The petitioners considered reproductive isolation with respect to eleven groups of pink salmon which have previously been identified in the State of Washington (WDF et al., 1993). In addition to those identified by the petitioner, previously identified pink salmon stocks include Snohomish River even-year pink salmon (the only even-year population in Washington, Oregon, Idaho, or California) and odd-year pink salmon populations in the following Washington rivers: (1) Nooksack, (2) Skagit, (3) Stillaguamish, (4) Snohomish, (5) Puyallup, (6) Nisqually, (7) Hamma Hamma, (8) Duckabush, (9) Dosewallips, and (10) upper Dungeness.

With respect to the two criteria established by NMFS to define a ''species'' of Pacific salmon, the petitioner contended that the lower Dungeness and Elwha River populations of pink salmon were both reproductively isolated from other pink salmon populations. Reproductive isolation was inferred primarily on the basis of distance to nearest neighboring population. For lower Dungeness River pink salmon, this distance is 10 km and for Elwha River pink salmon, this distance is 25 km. Genetic data, in the form of allozyme variation, support a hypothesis for at least partial reproductive isolation of the lower Dungeness River population (Shaklee et al., 1991), but no genetic data exist for the Elwha River population (WDF et al., 1993).

Considerable evidence exists that indicates that even- and odd-year pink salmon are reproductively isolated. As discussed above under Biological Background, pink salmon exhibit a rigid age structure that results in two separate broodlines, even- and odd-year pink salmon. Throughout much of the range of this species, many rivers which support pink salmon populations produce both even- and odd-year broodlines which have no opportunity for interbreeding. As a result, this life history characteristic yields in each of these rivers two temporally isolated populations with almost no prospect of genetic exchange.

Numerous genetic studies also support the belief that even- and odd-year pink salmon populations are reproductively isolated. Studies conducted by Okazaki (1984) and Reisenbichler (1992) found large genetic differences between even- and odd-year pink salmon from the same area, with the magnitude of the differences roughly comparable to that found between coastal and inland steelhead. Strong allozyme frequency differences between even- and odd-year broodlines spawning at the same locality have been reported in Alaska (Aspinwall, 1974; Johnson, 1979; McGregor, 1982), Canada (Beacham et al., 1985) and Russia (Salmenkova et al., 1981; Altukohov et al., 1983; Kartavstev, 1991) for many polymorphic enzyme coding loci. In addition, Shaklee and Varnavskaya (1994) reported a large genetic difference between even- and odd-year Snohomish River pink salmon.

Ecological/Genetic Diversity

For this criterion, NMFS considered environmental, ecological, and life history information in its assessment of potential pink salmon ESUs. Further, historic accounts of artificial propagation were considered to determine (1) How indigenous even- and odd-year west coast pink salmon populations have been altered, and (2) the relationship of historic populations to the presently defined ESUs.

Little information was provided by the petitioner regarding NMFS' evolutionary significance criterion. The petitioner believed that spatial and temporal isolation of the lower Dungeness River population from the upper Dungeness River population, due to differences in run timing and spawning location, contribute to the distinctiveness of the lower river population. No quantitative data are available to support a hypothesis for the distinctiveness of the Elwha River population.

Environmental, Ecological, and Life-History Information

Along the west coast of North America, climate varies primarily with latitude. As such, coastal regions exhibit north to south gradients of increasing average rainfall and decreasing average temperature. Streamflows in this region tend to be lowest in August and September, whereas water temperatures in northwestern Washington are generally highest in July and August (Hydrosphere Data Products, Inc., 1993). Run timing and spawn timing are sensitive to these factors. As a result, streamflow patterns determine the temporal availability and suitability of spawning and incubation habitat for pink salmon.

Pink salmon populations can vary considerably in run timing (Sheridan, 1962) and spawn timing within a single river system. This type of life-history variability can have consequences for a populations' fitness (Taylor, 1980; Mortensen et al., 1991) and therefore, is an important consideration when

attempting to identify distinct population units (Gharett and Smoker, 1993).

In its analysis of run timing, NMFS found the time period of peak spawning for odd-year pink salmon populations to be highly variable among river systems in northwestern Washington. Pink salmon populations in the Strait of Juan de Fuca exhibit the earliest average date of peak spawning, while peak spawning of Nisqually River populations typically occurs an average of 1 month later. Timing of peak spawning of even-year pink salmon in the Snohomish river is about 3 to 4 weeks earlier than that of odd-year fish, even though these two groups use much of the same habitat.

In addition to differences in run timing, considerable variation in body size and shape is apparent among pink salmon populations. Available data indicate significant variation in the length of odd-year pink salmon among various drainages in Washington. In general, the smallest fish appear in cold, turbid rivers in Puget Sound (Nooksack and Nisqually Rivers), and along the Strait of Juan de Fuca (lower and upper Dungeness River), while the largest fish tend to exist in Hood Canal. Limited data regarding Snohomish River even-year pink salmon suggest that this population contains the smallest pink salmon observed in Washington.

Comparisons of pink salmon length data among British Columbia and Washington indicate that, with the exception of Snohomish and Skagit River populations, odd-year pink salmon populations in Washington appear to be smaller than the average for odd-year British Columbia populations (Beacham and Murray 1985). However, this comparison is complicated by the fact that the Washington data were taken more recently than the British Columbia data. Even-year Snohomish River adult pink salmon are similar in size to pink salmon in even-year populations from the central mainland and northern Vancouver Island, but tend to be smaller than the even-year British Columbia average. Again, however, the data may not be strictly comparable, because they were taken in different years.

Some evidence exists for recent declines in body length of odd-year pink salmon in Washington. This aspect raises concern regarding the ability of natural populations of pink salmon to recover, since, in general, decreases in body size equate to decreased fecundity and decreased juvenile production (but see Ricker et al., 1978; Ricker, 1989). NMFS was unable to review any new data on body size in odd-year British Columbia pink salmon to determine whether size has declined in these stocks (Ricker et al., 1978; Ricker, 1989). However, the decline in body length of odd-year Washington pink salmon is qualitatively similar to a decline in length observed in pink salmon returning to Auke Creek, AK, over the last 20 years. Further, data estimated from catches of southeastern Alaska pink salmon suggest similarly declining body length trends over an even longer period (Marshall and Quinn, 1988). Therefore, NMFS believes that this factor should be closely monitored to ensure that natural populations remain viable in the future.

Homing and straying are prominent features of Pacific salmon biology that can have significant effects on population structure. Consequently, these issues are relevant to ESU determinations for these species. Pink salmon have a widespread reputation for straying at higher rates than other species of Pacific salmon (Horrall, 1981). If true, the result may be a less conspicuous population structure and, potentially, reduced opportunity for local adaptations to be maintained. Few technically sound studies have been conducted to estimate straying rates of Pacific salmon and provide empirical evidence supporting the hypothesis that pink salmon stray at relatively higher rates than other species of *Oncorhynchus* is mixed (Quinn, 1993; Altukhov and Salmenkova, 1994). However, the rapid colonization of systems newly available to pink salmon indicates that this species has an unusual ability to expand into suitable habitat when conditions are favorable (Merrell, 1962; Kwain and Laurie, 1981; Heard, 1991).

It is difficult to say with any degree of certainty that pink salmon stray more frequently relative to other species of Pacific salmon. It is apparent that straying in pink salmon may be highly dependent on spawning location and on conditions at time of spawning. The consequences of straying on pink salmon populations are not clear, but such consequences may contribute to less conspicuous population structure and reduced local adaptations.

Artificial Propagation

It is commonly believed that even-year pink salmon were historically either absent from Washington or were at an abundance too low to sustain harvest (Rounsefell, 1938; Ellis and Noble, 1959). Consequently, WDF made several attempts earlier in this century to establish even-year pink salmon runs in northwestern Washington (WDF, 1916–1964; Neave, 1965; Roppel, 1982). More than 82 million pink salmon eggs were transported from Alaska to various locations in Washington in even-numbered years between 1910 and 1932. In addition, more than one million odd-year Alaskan pink salmon eggs were brought into Washington from southeastern Alaska in 1929. An estimated 85 million juveniles released between 1911 and 1933 produced no recorded returns of even-year pink salmon adults to Washington rivers, including the Snohomish River (Ellis and Noble, 1959; Neave, 1965). Attempts to establish even-year pink salmon in Washington were renewed between 1944 and 1956 with the transport of nearly 4 million eggs from the Skeena River drainage in British Columbia, Canada. Of the 1.3 million fry released, at least several hundred are believed to have returned as adults. However, no evidence exists that returns were sustained beyond one or two generations (Ellis and Noble, 1959; Neave, 1965).

Even-year pink salmon in Washington are known only to occur in the Snohomish River (WDF et al., 1993). The origin of this population is uncertain; these fish may be endemic or may have resulted from one or more transplants of even-year fish from Alaska or Canada. Regardless of its origin, the Snohomish River even-year population has apparently been naturally self-sustaining for at least the last 18 generations (about 36 years).

In addition to stock transplants, relatively large numbers of pink salmon were produced in Washington hatcheries around Puget Sound from the early 1950's through the late 1980's. Transfers of fish among hatcheries and drainages were common during this period; however, very few pink salmon were transplanted to areas outside Puget Sound. Three hatcheries have dominated pink salmon production in Washington: Hood Canal Hatchery on Finch Creek in Hood Canal, Puyallup Hatchery on Voight Creek in south Puget Sound, and Dungeness Hatchery on the Dungeness River.

In recent years, only Hood Canal Hatchery has maintained an active pink salmon propagation program. Most hatchery production of pink salmon in Washington is composed of odd-year fish released from this facility. Originally, in 1953, broodstock for this hatchery was derived from adult pink salmon returning to the Dungeness and Dosewallips Rivers. Presently, this hatchery uses native broodstock, which are generally released into Finch Creek, the location of the hatchery. Over the past decade releases from Hood Canal hatchery have averaged about 1 million fry released every other year into Finch

Creek. Therefore, although artificial propagation of pink salmon in the past may have affected the population structure of odd-year pink salmon in Puget Sound, recent hatchery production has probably had little effect on this structure due in part to the use of native broodstocks.

ESU Determinations

Based on its evaluation of genetic, life-history, and ecological information pertaining to pink salmon, NMFS has determined that two ESUs exist for North American pink salmon in WA and southern British Columbia, Canada. These two ESUs include: (1) even-year pink salmon residing in the Snohomish River, Washington (and likely, even-year pink salmon populations in southern British Columbia); and (2) odd-year pink salmon occurring in Washington as far west as the Elwha River and in southern British Columbia, Canada (including the Fraser River and eastern Vancouver Island) as far north as Johnstone Strait. A summary of the information that led to these conclusions is presented below.

Even-Year Pink Salmon ESU

A single population of even-year pink salmon occurs in the United States south of Alaska—in the Snohomish River, WA. Genetically, this population is much more similar to even-year pink salmon from British Columbia and Alaska than it is to odd-year pink salmon from Washington. In addition, a similar pattern is found in phenotypic and life-history traits such as body size and run timing. This result is consistent with numerous studies that have found large genetic differences between even- and odd-year pink salmon from the same area (e.g., Aspinwall, 1974; Beacham et al., 1985; Kartavtsev 1991).

The Snohomish River even-year pink salmon population is geographically isolated by several hundred kilometers from other even-year pink salmon populations of appreciable size. However, life-history features of the Snohomish River even-year population are similar to those in other even-year populations from central British Columbia. For example, time of peak spawning of even-year pink salmon in the Snohomish River is comparable to that of even-year British Columbia pink salmon and 3–4 weeks earlier than that of odd-year pink salmon in the Snohomish River. Genetic analyses are highly dependent upon standardization between laboratories, but available data indicate that even-year Snohomish River pink salmon are among the most distinctive of any pink salmon sample from the United States or southern British Columbia.

At the present time, the Snohomish River even-year pink salmon population is relatively small, on the order of a few thousand adults per generation. In defining the term ''species'' as it applies to Pacific salmon, NMFS has previously stated that a population should not be considered an ESU if the historic size (or historic carrying capacity) is too small for it to be plausible to assume the population has remained isolated over an evolutionary important time period (Waples, 1991). The fact that small spawning populations are regularly observed may reflect the dynamic processes of extinction, straying, and recolonization (Waples, 1991). Therefore, the small size of the current Snohomish River even-year pink salmon population suggests that it may be part of a larger geographic unit on evolutionary time scales (hundreds or thousands of years). The odd-year Snohomish River pink salmon population, which has the same spawning habitat available, is 1–2 orders of magnitude larger; therefore, it is possible that the even-year population was once much larger in the past. If that were the case, long-term persistence of this population in isolation would be easier to explain, since larger, isolated populations are likely to be more resilient to extinction than a small population such as this one.

Odd-Year Pink Salmon ESU

Genetic information indicates that odd-year pink salmon from southern British Columbia and Washington are clearly in a different evolutionary lineage than nearby even-year populations and more northerly odd-year populations. Within the southern British Columbia-Washington pink salmon group, there is also evidence of geographic population genetic structure, with detectable differences among groups of populations from the Dungeness River, Hood Canal, Puget Sound, and Fraser River, and southern and central British Columbia, Canada. In some analyses, Nisqually and Nooksack River populations in Puget Sound, WA are genetic outliers not similar to each other. Even so, none of the genetic differences within the southern British Columbia-Washington pink salmon group is very large in absolute magnitude.

Based on currently available information, NMFS concludes that the northern boundary of the odd-year ESU corresponds to the Johnstone Strait region of British Columbia, Canada. The ESU does not include northern British Columbia, Alaskan, or Asian populations of pink salmon. In Washington, westernmost populations in this ESU are found in the Dungeness River, but the ESU presumably would also include the Elwha River population, if a remnant still exists (see Status of West Coast Pink Salmon ESUs). Some uncertainty exists whether populations in the Dungeness River (and possibly the Elwha River in Washington and southern Vancouver Island in British Columbia) belong in a separate ESU. Further, given the uncertainty associated with the presence of populations outside this range, NMFS believes that insufficient information presently exists to determine whether other populations of pink salmon on the Olympic Peninsula or locations further south should be included in this ESU.

Status of West Coast Pink Salmon ESUs

In considering whether these ESUs are threatened or endangered according to the ESA, NMFS evaluated both qualitative and quantitative information. Qualitative evaluations considered recent, published assessments by agencies or conservation groups of the status of pink salmon within the geographic area. Quantitative assessments were based on current and historical abundance information and time series data compiled from a variety of Federal, state, and tribal agency records.

Nehlsen et al. (1991) considered salmon stocks throughout Washington, Idaho, Oregon, and California and enumerated all stocks that they found to be extinct or at risk of extinction. Pink salmon stocks in the Klamath and Sacramento Rivers, located in California, were considered extinct. Three stocks were considered to be at high risk of extinction (Russian River, CA; Elwha River, WA; and Skokomish River, WA) and one at moderate risk of extinction (Dungeness River, WA). Pink salmon stocks that do not appear in their summary were either not considered to be at risk of extinction or there was insufficient information to classify them.

The WDF et al. (1993) categorized all salmon stocks in Washington on the basis of stock origin, production type, and status (healthy, depressed, critical, or unknown). Of the 15 pink salmon stocks identified by WDF et al. (1993), nine were classified as healthy, two as critical (lower Dungeness and Elwha Rivers), two as depressed (upper Dungeness and Dosewallips Rivers), and two as unknown (North and Middle Fork Nooksack, and South Fork Nooksack River). All runs were classified as wild production and all,

except those in the North and Middle Forks of the Nooksack River, were reported to be of native origin. In the planned 1995 revision of the Washington State Salmon and Steelhead Inventory, the WDF intends to recommend that Elwha River pink salmon be classified as extinct since no adult fish have been observed since 1989 despite extensive annual surveys (Northwest Fisheries Science Center BRT, 1995).

Based on available data, it is difficult to ascertain with any degree of certainty the extent of the ESU that contains the Snohomish River even-year pink salmon population. The small size of the current Snohomish River even-year population suggests that it may be part of a larger geographic unit over evolutionary time. The Snohomish River even-year population is geographically isolated by several hundred kilometers from other even-year populations of appreciable size; however, similar life history characteristics, such as time of peak spawning, are similar to that of even-year British Columbia pink salmon. Results of genetic data are heavily dependent on whether an adjustment is made for possible differences in methods for recording data. Further, it is not clear which analyses should be preferred, those with or without adjustment for possible bias.

Given the uncertainty associated with the extent of the even-year ESU, NMFS considered the status of this ESU under two scenarios: (1) The ESU is composed solely of the Snohomish River pink salmon population, and (2) the ESU contains populations of even-year pink salmon from British Columbia in addition to the Snohomish River population. Under both scenarios, NMFS was unable to demonstrate that this ESU is currently at risk of extinction or endangerment. Available information indicates that the Snohomish River pink salmon population is relatively small with, generally, an increasing trend in abundance in recent years. Further, even-year pink salmon populations in British Columbia are generally stable or increasing. Therefore, under both ESU scenarios, NMFS has concluded that even-year pink salmon do not presently warrant listing under the ESA.

Similar to the even-year ESU, uncertainty remains regarding the extent of the odd-year pink salmon ESU. Environmental and ecological characteristics generally show a strong north-south trend; however, NMFS was unable to identify any substantial differences that consistently differentiate Washington and British Columbia odd-year pink salmon populations. Although odd-year pink salmon show considerable variation in body size among populations in Washington, the range of variation does not exceed that found in British Columbia. Genetic information shows a clear distinction between nearby even-year pink salmon and more northerly odd-year populations. Within the southern British Columbia and Washington pink salmon group, evidence of geographic population structure exists; however, none of the genetic differences is very large in absolute magnitude. Even though genetic differences among odd-year pink salmon are relatively small, the consistent genetic differences among geographically isolated groups of populations suggest that there has been some degree of reproductive isolation among pink salmon populations in this region.

Most populations in the odd-year pink salmon ESU appear to be healthy, and overall abundance appears to be close to historic levels. The two most distinctive Puget Sound populations, the Nooksack and Nisqually River populations, both show non-significant trends in recent abundance. No other factors were identified by NMFS which would threaten the near-term survival of these populations. However, the two populations on the northern Olympic Peninsula (both of which occur in the Dungeness River and one of which, in the lower river, was petitioned for listing) appear to be at the greatest risk of extinction in this ESU. Nevertheless, because (1) most of the populations in this ESU are stable or increasing and (2) the two populations at greatest risk are not consistently differentiated from other populations in the ESU with regard to genetic or life history characters, NMFS concludes that the odd-year pink salmon ESU is not presently at risk of extinction or endangerment. Furthermore, NMFS concludes that the geographic boundaries of the even- and odd-year pink salmon ESUs should be regarded as provisional. As such, these geographic boundaries are subject to revision should substantial new information become available. The NMFS welcomes the submission of any new information that may help resolve uncertainties regarding the extent of these pink salmon ESUs.

Determination

After a thorough analysis of all available information, NMFS has determined that neither Elwha River nor lower Dungeness River pink salmon, as petitioned, constitute a ''species'' under the ESA. However, Elwha River and lower Dungeness River pink salmon are part of a larger ESU that includes all odd-year pink salmon stocks in Washington as far west as the Elwha River and in southern British Columbia, Canada (including the Fraser River and eastern Vancouver Island), as far north as Johnstone Strait. Further, NMFS has identified a second ESU for pink salmon which includes even-year pink salmon residing in the Snohomish River, WA. NMFS has determined that, at the present time, neither ESU warrants listing as a threatened or endangered species.

References

A list of references is available upon request (See **ADDRESSES**).

Dated: September 28, 1995.

Rolland A. Schmitten,

Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 95–24698 Filed 9–29–95; 4:08 pm]

BILLING CODE 3510–22–F

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50 CFR Part 285

[I.D. 092895D]

Atlantic Tuna Fisheries; Bluefin Tuna Quota Reallocation

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Quota reallocation and opening of the General category fishery in the New York Bight area.

SUMMARY: NMFS announces a transfer of 10 metric tons (mt) of Atlantic Bluefin Tuna (ABT) from the longline-south Incidental subcategory to the General category and establishes a geographic set-aside for the New York Bight area. NMFS has determined that the fisheries landing ABT under the longline-south Incidental subcategory will not achieve the full 1995 allocation. NMFS has also determined that variations in the seasonal distribution and migration patterns of ABT have prevented fishery participants in the New York Bight area from harvesting a share of the General category quota. This action is being taken to extend the season for the General category, provide for fishing opportunities in the New York Bight area, and ensure additional collection of biological assessment and monitoring data.

EFFECTIVE DATES: The longline inseason transfer is effective September 29, 1995. The General category fishery is opened in the New York Bight area effective

12:01 a.m. local time on October 1, 1995.

FOR FURTHER INFORMATION CONTACT: John Kelly, 301–713–2347, or Kevin B. Foster, 508–281–9260.

SUPPLEMENTARY INFORMATION: Regulations implemented under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) governing the harvest of ABT by persons and vessels subject to U.S. jurisdiction are found at 50 CFR part 285. Section 285.22 subdivides the U.S. quota recommended by the International Commission for the Conservation of Atlantic Tunas (ICCAT) among the various domestic fishing categories.

Implementing regulations for the Atlantic tuna fisheries in 1995 provided for an initial annual quota of 438 mt of large medium and giant Atlantic bluefin tuna to be harvested from the regulatory area by vessels permitted in the General category. NMFS previously determined that this quota had been reached and issued a closure notice (60 FR 48052, September 18, 1995).

Regulations effective in 1995 also provided for apportionment of the annual quota for the General category into period subquotas (60 FR 38505, July 27, 1995). These regulations require that overharvest in any period be subtracted from the subsequent period. Information submitted by tuna dealers indicates that over 550 mt had been harvested by vessels permitted in the General category prior to the closure. For this reason, no quota remains for the October period subquota previously set at 44 mt.

Under the implementing regulations at 50 CFR 285.22(f), the Assistant Administrator for Fisheries, NOAA (AA), has the authority to make adjustments to quotas involving transfers between vessel categories or, as appropriate, subcategories if, during a single year quota period or the second year of a biannual quota period as defined by ICCAT, the AA determines, based on landing statistics, present year catch rates, effort, and other available information, that any category, or as appropriate, subcategory, is not likely to take its entire quota as previously allocated for that year.

Given that determination, the AA may transfer inseason any portion of the quota of any fishing category to any other fishing category or to the reserve after considering the following factors: (1) The usefulness of information obtained from catches of the particular category of the fishery for biological sampling and monitoring the status of the stock, (2) the catches of the particular gear segment to date and the likelihood of closure of that segment of the fishery if no allocation is made, (3) the projected ability of the particular gear segment to harvest the additional amount of Atlantic bluefin tuna before the anticipated end of the fishing season, and (4) the estimated amounts by which quotas established for other gear segments of the fishery might be exceeded.

The bluefin tuna have migrated to their summer feeding grounds in New England waters and incidental catch by longline vessels operating south of 34° N. lat. is no longer expected to occur. A total of 45 mt currently remains of the amount allocated to this southern subcategory. Reallocating quota from the Incidental longline-south subcategory would allow for a General category fishery in October.

Such transfer responds to the four criteria listed above as follows: (1) General category landings are a major contributor to the collection of biological data on this fishery, (2) catch in the General category to date has precluded the October fishery as planned and this fishery cannot occur if no allocation is made, (3) the General category is projected to harvest the additional amount of Atlantic bluefin tuna before the anticipated end of the fishing season, and (4) the impact on other gear segments is minimal since sufficient quota remains for the incidental category, the purse seine fishery is managed under individual quotas and other gear segments of the fishery have previously been closed.

Landings information submitted to date indicates that the General and Harpoon categories have taken a combined 605 mt, requiring that 120 mt from the Reserve category be used to cover overharvest. While this leaves 25 mt available in the Reserve, NMFS estimates that the Angling category has exceeded its quota, thus requiring additional transfers from the Reserve. Given the level of General category harvest taken to date, and the lack of available reserve, NMFS has determined that 10 mt is an appropriate amount to transfer from the Incidental category.

Regulations at 50 CFR 285.22(a)(3) specify that if variations in seasonal distribution, abundance, or migration patterns of ABT, and the catch rate, prevent fishermen in an identified area from harvesting their share of the quota, the AA may set aside an allocation of up to 20 mt of the October quota for such area. A New York Bight set-aside has been established over the past 3 years at various quota levels. Data for 1995 indicate that only nine fish were landed in the General category fishery at New York ports and no fish were landed in New Jersey. Landing cards indicate that bluefin tuna were generally available to fishermen in all other traditional areas. As a result of the catch distribution documented to date for the 1995 fishing year, NMFS has determined that a New York Bight set-aside is the appropriate use of the 10 mt available for the October General category fishery.

For the reasons set forth above, NMFS exercises its regulatory authority to transfer 10 mt of ABT from the Incidental longline-south subcategory to the General Category and establishes a geographic allocation for the New York Bight area. The General category fishery for large medium and giant ABT is therefore reopened as of 12:01 a.m. on October 1, 1995, for the set-aside comprised of the waters in the area south and west of a straight line originating at a point on the southern shore of Long Island at 72°27′ W. longitude (near Shinnecock inlet) and running SSE 150° true. Persons aboard vessels permitted in the General category may fish, retain, and land in the set-aside area specified above, until the set-aside quota for that area has been harvested. NMFS will publish the date of the closure in the Federal Register.

Classification

This action is taken under 50 CFR 285.22 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 971 *et seq.*

Dated: September 29, 1995.

Charles Karnella,

Acting Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 95–24701 Filed 9–29–95; 4:08 pm]

BILLING CODE 3510–22–F

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50 CFR Part 630

[Docket No. 950522139–5219–02; I.D. 042495B]

RIN 0648–AH75

Atlantic Swordfish Fishery; Correction

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Correction to final regulation.

SUMMARY: This document contains correction to the final regulation [I.D. 042495B] that was published Friday, September 8, 1995 (60 FR 46775). The final rule amended the regulations governing the Atlantic swordfish fishery by reducing the minimum days allowed for public comment on proposed quota adjustments to 30 days.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Ronald G. Rinaldo or Rebecca Lent, 301–713–2347; fax: 301–713–0596.

SUPPLEMENTARY INFORMATION:

Background

The final regulation that is the subject of this correction reduces the minimum number of days allowed for public comment on proposed adjustments to the annual quota from 45 to 30. In § 630.24, paragraph (d)(5) was revised to change the minimum number of days allowed for public comment.

Need for Correction

As published, the final regulation contains an error. In § 630.24, paragraph (d)(6) is referenced instead of paragraph (d)(5).

Correction of Publication

Accordingly, the publication on September 8, 1995, of the final regulation [I.D. 042495B] that is the subject of FR Doc. 95–22238 is corrected as follows:

§ 630.24 [Corrected]

On page 46778, in the second column, in amendatory instruction 5, line 2, ''(d)(6)'' is corrected to read ''(d)(5)'', and in the third column, line 15, ''(6)'' is corrected to read ''(5)''.

Dated: September 27, 1995.

Nancy Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

[FR Doc. 95–24606 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–22–F

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50 CFR Part 672

[Docket No. 950206041–5041–01; I.D. 092995A]

Groundfish of the Gulf of Alaska; Sablefish in the Central Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration, Commerce.

ACTION: Closure.

SUMMARY: NMFS is prohibiting retention of sablefish by persons using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). NMFS is requiring that catches of sablefish in this area be treated in the same manner as prohibited species and discarded at sea with a minimum of injury. This action is necessary because the share of the sablefish total allowable catch (TAC) assigned to trawl gear in the Central Regulatory Area of the GOA has been reached.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), October 5, 1995, until 12 midnight A.l.t., December 31, 1995.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for the Groundfish Fishery of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

In accordance with § 672.24(c)(2), the share of the sablefish TAC assigned to trawl gear in the Central Regulatory Area of the GOA was established by the final 1995 harvest specifications of groundfish (60 FR 8470, February 14, 1995), as 1,720 metric tons.

The Director, Alaska Region, NMFS, has determined, in accordance with § 672.24(c)(3)(ii), that the share of the sablefish TAC assigned to trawl gear in the Central Regulatory Area of the GOA has been reached. Therefore, NMFS is requiring that further catches of sablefish by trawl gear in the Central Regulatory Area of the GOA be treated as prohibited species in accordance with § 672.20(e).

Classification

This action is taken under 50 CFR 672.24 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 29, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–24697 Filed 9–29–95; 4:08 pm]

BILLING CODE 3510–22–F

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50 CFR Part 672

[Docket No. 950509041–5041–01; I.D. 092895C]

Groundfish of the Gulf of Alaska; Pollock in the Western Regulatory Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Inseason adjustment; request for comments.

SUMMARY: NMFS issues an inseason adjustment closing the season for pollock by vessels catching pollock for processing by the inshore component in the Western Regulatory Area of the Gulf of Alaska (GOA). This adjustment is necessary to prevent the underharvest of pollock in the Western Regulatory Area.

EFFECTIVE DATE: 12 midnight A.l.t. October 1, 1995, until 12 midnight, A.l.t., December 31, 1995. Comments must be received at the following address no later than 4:30 p.m., A.l.t., October 16, 1995.

ADDRESSES: Comments may be sent to Ronald J. Berg, Chief, Fisheries Management Division, Alaska Region, NMFS, P.O. Box 21668, Juneau, AK 99802, Attn: Lori Gravel, or be delivered to the fourth floor of the Federal Building, 709 West 9th Street, Juneau, AK.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act). Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

As of September 16, 1995, 7,673 metric tons (mt) of pollock remain in the inshore allocation of the Western Regulatory Area pollock total allowable catch (TAC) specification. That amount would normally be available for harvest at 12 noon, A.l.t., October 1, 1995. Current information shows the catching capacity of vessels catching pollock for processing by the inshore component is in excess of 12,000 mt per day. In accordance with § 672.23 (e), directed fishing for pollock in the Western Regulatory Area of the Gulf of Alaska is scheduled from 12 noon, A.l.t., October 1 until 12 midnight, A.l.t., December 31, 1995, or until the TAC is reached, whichever occurs first.

Section 672.23(b) specifies that the time of all openings and closures of fishing seasons, other than the beginning and end of the calendar fishing year, is 12:00 noon, A.l.t. Therefore, a fishery opening normally must be a minimum of 24 hours. The Director, Alaska Region, NMFS, has determined that the remaining portion of the TAC allocated to the inshore component would be exceeded if a 24–hour fishery were allowed to occur. NMFS intends that the TAC should not be exceeded and will not allow a 24–hour directed fishery.

NMFS, in accordance with § 672.22(a)(1)(i), is adjusting the season for pollock by vessels catching pollock for processing by the inshore component in the Western Regulatory Area by allowing directed fishing for a 12–hour period from 12:00 noon, A.l.t., October 1, 1995, until 12:00 midnight, A.l.t., October 1, 1995. NMFS is taking this action to allow a controlled fishery to occur, thereby preventing the underharvest of the pollock TAC allocated to the inshore component as authorized by § 672.22(a)(2)(iii). In accordance with § 672.22(a)(4), NMFS has determined that closing the season at 12:00 midnight on October 1, 1995, is the least restrictive management adjustment to achieve the pollock TAC allocated to the inshore component and will allow other fisheries to continue in noncritical areas and time periods.

The Assistant Administrator for Fisheries, NOAA, finds for good cause that providing prior notice and public comment or delaying the effective date of this action is impracticable and contrary to the public interest. Without this inseason adjustment, NMFS could not allow this fishery, and a pollock TAC in the Western Regulatory Area of the GOA would not be harvested, resulting in an economic loss of more than 1.5 million dollars. Under § 672.22(c)(2), interested persons are invited to submit written comments on this action (see **ADDRESSES**).

Classification

This action is taken under § 672.22 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 29, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–24696 Filed 9–29–95; 4:08 pm]

BILLING CODE 3510–22–F

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50 CFR Part 672

[Docket No. 950509041–5041–01; I.D. 092995B]

Groundfish of the Gulf of Alaska; Northern Rockfish in the Central Regulatory Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Modification of a closure.

SUMMARY: NMFS is opening directed fishing for northern rockfish in the Central Regulatory Area in the Gulf of Alaska (GOA). This action is necessary to use the total allowable catch (TAC) for northern rockfish in this area.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), October 1, 1995, until 12 midnight, A.l.t., December 31, 1995.

FOR FURTHER INFORMATION CONTACT: Thomas Pearson, 907–486-6919.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

In accordance with § 672.20(c)(1)(ii)(B), the annual TAC for northern rockfish in the Central Regulatory Area was established by the final 1995 specifications of groundfish (60 FR 8470, February 14, 1995) as 4,610 metric tons (mt). NMFS has determined that as of September 2, 1995, 866 mt remain unharvested.

The Director, Alaska Region, NMFS, has determined that the 1995 TAC for northern rockfish in the Central Regulatory Area has not been reached. Therefore, NMFS is terminating the previous closure and is opening directed fishing for northern rockfish in the Central Regulatory Area.

All other closures remain in full force and effect.

Classification

This action is taken under 50 CFR 672.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: September 29, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–24714 Filed 9–29–95; 4:36 pm]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 60, No. 192
Wednesday, October 4, 1995

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.

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 50, 52, and 100

Revision of 10 CFR Parts 50, 52 and 100; Meeting

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The Nuclear Regulatory Commission staff will meet with the staff of the Nuclear Energy Institute (NEI) and other industry representatives to hear a clarification of industry comments on the non-seismic aspects of the proposed revision of 10 CFR parts 50, 52 and 100 and associated guidance documents.

DATES: October 19, 1995, 1:00 p.m.

ADDRESSES: Two White Flint North, 11145 Rockville Pike, Conference Rooms T–10A1 and T–10F3, Rockville, Maryland.

FOR FURTHER INFORMATION CONTACT: Mr. Leonard Soffer, Accident Evaluation Branch, Office of Nuclear Regulatory Research, Nuclear Regulatory Commission, Washington, DC 20555. Telephone: (301) 415–6574.

SUPPLEMENTARY INFORMATION: Proposed revisions to 10 CFR parts 50, 52, and 100 were published for public comment on October 17, 1994 (59 FR 522255). The availability of draft guidance documents was published on February 28, 1995 (60 FR 10810). The public comment period ended May 12, 1995. The proposed revision to 10 CFR parts 100 primarily consists of two separate changes, namely, the source term and dose considerations, and the seismic and earthquake engineering considerations of reactor siting. The purpose of this meeting is for the NRC staff to hear, at the industry's request, a clarification of industry comments on the source term and dose consideration aspects of the proposed rule.

Dated at Rockville, Maryland, this 28 day of September, 1995, for the Nuclear Regulatory Commission.

M. Wayne Hodges,

Director, Division of Systems Technology, Office of Nuclear Regulatory Research.

[FR Doc. 95–24644 Filed 10–3–95; 8:45 am]

BILLING CODE 7590–01–P]

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 701

Federal Credit Union Field of Membership and Chartering Policy

AGENCY: National Credit Union Administration (''NCUA'').

ACTION: Proposed Amendments to Interpretive Ruling and Policy Statement 94–1 (''IRPS 95–2'').

SUMMARY: The NCUA Board is proposing to amend its policies so that senior citizen and retiree groups will be required to meet the same conditions as other associational groups in order to qualify for a federal credit union charter or addition to an existing charter through a field of membership amendment. The Board is also proposing five technical amendments to clarify operational issues. The amendments clarify: The application of field of membership requirements to mergers; the streamlined expansion procedure; the documentation requirements for low-income communities; the use of surveys to support a community common bond; and appeal procedures.

DATES: Comments must be postmarked or received or posted on NCUA's electronic bulletin board by December 4, 1995. Do not fax and send by U.S. Mail.

ADDRESSES: Send comments to Becky Baker, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314 or via NCUA's electronic bulletin board to Becky Baker at 703–518–6480.

FOR FURTHER INFORMATION CONTACT: Michael J. McKenna, Staff Attorney, at the above address or telephone (703) 518–6540.

SUPPLEMENTARY INFORMATION:

The Senior Citizen and Retiree Association Policy

In 1984, NCUA adopted a policy that encouraged federal credit unions (FCUs) to accept local senior citizens and retirees through the formation of associations. The only requirement for adding these associations to a credit union charter was a written request from the FCU to the NCUA; no request from the group or copy of the associations charter or bylaws was necessary. This policy resulted in many FCUs creating and adding senior citizen/retiree associations to their charters. Subsequent policy statements, including IRPS 94–1 (the Chartering Manual), continued this policy. 59 FR 29066 (June 3, 1994).

In 1994, two bank trade associations and six Texas commercial banks filed suit against Communicators FCU, Houston, Texas, as a result of several additions to the FCUs field of membership. The suit challenged, among other additions, the 1994 addition of a senior citizen/retiree group formed solely for the purpose of acquiring credit union service. While upholding the other additions, the court vacated the addition of the senior citizen/retiree association and permanently enjoined NCUA from adding any similar associations to the FCU. *Texas Bankers Association, et al.* v. *NCUA, et al.*, 1995 WL 328319 (D.D.C., May 31, 1995) (the ''*Communicators FCU*'' decision).

An informal survey of credit unions with *Communicators FCU*-like senior citizen/retiree associations in their charters conducted by NCUAs regional office in Austin, Texas found that only a small percentage of potential members of such associations actually join the credit unions. The Board believes that the current policy may not sufficiently promote NCUAs goal of making quality credit union service available to all persons who wish to have it. It is also apparent that continuing the current policy may leave some FCUs exposed to costly litigation. Although the court's order applies only to Communicators FCU, the Board is reviewing the senior citizen/retiree policy and is now proposing to change that policy after considering public comment.

Proposed Policy

The Board is proposing to modify its senior citizen/retiree policy to require such groups to meet normal associational common bond requirements before seeking to join or charter an FCU. In determining whether

a group satisfies this common bond requirement, NCUA will consider the totality of the circumstances, such as whether the members pay dues, have voting rights, hold office, hold meetings, whether there is interaction among members and whether the group has its own bylaws. *See*, Chapter 1, Section II.B. of the Chartering Manual, 59 FR at 29076. Provided operational area requirements are met, senior citizen/retiree associations formed for purposes other than seeking credit union service will then qualify to join an existing FCU. An FCU may still assist a senior citizen group to form an association that will qualify under the Chartering Manual. Accordingly, the Board is proposing to eliminate the section of IRPS 94–1 which permits *Communicator FCU*-like senior citizen/retiree associations to join FCUs, Chapter 1, Section V.B of the Chartering Manual, 59 FR 29082.

The Board is requesting comment on this proposal as well as how to address existing senior citizen/retiree groups in other FCU's fields of membership that do not meet the proposed characteristics of an association. The Board requests comment on the following proposed treatment of existing groups. First, FCUs that currently have a senior citizen/retiree group in their field of membership and wish to continue to add members from this group must ensure that the group meets the normal associational common bond requirements. Many of these groups may already meet the proposed requirements. The examination program will monitor compliance. Second, no new group members may join an FCU that does not have the characteristics of an association. In this case, the group should be deleted from the FCUs charter. This will also be monitored through the exam process. However, if the FCU has adopted the once a member, always a member bylaw, it could continue to serve members that had joined based on their membership in the senior citizen/retiree group.

Until the Board approves a final policy, it is continuing its moratorium on FCUs adding self-created senior citizen/retiree groups to their field of membership. The moratorium has no effect on groups that are already in an FCU's field of membership and it does not apply to the addition of senior citizen groups that have the characteristics of an association as defined in the Chartering Manual. 59 FR at 29076.

Low-Income Associations

The Board is also considering the possible effects of the *Communicators FCU* decision on low-income group additions. Congress and the Board have long recognized that special efforts must be made for those who are attempting to serve the needs of persons of limited means. IRPS 94–1 provided new methods for credit unions to serve low-income persons with the establishment of two new policies. The first policy permitted any occupational, associational, multiple group or community FCU to include in its field of membership, without regard to location, communities satisfying the low-income definition of § 701.32 of NCUA's Regulations. The second policy allowed any FCU to add associational groups of low-income persons to their fields of membership. Current policy allows low-income groups to be formed solely for the purpose of obtaining credit union service without meeting the standard characteristics of an association.

The Board proposes that FCUs continue to be allowed to add low-income groups formed solely for the purpose of seeking credit union service. NCUA defines as ''low-income'' persons earning less than 80 percent of the average for all wage earners and persons whose annual household income falls at or below 80 percent of the median household income for the nation. 12 CFR 701.32(d)(2). The FCU Act was enacted ''to make more available to people of small means credit for provident purposes through a national system of cooperative credit.'' 12 U.S.C. 1751. Congress established a special segment of credit unions serving predominantly low-income members. 12 U.S.C. 1752(5). Congress also established and funded a Community Development Revolving Loan Fund for Credit Unions, designed to help, through loans to credit unions serving predominantly low-income persons, in providing ''basic financial and related services'' to low-income persons and in ''stimulating economic activities * * * which will result in increased income, ownership and employment opportunities for low-income residents.'' 12 CFR 705.2(a). See also, 12 U.S.C. 1766(k) (giving the Board authority over the Community Development Revolving Loan Fund for Credit Unions). The Board believes that the current low income credit union program continues to serve an important governmental purpose and is not proposing any changes to its low-income association policy.

Technical Changes

The Board is proposing five technical amendments to its policy to clarify operational issues. The amendments address: (1) The application of field of membership rules to credit union mergers; (2) the use of streamlined expansion procedure; (3) the documentation requirements for low-income community credit unions as well as low-income additions; (4) the use of surveys to support a community charter; and (5) appeal procedures.

Mergers

A. *Operational Area*. The Board wishes to clarify how it applies operational area and field of membership requirements to mergers. NCUA's field of membership expansion rules apply to mergers where the continuing credit union is a federal charter. If the merging credit union is state chartered, the field of membership rules for conversions from state to federal charter also apply. Chapter 2, Section III.A, Chartering Manual. 59 FR at 29086. The following is an explanation of how field of membership expansion, and particularly operational area, requirements apply in the merger context.

For each group in the merging credit union's field of membership, there are two means of merging into an occupational, associational or multiple group FCU. First, if the merging group is part of an occupational or associational common bond which constitutes a majority of the continuing credit union's field of membership, the group may be added regardless of location. These are called ''common bond additions.'' For any other occupational or associational common bond, the group must be within the credit union's operational area. These are commonly called ''select group additions.'' A ''select group'' can also be added if it is within the operational area of a planned service facility of the continuing credit union provided:

* The planned facility begins operation shortly after the group is added; and

* The current field of membership constitutes a significant portion of the total field of membership to be served initially by the proposed facility. Although the addition of a new select group is not enough to justify a planned service facility, it is permissible to include new groups as partial justification for such a facility.

Chapter 2, Section II.A.1 of the Chartering Manual, 59 FR at 29085. Mergers will usually fall into either the common bond addition or select group addition categories, but some may fall into both. Field of membership requirements are met for each merging group only if the group could have been added to the continuing credit union without the benefit of the merger. The continuing credit union must analyze

each group in the merging credit union's field of membership as if the continuing credit union was expanding its own field of membership without a merger. For those groups from the merging credit union that do not meet operational area requirements, only the members of record will be transferred to the continuing credit union. Merger applicants must provide NCUA with their own analysis of how the proposed field of membership conforms to the requirements set forth in the Chartering Manual.

The Board is seeking comment on the application of operational area requirements to mergers involving select group additions. Specifically, in addition to welcoming comment on the above analysis, the Board requests comment on whether mergers should be further limited to credit unions which primarily serve groups in the same geographic location. If so, the continuing credit union would only be permitted to continue to serve groups in that geographic location.

B. *Views of Overlapped Credit Unions.* The Chartering Manual does not require the Region when it reviews the merger plan to apply an overlap analysis to a group in a discontinuing credit union's field of membership that has service available from another credit union. The Board requests comment on whether such an analysis is necessary and whether an affected credit union should be notified of the merger and be given an opportunity to object to the continuing credit union retaining the overlapped group in its field of membership.

The Board also requests comment on whether credit unions that may be adversely affected by the merger should have the right to appeal the Regional Director's determination. An appeal after the merger is approved may pose administrative and procedural difficulties. Because of these potential problems, the Board is requesting comment on whether it should establish a formal process for credit unions to comment on a merger prior to the Regional Director making a determination. One procedure would be to require the merging credit unions to notify all affected credit unions of the proposed merger. Credit unions would have 30 days from receipt of the notification to send written comments regarding their views to the Regional Director. Only after consideration of the comments would the Regional Director make a determination.

C. *Waivers.* An operational area waiver procedure is available when a state-chartered credit union is merged into an FCU ''on a proper showing that the [continuing] credit union will continue to be able to provide quality service to its current field of membership as a federal credit union.'' Chapter 2, Section III.A, 59 FR at 29086. A waiver is discretionary on the part of NCUA and permits groups already receiving quality credit union services, who are located outside of the credit union's operational area, to continue to have credit union service after the merger. It is the responsibility of the merger applicants, not NCUA, to provide an adequate basis for a waiver. Absent any waivers, only members of record of those groups that do not meet operational area requirements may be transferred to the continuing credit union. Finally, operational areas requirements do not apply in emergency mergers. 12 U.S.C. 1785(h).

Streamlined Expansion Procedure (''SEP'')

SEP was adopted by the Board in IRPS 94–1 and permits well operated FCUs to add small groups of less than 100 persons with an occupational common bond without prior NCUA approval. The group must be located within 25 miles of one of the FCU's service facilities and have made a written request to the FCU for service. In general, the group must not have credit union service currently available. The Board is proposing three clarifications to the SEP program. First, an FCU may use SEP if the only other credit union service available is from a community credit union. NCUA does not afford overlap protection to a community credit union when it is being overlapped by an occupational group. Chapter I, IV.B.1, Chartering Manual, 59 FR at 29080. Second, consistent with standard field of membership expansions, the group as a whole will be considered to be within a credit union's 25 mile limit when: a majority of the group's members live, work, or gather regularly within the 25 mile limit; the group's headquarters is located within the 25 mile limit; or the group's ''paid from'' or ''supervised from'' location is within the 25 mile limit. Third, if an FCU has SEP in its charter and merges into a credit union without SEP, the continuing credit union must submit a charter amendment and receive NCUA approval if it wishes to use SEP. This can be accomplished as part of the merger process. The Board is proposing to amend the Chartering Manual to incorporate all three clarifications.

Documentation Requirements to Establish Low-Income Services

Generally, a low-income credit union is chartered as a community or associational credit union. To further the interest of making credit union service available to persons in low-income communities, NCUA also permits any occupational, associational, multiple group, or community FCU to include in its field of membership, without regard to location, communities satisfying the low-income definition of § 701.32 of NCUA's Regulation. The Board believes that any low-income community requesting either a new charter or inclusion in an existing field of membership expansion must meet the requirements of the Chartering Manual for demonstrating a community common bond, i.e., the geographic area's boundaries must be clearly defined; and the charter applicant must establish that the area is recognized as a distinct ''neighborhood, community or rural district.'' Chapter 1, Section II.C.1, 59 FR at 29077. In many cases, a low-income community already has the common interest and characteristic by lacking the basic financial services found in more affluent communities. The Board is proposing that for new low-income charters or community expansions, the Regional Director will decide what documentation satisfies the community common bond requirement. Such documentation must clearly define the area's geographic boundaries and whether the area is recognized as a distinct neighborhood, community or rural district.

Community Charters

Many credit unions use surveys to demonstrate the need for a community charter. A survey of the residents and employees of the area often indicates whether there is interest in credit union service. Although surveys are useful in demonstrating whether a community exists, they are not required if other evidence is more relevant or demonstrates the sentiment of the community. Consequently, the Board is proposing to amend the IRPS to clarify that surveys are not always required to demonstrate a community charter.

Procedures for Appealing Chartering and Field of Membership Determinations

IRPS 94–1 did not articulate any timeframes for an appeal of a Regional Director's decision. In order to deal with appeals expeditiously, the Board is proposing that all appeals of the Regional Director's determination be made within 60 days of his/her

decision. The Board is also requesting comment on whether there should be a time limit on the Board to render a decision on an appeal.

Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act requires the NCUA to prepare an analysis to describe any significant economic impact a proposed regulation may have on a substantial number of small credit unions (primarily those under $1 million in assets). The changes to NCUA policy resulting from the adoption of these proposed amendments to the IRPS would not have a significant economic impact on a substantial number of small credit unions. The changes are either legally required or simply clarify existing policy. Accordingly, the Board determines and certifies that this proposed rule does not have a significant economic impact on a substantial number of small credit unions and that a Regulatory Flexibility Act analysis is not required.

Paperwork Reduction Act

The proposed amendments to IRPS 94–1 do not impose any additional paperwork requirements.

Executive Order 12612

Executive Order 12612 requires NCUA to consider the effect of its actions on state interests. The proposed amendments apply to federal credit unions as well as state chartered credit unions that seek to become federal credit unions. Therefore, the actions will not affect state interests.

List of Subjects in 12 CFR Part 701

Chartering, Conversions, Credit union, Field of membership addition, Mergers.

By the National Credit Union Administration Board on September 28, 1995.

Becky Baker,

Secretary of the Board.

Accordingly, NCUA proposes to amend 12 CFR part 701, by amending IRPS 94–1 as follows:

PART 701—ORGANIZATION AND OPERATIONS OF FEDERAL CREDIT UNIONS

1. The authority citation for part 701 continues to read as follows:

Authority: 12 U.S.C. 1755, 1756, 1757, 1759, 1761a, 1761b, 1766, 1767, 1782, 1784, 1787, 1789, and 1798.

2. Section 701.1 is revised to read as follows:

§ 701.1 Federal credit union chartering, field of membership modifications, and conversions.

National Credit Union Administration practice and procedure concerning chartering, field of membership modifications, and conversions are set forth in Interpretive Ruling and Policy Statement 94–1—Chartering and Field of Membership Policy (IRPS 94–1), as amended by IRPS 95–2. Both IRPS are incorporated into this regulation.

Note: Neither the amendments nor the interpretive ruling and policy statement will appear in the Code of Federal Regulations.

3. Chapter 1, Section II.C.2 is revised to read as follows:

II.C.2—Special Documentation Requirements

Information to support that the area chosen represents one well-defined area, distinguishable from the immediate surrounding areas, includes:

- Political jurisdictions.
- Major trade areas (shopping patterns).
- Traffic flows.
- Shared/common facilities (for example, educational, medical, police and fire protection, school district, water, etc.).
- Organizations/clubs whose membership is made up exclusively of persons within the area.
- Newspapers or other periodicals published for and about the area.
- Census tracts.
- Common characteristics and background of residents (for example, income, religious beliefs, primary ethnic groups, similarity of occupations, household types, primary age group, etc.).
- History of area.
- In general, what causes the chosen area and its residents to be distinguishable from the immediate surrounding areas and residents—some examples are old, well-established ethnic neighborhoods, planned communities and small/rural towns or rural counties.

The following information must be provided to support a need for a community credit union or community field of membership expansion:

- A list of credit unions presently in the area and those credit union's positions regarding a new charter or field of membership expansion; and
- A list of other financial institutions (for example, banks, savings and loan associations) that service the area.
- Written documentation reflecting support for the application for the charter, field of membership expansion or conversion to a community credit union may be in the form of letters, surveys, studies, pledges, or a petition. Other types of evidence may also be acceptable. If a survey is used it should reflect the following:
- For the residents of the community:

Approximate number contacted
Number in favor of the credit union
Number against the credit union
Number who will join the credit union
Number who have pledged initial and/or systematic savings and amount of pledges

- For the employers in the community:

Number of area employers and number of employees
Number contacted
Number in favor of the credit union
Number against the credit union
Number willing to provide payroll deductions to the credit union
Number willing to provide other type(s) of support to the credit union

- For community organizations (including churches):

Number in area and number of members
Number contacted
Number in favor of the credit union
Number against the credit union
Number willing to provide some type of support to the credit union, i.e., advertising facilities, etc.
Letters of support from area civic leaders

If the community is also a recognized legal entity, it may be served as, or be included in, the field of membership—for example, ''DEF Township, Kansas'' or ''GHI County, Minnesota.''

4. Chapter 1, Section V.A.2 is revised to read as follows:

V.A.2—Special Common Bond Rules for Low-Income Federal Credit Unions

Generally, a low-income credit union is chartered as a community or associational credit union. The Regional Director will determine whether the applicants have provided sufficient evidence to demonstrate the need for a low-income community charter. Such evidence must establish that the geographic area's boundaries are clearly defined and that the area is recognized as a distinct neighborhood, community, or rural district. A low-income credit union that has a community common bond may include the following language in its field of membership:

''Persons who live in (the target area); persons who regularly work, worship, perform volunteer services, or participate in associations headquartered in (the target area); persons participating in programs to alleviate poverty or distress which are located in (the target area); incorporated

and unincorporated organizations located in (the target area) or maintaining a facility in (the target area); and organizations of such persons.''

In recognition of the special efforts needed to help make credit union service available to persons in low-income communities, NCUA permits credit union chartering and field of membership amendments based on associational groups formed for the sole purpose of making credit union service available to low-income persons. The association must be defined so that all its members will meet the low-income definition of § 701.32 of NCUA's Regulations. The association, in documenting its low-income membership, may use the same types of documentation as are currently permitted for determining whether a community is low-income under § 701.32 of NCUA's Regulations.

In addition, a proposed or existing low-income federal credit union whether community or associationally based, may include in its field of membership, without regard to location, one or more groups constituting an occupational, associational or community common bond. Except for the operational area requirements, the proposed or existing credit union must meet all the requisites for including the group in its charter. Moreover, the proposed or existing credit union must take care to ensure that it will continue to meet the requirements for low-income status.

5. Chapter 1, Section V.A.3 is revised to read as follows:

V.A.3—Special Common Bond Rules for Other Federal Credit Unions Seeking to Serve Low-Income Persons

In the interest of making credit union service available to persons in low-income communities, NCUA also permits any occupational, associational, multiple group, or community federal credit union to include in its field of membership, without regard to location, communities and associational groups satisfying the low-income definition of § 701.32 of NCUA's Regulations. The associational group may be formed for the sole purpose of providing eligibility for federal credit union service, but must comprise only persons meeting NCUA's low-income definition.

The federal credit union adding the low-income community or association must document that the community or association meets the low income definition in § 701.32 of NCUA's Regulations, just as is required for a designated low-income credit union. The Regional Director will ensure that the proposed low-income community addition is sufficient to establish a community common bond. A federal credit union adding such a community or association, however, would not be able to receive the benefits, such as expanded use of non member deposits and access to the Community Development Revolving Loan Program for Credit Unions, offered to low-income credit unions.

A federal credit union that desires to include a low-income community or association in its field of membership must first develop a business plan specifying how it will serve the entire low-income community. The business plan, at a minimum, must identify the credit and depository needs of the low-income community or association and detail how the credit union plans to serve those needs. The credit union will be expected to regularly review the business plan as well as loan penetration rates in the community to determine if the community is being adequately served. NCUA will require periodic service status reports on its service to the low-income community and may review the credit union's service to low-income persons during examinations.

6. Chapter 1, Section V.B is deleted and Sections V.C. and V.D. are redesignated V.B and V.C, respectively.

7. Chapter 1, Section VIII.D is revised to read as follows:

VIII.D—Appeal of Regional Director's Decision

If the Regional Director denies a charter application, the group may appeal the decision to the NCUA Board. If not included with the denial notice, a copy of these procedures may be obtained from the regional director who made the decision. An appeal will be sent to the appropriate regional office within sixty days of the denial. The Regional Director will then forward the appeal to the NCUA Board. NCUA central office staff will make an independent review of the facts and present the appeal to the Board.

Before appealing, the prospective group may, within thirty days of the denial, provide supplemental information to the regional director for reconsideration. In these cases, the request will not be considered as an appeal but as a request for reconsideration by the regional director. If the request is again denied, the group may proceed with the appeal process.

8. Chapter 2, Section II.A.3.a is revised to read as follows:

II.A.3.a—General

The special rules for credit unions serving low-income persons and serving employees at industrial parks, shopping centers and similar facilities apply equally to field of membership additions. However, there are two special situations unique to existing federal credit unions: (1) Corporate restructurings and (2) plant or base closings, and other kinds of distress to a substantial portion of a credit union's membership.

9. Chapter 2, Section III.A is revised to read as follows:

III.A—Mergers

Generally, the standards applicable to field of membership amendments apply to mergers where the continuing credit union is a federal charter. This requires analyzing each group in the merging credit union's field of membership as if the continuing credit union was proposing to expand its own field of membership without a merger. This analysis may include the use of the planned service facility concept. Merger applicants must provide NCUA with their own analysis of how the proposed field of membership conforms to this policy. For those groups from the merging credit union that do not meet operational area requirements, only the members of record will be transferred to the continuing credit union.

Where the merging credit union is state chartered, the field of membership rules for a credit union converting to a federal charter apply with the following differences:

- As to a merger involving a common bond addition, the requirements to provide a request for credit union service from the corporate, associational, or other unit to be added is not required, since the unit already has credit union service.
- As to a merger involving a select group addition:

For the same reason, the requirement for a letter from each group included in the credit union's field of membership is not required.

Where a state credit union is merging into a federal credit union, the operational area requirement may be waived if it can demonstrate that it will continue to be able to provide quality credit union service to its current field of membership as a federal credit union. The waiver is discretionary on the part of NCUA. Absent any waivers, only members of record of groups that do not meet operational area requirements will be transferred to the continuing credit union. Upon merging, the state credit union's field of membership will be

worded to conform to the NCUA standards set forth in Chapter 1. Any subsequent field of membership amendments must comply with applicable amendment procedures.

• As to a merger of a community credit union into a federal credit union of any type, the continuing credit union may be permitted to continue to provide service to the merging credit union's members of record as of the merger date where the operational area requirement is satisfied. Except in the case of an emergency merger or where the continuing credit union is low-income, the continuing federal credit union can obtain only the members of record of the merging community credit union.

Where both credit unions are community charters, the continuing credit union is a federal credit union, and the criteria for expanding the service area of a community federal credit union (as discussed previously in this Chapter) are satisfied, the entire field of membership of the merging credit union may be added to the continuing federal credit union's charter.

Mergers must be approved by all affected NCUA regional directors, and, as applicable, the state regulators.

10. Chapter 2, Section III.B. is revised to read as follows:

III.B—Emergency Mergers

A specifically designated emergency merger may be approved by NCUA without regard to field of membership or other legal constraints. An emergency merger involves NCUA's direct intervention. The credit union to be merged must either be insolvent or be likely to become insolvent within 12 months and NCUA must determine that:

• An emergency requiring expeditious action exists.

• Other alternatives are not reasonably available.

• The public interest would best be served by approving the merger.

In an emergency merger situation, NCUA takes an active role in finding a suitable merger partner (continuing credit union). NCUA is primarily concerned that the continuing credit union has the financial strength and management expertise to absorb the troubled credit union without adversely affecting its own financial condition and stability.

As a stipulated condition to an emergency merger, the field of membership of the merging credit union may be transferred intact to the continuing federal credit union without regard to any field of membership restrictions and without changing the character of the continuing federal credit union for future amendments. Under this authority, therefore, a federal credit union may take into its field of membership a group defined by a community or associational common bond permitted under state law, regardless of whether that common bond definition could be approved under the Federal Credit Union Act. If a federal credit union which has added groups or communities under an emergency merger later proposes to merge with another federal credit union, the groups or communities added pursuant to the emergency merger will not be subject to operational area or field of membership analysis.

11. Chapter 2, Section VIII.B is revised to read as follows:

VIII.B—Streamlined Expansion Procedure (SEP) for Small Occupational Groups

In keeping with the goals of NCUA chartering policy to provide service to all eligible groups desiring credit union service, well operated federal credit unions except those designated as ''distressed'' may take advantage of the SEP for adding occupational groups to their fields of membership.

To use this procedure, the federal credit union's board of directors must first apply to their respective NCUA regional director for a charter amendment. The charter amendment request must be signed by the presiding officer of the board of directors.

The following is a sample amendment for permitting a federal credit union to use the SEP authority:

Groups of persons with occupational common bonds which are located within 25 miles of one of the credit union's service facilities, which have provided a written request for service to the credit union, which do not presently have credit union service available, other than through a community credit union, which have no more members in the group than the maximum number established by the NCUA Board for additions under this provision: Provided, however, that the National Credit Union Administration may permanently or temporarily revoke the power to add groups under this provision upon a finding, in the Agency's discretion, that permitting additions under this provision are not in the best interests of the credit union, its members, or the National Credit Union Share Insurance Fund.

Once NCUA has approved the amendment and the credit union board has adopted it, the SEP authority may be implemented. The charter amendment permits approved federal credit unions to immediately begin serving employee groups meeting criteria set forth in this section. Under this procedure, there is no formal NCUA action necessary on each group being added.

The maximum number of persons for each group of employees which may be added under SEP will be established by the NCUA Board from time to time. The number will be based on potential primary members—that is, the persons sharing the basic occupational affinity to each sponsor group; family members and other derivative members are not included in the SEP limit. Several groups may be simultaneously added using these procedures; however, the maximum number of persons for each group must fall within the SEP limit.

The SEP does not apply to associational groups since NCUA must review membership requirements and geographical area prior to these groups being added to a field of membership. The procedure also does not apply to community charter expansions, because of the more individualized analysis required.

The following SEP steps and documentation requirements must be adhered to:

• The federal credit union must complete, for each group to be added, an Application for Field of Membership Amendment form, NCUA 4015, shown in Appendix D.

• The federal credit union must obtain a letter, on the group's letterhead where possible, signed by an official representative identified by title, requesting credit union service and stating that the group does not have any other credit union service available from any associational, occupational or multiple group credit union.

• The group must be located within 25 miles of one of the federal credit union's service facilities. The group will be considered to be within the 25 mile limit when: (1) a majority of the groups members live, work or gather regularly within the 25 mile limit; or (2) the groups headquarters is located within the 25 mile limit; or (3) the group's ''paid from'' or ''supervised from'' location is within the 25 mile limit.

• The group must indicate the number of potential members—the number of employees—seeking service.

• The federal credit union must maintain the above documentation permanently with its charter.

• The federal credit union must maintain a control log of groups added to its field of membership under the SEP procedure. The control log must include the date the group obtained service, the name and location of the sponsor group, the number of potential primary members added, the number of miles to

the nearest main or branch office, the federal credit union board of director's approval of the group and the date approved. See Appendix D for the SEP Control Log, NCUA 4016.

- The groups added under SEP must be reported to the federal credit union's board at the next regular board meeting and made a part of the meeting minutes.
- The control log and other SEP documentation must be made available to NCUA upon request.

The regional director may from time to time request service status reports on groups added under SEP. It is advisable to use some method, such as a sponsor prefix added to the member account number, to readily access data for such groups.

Should a federal credit union fail to provide quality credit union service, as determined by the group's members or employees, to a group added under SEP, NCUA may subsequently permit dual membership with another credit union.

Should a federal credit union fail to follow the above procedures or deteriorate financially or operationally, NCUA, at its discretion, may revoke the SEP privilege.

If a federal credit union that has SEP in its charter merges with another federal credit union that does not have SEP, the continuing credit union, if it desires to have SEP, must submit a charter amendment and receive approval from NCUA to implement SEP. Otherwise, the groups obtained by the merging credit union through SEP must be listed specifically in the continuing credit union's field of membership or a reference to the merging credit union's SEP log must be made in the continuing credit union's field of membership as of the date of the merger.

12. Chapter 2, Section VIII.G is revised to read as follows:

VIII.G—Appeal of Regional Director Decision

If a field of membership expansion, merger, or spin-off is denied by the Regional Director, the federal credit union may appeal the decision to the NCUA Board. If not included with the denial notice, a copy of these procedures may be obtained from the Regional Director who made the decision. An appeal must be sent to the appropriate regional office within sixty days of the denial. The Regional Director will then forward the appeal to the NCUA Board. NCUA central office staff will make an independent review of the facts and present the appeal to the Board with a recommendation.

The federal credit union may, within thirty days of the denial, request reconsideration and provide supplemental information to the regional director. The request for reconsideration will not be considered an appeal but will toll the sixty day requirement to file an appeal until a ruling is received on the request for reconsideration.

13. Chapter 3, Section 3.H, is added as follows:

III.H—Appeal of Regional Director Decision

If a conversion to a state charter is denied by the Regional Director, the credit union may appeal the decision to the NCUA Board. If not included with the denial notice, a copy of these procedures may be obtained from the Regional Director who made the decision. An appeal must be sent to the appropriate regional office within sixty days of the denial. The Regional Director will then forward the appeal to the NCUA Board. NCUA central office staff will make an independent review of the facts and present the appeal to the Board with a recommendation.

The federal credit union may, within thirty days of the denial, request reconsideration and provide supplemental information to the regional director. The request for reconsideration will not be considered an appeal but will toll the sixty day requirement to file an appeal until a ruling is received on the request for reconsideration.

* * * * *

[FR Doc. 95–24689 Filed 10–3–95; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 95–CE–46–AD]

Airworthiness Directives; Beech Aircraft Corporation Models 1900, 1900C, and 1900D Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Beech Aircraft Corporation (Beech) Models 1900, 1900C, and 1900D airplanes that do not have canted bulkhead Repair Kit No. 129–4005–1 S incorporated. The proposed action would require repetitively inspecting the canted bulkhead located at Fuselage Station 588.10 for cracks, and, if cracks are found that exceed certain limits, incorporating canted bulkhead Repair Kit No. 129–4005–1 S as terminating action for the repetitive inspection requirement. Numerous reports of multi-site cracks occurring in the canted bulkhead at Fuselage Station 588.10 on the affected airplanes prompted the proposed action. The actions specified by the proposed AD are intended to prevent the inability of the bulkhead to carry its ultimate design load because of cracks in the canted bulkhead, which, if not detected and corrected, could affect rudder cable tension and result in reduced rudder power.

DATES: Comments must be received on or before December 4, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–46–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Mr. Steve Potter, Aerospace Engineer, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone (316) 946–4124; facsimile (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact

concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–46–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–46–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has received numerous reports of multi-site cracks in the canted bulkhead at Fuselage Station 588.10 on three Beech Models 1900, 1900C, and 1900D airplanes. Specifically, these cracks were found at the outer flange radius and outer flange stringer cutouts of the canted bulkhead. This condition, if not detected and corrected, could prevent the bulkhead from carrying its ultimate design load because of cracks in the canted bulkhead, which, if not detected and corrected, could affect rudder cable tension and result in reduced rudder power.

Beech has issued Service Bulletin (SB) No. 2564, Revision 1, dated April 1995, which specifies procedures for inspecting the canted bulkhead at Fuselage Station 588.10. This service bulletin also references canted bulkhead Repair Kit No. 129–4005–1 S, which, when incorporated on the affected airplanes, reinforces this area at Fuselage Station 588.10.

After examining the circumstances and reviewing all available information related to the incidents described above including the referenced service information, the FAA has determined that AD action should be taken to prevent the inability of the bulkhead to carry its ultimate design load because of cracks in the canted bulkhead, which, if not detected and corrected, could affect rudder cable tension and result in reduced rudder power.

Since an unsafe condition has been identified that is likely to exist or develop in other Beech Models 1900, 1900C, and 1900D airplanes of the same type design that do not have canted bulkhead Repair Kit No. 129–4005–1 S incorporated, the proposed AD would require repetitively inspecting the canted bulkhead located at Fuselage Station 588.10 for cracks, and, if cracks are found that exceed certain limits, incorporating canted bulkhead Repair Kit No. 129–4005–1 S as terminating action for the repetitive inspection requirement. Accomplishment of the proposed inspections would be in accordance with Beech SB No. 2564, Revision 1, dated April 1995. Accomplishment of the proposed possible reinforcement would be in accordance with the instructions included with the above referenced kit.

The FAA estimates that 364 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 2 workhours per airplane to accomplish the proposed inspections, and that the average labor rate is approximately $60 an hour. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $43,680. This figure does not take into account the number of repetitive inspections an affected airplane owner/operator would incur and is based on the assumption that no canted bulkhead would be found cracked during the inspection. The FAA has no way of determining the number of repetitive inspections a particular airplane owner/operator would incur or how many canted bulkheads would be found cracked during the proposed inspections. This figure also does not take into account the number of affected airplane owners/operators that may have incorporated the inspection-terminating reinforcement kit.

Beech has notified the FAA that 36 reinforcement kits have been distributed to the affected airplane owners/operators. If each of the kits has been installed on an affected airplane, then the inspection requirement for these airplanes is eliminated. Based on this assumption, the cost impact of the proposed AD upon U.S. owners/operators of the affected airplanes would be reduced $4,320 from $43,680 to $39,360.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

Beech Aircraft Corporation: Docket No. 95–CE–46–AD.

Applicability: The following airplane models and serial numbers, certificated in any category, that do not have canted bulkhead Repair Kit No. 129–4005–1 S incorporated:

Model	Serial Nos.
1900	UA–1 through UA–3.
1900C	UB–1 through UB–74 and UC–1 through UC–174.
1900C (C12J)	UD–1 through UD–6.
1900D	UE–1 through UE–113.

Note 1: This AD applies to each airplane identified in the preceding applicability revision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (e) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated in the

body of this AD, unless already accomplished.

To prevent the inability of the bulkhead to carry its ultimate design load because of cracks in the canted bulkhead, which, if not detected and corrected, could affect rudder cable tension and result in reduced rudder power, accomplish the following:

Note 2: The paragraph structure of this AD is as follows:

Level 1: (a), (b), (c), etc.
Level 2: (1), (2), (3), etc.

Level 2 structures are designations of the Level 1 paragraph they immediately follow.

(a) Upon the accumulation of 5,000 hours time-in-service (TIS) or within the next 600 hours TIS, whichever occurs later, inspect the canted bulkhead at Fuselage Station 588.10. Accomplish this inspection in accordance with the Accomplishment Instructions section of Beech Service Bulletin (SB) No. 2564, Revision 1, dated April 1995.

(b) If, during the inspection, one or more of the limits specified in paragraphs (b)(1), (b)(2), or (b)(3) of this AD are found (also specified in Beech SB No. 2564), prior to further flight, incorporate Beech Kit No. 129–4005–1 S, which reinforces the canted bulkhead at Fuselage Station 588.10.

(1) Any one crack that is greater than 2.5 inches in length.

(2) The sum of all crack lengths in any 12 inches of consecutive frame length is greater than 4.0 inches

(3) Any crack that progresses through the width of the bulkhead.

(c) If no cracks are found during an inspection or a crack is found that does not exceed one of the limits specified in paragraphs (b)(1), (b)(2), or (b)(3) of this AD, accomplish one of the following:

(1) Repeat the inspection specified in paragraph (a) of this AD at intervals not to exceed 600 hours TIS, and prior to further flight, reinforce the canted bulkhead as specified in paragraph (b) of this AD if cracks are found that exceed one or more of the limits specified in paragraphs (b)(1), (b)(2), or (b)(3) of this AD; or

(2) Within 600 hours after the last canted bulkhead inspection, incorporate Beech Kit No. 129–4005–1 S. Incorporating this kit reinforces the canted bulkhead at Fuselage Station 588.10.

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(e) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office (ACO), 1801 Airport Road, Room 100, Mid-Continent Airport, Wichita, Kansas 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita ACO.

(f) All persons affected by this directive may obtain copies of the document referred to herein upon request to the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on September 26, 1995.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–24605 Filed 10–3–95; 8:45 am]

BILLING CODE 4910–13–U

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14 CFR Part 39

[Docket No. 95–CE–50–AD]

Airworthiness Directives; I.A.M. Rinaldo Piaggio S.p.A. Model P 180 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain I.A.M. Rinaldo Piaggio S.p.A. (Piaggio) Model P 180 series airplanes. The proposed action would require installing a shield on the front section of the engine cradle. A report of power control jamming as a result of freezing conditions during a high altitude flight prompted this AD action. The actions specified by the proposed AD are intended to prevent loss of engine power or the propeller controls from jamming as a result of freezing rain entering the engine nacelle, which, if not detected and corrected, could result in loss of control of the airplane.

DATES: Comments must be received on or before December 5, 1995.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–50–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from I.A.M. Rinaldo Piaggio, S.p.A., Via Cibrario, 4 16154, Genoa, Italy. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Delano D. Castle, Program Manager, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium; telephone (322) 513.3830, ext. 2716; facsimile (322) 230.6899; or Mr. J. Mike Kiesov, Project Officer, Small Airplane Directorate, Airplane Certification Service, FAA, 1201 Walnut, suite 900, Kansas City, Missouri 64105; telephone (816) 426–6932; facsimile (816) 426–2169.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 95–CE–50–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 95–CE–50–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The Registro Aeronautico Italiano (RAI), which is the airworthiness authority for Italy, recently notified the FAA that an unsafe condition may exist on certain Piaggio Model P 180 series airplanes. The RAI advised of an incident in which water entered the accessory gearbox zone during heavy rain conditions, and passed through the starter generator air discharge port or

through the interstices between the nacelle inspection hutch and the nacelle itself. The trapped water on the power and propeller controls resulted in the controls freezing and jamming while flying at high altitudes.

Piaggio has issued Service Bulletin (SB) 80–0066; Original Issue December 12, 1994, which specifies modifying the nacelle by installing a shield on the front section of the engine cradle to prevent water from getting into the power and propeller controls.

The RAI classified this service bulletin as mandatory and issued its AD number 95–087, dated April 6, 1995, in order to assure the continued airworthiness of these airplanes in Italy.

This airplane model is manufactured in Italy and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement between Italy and the United States. Pursuant to this bilateral airworthiness agreement, the RAI has kept the FAA informed of the situation described above.

The FAA has examined the findings of the RAI, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop in other Piaggio Model P 180 series airplanes of the same type design, the proposed AD would require modifying the nacelle by installing a shield on the front section of the engine cradle in accordance with Piaggio SB 80–0066; Original Issue: December 12, 1994.

The FAA estimates that 5 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 2 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $60 an hour. Parts will be furnished by the manufacturer at no cost to the owner/operators. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $600. This figure is based on the assumption that none of the affected airplanes have shields installed and that none of the affected owners/operators have modified the airplanes.

The compliance time of this AD is presented in both hours time-in-service (TIS) and calendar time. The FAA has determined that including calendar time compliance is also necessary because the unsafe condition is the result of adverse weather conditions which can affect the nacelle and power controls while not in use as well as in flight. Therefore, to ensure that the above-described condition is detected and corrected on all airplanes within a reasonable period of time without inadvertently grounding any airplanes, a compliance schedule based upon both TIS and calendar time instead of hours TIS is required.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES.**

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 USC 106(g), 40101, 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding a new airworthiness directive (AD) to read as follows:

I.A.M. Rinaldo Piaggio S.P.A.: Docket No. 95–CE–50–AD.

Applicability: Model P 180 Series Airplanes (serial numbers 1001, 1002, 1004, and 1006 through 1033), certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required initially within the next 100 hours time-in service (TIS), or within the next 3 calendar months, whichever occurs later, after the effective date of this AD, unless already accomplished.

Note 2: The initial compliance time in this AD takes precedence over the compliance time reflected in Piaggio Service Bulletin 80–0066, Original Issue, December 12, 1994.

To prevent loss of engine power or the propeller controls from jamming, as a result of freezing rain entering the engine nacelle, which, if not detected and corrected, could result in loss of control of the airplane, accomplish the following:

(a) Modify the nacelle by installing a shield on the front section of the engine cradle, in accordance with the ACCOMPLISHMENT INSTRUCTIONS section in Piaggio Service Bulletin (SB) No. 80–0066; Original Issue: December 12, 1994.

(b) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(c) An alternative method of compliance or adjustment of the compliance times that provides an equivalent level of safety may be approved by the Manager, Brussels Aircraft Certification Office, FAA, Europe, Africa, and Middle East Office, c/o American Embassy, B–1000 Brussels, Belgium. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Brussels Aircraft Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels Aircraft Certification Office.

(d) All persons affected by this directive may obtain copies of the document referred to herein upon request to I.A.M. Rinaldo Piaggio, S.p.A., Via Cibrario, 4 16154, Genoa, Italy; or may examine this document at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Issued in Kansas City, Missouri, on September 26, 1995.

Henry A. Armstrong,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 95–24640 Filed 10–3–95; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. 95N–0176]

Orthopedic Devices: Classification, Reclassification, and Codification of Pedicle Screw Spinal Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify certain unclassified preamendments pedicle screw spinal systems into class II (special controls), and to reclassify certain postamendments pedicle screw spinal systems from class III (premarket approval) to class II. FDA is also issuing for public comment the recommendations of the Orthopedic and Rehabilitation Devices Panel (the Panel) concerning the classification of pedicle screw spinal systems, and the agency's tentative findings on the Panel's recommendations. After considering any public comments on the Panel's recommendations and FDA's proposed classification, in addition to any other relevant information that bears on this action, FDA will publish a final regulation classifying the device. This action is being taken because the agency believes that there is sufficient information to establish special controls that will provide reasonable assurance of its safety and effectiveness.

DATES: Written comments by January 2, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mark N. Melkerson, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2036.

SUPPLEMENTARY INFORMATION:

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IX. Comments

I. Highlights of the Proposal

FDA is issuing for public comment several recommendations of the Panel concerning the classification of pedicle screw spinal systems. The Panel recommended that FDA classify into class II the unclassified preamendments pedicle screw spinal system intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the fifth lumbar vertebra in patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implant after the attainment of a solid fusion. The Panel also recommended that FDA reclassify the postamendments pedicle screw spinal system intended for degenerative spondylolisthesis and spinal trauma from class III to class II. For all other indications, pedicle screw spinal systems are considered postamendments class III devices for which premarket approval is required. The Panel made its recommendations after reviewing information presented at two public meetings on August 20, 1993 and July 23, 1994, and after reviewing information which was solicited in response to an April 3, 1995, letter. FDA is also issuing for public comment its tentative findings on the Panel's recommendations. FDA is proposing to expand the intended uses of the device identified by the Panel to include pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities and deformities, including spondylolisthesis, fractures and dislocations, scoliosis, kyphosis, and spinal tumors. Finally, FDA is proposing to codify the classification of both the preamendments and the postamendments device in one regulation. Comments received in response to this proposed rule, along with other relevant information that the agency may obtain, will be relied upon by the agency in formulating a final position on each of the foregoing issues and provide the basis for a final agency regulation.

II. Background

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: Class I, general controls; class II, special controls; and class III, premarket approval. Devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments) are classified under section 513 of the act (21 U.S.C. 360c) after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. A device that is first offered for commercial distribution after May 28, 1976, and is substantially equivalent to a device classified under this scheme, is also classified into the same class as the device to which it is substantially equivalent.

A device that was not in commercial distribution prior to May 28, 1976, and that is not substantially equivalent to a preamendments device, is classified by statute into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

The pedicle screw spinal system intended for indications other than severe spondylolisthesis is a postamendment device classified into class III under section 513 (f) of the act (21 U.S.C. 360c(f)). In accordance with sections 513(e) and (f) of the act and 21 CFR 860.134, based on new information with respect to the device, FDA, on its own initiative, is proposing to reclassify this device from class III to class II when intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of acute and chronic instabilities and deformities, including spondylolisthesis, fractures and dislocations, scoliosis, kyphosis, and

spinal tumors. Such intended uses encompass both degenerative spondylolisthesis and spinal trauma. In addition, FDA is proposing to classify the preamendments pedicle screw spinal system intended for the treatment of severe spondylolisthesis into class II, in accordance with section 513(d) of the act and 21 CFR 860.84.

FDA is proposing to place the pedicle screw spinal system in class II because it believes that there is sufficient information to establish special controls to provide reasonable assurance of its safety and effectiveness.

Two categories of spinal fixation implants that were in commercial distribution prior to the date of enactment of the amendments have been classified into class II: Posterior hook-rod fixation devices (classification: 21 CFR 888.3050, Spinal interlaminal fixation orthosis) and anterior plate-screw-cable fixation devices (classification: 21 CFR 888.3060, Spinal intervertebral body fixation orthosis). In addition, bone plates and screws were placed into class II when intended for general orthopedic use in long bone fracture fixation (classifications: 21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories). However, bone plates and screws were considered postamendments class III devices when incorporated into pedicle screw spinal systems. This proposal does not affect the classification of those devices.

Pedicle screw spinal systems include a broad category of multiple component implants. The first premarket notification submission (510(k)) for a multiple component device system intended for attachment to the spine via the pedicles of the vertebrae was submitted to FDA for marketing clearance in 1984. FDA determined that the device was not substantially equivalent to the following devices: (1) Single/multiple component metallic bone fixation appliances and accessories intended for long bone fracture fixation; and (2) interlaminal spinal fixation device systems that attached to the spine via sublaminar wiring or interlaminal hooks. FDA's decision was based on the fact that the sponsor had not established that there was a preamendments device incorporating pedicle screw components and that the device posed potential risks not exhibited by other spinal fixation systems, such as a greater chance of neurological deficit due to imprecise screw placement or the event of a screw failure; pedicle fracture during placement of screws; soft tissue damage or inadequate fusion due to bending or fracture of device components; and greater risk of pseudarthrosis due to instability of the device design. Because they were not found to be substantially equivalent to a preamendments device, these systems were automatically classified into class III under section 513(f)(1) of the act.

In 1985, in response to another 510(k), FDA determined that the interlaminal spinal fixation device (i.e., rods and hooks and/or sublaminar wires) with screws attached to the sacrum was substantially equivalent to the class II interlaminal spinal fixation device with hooks supported on a rod threaded into the iliac crests (21 CFR 888.3050). However, when the same device was fixed to the pedicles, FDA determined that the device was not substantially equivalent to the spinal interlaminal fixation orthosis (21 CFR 888.3050) and is therefore a postamendments class III device.

Clinical investigations of pedicle screw spinal systems under investigational device exemption (IDE) protocols began in 1985. No premarket approval application has been brought before the advisory panel or approved to date.

By mid-1992, FDA discovered that the use of pedicle screw spinal systems outside of approved IDE studies was widespread, and that pedicle screw fixation was considered to be the standard of care by the surgical community. To obtain guidance in resolving this issue in the best interests of the public health, FDA convened an advisory panel meeting on August 20, 1993, to review the available information pertaining to the safety and effectiveness of the device. Mechanical testing data, summaries of clinical studies conducted under FDA-approved IDE protocols, and presentations by experts in the field were presented to the Panel. After reviewing the information, the Panel concluded that pedicle screw spinal devices appear to be safe and effective when used as adjuncts to spinal fusion procedures, but that additional clinical information was needed in order to determine what regulatory controls should be required to provide reasonable assurance of their safety and effectiveness.

During a February 1993 meeting, FDA requested the orthopedic professional societies and spinal implant manufacturers to submit to FDA all available valid scientific data on the performance of pedicle screw spinal devices. In response, the Spinal Implant Manufacturers Group (SIMG) was formed to provide the financing for a nationwide study of the pedicle screw device. The SIMG consists of representatives from the American Academy of Orthopedic Surgeons, the Scoliosis Research Society, the North American Spine Society, the American Association of Neurological Surgeons, the Congress of Neurological Surgeons, and 25 manufacturers of spinal implant systems. The Scientific Committee of the SIMG, consisting of surgeons and scientists, was formed specifically to develop and implement a uniform research protocol to gather clinical experience from the use of the device. FDA also provided extensive input into the design of the study protocol. With the permission of individual IDE sponsors, FDA's scientific staff provided the Scientific Committee with information about current IDE clinical investigations, the types of diagnostic groups being studied, the patient inclusion and exclusion criteria utilized, the outcome variables under study, and insight into the types of problems encountered with these studies. FDA also made recommendations regarding the feasibility of various study designs, including an historical cohort model. Finally, FDA provided the Scientific Committee with extensive advice regarding statistical analysis of the data, validation of data, reduction of study bias, and sample size calculations. The Scientific Committee then conducted a nationwide historical cohort study according to this research protocol.

The Panel met on August 20, 1993, and July 22, 1994, in open public meetings to discuss the postamendments pedicle screw spinal system. At the July 22, 1994, meeting, new information was presented to the Panel by FDA and others, and recommendations were solicited from the Panel regarding the classification of pedicle screw spinal systems. During this meeting, the Panel heard testimony from FDA, the medical and scientific communities, manufacturers, and the public regarding the safety and effectiveness of the device. At this meeting, the SIMG presented clinical data from its nationwide ''Historical Cohort Study of Pedicle Screw Fixation in Thoracic, Lumbar, and Sacral Spinal Fusions'' (Cohort study). FDA presented a comprehensive review of the medical literature, an analysis of the Cohort study conducted by the SIMG, and a summary of the clinical data that had been released by IDE sponsors. Presentations of two meta-analyses of the literature pertaining to the clinical performance of the device were given by spinal surgeons. In addition, 38 persons gave presentations during the public comment portion of the panel meeting. Patients who had had spinal fusion

surgery with pedicle screw instrumentation gave personal testimonies of their experiences with the device, citing both successes and failures. Several litigation attorneys, representing patients involved in class action lawsuits against spinal implant manufacturers, addressed the Panel with their views. Five spine surgeons gave their professional opinions regarding the usefulness of the pedicle screw device in their practices. Three surgeons representing spinal professional societies presented their societies' viewpoints.

At the conclusion of the July 22, 1994, meeting, the Panel recommended that FDA reclassify the generic type of device from class III into class II when intended for the treatment of degenerative spondylolisthesis and spinal trauma. The Panel recommended further that FDA adopt special controls as deemed necessary by FDA under 513(a)(1)(B) of the act, and that FDA assign a low priority for the establishment of a performance standard for this generic type of device under section 514 of the act (21 U.S.C. 360d).

Since 1986, a number of manufacturers have sought to demonstrate that the pedicle screw spinal system is a preamendments device, that is, that it was commercially available prior to May 28, 1976, the enactment date of the 1976 amendments. In a 510(k) dated December 22, 1994, Sofamor Danek, Inc., provided sufficient evidence of the preamendments commercial distribution of a spinal system that utilized pedicle screws. In a letter to Sofamor Danek, Inc., dated January 20, 1995, FDA acknowledged that sufficient evidence now exists documenting that pedicle screw spinal systems were commercially available prior to May 28, 1976. The preamendments pedicle screw spinal fixation device system consisted of hooks, spinal rods, threaded sacral rods, and pedicle screws connected to the rods with wire. The device was intended only for lumbar and sacral spine fusions using autogenous bone graft in patients with severe spondylolisthesis (grades 3 and 4) with removal of the device after spinal fusion was achieved. On January 20, 1995, the first postamendments pedicle screw spinal system was found to be substantially equivalent to the preamendments device. Based on this new information, FDA has determined that the pedicle screw spinal system is an unclassified preamendments device when indicated for autogenous bone graft fusions of the fifth lumbar vertebra to the sacrum in patients with severe spondylolisthesis (grades 3 and 4) at L_5–S_1 with removal of the device after fusion has been achieved. In a letter, dated April 3, 1995, FDA asked the Panel to provide its recommendations on the classification of this preamendments device. The Panel unanimously recommended that the preamendments pedicle screw spinal system be classified into class II when intended for autogenous bone graft fusions of the fifth lumbar vertebra to the sacrum in patients with severe spondylolisthesis (grades 3 and 4) at L_5–S_1 with removal of the device after fusion has been achieved.

In this document, FDA is publishing the recommendations of the Panel with respect to classification of the preamendments device and reclassification of the postamendments device. FDA is also proposing to classify both the preamendments and postamendments devices into class II, and to codify them in one regulation.

III. Recommendations of the Orthopedic and Rehabilitation Devices Palen

The Orthopedic and Rehabilitation Devices Panel, an FDA advisory panel, made the following recommendations regarding the classification of the pedicle screw spinal system:

(1) *Identification.* A pedicle screw spinal system is a multiple component device, made of alloys such as 316L stainless steel (Ref. 11), 316LVM stainless steel (Ref. 11), 22Cr–13Ni–5Mn stainless steel (Ref. 12), unalloyed titanium (Ref. 9), and Ti–6Al–4V (Ref. 10), that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. A spinal implant assembly consists of anchors (e.g., bolts, hooks, and screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and plate/rod combinations); and transverse connectors. The device is used primarily in the treatment of acute and chronic instabilities and deformities, such as trauma, tumor, or degenerative spondylolisthesis.

(2) *Classification recommendation.* Class II (special controls). The Panel recommended that the establishment of a performance standard be low priority.

(3) *Summary of reasons for recommendation.* The Orthopedic and Rehabilitation Devices Panel recommended that pedicle screw spinal systems be classified into class II because the Panel believed that general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but that there is sufficient information to establish special controls to provide such assurance. The Panel also believed that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device. The Panel believed that public information demonstrates that the risks to health have been characterized and can be controlled. The Panel also believed that the relationship between these risks and the device's performance parameters have been established and are sufficiently understood to assure the safety and effectiveness of the device. Furthermore, the Panel recognized that there exist voluntary standards and test methods with respect to the production of the device.

(4) *Summary of data on which the recommendation is based.* The Orthopedics and Rehabilitation Devices Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and presentations at the open panel meeting. The Panel noted that, based upon clinical data from the Cohort study, IDE clinical investigations, and the literature, pedicle screw spinal systems performed at least equivalent to, and in some instances superior to, currently available class II anterior and posterior spinal fixation devices, as well as to treatments not utilizing internal fixation devices for degenerative spondylolisthesis and trauma.

The Panel noted that, based on the Cohort study, clinical investigations under IDE protocols and studies available from the scientific literature, the use of pedicle screw spinal systems, when intended for the treatment of degenerative spondylolisthesis and spinal trauma, produced statistically significantly higher spinal fusion rates than when no fixation or nonpedicle screw spinal fixation was used. In addition, the Panel believed that these studies demonstrated statistically significant improvements in patients' clinical outcomes in terms of pain, function, and neurologic status. The Panel believed that these studies demonstrated significant technical and clinical advantages from the use of the device (Ref. 66).

According to the Panel, the mechanical testing data presented at the August 20, 1993, panel meeting demonstrated that pedicle screw spinal systems exhibit adequate mechanical strength, rigidity, and fatigue resistance for the expected length of time required to stabilize the spine to allow fusion to occur (Ref. 65).

The Panel concluded that the data presented at the July 22, 1994, panel meeting provided clinical evidence that the device was effective in stabilizing

the spine in spinal fusions for degenerative spondylolisthesis and spinal trauma. The Panel also determined that the incidence rates of device breakage, deformation, and loosening were similar to those of commercially available device systems and that the rates were clinically acceptable. The types of device-related complications for pedicle screw spinal systems reported to FDA under the MedWatch device reporting program were comparable to those reported in clinical studies and the medical literature for commercially available spinal systems and included broken screws, neurologic injuries, and nonunions (Ref. 66).

The Panel did not find support in the literature or in clinical data for use of the device in the treatment of low back pain. The Panel specifically recommended that low back pain should not be included in the indications for use of the device until clinical data justify its inclusion (Ref. 66).

The Panel believed that the primary risks to health associated with pedicle screw spinal systems are similar to those associated with other class II spinal implant devices. The Panel believed that both clinical and nonclinical parameters need to be controlled to provide reasonable assurance of the safety and effectiveness of the device. The primary nonclinical parameters affecting safety and effectiveness are: (1) Biocompatibility of the materials used in the manufacture of the device; (2) device design; (3) device durability; (4) device strength, and (5) device rigidity. The primary measures of clinical effectiveness of the device are: (1) Fusion, (2) pain relief, (3) functional improvement, and (4) neurologic status. These concerns are the same as those associated with commercially available class II devices, including posteriorly placed interlaminal spinal fixation orthoses (21 CFR 888.3050) and anteriorly placed spinal intervertebral body fixation orthoses (21 CFR 888.3060).

The Panel reviewed the medical literature pertaining to the use of pedicle screw spinal systems in the treatment of severe spondylolisthesis (Refs. 5, 6, 14, 27, 28, 29, 30, 48, 52, 68, 81, 82, 83, 84, 92, 93, 147, 155, 159, 168, 169, 175, and 188) and determined that the risks associated with the device are no different than those associated with the use of the preamendments class II spinal fixation devices or those associated with pedicle screw spinal systems intended for the treatment of other acute or chronic instabilities and deformities. The Panel concluded that the effectiveness of the device is related to its mechanical strength and rigidity, which have been demonstrated to be superior to existing class II devices.

(5) *Risks to health.* The following risks are associated with the pedicle screw spinal system: (a) Mechanical failure. The screw may bend or fracture, loosen or pull-out, the plate or rod may bend or fracture, the connector may slip resulting in loss of fixation and loss of reduction; (b) soft tissue injury. The risks of tissue injury include screw over-penetration of the vertebral body with associated injury to major blood vessels or viscera; pedicle fracture; nerve root injury; spinal cord injury; cauda equina injury; dural tear or cerebrospinal fluid leak; blood vessel injury; and bowel injury; (c) pseudarthrosis. The risk of nonunion, or pseudarthrosis, signifies failure of bony fusion and persistent instability; and (d) need for reoperation. The risk of a possible reoperation includes reoperation for infection or bleeding; revision surgery; removal of device components for device failure, or symptomatic, painful, or prominent hardware; and reoperations for other reasons not related to fusion, such as nerve root decompression. In addition, there are theoretical risks, such as device-related osteoporosis, metal allergy, particulate debris, and metal toxicity, for which no reliable human data exist.

A. Safety and Effectiveness: Nonclinical

1. Biocompatibility of Materials

The biocompatibility of stainless steel and titanium metal alloys used in the fabrication of pedicle screw spinal systems has been investigated extensively with in vitro testing, implantation studies, mechanical testing, toxicological testing, corrosion testing, and clinical trials. These alloys have been demonstrated to be reasonably safe for human usage under a variety of conditions. (Refs. 23, 33, 67, 105, 111, 134, 135, 179, 180, 182, and 197).

Stainless steels, such as 316 L, 316 LVM, and 22Cr–13Ni–5Mn alloys, are susceptible to some degree of crevice, pitting, and stress corrosion. The presence of corrosion products can produce a localized chronic inflammatory response with granuloma formation, macrophage engorgement with particulate matter, and focal areas of necrosis (Refs. 41, 67, 76, 111, 167, 179, and 197). Metallic ion species from leaching or corrosion can produce allergic responses (Refs. 61, 67, 120, and 148). These are recognized and well-described tissue reactions to stainless steel implants and metal ions. Nevertheless, stainless steels have been used extensively with great clinical success for the fabrication of surgical implants, including bone plates, bone screws, and intramedullary rods. The biocompatibility of stainless steels has been regarded as acceptable for implants at various anatomic locations under different pathophysiologic conditions (Refs. 38, 67, 105, 134, 135, 157, 158, 165, 179, and 181).

The corrosion resistance of commercially pure (CP) titanium and Ti–6Al–4V alloy has been well-documented through in vitro testing, implantation studies, toxicological testing, corrosion testing, and clinical trials. Titanium and its alloys are susceptible to wear as well as corrosion, and thus may cause black discoloration of surrounding tissues and induce aseptic local fibrosis (Refs. 33, 42, 115, 121, 129, 139, 197, and 198). In the soft tissue surrounding titanium alloy orthopedic implants, T-lymphocytes in association with macrophages have been observed, implying an immunological response to the debris (Ref. 103). Macrophage release of bone-resorbing mediators in association with titanium wear debris has also been demonstrated (Ref. 85). The significance of these observations regarding the biologic and toxicologic effects of titanium ions and wear particles in spinal fusion is uncertain since these tissue reactions have been observed only in closed joint systems, such as hip replacements (Refs. 121 and 129). Despite these tissue responses, CP titanium and titanium alloys are still considered relatively safe biomaterials, and may be effectively used with minimal risk when not used as the articulating surface, which leads to the generation of large amounts of wear debris (Refs. 42, 121, 129, 139, 196, 197, and 198). Titanium and its alloys have been used extensively as implant materials since the mid-1960's for the fabrication of implants such as bone plates, bone screws, and hip implants (Refs. 105, 129, 182, 196, 197, and 198).

All available metallic implant materials are imperfect biomaterials. In the trade-off between the theoretical risks arising from metal ion release, corrosion products, and wear debris, and the known benefits of these materials, it appears that both stainless steel and titanium alloys are acceptable for human implantation in the spinal environment.

The Panel believed that the biocompatibility specifications of existing voluntary standards provide reasonable assurance of the safety and effectiveness of devices manufactured of

metals and metallic alloys (Refs. 65 and 66).

2. Mechanical Properties of the Device

It has been demonstrated that the multiple component pedicle screw spinal systems perform as well as other commercially available spinal fixation device systems in various modes and frequencies of loading (Refs. 8, 21, 45, 63, 67, 71, 73, 77, 98, 99, 100, 136, 137, 138, 142, 143, 144, 146, and 184).

Sufficient test methods exist to enable the evaluation of fatigue strengths and tensile, torsional, and bending strengths of the pedicle screw spinal fixation systems to assure its safety and effectiveness during the period of time needed for fusion to occur (Refs. 8, 13, 21, 45, 66, 72, and 78). There is adequate mechanical testing data for the pedicle screw spinal system for which clinical data was presented at the July 22, 1994, panel meeting. For example, one of the pedicle screw-plate systems had a static bending strength of 807.8 N, stiffness of 123.7 KN/M, and flexibility of 8.18×10^{-3} M/KN (Ref. 45). In cyclic fatigue testing, the same system endured 10^6 cycles with a 400 N load, 10^6 cycles with a 500 N load, and 212,960 cycles with a 600 N load (Ref. 45). Pedicle screw-rod systems have reported static bending strengths ranging from 544.9 to 1,289 N, stiffnesses ranging from 136.9 to 153.2 KN/M, and flexibilities ranging from 6.53 to 7.32 ($\times 10^{-3}$) M/KN (Ref. 45). In cyclic fatigue testing, the pedicle screw-rod fixation device systems have endured 10^6 cycles with a 400 N load, 202,769 to 10^6 cycles with a 500 N load, and 135,017 to 799,544 cycles with a 600 N load (Ref. 45).

B. Safety and Effectiveness: Clinical

The Panel based its recommendations on valid scientific evidence from the Cohort study, IDE clinical investigations, and the medical literature. These data sources allowed the Panel to evaluate the safety and effectiveness of pedicle screw spinal systems in terms of mechanical failure, soft tissue injury, pseudarthrosis, reoperation, fusion, pain, function, and neurologic status, as well as other potential harmful and beneficial effects of these devices.

Representatives of the SIMG presented the results of the Cohort study at the July 22, 1994, panel meeting. The Cohort study was an open, nonblinded, historical cohort study (Ref. 201). It was designed to recruit a maximum number of surgeons who would voluntarily participate by collecting clinical data on patients who had undergone spinal fusions. Physicians were recruited through announcements at professional society meetings and direct mailings to professional society memberships. Clinical data were collected from medical records of patients who had undergone spinal fusions during the period January 1, 1990, to December 31, 1991. This window was chosen to allow an adequate number of patients with a theoretical minimum followup of 2 years up to the time of the study onset. The concurrent control groups consisted of patients with identical entry criteria who had been operated on during the same time window (1/1/90–12/31/91). These control patients were either fused without instrumentation (noninstrumented) or were fused and instrumented with a control device (nonpedicle screw instrumentation). The data collection protocol was identical to that used for the study group.

Three hundred fourteen surgeons voluntarily participated in this study and contributed a total of 3,500 patients: 2,685 patients in the Degenerative Spondylolisthesis group and 815 patients in the Fracture (spinal trauma) group. In the Degenerative Spondylolisthesis group, the 2,685 patients were stratified by treatment: 2,177 patients were treated with pedicle screw instrumented fusions, 51 patients with nonpedicle screw instrumented fusion, and 457 patients with noninstrumented fusion. Similarly, in the Fracture group, the 815 patients were stratified by treatment: 587 patients were treated with pedicle screw instrumented fusions, 221 patients with nonpedicle screw instrumented fusion, and 7 patients with noninstrumented fusion.

Data from three clinical evaluation periods were collected from each patient record: Preoperatively, immediately postoperatively, and at the final evaluation which ranged from six months to two years postoperatively. The preoperative data included the patient's age, gender, weight, primary diagnosis, involved levels, identification of known prognostic variables (e.g., prior back surgery), and levels of pain, function, and neurologic status. Information regarding the operative procedure included the date of operation, type of bone grafting (if any), the levels instrumented and fused, the name of the pedicle screw device, and the number of each of the relevant components (e.g., rods, screws, connectors). Data collected at the final evaluation time point included the date of the last clinical and radiographic evaluations; fusion status; the date fusion was first diagnosed; maintenance of alignment; and neurologic, functional, and pain assessments. Intraoperative and postoperative adverse events and the incidence and cause of reoperations were recorded.

Ten prospective IDE clinical trials for multiple indications were analyzed. Five studies involving the treatment of degenerative spondylolisthesis (n = 268) and two studies involving the treatment of spinal fracture (n = 27) were compared to the results of the Cohort study and were presented to the Panel (Ref. 66).

A comprehensive search of the English-language medical literature from 1984 to the present was performed. One hundred one articles pertained to clinical performance of pedicle screw devices and were selected for inclusion in this review (Ref. 66). Only articles appearing in peer-reviewed journals were included. Meta-analyses of the medical literature for degenerative spondylolisthesis and spinal trauma were conducted and presented (Refs. 51, 66, and 119).

These data were analyzed and presented at the July 22, 1994, panel meeting.

1. Mechanical Failure

The Cohort study provided the incidence of mechanical device failures related to treatment with pedicle screw spinal systems, nonpedicle screw instrumentation, and noninstrumented fusion (Refs. 66 and 201). For the fracture group (n = 586), the pedicle screw group had a mechanical failure rate of 9.7 percent, compared to a 1.9 percent failure rate in the nonpedicle screw group. For the pedicle screw group, the incidence of screw fracture was 6.7 percent, screw loosening 2.1 percent, rod/plate fracture 0.3 percent, and connector loosening (slippage) 0.2 percent. For the nonpedicle screw group (n = 221), the incidence of rod/plate fracture was 0.9 percent, hook pull-out 0.5 percent, and connector slippage 0.5 percent

For the degenerative spondylolisthesis group, the device mechanical failure rate was 7.8 percent in the pedicle screw group (n = 2,153). The most frequent events for the pedicle screw group were screw loosening (2.8 percent), screw fractures (2.6 percent), rod or plate fractures (0.7 percent), and connector loosening (slippage) (0.7 percent). Mechanical device failures were not possible in the noninstrumented group because a surgical technique, not an instrument technique, was utilized.

The overall incidence of mechanical device failures in the IDE clinical investigations (n = 2,431) was 0.7 to 3.7 percent (mean = 1.2 percent) (Ref. 66). For all investigational pedicle screw

spinal systems reported, the incidence of rod/plate fractures for degenerative spondylolisthesis was 0.0 to 7.1 percent (mean = 1.5 percent), for fractures 0.0 percent, for degenerative disc disease 0.0 to 4.0 percent (mean = 1.1 percent), for scoliosis 0.0 to 9.1 percent (mean = 0.9 percent), for failed back syndrome 0.0 to 2.7 percent (mean = 0.3 percent), and for spinal stenosis 0.0 to 7.7 percent (mean = 5.0 percent) (Ref. 66). The incidence of screw fractures for degenerative spondylolisthesis was 0.0 to 18.6 percent (mean = 6.2 percent), for fractures 20.0 to 28.6 percent (mean = 22.2 percent), for degenerative disc disease 0.0 to 2.7 percent (mean = 0.6 percent), for scoliosis 1.8 percent, for failed back syndrome 0.0 to 3.4 percent (mean = 2.4 percent), and for spinal stenosis 0.0 to 14.3 percent (mean = 3.0 percent). The incidence of screw loosening or pull-out for degenerative spondylolisthesis was 0.0 to 9.3 percent (mean = 0.9 percent), for fractures 0.0 to 5.0 percent (mean = 3.7 percent), for degenerative disc disease 0.0 to 7.4 percent (mean = 0.7 percent), for scoliosis 0.0 to 3.5 percent (mean = 1.8 percent), for failed back syndrome 0.0 to 12.1 percent (mean = 1.6 percent), and for spinal stenosis 0.0 percent. The incidence of connector loosening was 0.0 percent for degenerative spondylolisthesis, fractures, scoliosis, and spinal stenosis, 0.0 to 2.1 percent (mean = 0.4 percent) for degenerative disc disease, and 0.1 percent for failed back syndrome.

A low rate of mechanical failure of pedicle screw fixation devices, when used in multiple indications, is further documented by the medical literature (Refs. 3, 5, 19, 22, 24, 32, 35, 37, 43, 47, 50, 58, 59, 60, 73, 77, 79, 87, 89, 90, 94, 95, 107, 109, 110, 113, 116, 122, 125, 150, 151, 152, 162, 163, 164, 173, 183, 185, 186, 187, 191, 192, 193, and 203). A meta-analysis of 58 clinical studies revealed no differences between pedicle screw fixation (n = 641), hook-rod fixation (n = 1128), anterior fixation (n = 255), and sublaminar wire-rod fixation (n = 48) groups in the rate of mechanical device failures (Refs. 51 and 119).

Survivorship analysis of pedicle screw device failures (defined as screw bending or breaking, infection, device loosening, rod or plate hardware problems, or neurologic complication requiring device removal) in patients treated for spondylolisthesis, postlaminectomy instability, pseudarthrosis, trauma, scoliosis, and tumor demonstrated a 90 percent survival of the instrumentation at 20 months, and 80 percent survival at 5 to 10 years (Ref. 124). The cumulative survivorship at 1 year was 84.0 percent and 91.3 percent for two devices used in the treatment of patients diagnosed with degenerative isthmic spondylolisthesis, degenerative segmental instability, and degenerative lumbar scoliosis (Ref. 26). Survivorship analysis performed on thoracolumbar burst fractures treated with pedicle screw fixation also demonstrated high survival rates for the implants: 100 percent at 22.4 months and 75 percent from 22.4 to 32 months (54).

2. Soft Tissue Injury

The incidence of device-related soft tissue injuries associated with the use of pedicle screw spinal systems for both degenerative spondylolisthesis and fracture groups is comparable to that associated with nonpedicle screw instrumented fusions and noninstrumented fusions (Refs. 66 and 201). Clinical studies have documented 0.1 percent and 0.2 percent rates of vascular injuries related to the use of pedicle screw spinal systems for the degenerative spondylolisthesis and fracture groups, respectively, and no visceral (intestinal) injuries for those groups. There were no differences found between treatment groups for intraoperative and postoperative neurological injuries, including nerve root and spinal cord injuries, as well as new radicular pain. For the degenerative spondylolisthesis and fracture groups, intraoperative nerve root injuries occurred in 0.4 percent and 0.2 percent of cases, respectively; intraoperative spinal cord injuries occurred in 0.1 percent and 0.2 percent of cases, respectively; postoperative radicular pain or deficits in 4.8 percent and 0.9 percent of cases, respectively; intraoperative device-related dural tears in 0.1 percent and 0.7 percent of cases, respectively; and postoperative dural tears or leaks in 0.3 percent and 0.0 percent of cases, respectively (Refs. 66 and 201).

The data released from the IDE clinical investigations reported an overall vascular injury rate of 0.7 percent; an intraoperative nerve root injury rate of 0.1 percent; a wound infection rate of 3.7 percent; a postoperative radicular pain or deficit rate of 2.2 percent; and a rate of postoperative dural tears or leaks of 0.8 percent. In these investigations, intraoperative spinal cord injuries did not occur (Ref. 66).

The medical literature documents a low incidence of soft tissue injuries related directly to the device when used in the treatment of fractures (Refs. 46, 49, 74, 106, 127, and 153), degenerative spondylolisthesis (Refs. 26, 27, 37, 49, 60, 113, 183, 185, 187, 191, and 192), isthmic spondylolisthesis (Ref. 147), degenerative disc disease (Refs. 47, 60, 113, 183, 187, 191, and 192), deformities (Ref. 25), scoliosis (Refs. 43 and 116), tumors (Ref. 126), spinal stenosis (Ref. 173), and multiple diagnoses (Refs. 112 and 122). A meta-analysis of the medical literature for treatment of degenerative spondylolisthesis and fracture demonstrates no differences in the rates of intraoperative and postoperative adverse events related to soft tissue injuries among pedicle screw fixation, hook-rod fixation, anterior fixation, and sublaminar wire-rod fixation treatment groups ($p < 0.05$) (Refs. 51 and 119).

These soft tissue injuries appear to be related to the surgical procedure, rather than the device itself. Misdirected pedicle screws can cause pedicle fracture, screw cutout, or screw penetration of the pedicle, potentially causing nerve root or spinal cord injuries, dural tears, or canal stenosis (Refs. 152, 166, 171, and 189). Meticulous surgical technique and attention to detail appear to minimize these adverse events (Refs. 24, 47, 60, 79, 90, and 190). Pedicle screws too large for the pedicle diameter can cause pedicle fracture. Likewise, over penetration of pedicle screws through the vertebral body from pedicle screws too long for the anterior-posterior dimensions of the vertebrae can cause retroperitoneal vascular or visceral injury (Refs. 101, 106, and 204). Thus, selection of the appropriate size of the pedicle screw is critical to prevent these injuries (Refs. 64 and 190). Operative technique guidelines have been developed to assure accurate placement of pedicle screws and minimize operative complications (Refs. 16, 56, 149, 164, and 172). In addition, the relevant surgical anatomy of the thoracic, lumbar, and sacral spine, including the pedicle dimensions and orientation, as well as surrounding soft tissue structures, have been thoroughly described in the medical literature (Refs. 7, 15, 20, 57, 62, 64, 69, 75, 87, 88, 91, 101, 102, 106, 117, 131, 132, 133, 141, 145, 156, 161, 166, 171, 176, 177, 189, 190, 195, 199, and 204).

3. Pseudarthrosis

In the Cohort study, radiographic data were available to determine the fusion status for 1,794 patients in the pedicle screw group and 382 patients in the noninstrumented group for the treatment of degenerative spondylolisthesis, and 506 patients in the pedicle screw group and 184 patients in the nonpedicle screw group for the treatment of fracture. There was a statistically significant reduction in

the incidence of pseudarthrosis in the degenerative spondylolisthesis group when treated with pedicle screw fixation (3.7 percent) compared to treatment without instrumentation (17.0 percent) ($p < 0.001$). However, there was no significant difference in the incidence of pseudarthrosis associated with the use of pedicle screw fixation in treating fractures (1.8 percent) compared to treatment with nonpedicle screw fixation devices (3.3 percent) ($p = 0.18$) (Refs. 66 and 201).

In the data released from the IDE clinical investigations, the incidence of pseudarthrosis for degenerative spondylolisthesis was 0.0 to 44.0 percent (mean = 12.6 percent), for fractures 10.0 to 14.3 percent (mean = 11.1 percent), for degenerative disc disease 0.0 to 37.0 percent (mean = 8.4 percent), for scoliosis 0.0 to 36.4 percent (mean = 3.7 percent), for ''failed back syndrome'' 0.0 to 47.2 percent (mean = 12.6 percent), and for spinal stenosis 5.1 to 14.3 percent (mean = 13.0 percent) (Ref. 66).

The medical literature similarly documents a low incidence of pseudarthrosis in those treated with pedicle screw spinal systems for fractures (Refs. 3, 17, 34, 35, 36, 47, 80, 153, and 154), degenerative spondylolisthesis (Refs. 32, 37, 96, 125, 173, and 174), deformities (Ref. 25), degenerative spondylosis (Refs. 22, 24, 169, and 194), degenerative disc disease (Ref. 205), and tumor (Refs. 50 and 126). Survivorship analysis for pseudarthrosis demonstrated a 98 percent fusion rate at one year, 97 percent at 12 to 20 months, 96 percent at 21 to 30 months, and 93 percent at 31 to 40 months (Ref. 124).

4. Reoperation

Reoperations were necessary in 17.6 percent and 23.2 percent of cases, respectively, for the degenerative spondylolisthesis and fracture groups in the Cohort study (Refs. 66 and 201). Device removals constituted the vast majority of reoperation procedures: 270 of 379 (71.2 percent) patients with reoperations in the degenerative spondylolisthesis group, and 109 of 136 (80.1 percent) patients with reoperations in the fracture group. Most device removals were performed for pain, irritation, or prominence of the device (6.3 percent and 7.2 percent in the degenerative spondylolisthesis and fracture groups, respectively). Only a small percentage of the devices were removed for device failure (0.6 percent and 1.5 percent in the degenerative spondylolisthesis and fracture groups, respectively).

In the data released from the IDE clinical investigations, the rates of reoperations reported for degenerative spondylolisthesis were 1.4 to 13.2 percent (mean = 5.0 percent), for fractures 10.0 to 14.3 percent (mean = 11.1 percent), for degenerative disc disease 1.4 to 10.5 percent (mean = 2.3 percent), for scoliosis 2.3 percent, for failed back syndrome 1.1 to 8.8 percent (mean = 1.6 percent), and for spinal stenosis 5.1 to 5.6 percent (mean = 5.0 percent) (Ref. 66). The medical literature documents rates of device-related and nondevice related reoperations of 7.0 percent to 24 percent for pedicle screw fixation cases for a variety of conditions (Refs. 50, 60, 86, and 173). Meta-analysis of the literature demonstrated that the reoperation rate for the treatment of fractures with pedicle screw spinal systems (5.8 percent) are comparable to the reoperation rates associated with hook-rod devices (8.9 percent) and anterior devices (2.7 percent) (Refs. 51 and 119).

5. Fusion

Comparing the degenerative spondylolisthesis and fracture groups in the Cohort study, patients treated with pedicle screw fixation had a significantly higher fusion rate (89.1 percent and 88.5 percent, respectively) than the nonpedicle (70.8 percent and 81.0 percent) and noninstrumented (70.4 percent and 50.5 percent) groups ($p < 0.0001$). Using actuarial analysis, the time-adjusted rates of fusion for the degenerative spondylolisthesis group demonstrated that treatment with pedicle screw fixation was associated with a significantly greater rate of fusion than treatment with no instrumentation (82.5 percent versus 74.5 percent, $p < 0.001$). The time-adjusted rates of fusion for the fracture patient group demonstrated that there was no significant difference in the rates of fusion when comparing pedicle screw fixation and nonpedicle screw fixation. For the degenerative spondylolisthesis group, the rate of fusion was higher in those treated with pedicle screw fixation than in those treated without instrumentation at every time interval beyond 3 months. These rates are evidence that fusion occurs faster in the pedicle group (Refs. 66 and 201).

In the data released from clinical investigations performed under IDE's, fusion rates associated with pedicle screw spinal systems were comparable to those associated with nonpedicle screw instrumentation and noninstrumentation. The fusion rates in patients with pedicle screw fixation were 82.1 to 89.5 percent (mean = 87.8 percent) in the treatment of degenerative spondylolisthesis, 71.4 to 80.0 percent (mean = 77.8 percent) for fractures, 82.9 to 93.1 percent (mean = 85.9 percent) for degenerative disc disease, 96.5 percent for scoliosis, 88.6 to 94.7 percent (mean = 91.9 percent) for ''failed back syndrome,'' and 85.7 to 92.3 percent (mean = 91.3 percent) for spinal stenosis (Ref. 66).

A high incidence of successful fusion after pedicle screw fixation is documented in the medical literature. The fusion rates for the treatment of spinal deformity was 100 percent (Ref. 86); for low back syndrome 100 percent (Ref. 109); for postlaminectomy instability 94 percent (Ref. 113); for fracture 88.5 percent to 100 percent (Refs. 55, 66, 80, and 201); for postsurgical failed back syndrome 91.6 percent (Ref. 173); for pseudarthrosis 80 percent to 94 percent (Refs. 113 and 186); for degenerative spondylosis 87 percent to 100 percent (Refs. 22, 169, 185, and 187); for spinal stenosis 96 percent to 100 percent (Refs. 113, 163, and 173); for scoliosis 100 percent (Ref. 163); for spondylolisthesis 78 percent to 100 percent (Refs. 27, 37, 49, 96, 113, 125, and 173); and for multiple diagnoses 77 percent to 100 percent (Refs. 49, 95, 110, 183, 192, 200, and 202). A randomized prospective trial comparing pedicle screw fixation with noninstrumented fusion demonstrated a significant improvement in the rate of successful fusion when pedicle fixation was utilized (94 percent fusion rate with rigid pedicle screw instrumentation versus 65 percent without instrumentation) (Ref. 202).

Meta-analyses of the medical literature compared the treatment outcomes with pedicle screw fixation with three types of class II spinal fixation systems, i.e., posterior hook-rod devices, anterior instrumentation, and sublaminar wire-rod instrumentation. For thoracolumbar spine fractures, patients treated with pedicle screw fixation had a significantly higher rate of successful fusion (99.4 percent) than those treated with hook-rod fixation (96.9 percent) or anterior fixation (94.8 percent), $p < 0.05$ (Ref. 51). There were no significant differences in the fusion rates for patients with degenerative spondylolisthesis treated with pedicle screw fixation (93 percent) and those treated with hook-rod/sublaminar wire-rod fixation (96 percent) or anterior fixation (94 percent) (Ref. 119).

6. Pain

For the degenerative spondylolisthesis patients in the Cohort study, the rate of improvement in back pain was significantly greater in the pedicle group (91.5 percent) when compared to the noninstrumented group (84.0 percent), $p < 0.001$. In contrast, the

rate of back pain improvement was greater in the nonpedicle group (95.2 percent) than the pedicle group (90.1 percent) for the fracture patient group, $p < 0.023$. The rate of improvement in leg pain was significantly greater in those degenerative spondylolisthesis patients treated with pedicle screw fixation (91.5 percent) than those treated without instrumentation (88.2 percent), $p < 0.027$. There were comparable improvements in pain in patients treated with pedicle screw fixation (90.1 percent) and nonpedicle screw instrumented fusion (95.2 percent) for the fracture patient group (Refs. 66 and 201).

Clinical investigations performed under IDE protocols have demonstrated rates of improvement in pain ranging from 79.1 to 89.3 percent (mean = 85.7 percent) in the treatment of degenerative spondylolisthesis, 70.0 to 85.0 percent (mean = 74.1 percent) for fractures, 71.7 to 86.2 percent (mean = 78.2 percent) for degenerative disc disease, 44.2 percent for scoliosis, 72.4 to 81.6 percent (mean = 76.8 percent) for failed back syndrome, and 71.4 to 84.6 percent (mean = 82.6 percent) for spinal stenosis (Ref. 66).

The medical literature also documents successful outcomes for pain in patients treated with pedicle screw fixation with success rates ranging from 67 percent to 100 percent (Refs. 2, 19, 27, 37, 80, 86, 95, 97, 109, 110, and 147). A meta-analysis of these data showed that the 83.3 percent rate of improvement in pain for patients treated with pedicle screw instrumentation was comparable to the 83.3 percent rate for hook-rod instrumentation and the 77.0 percent rate for anterior instrumentation in the treatment of fractures (Ref. 51). Similarly, the rate of satisfactory clinical (pain and function) outcomes in patients treated for degenerative spondylolisthesis with pedicle screw instrumentation was 85.7 percent, which was comparable to those treated with nonpedicle screw instrumentation (89.6 percent) or noninstrumented fusions (89.6 percent) (Refs. 51 and 119).

7. Function

In the Cohort study, data on functional status was available from 2,132 patients in the pedicle screw group and 451 patients in the noninstrumented group for the treatment of degenerative spondylolisthesis, and from 569 patients in the pedicle screw group and 211 patients in the nonpedicle screw group for the treatment of fracture. In the degenerative spondylolisthesis group, there was a significantly greater incidence of functional improvement associated with the use of pedicle screw fixation (90.4 percent) compared to treatment without instrumentation (86.7 percent) ($p < 0.02$). In contrast, in the fracture group, there was a significantly lower incidence of functional improvement associated with the use of pedicle screw fixation (87.9 percent) compared to treatment with nonpedicle screw fixation (93.4 percent) ($p < 0.027$) (Refs. 66 and 201).

In the IDE clinical investigations, the rate of functional status improvement for degenerative spondylolisthesis treated with pedicle screw instrumentation was 79.1 to 86.8 percent (mean = 84.4 percent), fractures 75.0 to 85.7 percent (mean = 77.8 percent), degenerative disc disease 74.1 to 75.7 percent (mean = 75.4 percent), scoliosis 34.9 percent, failed back syndrome 69.3 to 73.6 percent (mean = 71.6 percent) and spinal stenosis 71.4 to 74.4 percent (mean = 73.9 percent) (Ref. 66).

In the medical literature, the rate of successful functional outcomes in the treatment of spinal stenosis was 78 percent (Ref. 173); isthmic spondylolisthesis 90.9 percent (Ref. 147); postsurgical failed back syndrome 80.2 percent (Ref. 173); degenerative disc disease 60 percent (Ref. 206); and low back pain 72 percent (Ref. 109). A meta-analysis of these data showed that the 82.0 percent rate of improvement in functional outcomes of patients treated with pedicle screw instrumentation was comparable to the 74.8 percent rate for hook-rod instrumentation and the 73.2 percent rate for anterior instrumentation in the treatment of fractures (Ref. 51).

8. Neurologic Status

In the Cohort study, in the degenerative spondylolisthesis group, the rate of improvement of spinal cord neurologic function was comparable for those treated with pedicle screw fixation (3.6 percent) and those treated with noninstrumented fusion (1.2 percent). For the fracture group, there were no significant differences in the rates of improvement of spinal cord neurological assessments between the pedicle screw (13.3 percent) and nonpedicle screw instrumentation (13.0 percent) groups ($p < 0.91$) (Refs. 66 and 201).

For the degenerative spondylolisthesis group, the rate of root status improvement by one grade or more was significantly greater in patients treated with pedicle screw fixation (36.8 percent) than in patients treated without instrumentation (29.2 percent), or with nonpedicle screw fixation (25.5 percent), $p < 0.002$. In the fracture group, the rates of improvement in root neurological assessments were comparable in the pedicle screw instrumented group (24.1 percent) and the nonpedicle screw instrumented group (18.2 percent) ($p < 0.08$) (Refs. 66 and 201).

In the IDE clinical investigations, there was improved neurological root status in 11.8 to 32.6 percent of patients (mean = 19.3 percent) with degenerative spondylolisthesis, in 7.5 to 30.7 percent of patients (mean = 17.6 percent) with degenerative disc disease, in 12.2 to 32.2 percent of patients (mean = 20.5 percent) with failed back syndrome, in 5.8 percent of patients with scoliosis, in 28.6 percent of patients with spinal stenosis, and in 14.3 percent of patients with fracture (Ref. 66).

Improvement in the neurological status of patients treated with pedicle screw fixation in the medical literature ranged from 18.8 percent to 100 percent, and was found to be comparable to that resulting from nonpedicle screw instrumented fusions and noninstrumented fusions (Refs. 39, 49, 55, 80, 107, 153, 154, and 164). Meta-analysis of the literature for the treatment of thoracolumbar fractures demonstrated a statistically higher rate of neurologic improvement in the anterior instrumentation (51.4 percent) and hook-rod instrumentation (40.7 percent) treatment groups compared to the pedicle screw instrumentation group (24.3 percent) ($p < 0.05$). However, the pedicle screw treatment group had a significantly greater proportion of neurologically intact (Frankel E) preoperative neurological profiles compared to all other treatment groups and, hence, no potential for neurological recovery (Ref. 51). There were no significant differences between treatment groups in the number of patients who were neurologically worse or who had neurological complications (Ref. 51).

9. Potential Effects on Bone Density

Experimental work has demonstrated decreased pedicle screw fixation strength in bone with decreased bone mineral density (Refs. 40 and 167), and care must be taken, therefore, in patients with osteoporosis (Ref. 170). Animal studies have demonstrated significant device-related decrease in bone density following arthrodesis with rigid spinal instrumentation (Ref. 123). However, rates of successful fusion increase with increased mechanical rigidity of the spinal fixation systems used to stabilize the spine. The significance of these findings in the clinical setting has not been resolved.

10. Potential Benefits of Pedicle Screw Spinal Systems

The number of motion segments in fracture patients that were required to be fused when using pedicle screw fixation has been reported to be half that required when using hook-rod and sublaminar wire-rod instrumentation (Refs. 77, 109, 154, and 203). This reduction in the number of spinal segments fused preserves motion at the adjacent motion segments, particularly at the important caudal levels of the spine. In these same publications, the authors reported that, when using pedicle screw spinal systems, the frequency of disc degeneration at levels adjacent to the fused segments was found to occur at rates comparable to those occurring in hook-rod and sublaminar wire-rod instrumentation systems.

The rigid, segmental, three-column fixation achieved with pedicle screw fixation allowed successful fixation of severely unstable spines in cases of tumor (Refs. 31, 77, 94, and 114), severe fracture-dislocation (Refs. 2, 4, 17, 35, 46, 53, 58, 59, 73, 107, 108, 128, 130, 140, 153, 154, 160, and 178), deformities (Ref. 25), pseudarthrosis (Ref. 104), severe spondylolisthesis (Refs. 27, 77, and 175), and instability following extensive laminectomy (Refs. 113 and 118). Two authors reported that posterior distraction achievable with pedicle screw instrumentation may allow greater fracture reduction and spinal canal decompression, and may improve neurological recovery (Refs. 70 and 203).

IV. FDA's Tentative Findings

FDA agrees with the Orthopedic and Rehabilitation Devices Panel's recommendation and is proposing that the pedicle screw spinal system intended for the treatment of degenerative spondylolisthesis, severe spondylolisthesis, and spinal trauma be classified into class II. FDA believes that there exists sufficient information to develop special controls which will provide reasonable assurance of the safety and effectiveness of these devices. FDA believes that appropriate special controls should include mechanical testing standards of performance, special labeling requirements, and postmarket surveillance. FDA also believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

The data demonstrate that the use of pedicle screw-based instrumentation in the treatment of degenerative spondylolisthesis and fractures results in significantly higher fusion rates, improved clinical outcomes, and comparable complication rates when compared with treatment with no instrumentation or with currently available preamendments class II spinal devices (see section III.B. of this document).

The data also demonstrate that the use of pedicle screw-based instrumentation in the treatment of severe spondylolisthesis results in equivalent or higher fusion rates, similar clinical outcomes, and comparable complication rates when compared with treatment with no instrumentation or with currently available preamendments class II spinal devices (Refs. 5, 6, 14, 27, 28, 29, 30, 48, 52, 68, 81, 82, 83, 84, 92, 93, 147, 155, 159, 168, 169, 175, and 188).

V. Summary of Data Upon Which FDA's Findings are Based

A. Clinical and Mechanical Data

FDA analyzed the medical literature pertaining to pedicle screw spinal systems and presented its findings at the July 22, 1994, advisory panel meeting (Ref. 66). The literature pertaining to the clinical performance of pedicle screw spinal systems is extensive and describes clinical indications for use, descriptions of surgical techniques, definitions of clinical endpoints and outcome variables used to evaluate safety and effectiveness, and descriptions of the types, and estimates of the frequencies, of device-related complications. The literature pertaining to the mechanical characteristics of pedicle screw-based spinal instrumentation is also extensive and provides considerable data on the device materials, strength, and other mechanical characteristics of the device (see section II.A.2. of this document).

Review of publicly released IDE clinical investigation data from annual reports (Ref. 65), as well as data released by the study sponsors (Ref. 66), provided FDA clinical data from controlled investigations on clinical and radiographic outcomes, fusion rates, and device-related complication rates.

Review of the MedWatch and Medical Device Reporting (MDR) data bases, FDA's device problem reporting systems, provided information regarding the types of device-related complications associated with the use of spinal instrumentation devices. The complications associated with pedicle screw spinal systems reported to FDA were comparable to those associated with the use of commercially available class II spinal fixation devices (Ref. 66).

The Cohort study data, submitted to the agency by the Scientific Committee and presented to the panel at the July 22, 1994, meeting, provided data from a large cohort of patients with spinal fusions (Refs. 66 and 201). FDA evaluated the Cohort study and identified a number of shortcomings in the study design. FDA found that the Cohort study design has weaknesses inherent in all retrospective studies, including concerns of possible selection bias; comparability of the treatment groups; differences in the diagnostic inclusion criteria; treatment differences, including differences in surgeon skill and experience, surgical procedures, devices, and postoperative care; differences in outcome measurement and reporting; and the degree of completeness of medical records (Ref. 66). In addition, FDA found that a significant number of cases did not complete the 2-year followup period required for IDE clinical trials and that several issues regarding the pooling of data were not addressed (Ref. 66). However, many of these weaknesses were anticipated in the planning phase of the study and steps were taken to minimize these potential problems.

FDA has determined that, despite its weaknesses, the Cohort study was conducted in a scientifically sound manner (Ref. 66). The investigation provided adequate numbers of cases, followup times, clinical performance data, and complication rate data to permit assessment of the safety and effectiveness of the device. In addition, FDA has determined that the data meet the criteria for valid scientific evidence found in 21 CFR 860.7(c)(2), that is, they are from partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. Under this regulation, the evidence may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use.

FDA recognizes that the design and intent of the Cohort study was to investigate two demanding clinical situations rather than merely two diagnostic groups. The investigation of this device for these two diagnostic entities constituted a ''worst case scenario.'' FDA has concluded that these entities represented the extremes

of acute and chronic instabilities and deformities. Therefore, FDA had strongly recommended that the study design be limited to degenerative spondylolisthesis and spinal fracture in order to produce a more meaningful investigation (Ref. 66). These entities were well-recognized and easily definable diagnoses with established radiographic findings, clinical symptomatology, surgical indications, and treatment outcomes. These two diagnoses were expected to yield homogeneous patient groups in terms of recognized prognostic variables. More importantly, these diagnostic groups were recognized to be mechanically demanding and clinically challenging situations that would rigorously test the device. The fracture group, which included fractures and fracture-dislocations, represented the extreme of spinal instability, and was often accompanied by neurologic deficit, deformity, pain, and severe functional loss. The degenerative spondylolisthesis group represented chronic instability with deformity from degenerative disease.

FDA believes that the following special controls, in combination with the general controls applicable under the act, would provide reasonable assurance of the safety and effectiveness of pedicle screw spinal systems:

(1) Compliance with materials standards, such as ASTM F136, F138, and F1314 (serve to control risks of implant breakage, particulate debris, and metal toxicity); (2) Compliance with mechanical testing standards, such as ASTM PS–5–94, (serves to control risks of implant breakage, loss of fixation, loss of alignment, and loss of reduction); (3) Compliance with biocompatibility testing standards, such as ''Tripartite Biocompatibility Guidance for Medical Devices'' (9/86) and International Standards Organization (ISO) 10993–1 (serve to control biocompatibility concerns, such as metal toxicity and long-term theoretical risks of carcinogenicity); and (4) Compliance with special labeling requirements (serve to control risks such as nerve root or spinal cord injury, dural tears, vascular injury, visceral injury, pedicle fracture, vertebral body penetration, pseudarthrosis, and loss of fixation and alignment, by adequately warning physicians of potential risks related to the use of the device). For example, the following labeling would be required:

Warning: The safety and effectiveness of pedicle screw spinal systems have not been determined for spinal conditions other than those with significant mechanical instability or deformity requiring fusion with instrumentation. These include significant mechanical instability secondary to spondylolisthesis, vertebral fractures and dislocations; scoliosis, kyphosis, spinal tumors, and pseudarthrosis resulting from previously unsuccessful fusion attempts.

Warning: Implantation of pedicle screw spinal systems is a technically demanding surgical procedure with a significant potential risk of serious injury to patients. This procedure should only be performed by surgeons with adequate training and experience in both the specific surgical technique and use of the specific products to be implanted.

(5) Conduction of postmarket surveillance (PMS) studies for pedicle screw spine systems as a mechanism to address issues related to device specific design differences, surgical techniques, and device usage. Because complications most frequently occur intraoperatively or early post-operatively, yet important common complications occur late post-operatively, a potential PMS study design might include the first 1000 subjects evaluated for intraoperative and early complications and the first 100 subjects evaluated for a minimum of 2 years for late complications.

The agency invites comments on special controls, including labeling statements, which are appropriate to mitigate the risks from use of these devices as they are proposed to be reclassified.

B. Indications for Use

Spinal instability is defined in terms of real or potential neural dysfunction as measured by the degree of structural damage to the vertebral column. Instability has also been defined in terms of fracture patterns or neurologic deficit (Refs. 17 and 58), or excessive sagittal plane translation on flexion-extension radiographs or spondylolisthesis (Ref. 19). Spinal deformities include structural deformities, such as scoliosis, kyphosis, lordosis, and severe spondylolisthesis.

Fusion of the thoracic, lumbar, and sacral spine is often necessary in the treatment of disorders that involve instability and deformity. Fusion provides permanent stabilization of the involved unstable motion segments and correction of structural deformities, and prevents the long-term sequelae of these disorders.

Clinically, all entities that require fusion, either to treat acute or chronic instability or to correct a spinal deformity, may be indications for the use of adjunctive spinal instrumentation. Spinal instrumentation, including anterior instrumentation systems and posterior hook-rod, sublaminar wire-rod, or pedicle screw-based instrumentation systems, is used as an adjunct to fusion by immobilizing and stabilizing the involved vertebral motion segments until fusion occurs. Successful fusion is dependent on the maintenance of spinal alignment and elimination of motion at the fusion site. Spinal instrumentation systems are simply contrivances that promote fusion by providing immobilization and stabilization between intervertebral motion segments.

Mechanically, the stabilization of the involved motion segments and maintenance of alignment are accomplished by all types of spinal instrumentation systems by attaching anchors to vertical supporting members (Ref. 13). The posterior hook-rod and posterior sublaminar wire-rod device systems provide mechanical stabilization of the vertebrae with longitudinal rods attached to the laminae or spinous processes via hooks or wires. The anterior plate-screw-cable fixation devices provide stabilization with longitudinal plates or cables attached to the vertebral bodies via screws placed anteriorly or laterally. Similarly, pedicle screw spinal systems provide stabilization of vertebrae with longitudinal plates or rods attached to the vertebral bodies via screws through the pedicles. Mechanical testing has demonstrated that the pedicle screw spinal systems has equivalent or superior mechanical characteristics, such as static and fatigue strength, when compared to asti class II posterior hook-rod and anterior plate-screw-cable spinal devices (see section III.A.2. of this document). In addition, the rigidity of the vertebrae instrumented with pedicle screw spinal systems is greater than when instrumented with the other device systems (see section III.A.2. of this document). In vivo studies have demonstrated that the strength of the fusion is directly related to the rigidity of the spinal instrumentation (Ref. 123). Clinical studies also have verified that the rate of successful fusion is related to the rigidity of the spinal instrumentation (Ref. 202).

FDA believes that the indications for use of asti devices, as described in 21 CFR 888.3050 and 888.3060, are comparable to the proposed indications for pedicle screw spinal systems. Currently, the class II asti posterior hook-rod, sublaminar wire-rod, sacral screw-rod, and iliac screw-rod fixation devices, ''Spinal interlaminal fixation orthoses,'' are used to ''straighten and immobilize the spine to allow bone grafts to unite and fuse the vertebrae together'' (21 CFR 888.3050). The intended use is ''primarily in the treatment of scoliosis (a lateral curvature of the spine), but it also may

be used in the treatment of fracture or dislocation of the spine, grades 3 and 4 of spondylolisthesis (a dislocation of the spinal column), and lower back syndrome.'' (An exclusion of lower back syndrome is addressed below). The class II asti anterior plate-screw-cable fixation devices, ''Spinal intervertebral body fixation orthosis,'' are ''used to apply a force to a series of vertebrae to correct 'sway back,' scoliosis (lateral curvature of the spine), or other conditions'' (21 CFR 888.3060).

Scoliosis is a three-plane spinal deformity, but should also be considered a growth abnormality and a chronic instability. The predominant feature in scoliosis is a lateral curvature of the thoracic and lumbar vertebrae in the coronal plane, but is also accompanied by sagittal plane and rotational deformities. Untreated severe scoliosis can cause severe cosmetic deformity,degenerative facet joint and intervertebral disc disease, paraplegia, right heart failure, and death, and can compromise pulmonary function.

Spinal fractures and dislocations result in loss of bony or ligamentous integrity that cause spinal instability. Untreated traumatic spinal instability may lead to progressive spinal deformity, nonunion, pain, progressive neurologic deficit, and traumatic spinal stenosis.

Spondylolisthesis, whether degenerative or severe, is generally regarded as a chronic instability caused by loss of the structural integrity of posterior element structures, such as the pars interarticularis, as well as the intervertebral disc. Spondylolisthesis results in a chronic, sometimes progressive, anterior subluxation of the superior vertebra over the inferior vertebra. This may be a result of congenital vertebral anomalies (e.g., deficiency of the facets), acquired defects (e.g., traumatic pars defects, pedicle or facet fractures), metabolic bone diseases (e.g., osteogenesis imperfecta, osteoporosis), or degenerative processes (e.g., degenerative disc disease). Spondylolisthesis may cause severe back and leg pain, postural deformity, gait abnormalities due to hamstring tightness, and progressive neurologic deficits.

FDA believes that, for the purposes of device classification, all of the above indications can be categorized as acute and chronic instabilities and deformities.

Lower back syndrome is an ill-defined disorder and is not considered to be included in the indications of acute and chronic instabilities and deformities. Sway back, an obsolete term for lordosis, is a congenital or developmental sagittal plane deformity. Although 21 CFR 888.3060 states that the asti device is also indicated for ''other conditions'' that were not specified, the ''other conditions'' involve instability or a deformity in which fusion is indicated. Both of these asti devices are used as adjuncts to spinal fusion, providing immobilization and stabilization of the spinal segments while fusion takes place. Except for this ill-defined ''lower back syndrome,'' all these indications constitute acute and chronic instabilities or deformities. The common purpose of the treatment of these clinical entities is to prevent the short-term and long-term sequelae of instability and deformity, such as progressive neurologic deficit, severe pain, severe cosmetic deformity, pulmonary and cardiovascular compromise, and even death.

Acute and chronic instabilities or deformities therefore include scoliosis, fractures, dislocations, and spondylolisthesis, but may also include spinal tumors, pseudarthrosis, as well as kyphotic deformities. An extensive laminectomy for spinal stenosis, foraminal stenosis, or other indications may cause iatrogenic spinal instability by removing critical stabilizing posterior element structures (Refs. 78 and 118). Benign and malignant tumors cause instability of the spine by compromising the structural integrity of the anterior, middle, or posterior columns of the spine (Refs. 31, 94, 114, 118, and 126). Segmental defects or loss of posterior elements following tumor resection require instrumentation and fusion to reestablish spinal stability and prevent neurologic injury. The pathogenesis of kyphosis deformities are fracture, inflammation, tumor, congenital malformation, and laminectomy (Refs. 25, 36, and 118). The goal of treatment is immediate and long-term stability, nerve and cord decompression, and correction of angulation. Pseudarthrosis, or failure to achieve a successful fusion, causes symptomatic instability at the motion segment (Refs. 104, 169, and 202).

FDA believes that sufficient clinical data exist to justify including other indications such as scoliosis, spinal tumors, and failed previous fusion attempts (pseudarthrosis) in the intended use of the pedicle screw spinal system. The medical literature and data from IDE clinical investigations demonstrate that the device can effectively stabilize the spine and adequately maintain spinal alignment while fusion takes place, and provide adequate evidence that the device can safely and effectively treat these conditions (Ref. 66). FDA believes that the risks associated with the use of pedicle screw spinal systems intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of these acute and chronic instabilities and deformities are similar to those of the commercially available device systems (21 CFR 888.3050 and 888.3060) and that these rates are clinically acceptable (Ref. 66). FDA believes that the clinical data from the IDE clinical investigations and the medical literature adequately support the safety and effectiveness of pedicle screw spinal systems for these additional indications (Ref. 66). Moreover, FDA recognizes that these indications for use are similar to those of commercially available class II spinal fixation devices, such as the spinal interlaminal fixation orthosis classified under 21 CFR 888.3050 and the spinal intervertebral body fixation orthosis classified under 21 CFR 888.3060.

FDA believes the medical literature is also supportive of the use of pedicle screw spinal systems in the treatment of acute and chronic instabilities and deformities. As described above in section III.B. of this document, the rates of clinical complications related to the use of pedicle screw spinal systems in the treatment of acute and chronic instabilities and deformities are comparable to those for existing class II devices in terms of mechanical failures (Refs. 3, 5, 19, 22, 24, 32, 35, 37, 43, 47, 50, 51, 58, 59, 60, 73, 77, 79, 87, 89, 90, 94, 95, 107, 109, 110, 113, 116, 122, 125, 150, 151, 152, 162, 163, 164, 173, 183, 185, 186, 187, 191, 192, 193, and 205), soft tissue injuries (Refs. 25, 26, 27, 37, 46, 47, 49, 60, 74, 106, 112, 113, 126, 127, 147, 153, 183, 185, 187, 191, and 192), pseudarthrosis (Refs. 3, 17, 22, 24, 25, 32, 34, 35, 36, 37, 47, 50, 80, 96, 125, 126, 153, 154, 169, 173, 174, 194, and 205), and reoperation rates (Refs. 50, 51, 60, 74, 86, 119, and 173). The clinical performance is also comparable to existing spinal devices in terms of fusion rates (Refs. 1, 22, 27, 37, 49, 55, 66, 80, 86, 95, 96, 109, 110, 113, 125, 163, 169, 173, 183, 185, 186, 187, 192, 200, 201, and 202), rates of successful pain (Refs. 2, 18, 25, 27, 37, 80, 86, 95, 97, 109, 110, and 147), function (Refs. 51, 109, 119, 147, 173, and 206), and neurological outcomes (Refs. 39, 49, 55, 80, 90, 107, 153, 154, and 164).

FDA also recognizes the unique benefits of pedicle screw spinal systems compared to existing spinal instrumentation systems in the treatment of certain conditions involving severe instability or deformity. The rigid, segmental, three-column fixation achieved with pedicle

screw instrumentation allows successful fixation of severely unstable spines in cases of tumor (Refs. 31, 77, 94, and 114), severe fracture-dislocation (Refs. 2, 4, 17, 35, 46, 53, 58, 59, 73, 107, 108, 128, 130, 140, 153, 154, 160, and 178), and severe spondylolisthesis (Refs. 5, 27, 77, 81, 82, 83, 147, 169, and 175). In addition, the pedicle screw spinal systems provide the only means of posterior attachment of instrumentation in cases of iatrogenic instability in which the absence of the posterior elements precludes the use of existing posterior instrumentation systems, which require laminae or spinous processes for attachment to the spine (Refs. 113 and 118).

FDA did not find sufficient literature or other clinical data to support use of the device in the treatment of low back pain. FDA has determined that low back pain and other conditions not categorized as an acute or chronic instability or deformity should not be included in the indications for use unless further data justify their inclusion. Thus, if the device has such indications for use, the device is a class III device.

C. Associated Risks

The risks associated with the use of pedicle screw spinal systems include implant breakage, loss of fixation, nerve root or spinal cord injury, dural tears, vascular injury, visceral injury, pedicle fracture, vertebral body penetration, pseudarthrosis, loss of alignment or reduction, and symptomatic hardware requiring removal. FDA has determined that these risks are comparable to those associated with the use of the existing class II spinal fixation devices described in §§ 888.3050 888.3060. FDA agrees with the panel that the risks to health associated with the use of the device are reasonably well understood and can be adequately controlled through the application of special controls.

VI. References

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VII. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (e)(2) 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 is required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this proposal would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from the requirements of premarket approval, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

IX. Comments

Interested persons may, on or before January 2, 1996 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 name of the device and 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.

List of Subject in 21 CFR Part 888

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 888 be amended as follows:

PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 888.3070 is added to subpart D to read as follows:

§ 888.3070 Pedicle screw spinal system.

(a) *Identification.* A pedicle screw spinal system is a multiple component device, made of alloys such as 316L stainless steel, 316LVM stainless steel, 22Cr-13Ni-5Mn stainless steel, unalloyed titanium, and Ti-6Al-4V, that allows the surgeon to build an implant system to fit the patient's anatomical and physiological requirements. Such a spinal implant assembly consists of anchors (e.g., bolts, hooks, and screws); interconnection mechanisms incorporating nuts, screws, sleeves, or bolts; longitudinal members (e.g., plates, rods, and plate/rod combinations); and transverse connectors. The device is intended to provide immobilization and stabilization of spinal segments in the treatment of significant medical instability or deformity requiring fusion with instrumentation including significant medical instability secondary to spondylolisthesis, vertebral fractures, and dislocations, scoliosis, kyphosis, spinal tumors, and pseudarthrosis resulting from unsuccessful fusion attempts.

(b) *Classification.* Class II (special controls).

Dated: September 29, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95–24686 Filed 9–29–95; 3:31 pm]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 110–95]

Exemption of Records System Under the Privacy Act

AGENCY: Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Department of Justice, Bureau of Prisons (Bureau), proposes to exempt a Privacy Act system of records from the following subsections of the Privacy Act: (c) (3) and (4), (d), (e)(1), (e)(2), (e)(3), (e) (5) and (8), and (g). This system of records is the ''Access Control Entry/Exit System (JUSTICE/BOP–010).''

The exemptions are necessary to preclude the compromise of institution security, to ensure the safety of inmates, Bureau personnel and the public, to protect third party privacy, to protect law enforcement and investigatory information, and/or to otherwise ensure the effective performance of the Bureau's law enforcement functions.

DATES: Submit any comments by November 3, 1995.

ADDRESSES: Address all comments to Patricia E. Neely, Program Analyst, Systems Policy Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 850, WCTR Building).

FOR FURTHER INFORMATION CONTACT: Patricia E. Neely, Program Analyst, Systems Policy Staff, Justice Management Division, (202) 616–0178.

SUPPLEMENTARY INFORMATION: In the notice section of today's Federal

Register, the Bureau provides a description of the ''Access Control Entry/Exit System, JUSTICE/BOP–010.''

This Order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, this order will not have a significant economic impact on a substantial number of small entities.

List of Subjects in Part 16

Administrative practices and procedure, Freedom of Information Act, Government in the Sunshine Act, and Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793–78, it is proposed to amend 28 CFR part 16 as set forth below.

Dated: September 22, 1995.

Stephen R. Colgate,

Assistant Attorney General for Administration.

1. The authority for Part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552b(g) and 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717 and 9701.

2. It is proposed to amend 28 CFR 16.97 by redesignating paragraph (c) as paragraph (i), by revising the first sentence of newly-redesignated paragraph (i), and by adding paragraphs (c) and (d) to read as follows:

§ 16.97 Exemption of Federal Bureau of Prisons Systems-limited access.

* * * * *

(c) The following system of records is exempted pursuant to 5 U.S.C. 552a(j)(2) from subsections (c) (3) and (4), (d), (e)(1), (e)(2), (e)(3), (e)(5) and (8), and (g). In addition, the following system of records is exempted pursuant to 5 U.S.C. 552a(k)(2) from subsections (c)(3), (d), and (e)(1):

Bureau of Prisons Access Control Entry/Exit, (JUSTICE/BOP–010).

(d) These exemptions apply only to the extent that information in these systems is subject to exemption pursuant to 5 U.S.C. 552a (j)(2) or (k)(2). Where compliance would not appear to interfere with or adversely affect the law enforcement process, and/or where it may be appropriate to permit individuals to contest the accuracy of the information collected, e.g. public source materials, or those supplied by third parties, the applicable exemption may be waived, either partially or totally, by the Bureau. Exemptions from the particular subsections are justified for the following reasons:

(1) From subsection (c)(3) for similar reasons as those enumerated in paragraph (3).

(2) From subsection (c)(4) to the extent that exemption from subsection (d) will make notification of corrections or notations of disputes inapplicable.

(3) From the access provisions of subsection (d) to the extent that exemption from this subsection may appear to be necessary to prevent access by record subjects to information that may jeopardize the legitimate correctional interests of safety, security, and good order of Bureau of Prisons facilities; to protect the privacy of third parties; and to protect access to relevant information received from third parties, such as other Federal State, local and foreign law enforcement agencies, Federal and State probation and judicial offices, the disclosure of which may permit a record subject to evade apprehension, prosecution, etc.; and/or to otherwise protect investigatory or law enforcement information, whether received from other third parties, or whether developed internally by the Bureau.

(4) From the amendment provisions of subsection (d) because amendment of the records would interfere with law enforcement operations and impose an impossible administrative burden. In addition to efforts to ensure accuracy so as to withstand possible judicial scrutiny, it would require that law enforcement and investigatory information be continuously reexamined, even where the information may have been collected from the record subject. Also, where records are provided by other Federal criminal justice agencies or other State, local and foreign jurisdictions, it may be administratively impossible to ensure compliance with this provision.

(5) From subsection (e)(1) to the extent that the Bureau may collect information that may be relevant to the law enforcement operations of other agencies. In the interests of overall, effective law enforcement, such information should be retained and made available to those agencies with relevant responsibilities.

(6) From subsection (e)(2) because primary collection of information directly from the record subject is often highly impractical, inappropriate and could result in inaccurate information.

(7) From subsection (e)(3) because compliance with this subsection may impede the collection of information that may be valuable to law enforcement interests.

(8) From subsection (e)(5) because in the collection and maintenance of information for law enforcement purposes, it is impossible to determine in advance what information is accurate, relevant, timely and complete. Data which may seem unrelated, irrelevant or incomplete when collected may take on added meaning or significance as an investigation progresses or with the passage of time, and could be relevant to future law enforcement decisions.

(9) From subsection (e)(8) because the nature of Bureau of Prisons law enforcement activities renders notice of compliance with compulsory legal process impractical and could seriously jeopardize institution security and personal safety and/or impede overall law enforcement efforts.

(10) From subsection (g) to the extent that the system is exempted from subsection (d).

* * * * *

(i) Consistent with the legislative purpose of the Privacy Act of 1974 (Pub. L. 93–579) the Bureau of Prisons has initiated a procedure whereby federal inmates in custody may gain access and review their individual prison files maintained at the institution of incarceration. * * *

[FR Doc. 95–24613 Filed 10–3–95; 8:45 am]

BILLING CODE 4410–05–M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AB94 and 1010–AC00

Revision of Valuation Regulations Governing Oil and Gas Transportation and Processing Allowances, and Coal Washing and Transportation Allowances

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule; notice of extension of public comment period.

SUMMARY: The Minerals Management Service (MMS) gives notice that it is extending the public comment period on two Proposed Rulemakings, which were published in the Federal Register on August 7, 1995, (60 FR 40127, 40120). The proposed rules would revise the valuation regulations governing oil and gas transportation and processing allowances, and revise the valuation regulations governing coal washing and transportation allowances. MMS will extend the comment period

for both rules from October 6 to October 20, 1995.

DATES: Comments must be received by 4 p.m. mountain time on October 20, 1995.

ADDRESSES: Written comments should be sent to the Minerals Management Service, Building 85, Denver Federal Center, P.O. Box 25165, Mail Stop 3101, Denver, Colorado, 80225–0165, Attention: David S. Guzy.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Procedures Staff, telephone (303) 231–3432, fax (303) 231–3194.

Dated: September 28, 1995.

James W. Shaw,

Associate Director for Royalty Management.

[FR Doc. 95–24671 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–MR–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NC–76–1–7141b; FRL–5291–4]

Approval and Promulgation of Implementation Plans North Carolina: Approval of Revisions to the State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On March 23, 1995, the State of North Carolina, through the North Carolina Department of Environment, Health and Natural Resources, submitted revisions to the North Carolina State Implementation Plan (SIP). These revisions are the adoption of amendments to rules 15A NCAC 2D .0501 Compliance With Emission Control Standards, .0516 Sulfur Dioxide Emissions From Combustion Sources, and .0530 Prevention Of Significant Deterioration. These revisions were the subject of public hearings held on March 28 and 30, 1994. In the final rules section of this Federal Register, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the EPA views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: To be considered, comments must be received by November 3, 1995.

ADDRESSES: Written comments on this action should be addressed to Mr. Scott M. Martin at the EPA Regional Office listed.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 443, 401 M Street, SW., Washington DC 20460.

Environmental Protection Agency, Region 4 Air Programs Branch, 345 Courtland Street, NE., Atlanta, Georgia 30365.

North Carolina Department of Environmental, Health, and Natural Resources, Division of Environmental Management, Raleigh, North Carolina 27626–0535.

FOR FURTHER INFORMATION CONTACT: Mr. Scott M. Martin, Regulatory Planning and Development Section, Air Programs Branch, Air, Pesticides, and Toxics Management Division, Region 4 Environmental Protection Agency, 345 Courtland Street, Atlanta, Georgia 30365. The telephone number is 404/347–3555, extension 4216.

SUPPLEMENTARY INFORMATION: For additional information see the direct final rule which is published in the rules section of this Federal Register.

Dated: August 11, 1995.

Patrick M. Tobin,

Acting Regional Administrator,

[FR Doc. 95–23820 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–F

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48 CFR Parts 1510, 1532, 1552 and 1553

[FRL–5310–7]

Acquisition Regulation; Monthly Progress Reports and Submission of Invoices

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to amend the EPA Acquisition Regulation (EPAAR) to revise contract clauses for monthly progress reports, submission of invoices, and other related information.

DATES: Comments should be submitted by December 4, 1995.

ADDRESSES: Environmental Protection Agency, Office of Acquisition Management (3802F), 401 M Street SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Larry Wyborski, Telephone: (202) 260–6482.

SUPPLEMENTARY INFORMATION:

I. Background Information

As a result of an internal assessment of EPA's invoice review process for contracts, the Agency is proposing changes to certain EPAAR clauses and related information. This includes requesting more detailed cost information from contractors in a number of areas, including charges by subcontractors. These changes will enhance EPA's ability to determine whether contract costs are allowable for payment purposes.

II. Executive Order 12866

This is not a significant regulatory action under Executive Order 12866; therefore, no review is required at the Office of Information and Regulatory Affairs within OMB.

III. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection and recordkeeping requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. An OMB control number 2030–0005 has been assigned.

This rule is not estimated to change the annual burden of information collection and recordkeeping requirements, which is estimated to be 43 hours per response.

IV. Regulatory Flexibility Act

This rule is not expected to have a significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 et. seq. Under invoicing procedures, contractors submit payment requests to the Government based on known costs incurred. Compliance with this requirement will involve minimal cost or effort for any entity, large or small.

V. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) P.L. 104–4, establishes requirements for Federal

agencies to assess their regulatory actions on State, local, and tribal governments and the private sector.

EPA has determined that this rule does not contain a Federal mandate that may result in expenditures of $100 million of more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. Private sector costs for this action relate to paperwork requirements and associated man hour expenditures that are far below the level established for UMRA applicability. Thus, the proposed rule is not subject to the requirements of sections 202 and 205 of the UMRA.

List of Subjects in 48 CFR Parts 1510, 1532, 1552 and 1553

Government procurement.

For the reasons set forth in the preamble, Chapter 15 of Title 48 Code of Federal Regulations 1510, 1532, 1552 and 1553 is proposed to be amended as follows:

1. The authority citation for 48 CFR Parts 1510, 1532, 1552 and 1553 continues to read as follows:

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

1510.011–71 [Removed and reserved]

2. Section 1510.011–71 is removed and reserved.

3. Section 1510.011–72 is revised to read as follows:

1510.011–72 Monthly progress report.

Contracting Officers shall insert a contract clause substantially the same as the clause at 1552.210–72 when monthly progress reports are required.

1510.011–73 [Removed and reserved]

4. Section 1510.011–73 is removed and reserved.

1510.011–74 [Removed and reserved]

5. Section 1510.011–74 is removed and reserved.

6. Section 1532.170 is amended by revising paragraph (b) to read as follows:

1532.170 Forms.

(a) * * *

(b) EPA Form 1900–68, Notice of Contract Costs Suspended and/or Disallowed, at 1553.232–75, shall be inserted in all cost-reimbursement type and fixed-rate type contracts.

* * * * *

7. Section 1532.908 is revised to read as follows:

1532.908 Contract clauses.

The Contracting Officer shall insert a clause substantially the same as that at 1552.232–70 in all solicitations and contracts for cost reimbursable acquisitions. If a fixed-rate type contract is contemplated, the Contracting Officer shall use the clause with its Alternate I.

1552.210–71 [Removed and reserved]

8. Section 1552.210–71 is removed and reserved.

9. Section 1552.210–72 is revised to read as follows:

1552.210–72 Monthly progress report.

As prescribed in 1510.011–72, insert the following clause:

MONTHLY PROGRESS REPORT (XXX 1995)

(a) The contractor shall furnish _____ copies of the combined monthly technical and financial progress report stating the progress made, including the percentage of the project completed, a description of the work accomplished to support the cost, and a schedule of deliverables for the reporting period. If the work is ordered using work assignments or delivery orders, include the percentage of work ordered and completed during the reporting period for each work assignment or delivery order.

(b) Specific discussions shall include difficulties encountered and remedial action taken during the reporting period and anticipated activity with a schedule of deliverables for the subsequent reporting period.

(c) The contractor shall provide a list of outstanding actions awaiting Contracting Officer authorization, noted with the corresponding work assignment, such as subcontractor/consultant consents, overtime approvals, and work plan approvals.

(d) The report shall specify financial status at the contract level as follows:

(1) For the current reporting period, display the amount claimed.

(2) For the cumulative period and the cumulative contract life display: The amount obligated, amount originally invoiced, amount paid, amount suspended, amount disallowed, and remaining approved amount. The remaining approved amount is defined as the total obligated amount, less the total amount originally invoiced, plus total amount disallowed.

(3) Labor hours.

(i) A list of employees, their labor categories, and the numbers of hours worked for the reporting period.

(ii) For the current reporting period, display the expended direct labor hours and costs broken out by EPA contract labor hour category for the prime contractor and each subcontractor and consultant.

(iii) For the cumulative contract period and the cumulative contract life display: the negotiated, expended and remaining direct labor hours and costs broken out by EPA contract labor hour category for the prime contractor and each subcontractor and consultant.

(iv) Display the estimated direct labor hours and costs to be expended during the next reporting period.

(4) Display the current dollar ceilings in the contract, net amount invoiced, and remaining amounts for the following categories: Direct labor hours, total estimated cost, award fee pool (if applicable), subcontracts by individual subcontractor, travel, program management, and Other Direct Costs (ODCs).

(5) Unbilled allowable costs. Display the total costs incurred but unbilled for the current reporting period and cumulative for the contract.

(6) Average cost of direct labor. Compare the actual average cost per hour to date with the negotiated contract average for the current contract period.

(e) The report shall specify financial status at the work assignment or delivery order level as follows:

(1) For the current period, display the amount claimed.

(2) For the cumulative period display: amount shown on workplan, or latest work assignment/delivery order amendment amount (whichever is later); amount currently claimed; amount paid; amount suspended; amount disallowed; and remaining approved amount. The remaining approved amount is defined as: the workplan amount or latest work assignment or delivery order amount (whichever is later), less total amounts originally invoiced, plus total amount disallowed.

(3) Labor hours. (i) A list of employees, their labor categories, and the number of hours worked for the reporting period.

(ii) For the current reporting period, display the expended direct labor hours and costs broken out by EPA contract labor hour category for the prime contractor and each subcontractor and consultant.

(iii) For the current reporting period, cumulative contract period, and the cumulative contract life display: the negotiated, expended and remaining direct labor hours and costs broken out by EPA contract labor hour category for the prime contractor and each subcontractor and consultant.

(iv) Display the estimated direct labor hours and costs to be expended during the next reporting period.

(v) Display the estimates of remaining Level of Effort and costs required to complete the work assignment or delivery order.

(4) Unbilled allowable costs. Display the total costs incurred but unbilled for the current reporting period and cumulative for the work assignment.

(5) Average cost of direct labor. Display the actual average cost per hour with the cost per hour estimated in the workplan.

(f) This submission does not change the notification requirements of the ''Limitation of Cost'' or ''Limitation of Funds'' clauses requiring separate written notice to the Contracting Officer.

(g) The reports shall be submitted to the following addresses on or before the _____ of each month following the first complete reporting period of the contract. See EPAAR 1552.232–70, Submission of Invoices, paragraph (e), for details on the timing of submittals. Distribute reports as follows:

No. of copies	Addressee
_____	Project Officer.
_____	Contracting Officer.

10. Section 1552.210–73 is removed and reserved.

11. Section 1552.210–74 is removed and reserved.

12. Section 1552.232–70 is revised to read as follows:

1552.232–70 Submission of Invoices.

As prescribed in 1532.908, insert the following clause:

SUBMISSION OF INVOICES (XXX 1995)

In order to be considered properly submitted, an invoice or request for contract financing payment must meet the following contract requirements in addition to the requirements of FAR 32.905:

(a) Unless otherwise specified in the contract, an invoice or request for contract financing payment shall be submitted as an original and five copies. The contractor shall submit the invoice or request for contract financing payment to the following offices/individuals designated in the contract: the original and two copies to the Accounting Operations Office shown in Block _____ on the cover of the contract; two copies to the Project Officer (the Project Officer may direct one of these copies to a separate address); and one copy to the Contracting Officer.

(b) The contractor shall prepare its invoice or request for contract financing payment on the prescribed Government forms. Standard Forms Number 1034, Public Voucher for Purchases and Services other than Personal, shall be used by contractors to show the amount claimed for reimbursement. Standard Form 1035, Public Voucher for Purchases and Services other than Personal—Continuation Sheet, shall be used to furnish the necessary supporting detail or additional information required by the Contracting Officer. The contractor may submit self-designed forms which contain the required information.

(c)(1) The contractor shall prepare a contract level invoice or request for contract financing payment in accordance with the invoice preparation instructions identified as a separate attachment in Section J of the contract. If contract work is authorized by individual work assignments, the invoice or request for contract financing payment shall also include a summary of the current and cumulative amounts claimed by cost element for each work assignment and for the contract total, as well as detailed supporting data for each work assignment as identified in the instructions.

(2) The invoice or request for contract financing payment shall include current and cumulative charges by major cost element such as direct labor, overhead, travel, equipment, and other direct costs. For current costs, each major cost element shall include the appropriate supporting schedule identified in the invoice preparation instructions. Cumulative charges represent the net sum of current charges by cost element for the contract period.

(3) The charges for subcontracts shall be further detailed in a supporting schedule showing the major cost elements for each subcontract. The degree of detail for any subcontract exceeding $5,000 is to be the same as that set forth under (c)(2).

(4) The charges for consultants shall be further detailed in the supporting schedule showing the major cost elements of each consultant. For current costs, each major cost element of the consulting agreement shall also include the supporting schedule identified in the invoice preparation instructions.

(d) Invoices or requests for contract financing payment must clearly indicate the period of performance for which payment is requested. Separate invoices or requests for contract financing payment are required for charges applicable to the basic contract and each option period.

(e) Notwithstanding the provisions of the clause of this contract at FAR 52.216–7, Allowable Cost and Payment, invoices or requests for contract financing payment shall be submitted once per month unless there has been a demonstrated need and Contracting Officer approval for more frequent billings. When submitted on a monthly basis, the period covered by invoices or requests for contractor financing payments shall be the same as the period for monthly progress reports required under this contract. If the Contracting Officer allows submissions more frequently than monthly, one submittal each month shall have the same ending period of performance as the monthly progress report. Where cumulative amounts on the monthly progress report differ from the aggregate amounts claimed in the invoice(s) or request(s) for contract financing payments covering the same period, the contractor shall provide a reconciliation of the difference as part of the payment request.

Alternate I (XXX 1995)

If used in a fixed-rate type contract, substitute the following paragraphs (c) (1) and (2) for paragraphs (c) (1) and (2) of the basic clause:

(c) (1) The contractor shall prepare a contract level invoice or request for contract financing payment in accordance with the invoice preparation instructions identified as a separate attachment in Section J of the contract. If contract work is authorized by individual delivery orders, the invoice or request for contract financing payment shall also include a summary of the current and cumulative amounts claimed by cost element for each delivery order and for the contract total, as well as detailed supporting data for each delivery order as identified in the instructions.

(2) The invoice or request for contract financing payment that employs a fixed rate feature shall include current and cumulative charges by contract labor category and by other major cost elements such as travel, equipment, and other direct costs. For current costs, each cost element shall include the appropriate supporting schedules identified in the invoice preparation instructions.

* * * * *

13. Section 1553.232–75 is revised to read as follows:

1553.232–75 EPA Form 1900–68, Notice of Contract Costs Suspended and/or Disallowed.

As prescribed in 1532.170(b), the Contracting Officer shall insert EPA Form 1900–68 in all cost-reimbursement type contracts.

1553.232–76 [Removed and reserved]

14. Section 1553.232–76 is removed and reserved.

Dated: September 25, 1995.

Betty L. Bailey,

Director, Office of Acquisition.

Note: The following appendix will not appear in the Code of Federal Regulations.

Appendix—Notice of Contract Costs Suspended or Disallowed

BILLING CODE 6560–50–P

United States Environmental Protection Agency
Washington, DC 20460

NOTICE OF CONTRACT COSTS SUSPENDED AND/OR DISALLOWED

PAGE ___ OF ___ PAGES

TO: *(Name and Address of Contractor)*	Contract Number	Date
	Delivery Order Number *(If Applicable)*	Voucher Number Reference

1. SUSPENDED COSTS, as referred to herein, are costs which, for the reasons stated below, have been determined by the undersigned to be inadequately supported or otherwise questionable, and not appropriate for reimbursement under the contract terms at this time. Such costs may be determined reimbursable after the contractor provides the Contracting Officer and/or Project Officer additional documentation or explanation as specified below.
2. DISALLOWED COSTS, as referred to herein, are costs which, for the reasons stated below, have been determined by the undersigned to be unallowable, that is, not reimbursable under the contract terms.
3. This notice must be responded to by the contractor within 60 days of issuance. Any suspended costs will become disallowed if the contractor does not respond in the time allotted. These disallowed costs should be removed from the contractor's accounting records for this contract.
4. The contractor may not rebill any suspended costs on this form until notified by the Contracting Officer and/or Project Officer on this contract that the suspension has been lifted.
5. If the contractor disagrees with this/these determinations, the contractor may (1) request in writing the cognizant contracting officer to consider whether the unreimbursed costs should be paid and to discuss their findings with the contractor and/or (2) file a claim under the "Disputes" clause of the contract.
6. Copies of this Form 1900-68 should be distributed to the Contracting Officer, Project Officer, RTP Finance, and the applicable Cost Advisory Office.

A. COST SUSPENSION

		Date of Notice	Invoice Number
Contracting Officer and/or Project Officer	Name and Title of Authorized Official		Signature

ITEM	Description of Items and Reason for Action. Documentation needed in order to rebill suspended costs.	Amount of Costs

B. REMOVAL OF SUSPENSION

		Date of Notice	Invoice Number
Contracting Officer and/or Project Officer	Name and Title of Authorized Official		Signature

ITEM	Description of Items and Reason for Action.	Amount of Costs

C. DISALLOWANCE OF COSTS

		Date of Notice	Invoice Number
Contracting Officer	Name and Title of Authorized Official		Signature

ITEM	Description of Items and Reason for Action.	Amount of Costs

CONTRACTOR'S ACKNOWLEDGMENT OF RECEIPT - The contractor or its authorized representative shall acknowledge receipt of this notice to the Project Officer and/or Contracting Officer.

Date of Notice	Name and Title of Authorized Official	Signature

EPA Form 1900-68 (Rev. 05-95)

BILLING CODE 6560–50–C

Instructions for EPA Form 1900–68

When a PO or CO identifies costs in a voucher that are to be suspended or disallowed, the Form 1900–68 is used to identify those costs, the associated reasons and to communicate the action to all necessary parties. Examples of costs that a PO might suspend without CO involvement are: math errors, incorrect rates, and a lack of available funding. Examples of costs that CO involvement would be necessary to suspend or disallow costs include lack of authorization to incur costs, unnecessary costs incurred, and excessive costs. Section A, Cost Suspension, may be filled out by either the CO or PO. The PO and/or CO must fill out the Form 1900–68 explaining the suspended amount, sign and date the Form and send it to the contractor. The contractor must fill out the acknowledgement of receipt on the applicable area on Form 1900–68 and return a copy of it to either the PO or CO who made the suspension. A copy of the Form 1900–68 would go to RTP Finance with the Approval Forms package. Copies of the Form 1900–68 would be filed by PO and/or CO and a copy sent to the applicable Cost Advisory Office for use in interim and final audits.

The Form 1900–68 states that the contractor has 60 days to respond to the suspension, or the costs will be considered disallowed and those costs should be transferred to an unallowable account in the contractor's accounting records. If the contractor wishes to respond to the suspension, it must as a minimum furnish documentation specified on the Form 1900–68 for the costs to be considered allowable. The contractor will then resubmit this documentation to the PO and CO for review. Either the CO or PO who originally suspended the costs will consider the documentation and, if it is adequate, they will fill out a revised Form 1900–68 Block B. (Removal of Suspension) for some or all of the costs suspended. Copies of this revised Form 1900–68 would go to the contractor, CO and PO, RTP, FMC, and Cost Advisory Office.

The contractor may rebill suspended costs after receiving the Removal of Suspension using a separate invoice and attach the Form 1900–68 Removal of Suspension notice to the invoice. The contractor must then resubmit this bill for payment in accordance with contract invoicing requirements.

If the contractor prepares supporting documentation for suspended costs that the PO deems unacceptable, the PO will notify the CO of this and ask for a final determination on the allowability of the costs. If the CO agrees with the PO, a revised Form 1900–68 with Block C (Disallowance of Costs) should be completed and sent to the contractor instructing the contractor to eliminate such costs on future invoices and to move such costs to unallowable accounts on their accounting records. The contractor must acknowledge receipt of the disallowance notice by signing and returning the notice to the CO. Where the CO processed the suspension, the CO will inform the PO and disallow the cost. Copies of the revised Form 1900–68 should be sent to RTP Finance, the contract file, and the applicable Cost Advisory Office.

[FR Doc. 95–24455 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 222 and 227

[Docket No. 950919232–5232–01; I.D. 041995B]

RIN 0648–XX27

Threatened Fish and Wildlife; Change in Listing Status of Steller Sea Lions Under the Endangered Species Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS is proposing to reclassify the Steller sea lion, *Eumetopias jubatus.* This species currently is listed under the Endangered Species Act of 1973 (ESA) as threatened throughout its range, which extends from California and associated waters to Alaska, including the Gulf of Alaska and Aleutian Islands, and then into the Bering Sea and North Pacific and into Russian waters and territory.

Based on biological information collected since the species was listed as threatened in 1990, NMFS now proposes to re-classify Steller sea lions as two distinct population segments under the ESA. NMFS proposes to classify the Steller sea lion population segment west of 144° W. long. (a line near Cape Suckling, AK) as endangered, and to maintain the ESA threatened listing for the remainder of the U.S. population. NMFS is requesting public comments on this proposed action.

DATES: Comments and information must be received by January 2, 1996.

ADDRESSES: Comments and information should be addressed to Chief, Marine Mammal Division, Office of Protected Resources (F/PR), NMFS, 1315 East-West Highway, Silver Spring, MD 20910. Copies of the Steller sea lion status review document, the Steller Sea Lion Recovery Team (Recovery Team) meeting summary and recommendations regarding reclassification, and a Population Viability Analyses of Steller sea lions in Alaska may be obtained from Susan Mello, Protected Resources Management Division, Alaska Regional Office, NMFS, P.O.Box 21668, Juneau, AK 99802–1668.

FOR FURTHER INFORMATION CONTACT: Susan Mello, 907–586–7235 or Michael Payne, F/PR, NMFS, 301–713–2322.

SUPPLEMENTARY INFORMATION:

I. Background

NMFS determined that the Steller sea lion was a threatened species under the ESA (55 FR 49294, November 26, 1990; see also, 55 FR 50005, December 4, 1990). The species was listed throughout its range because of a precipitous decline in abundance. This decline was concentrated primarily in areas near the Gulf of Alaska and Aleutian Islands.

The final rule imposed protective regulations to reduce direct causes of Steller sea lion mortality, to restrict opportunities for intentional and unintentional harassment of Steller sea lions, and to minimize disturbance and interference with Steller sea lion behavior including disruption of foraging behavior, especially at pupping and breeding sites.

As a result of ESA section 7 consultations on the effects of the North Pacific federally-managed groundfish fisheries, NMFS implemented additional protective measures in 1991, 1992, and 1993 to reduce the effects of certain commercial groundfish fisheries on Steller sea lion foraging (see 56 FR 28112, June 19, 1991; 57 FR 2683, January 23, 1992; and 58 FR 13561, March 12, 1993; current protections are codified at 50 CFR 672.24(e) and 675.24(f) (1994)). NMFS has also published a Steller Sea Lion Recovery Plan (Recovery Plan) (58 FR 3008, January 7, 1993), and has designated critical habitat for the species (58 FR 45269, August 27, 1993). NMFS and other agencies are implementing the Recovery Plan.

Since 1990, NMFS and the Alaska Department of Fish and Game (ADFG) have conducted monitoring surveys that indicate that the decline of Steller sea

lions has continued throughout most of Alaska. Because of this continued decline, on November 1, 1993, NMFS initiated a formal population status review under the ESA to determine whether a change in its listing status as a threatened species is warranted (58 FR 58318, November 1, 1993).

II. Comments and Responses on Status Review Notice

NMFS received sixteen comments in response to the status review notice. Comments pertinent to the proposed listings and regulations are discussed below.

Separate Population Listings

Some comments noted that Steller sea lions have not declined in some portions of the species' geographic range, and suggested that NMFS consider treating the species as two separate populations for the purposes of listing under the ESA.

Under the ESA, only a ''species'' may be listed as threatened or endangered. The term ''species'' includes any subspecies of fish or wildlife and any distinct population segment of any species of fish or wildlife that interbreeds when mature. At the time Steller sea lions were listed as threatened, NMFS determined that there was insufficient information available to consider animals in different geographic regions as separate populations. However, additional data collected, particularly on population genetics, now indicate that Steller sea lions should be listed as two distinct population segments under the ESA. Supporting data and information for this proposed determination are detailed below.

Listing Classification

The majority of the comments did not express a preference for either a threatened or endangered listing status for Steller sea lions. Some comments indicated the belief that there is sufficient information to support a change in listing status to endangered. Other comments stated that the current listing of the species as threatened provides NMFS sufficient regulatory authority to protect Steller sea lions and, therefore, a change in listing status to endangered is not necessary. Some of these same commenters also suggested that an endangered listing should not be considered at this time, since it would result in greater economic effects to fishing communities and the fishing industry. Some commenters believe that no change in listing status should be considered while the reasons for the decline remain unclear.

The ESA is explicit that listing and reclassification decisions are to be made solely on the basis of the best scientific and commercial information available regarding the species' population status (section 4(b)(1)(A)). Economic effects are not to be considered in making a listing determination for a species under the ESA. Likewise, the lack of knowledge regarding causes of the Steller sea lion decline does not affect a species' status. Each of the five factors described in section 4(a)(1) of the ESA that must be considered in making a listing status determination are discussed below. The adequacy of existing regulatory mechanisms is one of these factors.

Population Viability Analysis

Some commenters expressed concern regarding the weight that would be given to the results of the Steller sea lion Population Viability Analysis (PVA) (PVA at Merrick and York, 1994). They noted the difficulties in predicting future population trends with confidence when causal relationships are not understood, and suggested that NMFS use the PVA results with caution in the listing status determination. One commenter indicated that the PVA should be peer reviewed by independent experts.

The PVA provides an estimate of extinction risk if current population trends continue. NMFS believes that the PVA provides the best estimate of extinction risk possible with existing data and scientific methods, and has submitted the PVA for review by outside, independent experts. However, NMFS recognizes the limitations of population modeling to accurately predict future trends for this population. Thus, although the PVA results have been considered in the status determination, these have not been given greater weight than objective population trend data and the scientific opinion of experts, both within and outside NMFS.

Protective Measures

Several commenters raised issues relative to the protective measures that have been implemented to aid recovery of Steller sea lions. Some commenters felt that additional regulations were needed to better protect Steller sea lions from the effects of commercial fisheries, and oil and gas exploration and development. Other commenters questioned the rationale for existing protections, particularly fishery closure areas.

NMFS has implemented various protective measures for Steller sea lions under the ESA and the Magnuson Fishery Conservation and Management Act (Magnuson Act). These measures are intended to reduce intentional and unintentional mortality and harassment, disturbance of breeding areas and reproduction, and the possible effects of commercial fishing on the availability of Steller sea lion prey.

NMFS is reevaluating existing management measures for Steller sea lions. NMFS expects to consider regulatory changes that may be needed to ensure that regulations provide the greatest potential to benefit Steller sea lions without unnecessarily restricting human activities. However, NMFS will involve state and Federal agencies, the North Pacific Fishery Management Council, Alaska Native organizations, fishing and environmental groups, and other affected members of the public in the early stages of the decision-making process for any changes in management regulations. NMFS is reinitiating consultation under section 7 of the ESA on Federally-managed groundfish fisheries off Alaska to consider new information and to evaluate whether existing protective regulations are adequate to ensure that agency actions are not likely to jeopardize the continued existence of the species. NMFS has not reached any definitive conclusions concerning the adequacy of existing regulatory mechanisms. This issue is discussed in more detail below.

Research Program

Several commenters recommended an expansion of existing research efforts, and offered specific recommendations for areas of research.

The Recovery Plan research program is a federally-funded effort, implemented jointly by NMFS and ADFG. Research priorities are defined in the Recovery Plan, and are limited by available funds. As described below, the Recovery Team has begun the process of synthesizing research program accomplishments with the intention of revising the Recovery Plan, as needed.

III. Recommendations of the Steller Sea Lion Recovery Team

The Recovery Team was appointed by NMFS in 1990 to draft a recovery plan for the species and to serve as an advisory body to NMFS on Steller sea lion research and management issues. On November 29–30, 1994, NMFS convened the Recovery Team specifically to consider the appropriate ESA listing status for the species and to evaluate the adequacy of ongoing research and management programs. In the course of that meeting, and in subsequent letters to the Assistant Administrator for Fisheries, NOAA

(AA), the Recovery Team made the following recommendations to NMFS:

(1) *Listing Status under the ESA:* The Recovery Team recommended that NMFS list the Steller sea lion as two separate population segments, split to the east and west of 144° W long. (a line near Cape Suckling, AK). The Recovery Team recommended that the western population segment be listed as endangered and that the eastern population segment be listed as threatened.

(2) *Commercial fisheries:* A change in food availability is the leading hypothesis for the cause of the Steller sea lion decline. Reduced juvenile recruitment appears to be the proximate cause of the decline and juvenile Steller sea lions appear to feed primarily in areas near rookeries and haulouts. The Recovery Team recommended that NMFS evaluate the need to close or otherwise regulate any or all nearshore fisheries around Steller sea lion rookeries and major haulouts west of 144° W long. in order to enhance food availability.

(3) *Research:* The Recovery Team recommended that the individual research projects being undertaken under the Recovery Plan be peer reviewed to assess the need for changes in research direction and priorities. In-depth research program reviews will be accomplished over the next few years and will include review by outside experts, as necessary. The four major components of the research program to be individually evaluated are: (1) Population monitoring (Peer review of the population monitoring program was completed in 1992 (Rosenberg 1992)); (2) satellite telemetry studies; (3) physiology/health studies; and (4) food habits and foraging ecology studies. Results of this peer review process are expected to be used to revise the Recovery Plan.

The Recovery Team also recommended that NMFS direct additional effort, and seek additional funding, to better assess Steller sea lion prey resources in the North Pacific.

(4) *Subsistence harvest:* The Recovery Team recommended that NMFS work with the newly formed Alaska Native Steller Sea Lion Commission toward the goals of developing self-management and monitoring of subsistence harvests, establishing biologically acceptable harvest levels, and reducing struck and lost rates.

The Recovery Team recommendations relative to reclassification of the species have been considered in this proposed determination. Management recommendations also are being considered and will be evaluated in more detail during the review of existing regulations and through the consultation process.

IV. Proposed Population Determinations

As described above, only a ''species'' may be listed as threatened or endangered under the ESA, and this term is defined to include any subspecies of fish or wildlife and any distinct population segment of any species of fish or wildlife that interbreeds when mature. On December 21, 1994, NMFS and the U.S. Fish and Wildlife Service proposed a policy to clarify their interpretation of the phrase ''distinct population segment'' for the purposes of listing, delisting, and reclassifying species under the ESA (59 FR 65884, December 21, 1994). Although this is only a proposed policy at this time, it represents the best available guidance for interpreting the term ''distinct population segment.'' NMFS proposes to use the criteria announced in the December 21, 1994 proposed policy to assess the presence of distinct populations of Steller sea lions.

The proposed policy outlines three elements that should be considered in any decision regarding the status of a possible distinct population segment: Discreteness of the population segment in relation to the remainder of the species to which it belongs; the significance of the population segment to the species to which it belongs; and the population segment's conservation status in relation to the ESA's standards for listing. The first two elements are discussed below, and conservation status is discussed separately for each proposed population segment in the following section and within the context of the five factors that are evaluated below.

(1) *Discreteness:* Under the proposed policy a population segment of a vertebrate species may be considered discrete if it is either markedly separated from other populations of the same taxon as a consequence of physical, physiological, ecological, or behavioral factors (quantitative measures of genetic or morphological discontinuity may provide evidence); or delimited by international governmental boundaries that are significant in light of section 4(a)(1)(D) of the ESA. The former criterion is particularly relevant for Steller sea lions.

Genetic studies provide the strongest evidence that discrete populations of Steller sea lions exist. Bickham et al. (in press) collected genetic samples from 224 Steller sea lion pups on rookeries in Russia, the Aleutian Islands, the western and central Gulf of Alaska, southeastern Alaska, and Oregon. Mitochondrial DNA analyses of these samples identified a total of 52 haplotypes (sets of alleles of closely linked genes that tend to be inherited together, uniquely identifying a chromosome) that could be further grouped together into eight lineages. Bickham et al. found a distinct break in haplotype distribution between the four western localities and the two eastern localities. Cluster analysis indicated that the eight lineages could be subdivided into two genetically differentiated populations, with the division at about Prince William Sound. Ono (1993) conducted similar analyses on samples obtained from 11 Steller sea lions on Año Nuevo Island, CA, and found seven haplotypes. Six of these were identical to those identified from southeastern Alaska and Oregon by Bickham et al., and one was unique to Año Nuevo Island.

Tagging and branding studies provide evidence that the breeding behavior of Steller sea lions probably reduces opportunities for genetic mixing among rookeries although Steller sea lions have been documented to travel large distances during the non-breeding season. The majority of females marked as pups, then later resighted as adults, have returned to their rookery of birth to breed (Calkins and Pitcher, 1982; NMFS, 1995). The few resighted females observed breeding at rookeries other than their natal site were all at rookeries near their birth rookery. This apparent natal site fidelity not only reduces genetic mixing among rookeries, but it also makes it less likely that declining rookeries will be bolstered by recruitment from other rookeries.

Satellite telemetry studies also provide evidence of ''homing'' behavior in Steller sea lions. Generally, tracked sea lions forage from a central place (either a rookery or nearby haulout) and return to that place at the end of a foraging trip that may vary in duration from hours to months (Merrick et al., 1994).

Population trend data provide further evidence of separation among these two population segments. The Steller sea lion population east of Cape Suckling (with the exception of the portion in southern California) has remained stable since the 1970s, whereas the population to the west has declined dramatically. It is also worth noting that the only break in the distribution of Steller sea lions along the Alaskan coast occurs in the Yakutat area, near the proposed longitudinal border that would delineate the western and eastern populations.

Loughlin (1994) used the phylogeographic approach proposed by Dizon et al. (1992) to discern population discreteness in Steller sea lions. Loughlin concluded, based on an evaluation of distribution, population response, phenotypic, and genotypic data, that Steller sea lions should be managed as two discrete populations, with the separation point at about 144° W. long.

The above information supports the conclusion that the western and eastern population segments of Steller sea lions are discrete.

(2) *Significance:* The proposed policy recommends that if population segments are determined to be discrete, then the biological and ecological significance of a population segment should be considered in light of the guidance in S. Rep. No. 151, 96th Cong., 1st Sess. (1979) that the authority to list distinct population segments be used sparingly and only when the biological evidence indicates that such action is warranted. The underlying question of significance depends on the relationship of a proposed population segment to the species as a whole.

In the case of Steller sea lions, the two population segments under consideration make up the entire range of the species. Extinction of either population segment would represent a substantial loss to the ecological and genetic diversity of the species as a whole.

The importance of each of the population segments indicates that the significance criterion of the proposed policy would be satisfied.

V. Current Status

Status of the Western Steller Sea Lion Population Segment

Population monitoring data: The western Steller sea lion population segment had suffered substantial declines prior to the 1990 ESA listing. Loughlin et al. (1992) estimate a 70 percent decrease in the number of adult and juvenile sea lions in this area between the 1960's and 1989. Since the 1990 listing, Steller sea lion trend counts for the western population segment have shown a continued decline. The number of adult and juvenile animals counted at trend sites during aerial surveys has dropped from 30,525 in 1990 to 24,104 in 1994 (a 21 percent decrease) (NMFS, 1995).

Regionally, decline rates differ: The western and eastern Gulf of Alaska (a 38 percent and a 36 percent decline, respectively) and the central and western Aleutian Islands (a 28 percent and a 13 percent decline, respectively) have shown the largest declines in adult/juvenile numbers since 1990. Counts of the eastern Aleutian Islands area and western Gulf of Alaska area have been relatively stable since 1990, while the Bering Sea region has shown an increase in adult/juvenile counts since 1990. However, the eastern Aleutian Islands and Bering Sea regions declined substantially prior to 1990, and populations there remain only a fraction of what they were 20 years ago.

Pup production has also decreased since the 1990 listing. Overall, a decline of about 28 percent has been observed between pup counts made in 1989–90 as compared to 1993–94 (excluding the western Aleutian Islands and Bering Sea where comparative counts are not available). Regional differences in the rate of change in pup production also are apparent. Pup production in the central Gulf of Alaska declined by 49 percent between 1989–90 and 1993–94. The central and eastern Aleutian Islands also had large decreases in pup production (a 19 percent and a 16 percent decline, respectively), while pup production in the eastern and western Gulf of Alaska was relatively stable over the time period.

Population Viability Analysis: Steller sea lion abundance trends within the decline area were modeled to provide an estimate of the likelihood of extinction given the available population data (Merrick and York, 1994). Two models were developed based on a stochastic model of exponential growth that required only count data and count variance to predict future trends (after Dennis et al., 1991), and using both the 1985–94 and 1989–94 population trends. One model (an aggregate Kenai-Kiska Island (trend sites) model) was based on the trajectory of the sum of the rookery populations within the area. The second model was based on a simulation of the population trajectories of individual rookeries in the Kenai-Kiska area.

Both models predicted that the Kenai-Kiska population would be reduced to low levels (<500 females) within 100 years from the present, if either the 1985–94 or 1989–94 trend continues into the future. The Kenai-Kiska regional model predicted a probability of extinction within 100 years of 100 percent from the 1985–94 trend data, and a probability of extinction within 100 years of 65 percent if the 1989–94 trend data are used.

The rookery model predicted longer times to extinction. Predicted probabilities of extinction within 100 years were 100 percent using the 1985–94 trend, and 10 percent using the 1989–94 trend data. Modeling results indicated that, if either trend persists, the next 20 years would be crucial to the survival of the western Alaska population. Under all modelling scenarios during the next 20 years, populations on individual rookeries are predicted to be reduced to low levels (mean size <100 adult females).

Criteria and considerations for endangered classification: The ESA does not provide objective criteria or specific guidance for determining when a population should be listed as endangered or threatened. The ESA simply defines an ''endangered species'' as one that is in danger of extinction and a ''threatened species'' as a species that is likely to become an endangered species within the foreseeable future. Other guidance and criteria for assessing population endangerment can be gleaned from scientific literature. This is discussed below in relation to the current status of the western population segment of Steller sea lions.

The Recovery Team recommended specific evaluation criteria for Steller sea lions, and considered the current abundance in the Kenai Peninsula to Kiska Island (trendsite) area in relation to a pre-decline benchmark population size, as well as the rate of decline in adult/juvenile animals counted within the trendsite area, the rate of decline in pup production in the trendsite area, and population trends in other geographic regions (NMFS, 1992). Application of the Recovery Team's criteria at this time would result in a determination that the western population segment should be listed as endangered. Indeed, the Recovery Team specifically recommended to NMFS that the western population segment be listed as endangered (Lowry, 1994).

Although a precise definition of ''endangered'' does not exist, a population that is not endangered is one that is likely to persist into the foreseeable future. Thus, the question of defining endangerment is one of determining the threshold probability of extinction that is too high to be acceptable to society (Goodman, 1994). Defining the acceptable probability of persistence and the appropriate time frame of reference that defines a minimum viable population (MVP) is a subjective decision that has been much discussed in the conservation biology literature. ''Acceptable'' persistence values in the scientific literature for an MVP range from a ''greater than'' 80 to 90 percent probability of persistence over 10 generations, to a ''greater than or equal to'' 50, 90, 95, and 99 percent probability of persistence over 100 years or a ''greater than or equal to'' 99 percent likelihood of persistence over

1000 years (Schaffer, 1981, 1987; Belovsky, 1987; Soule, 1987; Mace and Lande, 1991; Mace et al., 1993; Thompson, 1991). Thompson (1991) notes that although there are no clear theoretical grounds for a single choice of persistence probability and time frame reference, the relatively frequent use of a 95 percent probability of persistence over 100 years makes this a reasonable standard for an MVP, i.e., an unendangered population. Considering the converse, an endangered population may be defined as one with a greater than 5 percent chance of extinction over the next 100 years. Evaluating the western Steller sea lion population PVA results (at Merrick and York, 1994) in light of this ''standard'' would lead to a determination that the western population of Steller sea lions is endangered.

Various ''rules of thumb'' also have been proposed for the minimum population size needed to ''ensure'' population persistence over time; however, most authors caution against using such ''magic numbers'' offhandedly. For example, the 1994 estimate of adult/juvenile Steller sea lions within the western population segment of 33,600 (NMFS, 1995) is well above most of the MVP ''rules of thumb'' commonly cited (Soule, 1987; Belovsky, 1987; Thomas, 1990). A ''rule of thumb'' approach is inadequate, however, for evaluating the status of Steller sea lions under the ESA. A ''rule of thumb'' assessment may be useful in assessing long-term viability of stable populations, but the severe, continuous decline in the western Steller sea lion population trend would be overlooked by such an approach. As noted by the Recovery Team in their criteria, the rate of population decline, as well as the magnitude and spatial extent of the decline, are critical factors in determining endangerment for this population.

Mace and Lande (1991) and Mace et al. (1993) outline criteria for classifying species considered by the International Union for the Conservation of Nature (IUCN), which incorporate various types of population data and analyses, e.g., population size, geographic range, population decline rate, probability of persistence within a given time frame from PVA. Consideration of all available data on a population allows a more robust estimate of population status than ''rule of thumb'' or PVA approaches alone. It should be emphasized that in both IUCN proposals probabilistic criteria are considered in conjunction with other data, thus, the most conservative classification derived by considering all available data/analyses would be chosen.

Conclusions concerning the western population: An analysis of the conservation status of the western population segment of the Steller sea lion in relationship to the standards for threatened and endangered status indicates that this population segment would satisfy the third criterion of the proposed population policy. In addition, the available data and information concerning the status of this stock indicates that the western population should be proposed for endangered status under the ESA.

The western population is proposed to consist of Steller sea lions from breeding colonies located west of 144 °W. long.

Status of the Eastern Steller Sea Lion Population Segment

Population monitoring data: The 1990 ESA listing of Steller sea lions resulted primarily from the declines observed in the western population area; in the eastern population, a decline has been noted only in the California part of the range. Since the 1990 listing, trend counts of the eastern population segment show about a 17 percent increase overall in adult/juvenile numbers. Similar to the western population, regional differences in trends within the eastern population are evident.

California experienced a large decline in Steller sea lion numbers prior to 1980; NMFS (1995) estimated a greater than 50 percent decline between about 1950 and 1980. Some of the available data indicate that a northward shift in the Steller sea lion range may be occurring, which may exacerbate the decline at southern rookeries. Steller sea lion counts in California have been relatively stable since 1980 (1980 count was 982) although counts declined 19 percent from 1990–94 (from 1,123 animals to 915) (NMFS, 1995). The reasons for the historical decline in Steller sea lion total abundance and the current decline at southern locations in California is not known. Causal factors under investigation include changes in prey base, possible effects of anthropogenic contaminants and disease, disturbance, and competition with other pinniped populations that are increasing in abundance in California, e.g., California sea lions, elephant seals, northern fur seals.

Steller sea lion adult/juvenile counts at Oregon trend sites show a relatively large increase from 1990–94 (from 2,005 to 2,696) but this may be, at least partially, due to improved counting techniques (NMFS, 1995). Steller sea lion adult/juvenile counts in Southeast Alaska increased 15 percent from 1990 to 1994 (from 7,629 to 9,005), and pup counts increased by about 10 percent (from a mean of 2,568 in 1989–90 to a mean of 3,701 in 1993–94).

The British Columbia portion of the eastern population has also apparently been increasing slowly since the 1970s. Reports from aerial surveys conducted by the Canadian Department of Fisheries and Oceans indicate that adult/juvenile counts at rookeries and haulouts in British Columbia increased about 10 percent between 1992 and 1994 (from 7,376 to 8,091) (Olesiuk, pers. comm.).

Criteria and considerations for threatened status and conclusions concerning the eastern population: The overall trend of the eastern population segment of Steller sea lions since 1980 has been stable to increasing although significant declines in the number of Steller sea lions occurring within California prior to 1980 have been documented. Population modeling of the number of sea lions at the rookeries to assess the viability of the eastern population segment has not been specifically conducted by NMFS. Since this population's trend has been stable to increasing, modelling, such as that conducted for the western population, would be expected to predict persistence of this population segment for the foreseeable future (NMFS, 1995).

The estimated size of the eastern population of Steller sea lions within U.S. boundaries in 1994 was 18,600 animals. About 10,000 more animals of this population are estimated to occur within British Columbia. The British Columbia estimate was derived by adjusting Olesiuk's 1994 adult/juvenile count to account for animals at sea, using the methods of Loughlin et al. (1992).

Comparison of this population size with the typical range of most ''rules of thumb'' for minimum viable population size (from 1000 to 10,000 individuals (Thompson, 1991)) provides an additional indication that this population is not vulnerable to extinction in the foreseeable future. Similarly, this population segment, when considered alone, would not meet any of the draft IUCN vulnerability criteria discussed in Mace and Lande (1991) and Mace et al. (1993).

Evaluating the population status of the eastern population segment without a consideration of its place in the overall species population, however, may be inappropriate. Prior to the decline, the proportion of the U.S. population of Steller sea lions that resided within the eastern population

area was less than 10 percent (NMFS, 1995). Because of the western population's decline, the eastern population's numerical significance has increased. NMFS (1995) estimates that the total U.S. population of Steller sea lions has declined by 73 percent between the 1960s and 1994 (NMFS, 1995). The overall trend for the entire species is a continuing decline. Also, between 1991 and 1994 pup numbers decreased in all regions of Alaska. There was a 20.8 percent decrease in the number of pups born in the area from southeastern Alaska to central Alaska. These declines reverse the apparent stability in pup numbers in southeastern Alaska.

Thus, although for listing purposes the western and eastern population segments may be considered discrete, the substantial population decline that has occurred in the eastern Gulf of Alaska through the Aleutian Islands represents a threat to the continued existence of the entire species, including the eastern population. Therefore, the vulnerability of the eastern population remains a serious concern as long as the cause of the decline of the western population remains undetermined. These populations, while separate, are not isolated, and factors causing the decline in Alaska could move eastward and pose a threat to the continued existence of the eastern population. The recent declines in pup production in the eastern population are of serious concern. In addition, the decline numbers of Steller sea lions in California, in the southern extremity of their range, is also of concern.

The Recovery Team's population evaluation criteria focused on population parameters within the western population segment, and thus, offer no guidance for evaluating the status of the eastern population segment. Recently, the Recovery Team recommended that the eastern population segment remain listed as threatened because of concerns regarding (1) the decline in Steller sea lions numbers in southern California, (2) the potential that the decline in the western population could spread east, (3) a slight decrease in pup counts in Southeast Alaska and Oregon in 1994, and (4) a concern that since animals in the western population may occur within the eastern population's geographic range, animals from the western population could be affected by a lack of protective management mechanisms (Lowry, 1994).

An analysis of the conservation status of the eastern population segment of the Steller sea lion in relationship to the standards for threatened status indicates that this population remains vulnerable, but in a manner and to an extent that differs from the vulnerability of the western population segment. This analysis indicates that the third criterion of the proposed population policy is satisfied. Likewise, the available data and information concerning the status of this stock indicates that the eastern population should continue to be considered threatened.

NMFS proposes a separate listing for the eastern population of the Steller sea lion as a threatened species under the ESA. The eastern population segment would consist of Steller sea lions from breeding colonies located east of 144 °W. long.

Listing Procedures: Summary of Factors Affecting the Species

Species may be determined to be endangered or threatened due to one or more of five factors described in section 4(a)(1) of the ESA. These factors as they apply to the western and eastern Steller sea lions population segments are discussed below.

A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

Western Population Segment: Steller sea lions breed, pup, and seek rest and refuge on relatively remote islands and points of land along the Alaska coastline. There is no evidence that the availability of rookery or haulout space is a limiting factor for this species. As the number of animals in the western population segment continues to decline, some rookeries and haulouts have been abandoned and the availability of suitable terrestrial habitat is increasing. Terrestrial habitat destruction and modification do not appear to be significant issues for this population segment, or have a significant role in its population decline.

There are indications that Steller sea lion declines may be related to changes in the availability or quality of sea lion prey, as a result of environmental changes or human activities (Alverson, 1991; Calkins and Goodwin, 1988; Loughlin and Merrick, 1991; Merrick et al., 1987; NMFS, 1992; NMFS, 1995). This issue is discussed in more detail below in the section analyzing other factors affecting the species.

Eastern Population Segment: Modification or destruction of habitat, including both terrestrial and aquatic habitat, does not appear to be a significant factor affecting Steller sea lions in Southeast Alaska. In Oregon, human disturbance of sea lions at Three Arch Rock and Orford Reef was found to have a significant effect on the number of Steller sea lions using these sites (R. Brown, pers. comm.; NMFS, 1992). State regulations have been implemented, however, to restrict vessel traffic and reduce human disturbance.

In California, the reason for the decline of Steller sea lions is not known. Former rookery habitat has been abandoned (San Miguel Island), and some other rookeries (Año Nuevo Island, Farallon Islands) are at lower than historical abundance levels. The availability of suitable terrestrial habitat does not appear to be a factor in the sea lion decline in parts of California. A redistribution of Steller sea lions from disturbed to undisturbed habitats, however, has been reported in the Farallon Islands (D. Ainley in NMFS, 1992), which may be indicative of unreported disturbance limiting habitat use in other areas. Similarly, with respect to aquatic habitat, changes in the availability and quality of Steller sea lion prey resources due to natural cycles, fisheries, and toxic substances may be a factor in observed population trends in California.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Western and Eastern Population Segments: Steller sea lion pups were harvested commercially in the past, with significant levels of harvest occurring in eastern Aleutian Islands and the Gulf of Alaska during the 1960's and early 70's. Commercial harvest of Steller sea lions has not occurred since 1972. In the past there have been reports of people shooting at Steller sea lions at rookeries and haulout sites and in the water near boats. Although illegal, shooting of sea lions probably continues, but the magnitude and significance of this mortality source is not known. In addition, in some cases, the animals may be disturbed as a result of recreational activities. While the commercial harvest and illegal shooting of Steller sea lions may have been significant factors in past declines, especially with respect to the western population, these harvests probably are not a major or substantial cause of recent population changes.

Intentional lethal takings of small numbers of Steller sea lions for scientific purposes have occurred in the past. Since the 1990 ESA listing, however, scientists have relied on non-lethal sampling techniques. Research often results in the temporary harassment and occasionally results in the injury of Steller sea lions. Prior to 1990, a small number of animals were taken from the wild for public display

purposes, but no such removals have been authorized since listing. While occasionally the subject of observation and harassment, especially in some areas, Steller sea lions usually are not utilized for educational purposes in a manner that would have a significant negative impact on the animals. It is unlikely that utilization of Steller sea lions for scientific or educational purposes has been a significant or contributing factor that has affected either population segment.

C. Disease or Predation

Western and Eastern Population Segments: Sharks and killer whales are known to prey on Steller sea lions, primarily pups. The magnitude and significance of predator-related mortality, however, is not known. Natural mortality from predation is not currently considered to be a significant factor for either Steller sea lion population segment. Nonetheless, should the western population segment continue to decline and the amount of mortality resulting from natural predation by killer whales remain unchanged, natural mortality could exacerbate the decline, especially in some areas of the western population.

Studies to assess the significance of disease in the Steller sea lion population are ongoing. To date, researchers have not found any evidence that disease is a significant factor affecting either population of Steller sea lions. Various pathogens have been isolated from animals collected by researchers or carcasses found on the beach but their significance to the overall population remains unclear. One area of ongoing research is determining the role, if any, of pathogens in the relatively high rate of abortions observed in Gulf of Alaska Steller sea lions.

D. The Inadequacy of Existing Regulatory Mechanisms

NMFS has the authority to implement regulations necessary to protect Steller sea lions under the ESA and the MMPA. Similarly, under the Magnuson Act, NMFS has the authority to regulate fishing activities that may be affecting sea lions, directly or indirectly. However, the adequacy or inadequacy of existing regulatory mechanisms and protective regulations is difficult to evaluate because of the lack of a clear cause and effect relationship between human activities and the decline in the western population segment. Various regulations that have been implemented, or that have been suggested or proposed for implementation, are considered below.

Take prohibitions. Under the MMPA, it is unlawful for any person subject to the jurisdiction of the United States to take a marine mammal on the high seas or in waters or lands under U.S. jurisdiction. ''Take'' is defined as harass, hunt, capture, or kill or attempt to harass, hunt, capture, or kill any marine mammal. Certain exceptions are provided.

Similarly, under the ESA, certain statutory prohibitions apply once a species is listed as endangered. For example, under section 9 of the ESA, no person subject to the jurisdiction of the United States may take such a species within the U.S., the territorial sea of the U.S., or upon the high seas. ''Take'' is defined as harass, harm, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in such conduct. Certain exceptions are provided.

Often prohibitions similar to the section 9 prohibitions for endangered species are implemented by regulation with respect to species that are listed as threatened. Such action was not taken with respect to Steller sea lions when the species originally was listed as threatened in 1990, in part, because similar take prohibitions existed under the MMPA, and in part, because of the difficulty of authorizing incidental takings if such prohibitions had been implemented.

The regulatory mechanisms prohibiting the taking of Steller sea lions generally have been effective.

Regulations prohibiting the discharge of firearms: Regulations adopted with the original listing of Steller sea lions as threatened prohibited the discharge of firearms at or near these animals. Although intentional lethal taking of sea lions was prohibited at that time, there had been reports that firearms were used to deter sea lions from interfering with fishing operations.

In a separate action, NMFS has proposed regulations and guidelines for deterring marine mammals as required under new section 101(a)(4) of the MMPA (60 FR 22345, May 5, 1995). These deterrence measures would prohibit the use of firearms for deterring marine mammals from interacting with fishing gear or catch. In addition, new section 118(a)(5) of the MMPA prohibits intentional lethal taking of any marine mammal during commercial fishing operations, except in defense of human life (60 FR 6036, Feb. 1, 1995).

As noted above, illegal shooting of Steller sea lions may be continuing, but the regulations adopted at the time of the original listing of the species as threatened are viewed, in general, as effective and adequate. NMFS proposes to continue these types of protections for both the eastern and western population segments. The proposed regulation in this action would expand the definition of ''firearm'' to make the definition consistent with the approach proposed in the marine mammal deterrence measures.

No approach in buffer areas: Regulations adopted with the original listing of Steller sea lions as threatened, prohibited any vessel from approaching within three miles of specific Steller sea lion rookeries; likewise, approach on non-private land within one-half mile of these specific rookery sites was prohibited. A variety of exceptions were provided. All of the specified rookery sites are within the range of the western population segment.

The purposes of the buffer areas were to restrict opportunities for individuals to shoot at sea lions and to facilitate enforcement of this restriction; to reduce interactions with sea lions, such as accidents or incidental takings, in areas where concentrations of these animals are expected to be high; to minimize disturbance and interference with sea lion behavior including foraging behavior, especially at pupping and breeding sites; and to avoid or minimize other human impacts and related adverse effects. To date, these regulations generally are viewed as effective.

NMFS is proposing to continue the existing regulatory buffer areas in the western area. At this time, NMFS is not proposing additional buffer areas in the western area or any buffer area protections for rookery sites in the eastern area. Specific case-by-case buffer area or related protections may be considered in the context of section 7 consultations. Comments are invited with respect to the need for changes in buffer area protections.

Quotas on incidental takings: On April 30, 1994, the reauthorized and amended MMPA established a new regime to govern the take of marine mammals incidental to commercial fishing operations to replace the interim exemption program that was established by the 1988 amendments to the MMPA. Under the 1988 Interim Marine Mammal Exemption Program, up to 1,350 Steller sea lions were authorized to be taken annually incidental to commercial fisheries and emergency regulatory actions were required if more than 1,350 animals were incidentally killed in any year. The new MMPA management regime replaces the previous quota system and focuses on reducing the incidental mortality and serious injury of marine mammals from strategic stocks, i.e., those that are listed as endangered or threatened under the

ESA, those that are listed as depleted under the MMPA, and those for which human-caused mortality exceeds the estimated potential biological removal (PBR) for the stock. Under this new regime, NMFS is required to permit the take of endangered and threatened marine mammals incidental to commercial fishing under section 101(a)(5)(E) of the MMPA, provided that (1) the incidental mortality and serious injury would have a negligible impact on the affected species or stock, (2) a recovery plan for that species or stock has been developed or is being developed, and (3) where required under section 118 of the MMPA, a monitoring program has been established, vessels are registered, and a take reduction plan has been developed or is being developed.

The 1994 Amendments to the MMPA defined PBR as the maximum level of animals, not including natural mortalities, that can be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population. Stocks of marine mammals listed as threatened or endangered under the ESA are considered ''strategic stocks'' under the MMPA, and NMFS is to develop and implement take reduction plans for such stocks that have either frequent or occasional interactions with commercial fisheries.

The goal of these plans is to reduce incidental mortality or serious injury of marine mammals during commercial fishing operations to less than the PBR level within 6 months of implementation and to insignificant levels approaching a zero mortality and serious injury rate by April 30, 2001. NMFS is committed to convening take reduction teams to develop take reduction plans for strategic stocks of marine mammals, including both the western and eastern populations of Steller sea lions.

In addition to take reduction plan implementation, section 101(a)(5) of the MMPA allows NMFS to authorize the take of threatened and endangered marine mammals incidental to commercial fishing operations only if, among other things, that take will have a ''negligible impact'' on the stock. NMFS issued an Incidental Take Statement (on August 25, 1995) that authorizes, under section 7(b)(4) of the ESA, the incidental mortality and serious injury in commercial fisheries.

Subsistence harvests: Under section 10(e) of the ESA, prohibitions on the taking of threatened and endangered species normally do not apply to takings by native Alaskans if such taking is primarily for subsistence purposes. To date, no action has been taken to regulate, or otherwise manage, the subsistence harvest of Steller sea lions by Alaska native groups. If subsistence takings materially and negatively affect the species, regulations or restrictions may be imposed only after a hearing and decision on the record.

Section 119 of the MMPA allows the Secretary of Commerce to enter into cooperative agreements with Alaska Native organizations to conserve marine mammals and provide co-management of subsistence uses. In 1994, an interim Alaska Native Steller Sea Lion Commission consisting of representatives from Alaska communities that take Steller sea lions for subsistence needs was formed to improve communication among indigenous communities that use sea lions, to advocate for conservation of Steller sea lions, to advocate for protection of customary and traditional rights of indigenous peoples with regard to access and use of sea lions, and to serve as the focal point for development of co-management agreements with NMFS. Through co-management agreements between NMFS and the Alaska Native Sea Lion Commission or tribal entities, self-management and regulation of the subsistence harvest by Alaska Native tribes, communities, or the Commission will be developed. NMFS is not considering regulation of the subsistence harvest at this time but hopes to work with Alaska Native communities and representatives to ensure that subsistence harvest does not adversely affect the Steller sea lion population.

Critical habitat: Currently, designated critical habitat for Steller sea lions includes major rookeries in Alaska, Oregon and California, major haulout areas in Alaska, and three special aquatic foraging areas in waters off Alaska, the Shelikof Strait are, the Bogoslof area, and the Seguam Pass area.

Critical habitat provides the public and other Federal agencies with notice of particular areas and features that are essential to the conservation of Steller sea lions. Consultation under section 7(a)(2) of the ESA is required for any agency action that may affect critical habitat. NMFS believes that the current designation of critical habitat is adequate and is not proposing to revise that designation at this time.

Restrictions on fishing activities: Although the relationship between commercial fisheries and the ability of Steller sea lions to obtain adequate food is not clear, a change in food availability, especially for juvenile Steller sea lions, is a leading hypothesis of the continuing decline in the western population segment. The Gulf of Alaska (GOA)/Bering Sea and Aleutian Island management area (BSAI) is the geographic region where Steller sea lions have experienced the greatest population decline and is also an area where large commercial fisheries have developed. As a result, NMFS has implemented protective regulations to reduce the possible effects of certain commercial groundfish fisheries on Steller sea lions, especially the groundfish fisheries of the GOA and the BSAI.

Many of the Steller sea lion's preferred prey species are harvested by commercial fisheries in this region, and food availability to Steller sea lions may be affected by fishing. Because of concerns that commercial fisheries in these essential sea lion habitats could deplete prey abundance, NMFS amended the BSAI and GOA groundfish fishery management plans. Under the Magnuson Act, NMFS: (1) Prohibited trawling year-round within 10 nm of listed GOA and BSAI Steller sea lion rookeries; (2) prohibited trawling within 20 nm of the Akun, Akutan, Sea Lion Rock, Agligadak, and Seguam rookeries during the BSAI winter pollock roe fishery to mitigate concentrated fishing effort on the southeastern Bering Sea shelf and in Seguam Pass; and (3) placed spatial and temporal restrictions on the GOA pollock harvest to divert some fishing effort away from sea lion foraging areas and to spread effort over the calendar year.

NMFS also seasonally expanded the 10 nm no-trawl zone around Ugamak Island in the eastern Aleutians to 20 nm (58 FR 13561, March 12, 1993). The expanded seasonal ''buffer'' at Ugamak Island better encompassed Steller sea lion winter habitats and juvenile foraging areas in the eastern Aleutian Islands region during the BSAI winter pollock fishery.

Consultations under section 7 of the ESA have been conducted on annual total allowable catch specifications for the GOA and BSAI fisheries as well as all other changes in the fishery. However, NMFS is concerned about the adequacy of these protective measures and believes that reevaluation of the regulations is needed. Further, the Recovery Team has recommended NMFS evaluate the need for additional measures in order to enhance food availability near rookeries and haulouts in the western area. Current regulations of the groundfish fisheries in the GOA and BSAI were implemented under the Magnuson Act. NMFS anticipates that additional protections or changes in these measures would also be

implemented under that Act. NMFS is not proposing such revisions at this time although comments on this issue are invited.

Other regulatory mechanisms: The inadequacy of other regulatory mechanisms has been suggested as a factor in the decline or vulnerability of both Steller sea lion populations. As mentioned above comments received on the status review notice included suggestions that additional regulations were needed to protect Steller sea lions from the effects of oil and gas exploration and development.

In most cases, other agencies, such as Minerals Management Services and the Forest Service, are more involved in the direct regulation of these types of activities. Of course, these agencies are expected to consult with NMFS on actions they authorize, fund, or carry out to ensure these actions are not likely to jeopardize the continued existence of listed species or to destroy or adversely modify critical habitat. Reinitiation of consultation is expected in most situations, given recent information concerning the status of the Steller sea lions. Comments received concerning the adequacy of regulations issued by other agencies will be considered during the consultation process.

Conclusions regarding the inadequacy of existing regulatory mechanisms: NMFS has not made a final determination with respect to the adequacy or inadequacy of existing regulatory mechanisms. NMFS recognizes the need for further consideration of the need for, the adequacy of, and the benefits of existing regulations. In some cases, even after further study, it may be difficult or impossible to make definite determinations about the adequacy of specific regulations because of the lack of knowledge or understanding of the mechanisms contributing to the decline or vulnerability of Steller sea lion populations.

NMFS is in the process of reinitiating or requesting reinitiation of consultation under section 7 of the ESA with respect to various agency actions that may affect Steller sea lions. Reinitiation is necessary because of new information about the status of Steller sea lions and is expected to help NMFS assess the adequacy of certain regulatory mechanisms.

In some cases, NMFS anticipates that regulations may be needed to be revised to protect Steller sea lions or to aid population recovery. Review and revision of Steller sea lion management regulations, to the maximum extent practicable, will be undertaken in full consultation with affected parties, Federal and state agencies, and public interest groups. Except with respect to the regulatory measures proposed in this action, NMFS anticipates that major regulatory revisions will be implemented by rulemaking that is separate from any final ESA listing reclassification.

E. Other Natural or Manmade Factors Affecting its Continued Existence

Other factors also may affect either or both populations of Steller sea lions. In particular, removals of Steller sea lions from the wild, resulting from direct and incidental takings, may be a contributing factor in past and continuing declines. Changes in food availability is another factor that may be causing declines. Contaminants are also a concern. These other factors are discussed in more detail in the following sections.

Removals from the Western Population Segment: Steller sea lions frequently interact with commercial fisheries, and many have been reported incidentally taken in fisheries in the Gulf of Alaska, Bering Sea, and Aleutian Islands area. Estimates of the total number of Steller sea lions taken in commercial trawl fisheries in these waters from 1966 through 1988 exceed 20,000 animals (NMFS, 1995). Incidental catch appears to have been a contributing factor in the population decline in some areas of the Aleutian Islands and Gulf of Alaska during certain time periods. In recent years, the number of Steller sea lions taken in Federally-managed commercial groundfish fisheries in the Gulf of Alaska, Bering Sea, and Aleutian Islands has been relatively low (less than 30/year), and incidental take in these fisheries is no longer thought to be a major factor affecting the western population.

Alaska Native subsistence hunters have been estimated to take about 500 Steller sea lions annually in recent years; virtually all of the subsistence harvest in Alaska occurs within the range of the western population segment (Wolfe and Mischler, 1993; 1994). These removals have an impact on the population although the magnitude of estimates in comparison to the reported declines indicate that subsistence harvest has not been a significant factor in the decline. However, should the western population segment continue to decline and the subsistence harvest continue at the same level, it may become significant.

Removals from the Eastern Population Segment: Accurate data on incidental takes of Steller sea lions in other fisheries in Southeast Alaska, Oregon, and California are not available, but estimates from available sources are low. Alaska Native takes of Steller sea lions within the eastern population (Southeast Alaska) have been estimated at less than 10 animals annually (Wolfe and Mischler, 1993; 1994).

The calculated PBR for the eastern population of Steller sea lion is 706 animals, well above the current level of human-caused mortality.

Food availability for the western population segment: Steller sea lions are opportunistic feeders, that feed primarily on schooling demersal fish, such as walleye pollock, Atka mackerel, herring, and capelin. Declines in sea lion abundance may be related to changes in the availability of sea lion prey. Changes in the quantity or quality of available prey could have a chronic negative influence on the health and fitness of individual sea lions, resulting in reduced reproductive potential, increased susceptibility to disease, or death (Loughlin and Merrick, 1989). Calkins and Goodwin (1988) observed that Steller sea lions collected in the Kodiak Island area in 1985–86 were significantly smaller at age than animals collected from 1975–78, and hypothesized that nutritional stress was the cause. Juvenile sea lions, which are less adept foragers, may be most affected by changes in food availability. Demographic studies at Ugamak and Marmot Island rookeries suggest that juvenile survival has been greatly reduced over the last 20 years, and that this reduced juvenile survival may be the proximate cause of the population decline (NMFS, 1995). The role of food availability in the population decline remains unclear and is being investigated by researchers.

The BSAI and GOA commercial groundfish fisheries target important prey species of Steller sea lions, notably wallege pollock and Atka mackerel. Whether these fisheries actually deplete food resources of Steller sea lions is unclear. Analyses that have compared fishery harvests with changes in Steller sea lion abundance have been inconclusive, but the limitations of the available data may confound results (Loughlin and Merrick, 1989; Ferrero and Fritz, 1994).

One working hypothesis is that where and how fisheries operate is significant to Steller sea lions even if overall fishery removal levels are conservative of fish stocks. Fisheries that harvest large quantities of fish in relatively small geographic areas and short periods of time may deplete the local abundance of fishery resources. When such a fishery occurs in important Steller sea lion foraging habitat and

targets, or has a significant bycatch of, Steller sea lion prey species (as the pollock and Atka mackerel fisheries do), the fishery may make it more difficult for sea lions to obtain food. This is likely to be more important in the winter when alternate food resources are fewer and sea lion metabolic costs higher, and to be more significant to newly-weaned juveniles, which are less adept foragers. Based on these hypotheses, NMFS established no groundfish trawl zones around listed Steller sea lion rookeries in the GOA and BSAI (to reduce harvest in important foraging habitats), and created geographic fishery allocation areas in the GOA for pollock (to disperse fishing effort).

The hypothesized change in prey availability to Steller sea lions could also be related to environmental change. Changes in the abundance of several species of fish, shellfish, birds, and other marine mammals in the BSAI and GOA have been documented over the last 20 years. In particular, some important forage fish stocks, such as capelin and sand lance, appeared to have declined in both the BSAI and GOA during the 1970's and 1980's. Some of these observed changes in the ecosystem can be linked to human activities (e.g., fisheries, marine mammal harvests, hatcheries) whereas others appear to be related to natural phenomena (e.g., oceanic temperature changes).

Contaminants affecting both populations: Concern has been expressed about the possible adverse effects of anthropogenic contaminants on the health and productivity of Steller sea lions, particularly in the western population and in California. Presently, the significance, if any, of toxic substances in Steller sea lion population declines is not known, and additional research is warranted.

Proposed Determinations

The best available information indicates that Steller sea lions should be managed as two discrete population segments and NMFS proposes separate listings of the eastern and the western population segments of the Steller sea lion for the purposes of the ESA.

Available data on population trends indicate that the western population of Steller sea lions is in danger of extinction throughout all or a significant part of its range. This population had exhibited a precipitous, large population decline at the time that the Steller sea lion was listed as a threatened species in 1990, and has continued to decline since the listing. Although the precise cause(s) of the decline have not been determined, it is likely that the current condition is caused by a combination of the factors specified under section 4(a)(1) of the ESA.

Therefore, NMFS proposes that the western population of Steller sea lions be listed as an endangered species under the ESA.

The eastern population segment was originally listed as a threatened species in 1990 when the entire species was listed. The eastern population has exhibited a stable to increasing population trend for the last 15 years; however, NMFS believes that the large decline within the overall U.S. population threatens the continued existence of the entire species. This is particularly true since the underlying causes of the decline remain unknown, and thus, unpredictable.

Therefore, despite the apparent stability of the eastern population segment, NMFS proposes to maintain a threatened listing for this portion of the geographic range. This proposed determination allows a differentiation between the two populations that acknowledges the different individual population trends, but does not lose sight of the overall trend for the species. NMFS, in conjunction with the Recovery Team, will develop appropriate delisting criteria for the eastern population segment.

NMFS Policies on Endangered and Threatened Wildlife

On July 1, 1994, NMFS, jointly with the U.S. Fish and Wildlife Service, published a series of new policies regarding listings under the ESA, including a policy for peer review of scientific data (59 FR 34270) and a policy to identify, to the maximum extent possible, those activities that would or would not constitute a violation of section 9 of the ESA (59 FR 34272).

Role of peer review: The intent of the peer review policy is to ensure that listings are based on the best scientific and commercial data available. Prior to a final listing, the Services will solicit the expert opinions of three appropriate and independent specialists. Further, independent peer reviewers will be selected from the academic and scientific community, Tribal and other native American groups, Federal and state agencies, and the private sector.

Identification of those activities that would constitute a violation of Section 9 of the ESA: Section 9 of the ESA prohibits certain activities that directly or indirectly affect endangered and threatened species. Under the ESA and regulations, it is illegal to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture or collect) or to attempt to take any endangered and most threatened species. Activities considered by the Agency to constitute a ''take'' of an endangered or threatened Steller sea lion include:

1. Shooting at or near a Steller sea lion. An example would be an individual who shoots at a Steller sea lion to deter or distract it from taking fish off the individual's fishing gear; another example is shooting a Steller sea lion with a paint ball gun;

2. Collecting Steller sea lion parts. The ESA prohibits the collection of an endangered species or parts therefrom. Therefore, it would be illegal to collect parts from a dead Steller sea lion that has washed ashore;

3. Pursuing or harassing Steller sea lions. An example would be pursuing a Steller sea lion in an attempt to watch its behavior or to obtain a better view of it from a vessel. These illegal activities can be committed by guided marine life tour operators as well as individual recreational boaters. Persons who wish to view Steller sea lions would be required to avoid any actions that harass the Steller sea lion or actions that would constitute pursuit of Steller sea lions either in the water or on land. Trying to get the perfect photograph may result in actions that constitute harassment or pursuit of a Steller sea lion;

4. Approaching within three nautical miles of a listed Steller sea lion rookery site. This includes, but is not limited to, transitting through the rookery site in a vessel, anchoring within any rookery site or fishing within any rookery site; and

5. The take of Steller sea lions for the production of authentic native articles of handicrafts and clothing only. The ESA only provides for the take of endangered species for subsistence purposes and the take must not be done in a wasteful manner.

This list is *not* exhaustive. It is provided to give the reader some examples of the types of activities that would be considered by the Agency as constituting a ''take'' of an endangered or threatened Steller sea lion under the ESA and regulations.

With regard to activities that may affect Steller sea lions or their habitat, and whose likelihood of violation of section 9 is uncertain, the NMFS/Alaska Regional Office (see **ADDRESSES**) should be contacted to assist in determining whether a particular activity constitutes a prohibited act under section 9.

References Cited

A complete list of all references cited herein are available upon request (see **ADDRESSES**).

Classification

Section 4(b)(1) of the ESA restricts the information that may be considered when assessing species for listing. Based on this limitation and the opinion in *Pacific Legal Foundation v.* Andrus, 657 F.2d 829 (6th Cir. 1981), listing actions under the ESA are excluded from the normal requirements of the National Environmental Policy Act.

As noted in the Conference report on the 1982 amendments to the ESA (H.R. Conf. Rep. No. 835, 97th Cong., 2d Sess 20. (1982)), economic considerations have no relevance to determinations regarding the status of species. Therefore, the economic analysis requirements of Executive Order 12866, the Regulatory Flexibility Act, and the Paperwork Reduction Act are not applicable to the listing process.

Dated: September 28, 1995.

Nancy Foster,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

List of Subjects

50 CFR Part 222

Administrative practice and procedure, Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine mammals, Transportation.

For the reasons set out in the preamble, 50 CFR parts 222 and 227 are proposed to be amended as follows:

PART 222—ENDANGERED FISH OR WILDLIFE

1. The authority citation for part 222 is revised to read as follows:

Authority: 16 U.S.C. 1361 *et seq.* and 1531–1543.

2. In § 222.23, in paragraph (a) after ''Saimaa seal (*Phoca hispida saimensis*);'' insert ''Steller sea lion (*Eumetopias jubatus*), western population (the western population consists of Steller sea lions from breeding colonies located west of 144° W. long.);''.

* * * * *

3. Section 222.32 is added to subpart D to read as follows:

§ 222.32 Special prohibitions relating to endangered Steller sea lion protection.

General. Special rules relating to endangered Steller sea lions are provided at part 227, subpart B.

PART 227—THREATENED FISH AND WILDLIFE

4. The authority citation for part 227 is revised to read as follows:

Authority: 16 U.S.C. 1361 *et seq.* and 1531–1543.

§ 227.12 [Amended]

5. In § 227.12, paragraphs (a) introductory text, (a)(1), (a)(2), (a)(4), and (b)(2) are revised to read as follows:

(a) *General prohibitions.* Except as provided under paragraph (b) of this section, the prohibitions of section 9 of the Act (16 U.S.C. 1538) relating to the western population of Steller sea lions identified at part 222 also apply to the eastern population which consists of Steller sea lions from breeding colonies located east of 144° W. long.

(1) *No discharge of firearms or similar devices.* Except as provided in paragraph (b) of this section, no person subject to the jurisdiction of the United States may discharge a firearm or similar device at or within 100 yards (91.4 meters) of a Steller sea lion. A firearm or similar device includes any weapon capable of propelling an object resulting in, or likely to result in, injury including, without limitation, guns, crossbows, spearguns, bangsticks, archery gear, harpoons and spears.

(2) *No approach in buffer areas.* Except as provided in paragraph (b) of this section:

(i) No owner or operator of a vessel may allow the vessel to approach within 3 nautical miles (5.5 kilometers) of a Steller sea lion rookery site listed in paragraph (a)(3) of this section;

(ii) No person may approach on land not privately owned within one-half statutory miles (0.8 kilometers) or within sight of a Steller sea lion rookery site listed in paragraph (a)(3) of this section, whichever is greater, except on Marmot Island; and

(iii) No person may approach on land not privately owned within one and one-half statutory miles (2.4 kilometers) or within sight of the eastern shore of Marmot Island, including the Steller sea lion rookery site listed in paragraph (a)(3) of this section, whichever is greater.

* * * * *

(4) *Quota.* The incidental mortality and serious injury of endangered and threatened Steller sea lions in commercial fisheries can be authorized in compliance with sections 101(a)(5) and 118 of the Marine Mammal Protection Act.

(b) * * *

(2) *Official activities.* The taking of Steller sea lions should be reported within 30 days to the Director, Alaska Region, National Marine Fisheries Service, P.O. Box 21668, Juneau, AK 99802. Paragraph (a) of this section does not prohibit or restrict a Federal, state or local government official, or his or her designee, who is acting in the course of official duties from:

(i) Taking a Steller sea lion in a humane manner, if the taking is for the protection or welfare of the animal, the protection of the public health and welfare, or the nonlethal removal of nuisance animals; or

(ii) Entering the buffer areas to perform activities that are necessary for national defense, or the performance of other legitimate governmental activities.

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[FR Doc. 95–24638 Filed 9–29–95; 1:37 pm]

BILLING CODE 3510–22–W

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50 CFR Part 651

[I.D. 092695D]

New England Fishery Management Council; Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Public meeting; request for comments.

SUMMARY: The New England Fishery Management Council (Council) will hold a 1-day public meeting to consider actions affecting New England fisheries in the exclusive economic zone (EEZ).

DATES: Written comments will be accepted through October 9, 1995, on Framework Adjustment 12 and through October 18, 1995, on draft Amendment 7 to the Fishery Management Plan for the Northeast Multispecies Fishery. The meeting will be held on Wednesday, October 11, 1995, at 10 a.m.

ADDRESSES: The meeting will take place at the Holiday Inn, One Newbury Street, at the intersection of Routes 1 and 128, Peabody, MA 01960; telephone: (508) 535–4600. Requests for special accommodations should be addressed to the New England Fishery Management Council, 5 Broadway, Saugus, MA 01906–1097; telephone: (617) 231–0422.

FOR FURTHER INFORMATION CONTACT: Douglas G. Marshall, Executive Director, New England Fishery Management Council (617) 231–0422.

SUPPLEMENTARY INFORMATION: The Council will consider final action on a framework adjustment to the Northeast Multispecies (Groundfish) Fishery Management Plan (FMP) intended to reduce the incidental take of harbor porpoise in the Gulf of Maine sink gillnet fishery. The Aquaculture Committee report will follow with a discussion for development of a policy or process that could guide future Council actions related to aquaculture in the EEZ. The Groundfish Committee will discuss public comments received to date on draft Amendment 7 to the FMP. This preliminary review is scheduled in light of the volume of information forwarded to the Council. No formal decisions will be made until after the deadline for submission of written comments on the Council's draft Amendment 7 due October 18, 1995. Other business may be added to the agenda as necessary.

Abbreviated Rulemaking Action—Framework Adjustment 12 to the FMP

The Council may take final action on Framework Adjustment 12 to the FMP under the framework for abbreviated rulemaking contained in 50 CFR 651.32. The action would extend the time and area of the Mid-coast Closure Area initiated in Framework Adjustment 4 to reduce the bycatch of harbor porpoise in the Gulf of Maine sink gillnet fishery. The area closure is presently in effect from November 1 through November 30 of each fishing year and is described below.

Latitude	*Longitude*
42°45′ N.	Massachusetts shoreline
42°45′ N.	70°15′ W.
43°15′ N.	70°15′ W.
43°15′ N.	69°00′ W.
Maine shoreline	69°00′ W.

The Council is considering a change that would extend the timing of the closure through December 31 and that would incorporate a region referred to as the Jeffreys Ledge Band west of 69°30′ W. Relative to the Mid-coast Closure Area, it is described as east on 42°30′ N. from the shore to 70°00′ W., north along 70°00′ W. to 43°00′ N., then east on 43°00′ N. to 69°30′ W., then north on 69°30′ W. to 43°15′ N. According to the NMFS sea sampling data base, the harbor porpoise bycatch in this band has been relatively high as compared to other Gulf of Maine areas during previous years. Analyses of 1994 data indicate that bycatch rates in the 1994 fall period were about 3 times higher than those observed since 1991.

The harbor porpoise bycatch issue was discussed at a Marine Mammal Committee meeting held on September 12, 1995, and at the September 13–14, 1995, Council meeting held in Portland, ME. Documents summarizing the Council's proposed action, the biological analyses upon which this decision will be based, and potential economic impacts will be available to the public 5 days prior to the October 11, 1995, meeting. Written comments will be accepted through October 9, 1995, on the abbreviated rulemaking action (Framework Adjustment 12). The Council will consider public comments in making its recommendations to the Director, Northeast Region, NMFS (Regional Director), under the provisions for abbreviated rulemaking cited above. If the Regional Director concurs with the measures proposed by the Council, he will publish them as a final rule in the Federal Register.

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Douglas G. Marshall (see **ADDRESSES**) at least 5 days prior to the meeting date.

Dated: September 28, 1995.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–24675 Filed 10–3–95; 8:45 am]

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Notices

Federal Register
Vol. 60, No. 192
Wednesday, October 4, 1995

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 Marketing Service

[TM–95–00–3]

Notice of Meeting of the National Organic Standards Board

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the Agricultural Marketing Service (AMS) announces a forthcoming meeting of the National Organic Standards Board (NOSB).

DATES: October 30, 1995 at 8 a.m. through November 3, 1995 at 5 p.m. for the NOSB.

PLACE: Holiday Inn, Austin—Town Lake, 20 North Interregional, Austin, Texas 78701. Phone: (512) 472–8211. All meetings of the NOSB for the week will be held at that address.

FOR FURTHER INFORMATION CONTACT: Dr. Harold S. Ricker, Staff Director, NOSB, Room 2945 South Building, U.S. Department of Agriculture (USDA), AMS, Transportation and Marketing Division, P. O. Box 96456, Washington, D.C. 20090–6456. Phone: (202) 720–2704.

SUPPLEMENTARY INFORMATION: Section 2119 (7 U.S.C. 6518) of the Food, Agriculture, Conservation, and Trade Act of 1990 (FACT Act), as amended (7 U.S.C. Section 6501 *et seq.*) requires establishment of a NOSB. The purpose of the NOSB is to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of Title XXI of the FACT Act. The NOSB met for the first time in Washington, D.C., in March 1992 and currently has five committees to work on various aspects of the program. The committees are: Crops Standards; Processing, Labelling and Packaging; Livestock Standards; Accreditation; and International Issues. At the last meeting, the NOSB began the review of substances for consideration for the National List as allowed synthetics for use in organic production and processing. Technical advisory panels provided information on approximately 50 substances for NOSB consideration.

The NOSB reviewed the materials and determined whether they would be considered nonsynthetic or synthetic. If synthetic, then the NOSB determined whether they should be placed on the list of allowed synthetic substances for use in organic processing and production. Approximately 25 substances were placed on the allowed synthetic list. Others were determined to be nonsynthetic or required more information.

Purpose and Agenda

The main focus of this meeting is to continue the discussion of additional materials for consideration for placement on the National List of allowed synthetics and prohibited natural substances for use in organic production and processing of organic foods. Main emphasis will be placed on the review of approximately 70 substances for which a review has been conducted by the technical advisory panel.

Additional topics to be covered in the full NOSB meeting include: the Livestock Committee will present recommendations for the use of antibiotics and parasiticides in laying flocks and recommendations regarding use of synthetic vitamins, minerals, vaccines, innoculants, and amino acids; the Crops Committee will present recommendations for use of sewage sludge, and an amendment to the Planting Stock Policy concerning banana rhizomes; the Processing Committee will present recommendations for natural flavors and synthetic vitamin fortifications in organic foods, and oil extraction issues.

A final agenda will be available on October 13, 1995. Persons requesting copies should contact Ms. Karen Thomas at the above address or phone (202) 720–3252.

Type of Meeting

All meetings will be open to the public. Individuals and organizations wishing to provide written comments on these issues or to comment orally on any organic issues should forward the request to Dr. Harold S. Ricker at the above address or FAX to (202) 205–7808 by October 25, 1995, in order to be scheduled. The NOSB has scheduled time for public input on Tuesday, October 31, 1995, beginning at 1 p.m. and continuing until 5 p.m. While people may sign up to speak at the door, advance scheduling assures an opportunity in the time allowed and helps the NOSB plan its activities. Each individual or organization will be allocated 10 minutes for presenting orally the key issues of concern, and should provide 16 copies of written material elaborating on those issues for the NOSB.

Dated: September 27, 1995.

Lon Hatamiya,

Administrator, Agricultural Marketing Service.

[FR Doc. 95–24626 Filed 10–3–95; 8:45 am]

BILLING CODE 3410–02–P

Food Safety and Inspection Service

[Docket No. 95–045N]

National Advisory Committee on Microbiological Criteria for Foods; Meeting

A meeting of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will be held October 16 through October 19, 1995, in Room 4347, South Building, U.S. Department of Agriculture, Washington, DC 20250. The Fresh Produce Subcommittee will meet on Monday, October 16 from 1:00 p.m. to 5:00 p.m. The full Committee will meet in Room 800 of the Hubert Humphrey Building, Department of Health and Human Services, Independence Ave., SW, Washington, DC 20204 on Tuesday, October 17 from 8:30 a.m. to 12:00 p.m. and on Thursday, October 19 from 8:30 a.m. to 12:00 p.m. Other Subcommittees will meet on Tuesday, October 17 from 1:00 p.m. to 5:00 p.m., and on Wednesday, October 18, from 8:30 a.m. to 5:00 p.m.

The NACMCF provides advice and recommendations to the Secretaries of Agriculture, and Health and Human Services concerning the development of microbiological criteria by which the

safety and wholesomeness of food can be assessed, including criteria pertaining to microorganisms that indicate whether food has been processed using good manufacturing processes. The meeting will include discussion of the following topics as time permits:

I. Role of the Food Safety and Inspection Service in Eggs and Egg Products Food Safety
II. FSIS Emergency Programs
III. HACCP Issues in Codex Alimentarius
IV. Collaborative Efforts and Sentinel Sites
V. New FDA Seafood Regulations
VI. FDA HACCP Pilot Projects
VII. Reports from Chairs of the Subcommittees
VIII. Meetings of the Subcommittees
IX. Public Comments

The NACMCF meeting is open to the public on a space available basis. Interested persons may file comments on the topics above prior to and following the meeting. These comments should be addressed to: Mr. Craig Fedchock, Advisory Committee Specialist, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 311, 1255 22nd Street, NW., Washington, DC 20250–3700. Comments may also be sent to Mr. Fedchock on FAX No. (202) 254–2530. Background materials are available for inspection by contacting Mr. Fedchock on (202) 254–2517.

Done at Washington, DC, on: September 29, 1995.

Michael R. Taylor,

Administrator.

[FR Doc. 95–24650 Filed 9–29–95; 1:24 pm]

BILLING CODE 3410–DM–P

ASSASSINATION RECORDS REVIEW BOARD

Formal Determinations on Records Release

AGENCY: Assassination Records Review Board.

ACTION: Notice of Formal Determinations.

SUMMARY: The Assassination Records Review Board (Review Board) met in closed meeting on September 20 and 21, 1995, and made formal determinations on the release of records under the President John F. Kennedy Assassination Records Collection Act of 1992 (JFK Act). By issuing this notice, the Review Board complies with the section of the JFK Act that requires the Review Board to publish the results of its decisions on a document-by-document basis in the Federal Register within 14 days of the date of the decision.

FOR FURTHER INFORMATION CONTACT:

T. Jeremy Gunn, Acting General Counsel and Associate Director for Research and Analysis, Assassination Records Review Board, Second Floor, 600 E Street, NW., Washington, DC 20530, (202) 724–0088, fax (202) 724–0457.

SUPPLEMENTARY INFORMATION: This notice complies with the requirements of the *President John F. Kennedy Assassination Records Collection Act of 1992*, 44 U.S.C. 2107.9(c)(4)(A) (1992). On September 20 and 21, 1995, the Review Board made formal determinations on records it reviewed under the JFK Act. These determinations are listed below. The assassination records are identified by the record identification number assigned in the President John F. Kennedy Assassination Records Collection database maintained by the National Archives. For each document, the number of releases or previously redacted information is noted as well as the number of sustained postponements.

REVIEW BOARD DETERMINATIONS—FBI DOCUMENTS

Record No.	ARRB releases	Sustained postponements	Status of document	Next review date
124–10006–10342	4	2	Postponed in Part	10/26/2017
124–10035–10065	4	2	Postponed in Part	10/26/2017
124–10070–10354	8	1	Postponed in Part	10/26/2017
124–10108–10142	8	1	Postponed in Part	10/26/2017
124–10119–10078	5	0	Open in Full	N/A
124–10170–10064	4	2	Postponed in Part	10/26/2017
124–10184–10256	11	9	Postponed in Part	10/26/2017
124–10232–10345	4	2	Postponed in Part	10/26/2017
124–10243–10367	4	2	Postponed in Part	10/26/2017
124–10244–10077	4	2	Postponed in Part	10/26/2017

Dated: September 28, 1995.

David G. Marwell,

Executive Director.

[FR Doc. 95–24641 Filed 10–3–95; 8:45 am]

BILLING CODE 6118–01–M

COMMISSION ON CIVIL RIGHTS

Agenda and Notice of Public Meeting of the Colorado Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a meeting of the Colorado Advisory Committee will be held on October 25, 1995, from 1–4 p.m., at the Mile High Center, Tower 1, 1700 Broadway, Suite 490, Denver, Colorado 80290. The purpose of meeting is to plan future activities and discuss civil rights developments.

Persons desiring additional information, or planning a presentation to the Committee, should contact Committee Chairperson Joseph Archese, 303–556–3139, or John F. Dulles, Director of the Rocky Mountain Regional Office, 303–866–1040 (TDD 303–866–1049). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least five (5) working days before the scheduled date of the meeting.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, September 26, 1995.

Carol-Lee Hurley,

Chief, Regional Programs Coordination Unit.

[FR Doc. 95–24617 Filed 10–3–95; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Bureau of Export Administration

Regulations and Procedures Technical Advisory Committee; Partially Closed Meeting

A meeting of the Regulations and Procedures Technical Advisory Committee will be held October 26, 1995, 9:00 a.m., in the Herbert C. Hoover Building, Room 3884, 14th Street, NW., Washington, D.C. The Committee advises the Office of the Assistant Secretary for Export Administration on implementation of the Export Administration Regulations (EAR) and provides for continuing review to update the EAR as needed.

Agenda

Open Session

1. Opening Remarks by the Chairman.
2. Presentation of Papers or Comments by the Public.
3. Update on Bureau of Export Administration initiatives.
4. Presentation/discussion on reform of the Export Administration Regulations (EAR).
5. Update on status of the New Forum.
6. Reports from working groups.
7. Discussion of work plans.

Closed Session

8. Discussion of matters properly classified under Executive Order 12356, dealing with the U.S. export 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 meting. However, to facilitate the 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: Ms. Lee Ann Carpenter, TAC Unit/OAS/EA, Room 3886C, Bureau of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on December 22, 1994, pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, that the series of meetings or portions 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 and copying in the Central Reference and Records Inspection Facility, Room 6020, U.S. Department of Commerce, Washington, D.C. For further information, call Lee Ann Carpenter at (202) 482–2583.

Dated: September 29, 1995.

Lee Ann Carpenter,

Director, Technical Advisory Committee Unit.

[FR Doc. 95–24680 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–DT–M

International Trade Administration

[C–333–002]

Cotton Yarn From Peru; Termination of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Termination of Countervailing Duty Administrative Review.

SUMMARY: The Department of Commerce (the Department) is terminating the countervailing duty administrative review of cotton yarn from Peru initiated on March 15, 1995.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Gayle Longest or Kelly Parkhill, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; Telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION: On February 2, 1995, the Department published in the Federal Register (60 FR 6524) a notice of ''Opportunity to Request Administrative Review'' on the countervailing duty order (48 FR 4508) on cotton yarn from Peru for the period January 1, 1994 through December 31, 1994. On February 28, 1995, the Government of Peru (GOP) and Southeastern Yarn Sales, a U.S. importer of cotton yarn, separately requested an administrative review of the merchandise subject to the countervailing duty order. On March 15, 1995, the Department published a notice of initiation of a review of the order (60 FR 13955). On June 16, 1995, the Department sent a letter asking these interested parties to amend their original request for an administrative review in accordance to the Department's Interim Regulations.

On June 19, 1995, Southeastern Yarn Sales indicated that it was no longer interested in a separate request for review. *See* Memorandum to File dated June 22, 1995 regarding Request for Administrative Review on Cotton Yarn from Peru, which is on file in the Central Records Unit, Room B–099 of the Department of Commerce. The request of the GOP was amended on June 23, 1995 to include only Industria Textil Piura S.A., Hilanderia San Antonio S.A., and Textil Trujillo S.A., foreign producers of the subject merchandise. On September 1, 1995, the Department published an amendment to the initiation notice of March 15, 1995 (60 FR 45697).

On August 23, 1995, the GOP and the three foreign producers withdrew their amended request for an administrative review. Because the request for withdrawal was timely pursuant to 19 CFR 355.22(a)(3), the Department is terminating this review.

Dated: September 27, 1995.

Joseph A. Spetrini,

Deputy Assistant Secretary for Compliance.

[FR Doc. 95–24681 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–DS–P

[C–557–806]

Extruded Rubber Thread From Malaysia; Final Results of Countervailing Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

ACTION: Notice of Final Results of Countervailing Duty Administrative Review.

SUMMARY: On May 22, 1995, the Department of Commerce (the Department) published in the Federal Register its preliminary results of administrative review of the countervailing duty order on extruded rubber thread from Malaysia for the period January 1, 1993 through December 31, 1993. We have completed this review and determine the net subsidy to be 1.00 percent *ad valorem*. We will instruct the U.S. Customs Service to assess countervailing duties as indicated above.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Judy Kornfeld or Rick Herring, Office of Countervailing Compliance, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230; telephone: (202) 482–2786.

SUPPLEMENTARY INFORMATION:

Background

On May 22, 1995, the Department published in the Federal Register (60 FR 27080) the preliminary results of its administrative review of the countervailing duty order on extruded rubber thread from Malaysia. The Department has now completed this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

We invited interested parties to comment on the preliminary results. On June 21, 1995, a case brief was submitted by the Government of Malaysia (GOM) and Heveafil Sdn. Bhd., (Heveafil), Filmax Sdn. Bhd. (Filmax), Rubberflex Sdn. Bhd. (Rubberflex), Filati Lastex Elastofibre Sdn. Bhd., (Filati) and Rubfil Sdn. Bhd. (Rubfil), producers of the subject merchandise which exported extruded rubber thread to the United States during the review period (respondents). The review covers the period January 1, 1993 through December 31, 1993. The review involves 5 companies and 12 programs.

Applicable Statute and Regulations

The Department is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Unless otherwise indicated, all citations to the statute and to the Department's regulations are in reference to the provisions as they existed on December 31, 1994. However, references to the Department's *Countervailing Duties; Notice of Proposed Rulemaking and Request for Public Comments*, 54 FR 23366 (May 31, 1989) (*Proposed Regulations*), are provided solely for further explanation of the Department's countervailing duty practice. Although the Department has withdrawn the particular rulemaking proceeding pursuant to which the *Proposed Regulations* were issued, the subject matter of these regulations is being considered in connection with an ongoing rulemaking proceeding which, among other things, is intended to conform the Department's regulations to the Uruguay Round Agreements Act. *See* 60 FR 80 (Jan. 3, 1995).

Scope of the Review

Imports covered by this review are shipments of extruded rubber thread from Malaysia. Extruded rubber thread is defined as vulcanized rubber thread obtained by extrusion of stable or concentrated natural latex of any cross sectional shape; measuring from 0.18 mm, which is 0.007 inch or 140 gauge, to 1.42 mm, which is 0.056 inch or 18 gauge, in diameter. Such merchandise is classifiable under item number 4007.00.00 of the Harmonized Tariff Schedule (HTS). The HTS item number is provided for convenience and Customs purposes. The written description is dispositive.

Calculation Methodology for Assessment and Cash Deposit Purposes

We calculated the net subsidy on a country-wide basis by first calculating the subsidy rate for each company subject to the administrative review. We then weight-averaged the rate received by each company using as the weight its share of total Malaysian exports to the United States of subject merchandise, including all companies, even those with *de minimis* and zero rates. We then summed the individual companies' weight-averaged rates to determine the subsidy rate from all programs benefitting exports of subject merchandise to the United States.

Since the country-wide rate calculated using this methodology was above *de minimis*, as defined by 19 CFR 355.7 (1994), we proceeded to the next step, and examined the net subsidy rate calculated for each company to determine whether individual company rates differed significantly from the weighted-average country-wide rate, pursuant to 19 CFR 355.22(d)(3).

None of the companies had net subsidy rates which were significantly different pursuant to 19 CFR 355.22(d)(3). Therefore, all companies are assigned the country-wide rate.

Analysis of Programs

Based upon our analysis of our questionnaire and written comments from the interested parties we determine the following:

I. Programs Conferring Subsidies

1. Export Credit Refinancing

In the preliminary determination we found that this program conferred countervailable benefits on the subject merchandise. Our analysis of the comments submitted by the interested parties, summarized below, has not led us to reconsider our findings in the preliminary determination. On this basis, the net subsidy for this program is 0.72 percent.

2. Pioneer Status

In the preliminary determination we found that this program conferred countervailable benefits on the subject merchandise. Our analysis of the comments submitted by the interested parties, summarized below, has not led us to reconsider our findings in the preliminary determination. On this basis, the net subsidy for this program is 0.28 percent.

II. Programs Found Not to be Used

In the preliminary determination, we found the following programs to be not used:

1. Investment Tax Allowance
2. Abatement of Five Percent of Taxable Income Due to Location in a Promoted Industrial Area
3. Allowance of a Percentage of Net Taxable Income Based on the F.O.B. Value of Export Sales
4. Double Deduction of Export Credit Insurance Payments
5. Abatement of Taxable Income of Five Percent of Adjusted Income of Companies Due to Capital Participation and Employment Policy Adherence
6. Preferential Financing for Bumiputras
7. Abatement of Income Tax Based on the Ratio of Export Sales to Total Sales
8. Industrial Building Allowance
9. Double Deduction for Export Promotion Expenses

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to reconsider our findings in the preliminary determination.

III. Programs Found to be Terminated

In the preliminary determination we found the following program to be terminated and not to provide any residual benefits:

- Abatement of Five Percent of the Value of Indigenous Malaysian Materials Used in Exports.

Our analysis of the comments submitted by the interested parties, summarized below, has not led us to reconsider our findings in the preliminary determination.

Analysis of Comments

Comment 1: Respondents allege that the Department initiated the original investigation pursuant to Section 303(a)(2) of the Act, and, therefore, the Department can impose countervailing duties under this section only if there is an injury determination by the International Trade Commission (ITC).

(The ITC discontinued its injury determination under Section 303(a)(2) because the duty-free status of rubber thread from Malaysia was terminated.) Respondents contend that without an injury determination, the Department had no authority to issue a countervailing duty order and to require the payment of cash deposits. Respondents further maintain that the Department cannot simply transfer the jurisdiction for an investigation from Section 303(a)(2) to Section 303(a)(1) without issuing a public notice that it intends to proceed with the investigation under a different statutory provision. *See, Certain Textile Mill Products and Apparel from Turkey* (50 FR 9817; March 12, 1987); *Certain Textile Mill Products and Apparel from the Philippines* (50 FR 1195; March 26, 1985 and *Certain Textile Mill Products and Apparel from Indonesia* (50 FR 9861; March 12, 1985). Furthermore, because there was no initiation notice or a preliminary determination under section 303(a)(1), a final determination under that section was not appropriate. If the Department wanted to proceed with the investigation, it was required to re-initiate under the appropriate provision.

Department's Position: As the Department pointed out in the previous review, respondents' challenge to the Department's authority to issue the order is untimely. Challenges to the issuance of an order must be filed within 30 days of the date the order is published. The countervailing duty order on extruded rubber thread from Malaysia was published on August 25, 1992. Respondents voluntarily withdrew a timely-filed complaint challenging the order on these same grounds. Respondents' attempt to revive that challenge in this proceeding is untimely.

Comment 2: Respondents contend that the Department overstated the benefit received under the ECR program in its administrative review. They argue that the Department must use the ''cost of funds'' to the government as the benchmark as required by item ''k'' of the Illustrative List of Export Subsidies annexed to the Subsidies Code, and the appropriate ''cost of funds'' is the 90-day rate for government bonds. Respondents assert that if the Department continues to use the cost to the recipient as a benchmark, it should also continue its past practice and use the bankers' acceptances (BA) rates because they are identical to ECR financing in terms of risk, maturity and purpose. Respondents further contend that the Department should interpret the ''predominant'' form of financing as the most comparable form of financing. They assert that it makes no sense to compare trade financing to other financing such as short-term loans and overdrafts. Furthermore, if the Department uses the weighted-average of commercial rates, it should account for the differences in the terms of financing.

Respondents further argue that if the Department does not use the BA benchmark, it should use the Average Lending Rate (ALR) provided in the Bank Negara Statistical Bulletin rather the Base Lending Rate (BLR) plus an estimated spread. If the Department, nevertheless, uses this method, then the spread should be calculated by deducting the average BLR rate calculated by the Department from the ALR published in the *Bank Negara Statistical Bulletin.*

Department's Position: We disagree with respondents. As explained in the previous review, the Illustrative List identifies common forms of export subsidies but does not necessarily instruct the Department how to value them. The Department has a longstanding practice of valuing the benefit to the recipient rather than the cost to the government for the purpose of calculating countervailing duty rates.

The Department's practice is to use the rate for the predominant form of short-term financing in the country under review as the benchmark for short-term loans. *See, Proposed Regulations* (19 CFR 23380; May 31, 1989). Where there is no single predominant source of short-term financing in the country in question, the Department may use a benchmark composed of the interest rates for two or more sources of short-term financing in the country in question. *See, Final Affirmative Countervailing Duty Determination and Countervailing Duty Order; Steel Wire Rope from Thailand* (56 FR 46299; September 11, 1991). BAs constitute an extremely small percentage of short-term financing in Malaysia and, therefore, it would be inappropriate to use the BA rates as a benchmark. The *Bank Negara Statistical Bulletin,* provided in Exhibit 4 to the Government of Malaysia's Questionnaire Response dated November 18, 1994, lists the commercial bank BLR rates prevailing during the review period. The rates ranged from 8.25 percent to 9.50 percent. According to commercial bank officials, the banks add a 1.00 to 2.00 percent spread to the BLR. (*See Memorandum to the File from Chris Jimenez Regarding Conversation With Bank of America Official in Malaysia Regarding Spread Used by Commercial Banks in 1993* dated May 10, 1995, on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce).

During verification of the 1992 administrative review, we found that ALR rates published in the *Bank Negara Statistical Bulletin* included both short-term and long-term rates, while the BLR rates are strictly based on short-term loans. (*See Memorandum to the File from Judy Kornfeld and Lorenza Olivas Regarding Extruded Rubber Thread from Malaysia; Benchmark Information* dated August 15, 1995, on file in the public file of the Central Records Unit, Room B–099 of the Department of Commerce). Therefore, we disagree with respondents that we should use the ALR rate because it would improperly include long-term rates. Rather, we have determined that it is appropriate to continue to use the average of the commercial BLR rates published in *Bank Negara Statistical Bulletin,* plus an average 1.5 percent spread, as a benchmark, in accordance with section 355.44(b)(3)(i) of the Department's *Proposed Rules*. Respondents' argument, that if the Department, nevertheless, uses this method, it should calculate the spread by deducting the average BLR rate from the average of the ALR rates, would again improperly include long-term rates in the benchmark calculation.

Comment 3: Respondents argue that the Department overstated the net subsidy for the review period and for the duty deposit purposes because the Department failed to take account of the exclusion by Heveafil and Filmax of U.S. exports from the calculation of eligibility for the pre-shipment export financing. In addition, respondents claim that the two companies did not use funds from exports to the United States to repay any of the pre-shipment loans. They claim that in a similar situation, the Department concluded that exports to the United States did not receive benefits from short-term financing. *See, Suspension of Countervailing Duty Investigation; Certain Forged Steel Crankshafts from Brazil* (52 FR 28177, 28179; July 28, 1987) (*Brazilian Crankshafts Suspension Agreement*). Respondents' claim that in the first administrative review, the Department incorrectly rejected this method of eliminating the effect of a subsidy. Therefore, respondents maintain that Heveafil and Filmax received no benefit with regard to U.S. shipments.

Respondents further assert that the Department found a subsidy in this case in part because there was no strict segregation of U.S. exports and the

materials used in their manufacture from materials and exports to other markets financed with ECR loans. However, according to the respondents, the Department was presented with exactly the same issue in *Crankshafts from Brazil* and in that case the Department did not require that the exporters segregate raw materials purchased with export financing.

Department's Position: The GOM provides ECR financing based on export performance. The explicit purpose of this program is to promote the export of manufactured and approved agricultural products. Two types of ECR financing are available: pre-shipment and post-shipment financing. There is no evidence that the GOM limits these ECR loans to increase exports to markets other than the United States, nor is there evidence of a provision that prevents exporters from receiving ECR loans for exports to the United States.

During the review period, both Heveafil and Filmax applied for and used pre-shipment financing based on certificates of performance (CP). Pre-shipment financing based on CPs is a line of credit based on previous exports and, when received, cannot be tied to specific sales in specific markets. Because pre-shipment loans were not shipment-specific, we included all loans in calculating the country-wide duty rate. By excluding exports to the United States from their application for export financing, the companies merely reduced the amount of financing they received.

We disagree with respondents that in similar circumstances the Department has concluded that the exclusion of U.S. exports from applications in the manner described by respondents eliminates any countervailable subsidy that would otherwise be present. Where a benefit is not tied to a particular product or market, it is the Department's practice to allocate the benefit to all products exported by a firm where the benefit is received pursuant to an export program. *See* 19 C.F.R. 355.47(c) of the *Proposed Regulations* (54 FR 23375, May 31, 1989). A benefit is tied to a particular product or market at the time of receipt. Respondents cannot demonstrate that, at the time of receipt, ECR loans were tied solely to non-U.S. exports. Further, respondents' reliance on the *Crankshafts from Brazil* suspension agreement is misplaced. Suspension agreements are unusual, negotiated arrangements in which parties to a proceeding agree to renounce countervailable subsidies. As such, unlike final determinations, they do not serve as administrative precedent. Moreover, the *Crankshafts from Brazil* suspension agreement is consistent with our allocation practice, as described in the *Proposed Regulations.*

Comment 4: Respondents argue that the Department previously found the Pioneer Status Program not countervailable. *See, Carbon Steel Wire Rod from Malaysia; Final Results of Countervailing Duty Administrative Review (Wire Rod from Malaysia)* (56 FR 14927; April 12, 1991). Respondents assert that it is not countervailable because tax benefits under this program are not limited to any sector or region of the Malaysian economy, nor is the program exclusively available to exporting companies. They contend that the Department confirmed in the first administrative review, both the *de jure* and *de facto* availability of this program to the entire Malaysian economy, and that the pioneer status tax benefits are not targeted to specific industries or companies in a discriminatory manner. Furthermore, the Department verified in the original investigation that the internal guidelines used to grant pioneer status are characterized by neutral criteria unrelated to exports, location or any other factors that could require a determination that the program is countervailable.

Respondents further argue that the Department verified in the first administrative review that the GOM does not require export commitments, or view them as preponderant, in evaluating applications; that export potential is merely one of 12 factors considered in granting status; and that a product will not be accepted based on export potential alone. Furthermore, respondents argue that the Department verified in the first administrative review that the GOM commonly approves companies who do not make export commitments as well as some who do make them. Therefore, export performance is not viewed as a preponderant factor, but as one of many neutral criteria.

Department's Position: We addressed this identical argument in the previous review. In *Wire Rod from Malaysia,* we concluded that benefits were not used by a specific industry or group of industries and that no industry or group of industries used the program disproportionately and found the program not to be countervailable. That determination, however, did not specifically address situations where companies had a specific export condition attached to their pioneer status approval. In the *Wire Rod* investigation, petitioner raised the issue of an export requirement. Although the requirement per se is not new, it was not at issue with the companies investigated in *Wire Rod.*

As stated in the *Final Affirmative Countervailing Duty Determination and Countervailing Duty Order; Extruded Rubber Thread from Malaysia,* 57 FR 38472 (August 25, 1992) (*Malaysian Final Determination*), we continue to view the ''domestic'' side of the Pioneer Statue Program to be not countervailable. However, in this instance, recipients of the tax benefits conferred by this program can be divided into two categories: industries and activities that will find market opportunities in Malaysia and elsewhere, and those that face a saturated domestic market. At verification of the first administrative review, we established that an export requirement may sometimes be applied to certain industries after it is determined that the domestic market will no longer support additional producers. The extruded rubber thread industry is among these industries.

The combination of the necessary export orientation of the industry due to lack of domestic market opportunities and the explicit export condition attached to pioneer status approval in the rubber thread industry lead us to conclude that the ''export'' side of the Pioneer Status Program constitutes an export subsidy to the rubber thread industry, Whether or not the commitment was voluntary, as respondents suggest, the company has obligated itself to export a very large portion of its production, and that commitment was a condition for approval of benefits. For further information, *see Malaysian Final Determination.*

Comment 5: Respondents argue that the Department overstated the benefit from the Pioneer Status Program because it fails to deduct normal capital allowance that would have been allowed if the program had not been used. Respondents claim that Rubberflex, in fact, received no cash benefits from this program. Furthermore, they claim, the Department incorrectly allocated pioneer status tax benefits over only export sales even though pioneer status tax benefits are also applicable to profits on domestic sales. According to the respondents, this is consistent with the Department's practice to allocate benefits over total sales to which they are ''tied.''

Department's Position: We disagree with respondents. When a company receives pioneer status, it is allowed to accumulate normal capital allowance for use in future years. Thus, these allowances were not used to offset

current benefits during the review period. Moreover, export sales should form the denominator because receipt of pioneer status tax benefits for the companies under review is contingent upon exportation. Accordingly, we have not overstated the benefit from the Pioneer Status Program. *See* section 355.47(a)(2) of the *Proposed Rules. See also Final Affirmative Countervailing Duty Determination; Oil Country Tubular Goods From Brazil* (49 FR 46570; November 27, 1984) and *Final Affirmative Countervailing Duty Determination; Certain Agricultural Tillage Tools From Brazil* (50 FR 34525; August 26, 1985).

Final Results of Review

For the period January 1, 1993 through December 31, 1993, we determine the net subsidy to be 1.00 percent *ad valorem* for all companies.

The Department will instruct the U.S. Customs Service to assess a countervailing duty rate of 1.00 percent.

This countervailing duty order was determined to be subject to section 753 of the Act (as amended by the Uruguay Round Agreements Act of 1994). *Countervailing Duty Order; Opportunity to Request a Section 753 Injury Investigation*, 60 FR 27,963 (May 26, 1995), amended 60 FR 32,942 (June 26, 1995). In accordance with section 753(a), domestic interested parties have requested an injury investigation with respect to this order with the International Trade Commission (ITC). Pursuant to section 753(a)(4), liquidation of entries of subject merchandise made on or after January 1, 1995, the date Malaysia joined the World Trade Organization, is suspended until the ITC issues a final injury determination. We will not issue assessment instructions for any entries made after January 1, 1995; however, we will instruct Customs to collect cash deposits in accordance with the final results of this administrative review.

Therefore, the Department will instruct the U.S. Customs Service to collect a cash deposit of estimated countervailing duties of 1.00 percent of the f.o.b. invoice price on all shipments of the subject merchandise from Malaysia entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 355.43(d). Timely written notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: September 26, 1995.

Susan G. Esserman,

Assistant Secretary for Import Administration.

[FR Doc. 95–24685 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–DS–P

National Oceanic and Atmospheric Administration

[I.D. 090695A]

Gulf of Mexico Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of change of public meeting date.

SUMMARY: The date for the meeting of the Gulf of Mexico Fishery Management Council's (Council) Reef Fish Stock Assessment Panel has changed.

FOR FURTHER INFORMATION CONTACT: Wayne E. Swingle, Executive Director, Gulf of Mexico Fishery Management Council; telephone: (813) 228–2815.

SUPPLEMENTARY INFORMATION: The Council's Reef Fish Stock Assessment Panel meeting, originally scheduled for October 2 through October 5, as published on September 13, 1995 (60 FR 47547), has been changed to October 23 through October 26, 1995. The times and location of the meeting remain the same.

All other information as printed in the previous publication remains unchanged.

Dated: September 28, 1995.

Richard H. Schaefer,

Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–24674 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092595B]

Mid-Atlantic Fishery Management Council; Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's Scup Industry Advisory Committee will hold a public meeting.

DATES: The meeting will be held on October 12, 1995, from 10:00 a.m. until 4:00 p.m.

ADDRESSES: The meeting will be held at the Radisson Hotel Philadelphia, 500 Stevens Drive, Philadelphia, PA; telephone 610–521–5900.

Council Address: Mid-Atlantic Fishery Management Council, 300 S. New Street, Dover, DE 19901.

FOR FURTHER INFORMATION CONTACT: David R. Keifer, Executive Director, Mid-Atlantic Fishery Management Council; telephone: (302) 674–2331.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to review the hearing summaries and written comments on the Scup Fishery Management Plan.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Joanna Davis on (302) 674–2331, at least 5 days prior to the meeting dates.

Dated: September 26, 1995.

Richard W. Surdi,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 95–24636 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–22–F

[I.D. 092695A]

Endangered Species; Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Issuance of modification 5 to permit 747 (P45H) and modification 3 to permit 823 (P503C).

SUMMARY: Notice is hereby given that NMFS has issued modifications to permits authorizing takes of listed species for the purpose of scientific research and enhancement, subject to certain conditions set forth therein, to the U.S. Fish and Wildlife Service (USFWS) and the Idaho Department of Fish and Game (IDFG).

ADDRESSES: The applications and related documents are available for review in the following offices, by appointment:

Office of Protected Resources, F/PR8, NMFS, 1315 East-West Highway, Silver

Spring, MD 20910–3226 (301-713-1401); and

Environmental and Technical Services Division, F/NWO3, NMFS, 525 NE Oregon Street, Portland, OR 97232–4169 (503–230–5400).

SUPPLEMENTARY INFORMATION: Modification 5 to permit 747 and modification 3 to permit 823 were issued under the authority of section 10 of the Endangered Species Act of 1973 (ESA) (16 U.S.C. 1531–1543) and the NMFS regulations governing listed fish and wildlife permits (50 CFR parts 217–222).

Notice was published on April 27, 1995 (60 FR 20673) that an application had been filed by USFWS, located in Red Bluff, CA, for modification 5 to permit 747. Permit 747 authorizes a take of adult and juvenile, endangered, Sacramento River winter-run chinook salmon (*Oncorhynchus tshawytscha*) associated with a number of scientific research and enhancement projects. For modification 5, USFWS is authorized an increase in the annual take of listed juvenile salmon associated with the research activities of Study 1, a census of juvenile salmon downstream migration. USFWS needs the increased take to expand the understanding of juvenile salmonid rearing and outmigration and to assist with the evaluation of juvenile salmonid abundance and outmigration timing in the vicinity of the Red Bluff Research Pumping Facility. An increased number of listed fish will be captured and handled, resulting in a corresponding increase in the potential number of indirect mortalities. USFWS is also authorized to collect non-lethal fin-clips from a number of the listed fish authorized to be handled for Study 1 and to analyze the collected tissue samples for genetic attributes. Modification 5 to Permit 747 was issued to USFWS on September 14, 1995. The modification will be in effect for the duration of the permit. Permit 747 expires on December 31, 1995.

Modification 3 to Permit 823 was issued to IDFG on September 22, 1995. Permit 823 authorizes a take of adult and juvenile, listed, naturally-produced and artificially-propagated, Snake River spring/summer chinook salmon (*Oncorhynchus tshawytscha*), adult and juvenile, listed, Snake River fall chinook salmon (*Oncorhynchus tshawytscha*), and adult and juvenile, endangered, Snake River sockeye salmon (*Oncorhynchus nerka*) associated with a wide range of scientific research activities in Idaho. For Modification 3, IDFG is authorized an increase in the annual lethal take of listed juvenile sockeye salmon associated with a new task, the monitoring research of Pettit Lake. In July 1995, IDFG released 8,400 listed juvenile sockeye salmon from their captive broodstock program into Pettit Lake, as authorized by Modification 6 to Permit 795 (60 FR 37052). The Pettit Lake *O. nerka* population structure must be monitored to build trend data over time, essential for the development of future release plans. The research will contribute to the understanding of population make-up (genetic origin), growth, diet, and population age structure in the lake. Modification 3 is valid for the duration of the permit. Permit 823 expires on November 30, 1997.

Issuance of these permit modifications, as required by the ESA, was based on a finding that such actions: (1) Were applied for in good faith, (2) will not operate to the disadvantage of the listed species that are the subject of the permits, and (3) are consistent with the purposes and policies set forth in section 2 of the ESA and the NMFS regulations governing listed species permits.

Dated: September 27, 1995.

Russell J. Bellmer,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 95–24607 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–22–F

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Limits and Guaranteed Access Levels for Certain Cotton, Wool and Man-Made Fiber Textile Products Produced or Manufactured in the Dominican Republic

September 28, 1995.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs adjusting import limits and guaranteed access levels.

EFFECTIVE DATE: October 4, 1995.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927–5850. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

On the request of the Government of the Dominican Republic, the U.S. Government agreed to increase the 1995 Guaranteed Access Levels for Categories 338/638, 339/639, 444 and 633. Also, the current limit for Categories 351/651 is increased for swing, reducing the limit for Categories 342/642 to account for the increase.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see Federal Register notice 59 FR 65531, published on December 20, 1994). Also see 60 FR 17321, published on April 5, 1995.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing, but are designed to assist only in the implementation of certain of their provisions.

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

September 28, 1995.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on March 30, 1995, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool and man-made fiber textile products, produced or manufactured in the Dominican Republic and exported during the twelve-month period which began on January 1, 1995 and extends through December 31, 1995.

Effective on October 4, 1995, you are directed to adjust the limits for the following categories, as provided for under the Uruguay Round Agreements Act and the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted twelve-month limit [1]
342/642	287,231 dozen.
351/651	937,201 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1994.

The 1995 Guaranteed Access Levels (GALs) for Categories 342/642 and 351/651 remain unchanged. The GALs for textile products in the following categories shall be increased:

Category	Guaranteed Access Level
338/638	1,450,000 dozen.
339/639	1,550,000 dozen.
444	180,000 numbers.
633	100,000 dozen.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception of the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

D. Michael Hutchinson,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 95–24645 Filed 10–3–95; 8:45 am]

BILLING CODE 3510–DR–F

DEPARTMENT OF DEFENSE

Office of the Secretary

Manual for Courts-Martial

AGENCY: Joint Service Committee on Military Justice.

ACTION: Notice of proposed amendment.

SUMMARY: The Joint Service Committee on Military Justice has completed its review of Federal Rules of Evidence 413 and 414, as implemented by the Violent Crime Control and Law Enforcement Act of 1994. Per Military Rule of Evidence 1102, these rules will apply to the military effective 6 January 1996, unless contrary action is taken by the President. The Department of Defense is considering the addition of Military Rules of Evidence 413 and 414, in place of the automatically incorporated Federal Rules, in order to adapt and tailor the rules to military practice. The proposed rules are contained in this notice.

The proposed changes have not been coordinated within the Department of Defense under DoD Directive 5500.1, ''Preparation and Processing of Legislation, Executive Orders, Proclamations, and Reports and Comments Thereon,'' May 21, 1964, and do not constitute the official position of the Department of Defense, the Military Departments, or any other government agency.

This notice is provided in accordance with DoD Directive 5500.17, ''Review of the Manual for Courts-Martial'', January 23, 1985. This notice is intended only to improve the internal management of the Federal government. It is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, it agencies, its officers, or any person.

The proposed Rules follow in their entirety:

Rule 413. Evidence of Similar Crimes in Sexual Assault Cases

(a) In a court-martial in which the accused is charged with an offense of sexual assault, evidence of the accused's commission of another offense or offenses of sexual assault is admissible, and may be considered for its bearing on any matter to which it is relevant.

(b) In a court-martial in which the Government intends to offer evidence under this rule, the Government shall disclose the evidence to the accused, including statements of witnesses or a summary of the substance of any testimony that is expected to be offered, at least five days before the scheduled date of trial or at such later time as the military judge may allow for good cause.

(c) This rule shall not be construed to limit the admission or consideration of evidence under any other rule.

(d) For purposes of this rule, *offense of sexual assault* means an offense punishable under the Uniform Code of Military Justice, or a crime under Federal law or the law of a State that involved—

(1) Any sexual act or sexual contact, without consent, proscribed by the Uniform Code of Military Justice, Federal law, or the law of a State;

(2) Contact, without consent, between any part of the accused's body or an object and the genitals or anus of another person;

(3) Contact, without consent, between the genitals or anus of the accused and any part of another person's body;

(4) Deriving sexual pleasure or gratification from the infliction of death, bodily injury, or physical pain on another person; or

(5) An attempt or conspiracy to engage in conduct described in paragraphs (1)–(4).

(e) For purposes of this rule, the term *sexual act* means:

(1) Contact between the penis and the vulva or the penis and the anus, and for purposes of this rule contact involving the penis occurs upon penetration, however slight;

(2) Contact between the mouth and the penis, the mouth and the vulva, or the mouth and the anus:

(3) The penetration, however slight, of the anal or genital opening of another by hand or finger or by any object, with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person; or

(4) The intentional touching, not through the clothing, of the genitalia of another person who has not attained the age of 16 years with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person.

(f) For purposes of this rule, the term *sexual contact* means the intentional touching, either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh, or buttocks of any person with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person.

(g) For purposes of this rule, the term ''State'' includes a State of the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and any other territory or possession of the United States.

Rule 414. Evidence of Similar Crimes in Child Molestation Cases

(a) In a court-martial in which the accused is charged with an offense of child molestation, evidence of the accused's commission of another offense or offenses of child molestation is admissible, and may be considered for its bearing on any matter to which it is relevant.

(b) In a court-martial in which the Government intends to offer evidence under this rule, the Government shall disclose the evidence to the accused, including statements of witnesses or a summary of the substance of any testimony that is expected to be offered, at least five days before the scheduled date of trial or at such later time as the military judge may allow for good cause.

(c) This rule shall not be construed to limit the admission or consideration of evidence under any other rule.

(d) For purposes of this rule, *child* means a person below the age of sixteen, and *offense of child molestation* means an offense punishable under the Uniform Code of Military Justice, or a crime under Federal law or the law of a State that involved—

(1) Any sexual act or sexual contact with a child, proscribed by the Uniform Code of Military Justice, Federal law, or the law of a State;

(2) Any sexually explicit conduct with children, proscribed by the Uniform Code of Military Justice, Federal law, or the law of a State;

(3) Contact between any part of the accused's body or an object and the genitals or anus of a child;

(4) Contact between the genitals or anus of the accused and any part of the body of a child;

(5) Deriving sexual pleasure or gratification from the infliction of death, bodily injury, or physical pain on a child; or

(6) An attempt or conspiracy to engage in conduct described in paragraphs (1)–(5).

(e) For purposes of this rule, the term *sexual act* means:

(1) Contact between the penis and the vulva or the penis and the anus, and for purposes of this rule contact involving the penis occurs upon penetration, however slight;

(2) Contact between the mouth and the penis, the mouth and the vulva, or the mouth and the anus;

(3) The penetration, however slight, of the anal or genital opening of another by hand or finger or by any object, with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person; or

(4) The intentional touching, not through the clothing, of the genitalia of another person who has not attained the age of 16 years with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person.

(f) For purposes of this rule, the term *sexual contact* means the intentional touching, either directly or through the clothing, of the genitalia, anus, groin, breast, inner thigh, or buttocks of any person with an intent to abuse, humiliate, harass, degrade, or arouse or gratify the sexual desire of any person.

(g) For purpose of this rule, the term *sexually explicit conduct''* means actual or simulated:

(1) Sexual intercourse, including genital-genital, oral-genital, or oral-anal, whether between persons of the same or opposite sex;

(2) Bestiality;

(3) Masturbation;

(4) Sadistic or masochistic abuse; or

(5) Lascivious exhibition of the genitals or pubic area of any person.

(h) For purposes of this rule, the term ''State'' includes a State of the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, and any other territory or possession of the United States.

The proposed analysis for the Rules (Appendix 22, M.R.E.) is as follows:

Rule 413. Evidence of Similar Crimes in Sexual Assault Cases

1996 Amendment. This amendment is intended to provide for more liberal admissibility of character evidence in criminal cases of sexual assault where the accused has committed a prior act of sexual assault.

Rule 413 is nearly identical to its Federal Rule counterpart. A number of changes were made, however, to tailor the Rule to military practice. First, all references to Federal Rule 415 were deleted, as it applies only to civil proceedings. Second, military justice terminology was substituted where appropriate (*e.g.* accused for defendant, court-martial for case). Third, the five-day notice requirement in Rule 413(b) replaced a fifteen-day notice requirement in the Federal Rule. A five-day requirement is better suited to military discovery practice. Fourth, Rule 413(d) has been modified to include violations of the Uniform Code of Military Justice. Also, the phrase ''without consent'' was added to Rule 413(d)(1) to specifically exclude the introduction of evidence concerning adultery or consensual sodomy. Last, all incorporation by way of reference was removed by adding subsections (e), (f), and (g). The definitions in those subsections were taken directly from title 18, United States Code §§ 2246(2), 2246(3), and 513(c)(5), respectively.

Although the Rule states that the evidence ''is admissible,'' the drafters' intend that the courts apply Rule 403 balancing to such evidence. Apparently, this also was the intent of Congress. The legislative history reveals that ''the general standards of the rules of evidence will continue to apply, including the restrictions on hearsay evidence and the court's authority under Evidence Rule 403 to exclude evidence whose probative value is substantially outweighed by its prejudicial effect.'' 156 F.R.D. 51 (1995) (Reprint of the Floor Statement of the Principal House Sponsor, Representative Susan Molinari, Concerning the Prior Crimes Evidence Rules for Sexual Assault and Child Molestation Cases).

When ''weighing the probative value of such evidence, the court may, as part of its Rule 403 determination, consider proximity in time to the charged or predicate misconduct; similarity to the charged or predicate misconduct; frequency of the other acts; surrounding circumstances; relevant intervening events; and other relevant similarities or differences.'' 156 F.R.D. 51, 55 (1995) (Report of the Judicial Conference of the United States on the Admission of Character Evidence in Certain Sexual Midconduct Cases).

Rule 414. Evidence of Similar Crimes in Child Molestation Cases

1996 Amendment. This amendment is intended to provide for more liberal admissibility of character evidence in criminal cases of child molestation where the accused has committed a prior act of sexual assault or child molestation.

Rule 414 is nearly identical to its Federal Rule counterpart. A number of changes were made, however, to tailor the Rule to military practice. First, all references to Federal Rule 415 were deleted, as it applies only to civil proceedings. Second, military justice terminology was substituted where appropriate (*e.g.* accused for defendant, court-martial for case). Third, the five-day notice requirement in Rule 414(b) replaced a fifteen-day notice requirement in the Federal rule. A five-day requirement is better suited to military discovery practice. Fourth, Rule 414(d) has been modified to include violations of the Uniform Code of Military Justice. Last, all incorporation by way of reference was removed by adding subsections (e) (f), (g), and (h). The definitions in those subsections were taken directly from title 18, United States Code §§ 2246(2), 2246(3), 2256(2), and 513(c)(5), respectively.

Although the Rule states that the evidence ''is admissible,'' the drafters' intend that the courts apply Rule 403 balancing to such evidence. Apparently, this was also the intent of Congress. The legislative history reveals that ''the general standards of the rules of evidence will continue to apply, including the restrictions on hearsay evidence and the court's authority under Evidence Rule 403 to exclude evidence whose probative value is substantially outweighed by its prejudicial effect.'' 156 F.R.D. 51 (1995) (Reprint of the Floor Statement of the Principal House Sponsor, Representative Susan Molinari, Concerning the Prior Crime Evidence Rules for Sexual Assault and Child Molestation Cases).

When ''weighing the probative value of such evidence, the court may, as part of its Rule 403 determination, consider proximity in time to the charged or predicate misconduct; similarity to the charged or predicated misconduct; frequency of the other acts; surrounding circumstances; relevant intervening events; and other relevant similarities or differences.'' 156 F.R.D. 51, 55 (1955) (Report of the Judicial Conference of the United States on the Admission of Character Evidence in Certain Sexual Misconduct Cases.).

EFFECTIVE DATE: These amendments would apply, upon approval by the President, only in cases in which arraignment has been completed on or after the effective date.

ADDRESSES: Copies of the proposed changes may be examined at the Office of the Judge Advocate General, Criminal Law Division, Building 111, Washington Navy Yard, Washington, DC 20374. A copy of the proposed changes may be obtained by mail upon request from the foregoing address, ATTN: LT J. Russell McFarlane.

DATES: Comments on the proposed changes must be received no later than December 18, 1995 for consideration by the Joint Service Committee on Military Justice.

FOR FURTHER INFORMATION CONTACT: LT J. Russell McFarlane, JAGC, USNR, Executive Secretary, Joint Service Committee on Military Justice, Office of the Judge Advocate General, Criminal Law Division, Building 111, Washington Navy Yard, Washington, DC 20374–1111; (202) 433–5895.

Dated: September 29, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Office, Department of Defense.

[FR Doc. 95–24663 Filed 10–3–95; 8:45 am]

BILLING CODE 5000–04–M

Joint Service Committee on Military Justice: Public Meeting

AGENCY: Joint Service Committee on Military Justice (JSC).

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a public meeting of the JSC. This notice also describes the functions of the JSC.

DATES: Wednesday, November 1, 1995, 10:00 a.m. to 12:00 p.m.

ADDRESSES: Building 111, Washington Navy Yard, Washington, DC.

FUNCTION: The JSC was established by the Judge Advocates General in 1972. The JSC currently operates under Department of Defense Directive 5500.17 of January 23, 1985. It is the function of the JSC to improve military justice through the preparation and evaluation of proposed amendments and changes to the Uniform Code of Military Justice and the Manual for Courts-Martial.

AGENDA: The JSC will receive public comment concerning proposed Military Rules of Evidence 413 and 414. Per Military Rule of Evidence 1102, Federal Rules 413 and 414 will apply to the military effective 6 January 1996, unless contrary action is taken by the President. The Department of Defense is considering the addition of Military Rules of Evidence 413 and 414, in place of the automatically incorporated Federal Rules, in order to adapt and tailor the rules to military practice. The proposed rules were published on October 4, 1995.

FOR FURTHER INFORMATION CONTACT: LT J. Russell McFarlane, JAGC, USNR, Executive Secretary, Joint Service Committee on Military Justice, Building 111, Washington Navy Yard, Washington, DC 20374–1111; (202) 433–5895.

Dated: September 29, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–24661 Filed 10–3–95; 8:45 am]

BILLING CODE 5000–04–M

Defense Science Board Task Force on Quality of Life

ACTION: Notice of Advisory Committee Meeting.

SUMMARY: The Defense Science Board Task Force on Quality of Life will meet in open session on October 19, 1995 at the Embassy Suites Hotel, 1900 Diagonal Road, Alexandria, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense.

Persons interested in further information should call LtCol Dave Witkowski at (703) 695–3769.

Dated: September 29, 1995.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 95–24662 Filed 10–3–95; 8:45 am]

BILLING CODE 5000–04–M

Department of the Army

Army Science Board Notice of Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463), announcement is made of the following Committee Meeting:

Name of Committee: Army Science Board (ASB).

Date of Meeting: 24 & 25 October 1995.

Time of Meeting: 0800–1700, 24 October 1995; 0800–1200, 25 October 1995.

Place: Killeen, Texas.

Agenda: The Army Science Board will meet for their Fall General Membership Meeting to discuss ongoing ASB studies. These meetings will be closed to the public in accordance with Section 552b(c) of title 5, U.S.C., specifically subparagraph (4) thereof, and title 5, U.S.C., Appendix 2, subsection 10(d).The proprietary matter to be discussed is so inextricably intertwined so as to preclude opening any portion of these meetings. For further information, please contact Michelle Diaz at (703) 695–0781.

Michelle P. Diaz,

Acting Administrative Officer, Army Science Board.

[FR Doc. 95–24618 Filed 10–3–95; 8:45 am]

BILLING CODE 3710–08–M

Privacy Act of 1974; Notice to Amend Systems of Records

AGENCY: Department of the Army, DOD.

ACTION: Notice to amend systems of records.

SUMMARY: The Department of the Army is amending three systems of records notices, and deleting one system in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

The first amendment consolidates A0381–45cDAMI into A0381–45aDAMI. The system identifier and system name change from A0381–45aDAMI to A0381–20bDAMI entitled 'Counterintelligence/Security Files'. The exemption rules for A0381–45aDAMI and A0381–45cDAMI will be revised and deleted, respectively.

The second amendment revises system of records notice A0381–45bDAMI. One of the amendments changes the system identifier A0381–45bDAMI to A0614–115DAMI.

The third amendment revises system of records notice A0381–100aDAMI.

DATES: These proposed actions will be effective without further notice on November 3, 1995, unless comments are received which result in contrary determinations.

ADDRESSES: Privacy Act Officer, U.S. Army Information Systems Command, ATTN: ASOP-MP, Fort Huachuca, AZ 85613–5000.

FOR FURTHER INFORMATION CONTACT: Ms. Pat Turner at (602) 538–6856 or DSN 879–6856.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the Federal Register and are available from the address above.

The Department of the Army is amending three systems of records notices, and deleting one system in its existing inventory of record systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

The first amendment consolidates A0381–45cDAMI into A0381–45aDAMI. The system identifier and system name change from A0381–45aDAMI to A0381–20bDAMI entitled

'Counterintelligence/Security Files'. The exemption rules for A0381–45aDAMI and A0381–45cDAMI will be revised and deleted, respectively.

The second amendment revises system of records notice A0381–45bDAMI. One of the amendments changes the system identifier A0381–45bDAMI to A0614–115DAMI.

The third amendment revises system of records notice A0381–100aDAMI.

The specific changes to the records systems being amended are set forth below, followed by the notices published in their entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: September 28, 1995.

Patricia Toppings,
Alternate OSD Federal Register Liaison Officer, Department of Defense.

DELETION
A0381–45cDAMI

SYSTEM NAME:

Counterintelligence Operations Files *(February 22, 1993, 58 FR 10126).*

Reason: System is being consolidated into A0381–20bDAMI.

A0381–45aDAMI

SYSTEM NAME:

USAINSCOM Investigative Files System *(February 22, 1993, 58 FR 10123).*

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'A0381–20bDAMI.'

SYSTEM NAME:

Delete entry and replace with 'Counterintelligence/Security Files.'

SYSTEM LOCATION:

Delete entry and replace with 'U.S. Army Intelligence and Security Command, 8825 Beulah Street, Fort Belvoir, VA 22060–5246.

Decentralized segments are located at U.S. Army Intelligence brigades, groups, battalions, companies, detachments, field offices and residents offices worldwide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Military personnel of the U.S. Army, including active duty, National Guard, reservists and retirees; civilian employees of the Department of the Army, including contract, temporary, part-time, advisory, and volunteer, citizen and alien employees located both in the U.S. and in overseas areas; industrial or contractor personnel who are civilians working in private industry for firms which have contracts involving access to classified Department of Defense information; aliens granted limited access authorization to U.S. Defense information; alien personnel investigated for visa purposes; certain non-DoD affiliated persons whose activities involve them with the DoD, namely activities involving requests for admission to DoD facilities or requests for certain information regarding DoD personnel, activities, or facilities; persons formerly affiliated with the DoD; persons who applied for or are/were being considered for employment with or access to DoD such as applicants for military service, pre inductees and prospective contractors; individuals residing on, having authorized official access to, or conducting or operating any business or other function at any DoD installation and facility; and U.S. Army Intelligence sources; and U.S. persons who have been declared missing, prisoners of war (POW), civilian persons who are being detained or held hostage or personnel recovered from hostile control; individuals about whom there is reasonable basis to believe that they are engaged in, or plan to engage in, activities such as (1) sabotage, (2) possible compromise of classified defense information by unauthorized disclosure or by espionage,treason or spying, (3) subversion of loyalty, discipline or morale of Department of Army military or civilian personnel by actively encouraging violation of lawful orders and regulations or disruption of military activities, and (4) activities that are a direct threat to the conduct of military operations or DoD personnel, facilities and material or classified Defense contractor facilities.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Requests for and results of investigations or inquiries conducted by U.S. Army Intelligence or other DoD, Federal, State or local investigative agency. Record includes: personal history statements; fingerprint cards; personnel security questionnaire; medical and/or educational records and waivers for release; requests for and National Agency checks; local agency checks; military records; birth records; employment records; education records; credit records and waivers for release; interviews of education, employment, and credit references; interviews of listed and developed character references; interviews of neighbors; requests for, documentation pertaining to, results of electronic surveillance, intelligence polygraph examinations and technical documents, physical surveillance, and mail cover and or search; polygraph examination summaries; documents which succinctly summarize information in subject's investigative file; case summaries prepared by both investigative control offices and requesters of investigative interrogation reports; temporary documents concerning security, suitability, and criminal incidents lawfully collected by U.S. Army counterintelligence units in the performance of the counterintelligence mission; correspondence pertaining to the investigation, inquiry, or its adjudications by clearance or investigative authority to include; (1) the chronology of the investigation, inquiry, and adjudication; (2) all recommendations regarding the future status of the subject; (3) actions of security/loyalty review boards (4) final actions/determinations made regarding the subject; and (5) security clearance, limited access authorization, or security determination; index tracing reference which contains aliases and the names of the subject and names of co-subjects; security termination and inadvertent disclosure statements; notification of denial, suspension, or revocation of clearance; and reports of casualty, biographic data and intelligence/counterintelligence debriefing reports concerning U.S. personnel who are missing, captured, or detained by a hostile entity. Case control and management documents that serve as the basis for conducting the investigation such as documents requesting the investigation and documents used in case management and control such as lead sheets, other field tasking documents, and transfer forms. Administrative records required by the U.S. Army Investigative Records Repository (IRR) for records management purposes such as form transmitting investigative or operational material to the IRR and providing instructions for indexing the record in the Defense Central Index of Investigations (Defense Clearance and Investigations Index) (System Notice

V5–02) and release of material contained therein, form indicating dossier has been reviewed and all material therein conforms to DoD policy regarding retention criteria, form pertaining to the release of information pertaining to controlled records, form to indicate material has been removed and forwarded to other authorized Federal agencies such as the Defense Investigative Service, cross reference sheet to indicate the removal of investigative documents requiring limited access, form identifying material that has been segregated and or is exempt from release, and records accounting for the disclosure of intelligence, counterintelligence and security information made outside of the DoD.

Paper and automated indices of personnel investigations/operations which are under controlled access within the IRR, such as key USAINSCOM personnel, general officers, file procurement officers and their agencies, and sensitive spying, treason, espionage, sabotage, sedition, and subversion investigations and/or counterintelligence operations.

Microform and automated indices and catalogue files, which constitute an index to all IRR holdings contained in microfilmed investigative and operational records.

Automated record indices maintained by the IRR to keep a record of all original dossiers charged out of the IRR on loan to user agencies or permanently transferred to National Archives and Records Administration.

Paper, card file, microform and computerized case and incident indices containing name, date/place of birth, address, case or incident title and number, and brief summary of case or incident of current interest to investigative activities.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with 'E.O. 10450, Security Requirements for Government Employees, in particular sections 2, 3, 4, 5, 6, 7, 8, 9, and 14; E.0. 12333, United States Intelligence Activities, in particular paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6; the National Security Act of 1947, as amended, (10 U.S.C. 3013(b), (c) and (g)); the Defense Authorization Act for FY 1988 and 1989; the Foreign Intelligence Surveillance Act of 1978 (50 U.S.C. 401) and E.O. 9397.'

PURPOSE(S):

Delete rest of entry after 'national security;' and add 'to document U.S. Intelligence, counterintelligence and security investigations and operations pertaining to the U.S. Army's responsibilities for counterintelligence, and to detect, identify, and neutralize foreign intelligence and international terrorist threats to the DoD; and to temporarily document security, suitability, and criminal incident information not within U.S. Army counterintelligence jurisdiction to investigate, which is lawfully provided to U.S. Army counterintelligence units by cooperating sources of information collected incidental to the counterintelligence mission.'

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete all but the following paragraphs. '*In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:*

To the Department of Veterans Affairs for use in benefit determinations.

To the Immigration and Naturalization Service, Department of Justice for use in alien admission and naturalization inquiries conducted under section 105 of the Immigration and Nationality Act of 1952, as amended.

The 'Blanket Routine Uses' set forth at the beginning of the Army's compilation of systems of records notices apply to this system. *The distribution of investigative information is based on the Army's evaluation of the requesting agency's needs and the relevance of the information to the use for which it is provided. Information collected for one purpose is not automatically used for other purposes or by the other users indicated in this description.*

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

Delete entry under this category.

STORAGE:

Delete entry and replace with 'Maintained on paper records in file folders, audio or audiovisual tapes, microimaging, optical digital data disk, computers, and computer output products.'

* * * * *

RETRIEVABILITY:

Delete entry and replace with 'By name, aliases, or title in combination with social security number or regular dossier number, military service number for prisoners of war and U.S. service persons declared missing in action, date and or place of birth. For those subjects who have no identifying data other than the name, the name only index is searched. Additionally, a nonstandard search is required. The name only index will provide a subject's name and dossier number only. The nonstandard search will provide a listing of all subjects with identifying data. In some instances, some other identifying data must be furnished such as address. Dossiers possibly identical with the subject may be forwarded to the requester.'

SAFEGUARDS:

Delete entry and replace with 'Buildings employ alarms, security guards, and or rooms are security controlled areas accessible only to authorized persons. Paper and microform records are maintained in General Service Administration approved security containers. Paper and microform records in the IRR are stored in security controlled areas accessible only to authorized persons. Electronically and optically stored records are maintained in 'fail-safe' system software with password protected access. Records are accessible only to authorized persons with a need-to-know who are properly screened, cleared, and trained.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Personnel security/adjudicative records on non-DoD persons who are considered for affiliation with DoD are destroyed after 1 year if affiliation is not completed.

Personnel security investigations and adjudicative records of a routine nature are retained in the active file until no longer needed; retired to the U.S. Army Investigative Records Repository (IRR) and retained for 15 years after last action reflected in the file, except that files which contain significant derogatory information and or resulted in adverse action(s) against the individual are destroyed after 25 years. However, once affiliation is terminated, acquiring and adding material to the file is prohibited unless affiliation is renewed. Records determined to be of historical value, of wide spread value, or Congressional interest and investigations of treason, spying, espionage, sabotage, sedition, and subversion or other major investigations or operations of a counterintelligence or security nature are permanent. They will be retained in the IRR for 25 years after the date of the last action reflected in the file and then permanently transferred to the National Archives.

Records pertaining to U.S. persons declared POW, missing, or detainees will be maintained in the active file until no longer needed, retired to the IRR and retained for 50 years after the date of the last action reflected in the file or the subject is declared Killed in Action or dead and then permanently transferred to the National Archives.

Records pertaining to counterintelligence polygraph technical files will be maintained in the active file until no longer needed and then disposed of after the final quality control review as follows: (1) For counterintelligence scope cases, 90 days for favorably resolved cases or 15 years for other than favorably resolved cases, (2) for counterintelligence investigative cases, 15 years, and (3) for offensive counterintelligence operations and Human Intelligence cases, material is transferred to the IRR, incorporated into an operational dossier, and disposed of according to the disposition guidance for the operational file under system notice A0381–100aDAMI.

Security, suitability, and criminal incident information that is collected in the performance of the counterintelligence mission and which is not within the U.S. Army counterintelligence jurisdiction to investigate is retained at the location only so long as necessary to transmit it to the appropriate law enforcement or investigative agency having jurisdiction for this incident.

Summarized records pertaining to local intelligence, counterintelligence or incidents of interest to the local military intelligence activity are reviewed annually and destroyed when determined to be of no further operational value.

Destruction of records will be by shredding, burning, or pulping for paper records; magnetic erasing for computerized records. Optical digital data records should not be destroyed pending the development of a satisfactory destruction method.'

* * * * *

A0381–20bDAMI

SYSTEM NAME:

Counterintelligence/Security Files.

SYSTEM LOCATION:

U.S. Army Intelligence and Security Command, 8825 Beulah Street, Fort Belvoir, VA 22060–5246

Decentralized segments are located at U.S. Army Intelligence brigades, groups, battalions, companies, detachments, field offices and resident offices worldwide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Military personnel of the U.S. Army, including active duty, National Guard, reservists and retirees; civilian employees of the Department of the Army (DA), including contract, temporary, part-time, and advisory, citizen and alien employees located both in the U.S. and in overseas areas; industrial or contractor personnel working in private industry which have contracts involving classified Department of Defense (DoD) information; aliens granted limited access authorization to U.S. Defense information; alien personnel investigated for visa purposes; certain non-DoD affiliated persons whose activities involve them with the DoD, namely, activities involving requests for admission to DoD facilities or requests for certain information regarding DoD personnel, activities, or facilities; persons formerly affiliated with the DoD; persons who applied for or are/were being considered for employment with or access to DoD such as applicants for military service, pre inductees and prospective contractors; individuals residing on, having authorized official access to, or conducting or operating any business or other function at any DoD installation and facility; and U.S. Army Intelligence sources; and U.S. persons who have been declared missing, prisoners of war (POW), civilian persons who are being detained or held hostage or personnel recovered from hostile control; individuals about whom there is a reasonable basis to believe that they are engaged in, or plan to engage in, activities such as (1) sabotage, (2) possible compromise of classified defense information by unauthorized disclosure or by espionage, treason or spying, (3) subversion of loyalty, discipline or morale of DA military or civilian personnel by actively encouraging violation of lawful orders and regulations or disruption of military activities, and (4) activities that are a direct threat to the conduct of military operations or DoD personnel, facilities and material or classified Defense contractor facilities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Requests for and results of investigations or inquiries conducted by U.S. Army Intelligence or other DoD, Federal, State or local investigative agency. Record includes: Personal history statements; fingerprint cards; personnel security questionnaire; medical and/or educational records and waivers for release; requests for and National Agency checks; local agency checks; military records; birth records; employment records; education records; credit records and waivers for release; interviews of education, employment, and credit references; interviews of listed and developed character references; interviews of neighbors; requests for, documentation pertaining to, results of electronic surveillance, intelligence polygraph examinations and technical documents, physical surveillance, and mail cover and or search; polygraph examination summaries; documents which succinctly summarize information in subject's investigative file; case summaries prepared by both investigative control offices and requesters of investigative interrogation reports; temporary documents concerning security, suitability, and criminal incidents lawfully collected by U.S. Army counterintelligence units in the performance of the counterintelligence mission; correspondence pertaining to the investigation, inquiry, or its adjudications by clearance or investigative authority to include; (1) The chronology of the investigation, inquiry, and adjudication; (2) all recommendations regarding the future status of the subject; (3) actions of security/loyalty review boards (4) final actions/determinations made regarding the subject; and (5) security clearance, limited access authorization, or security determination; index tracing reference which contains aliases and the names of the subject and names of co-subjects; security termination and inadvertent disclosure statements; notification of denial, suspension, or revocation of clearance; and reports of casualty, biographic data and intelligence/counterintelligence debriefing reports concerning U.S. personnel who are missing, captured, or detained by a hostile entity. Case control and management documents that serve as the basis for conducting the investigation such as documents requesting the investigation and documents used in case management and control such as lead sheets, other field tasking documents, and transfer forms. Administrative records required by the U.S. Army Investigative Records Repository (IRR) for records management purposes such as form transmitting investigative or operational material to the IRR and providing instructions for indexing the record in the Defense Central Index of Investigations [Defense Clearance and

Investigations Index] (System Notice V5–02) and release of material contained therein, form indicating dossier has been reviewed and all material therein conforms to DoD policy regarding retention criteria, form pertaining to the release of information pertaining to controlled records, form to indicate material has been removed and forwarded to other authorized Federal agencies such as the Defense Investigative Service, cross reference sheet to indicate the removal of investigative documents requiring limited access, form identifying material that has been segregated and or is exempt from release, and records accounting for the disclosure of intelligence, counterintelligence and security information made outside of the DoD.

Paper and automated indices of personnel investigations/operations which are under controlled access within the IRR, such as key USAINSCOM personnel, general officers, file procurement officers and their agencies, and sensitive spying, treason, espionage, sabotage, sedition, and subversion investigations and/or counterintelligence operations.

Microform and automated indices and catalogue files, which constitute an index to all IRR holdings contained in microfilmed investigative and operational records.

Automated record indices maintained by the IRR to keep a record of all original dossiers charged out of the IRR on loan to user agencies or permanently transferred to National Archives and Records Administration.

Paper, card file, microform and computerized case and incident indices containing name, date/place of birth, address, case or incident title and number, and brief summary of case or incident of current interest to investigative activities.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

E.O. 10450, Security Requirements for Government Employees, in particular sections 2, 3, 4, 5, 6, 7, 8, 9, and 14; E.0. 12333, United States Intelligence Activities, in particular paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6; the National Security Act of 1947, as amended, (10 U.S.C. 3013(b), (c) and (g)); the Defense Authorization Act for FY 1988 and 1989; the Foreign Intelligence Surveillance Act of 1978 (50 U.S.C. 401) and E.O. 9397.

PURPOSE(S):

To provide information to assess an individual's acceptability for assignment to or retention in sensitive positions consistent with the interest of national security; to document U.S. Intelligence, counterintelligence and security investigations and operations pertaining to the U.S. Army's responsibilities for counterintelligence, and to detect, identify, and neutralize foreign intelligence and international terrorist threats to the DoD; and to temporarily document security, suitability, and criminal incident information not within U.S. Army counterintelligence jurisdiction to investigate, which is lawfully provided to U.S. Army counterintelligence units by cooperating sources of information collected incidental to the counterintelligence mission.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as routine uses pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Immigration and Naturalization Service, Department of Justice for use in alien admission and naturalization inquiries conducted under section 105 of the Immigration and Naturalization Act of 1952, as amended.

To the Department of Veterans Affairs for use in benefit determinations.

The 'Blanket Routine Uses' published at the beginning of the Army's compilation of systems of records notices apply to this system. *The distribution of investigative information is based on the Army's evaluation of the requesting agency's needs and the relevance of the information to the use for which it is provided. Information collected for one purpose is not automatically used for other purposes or by the other users indicated in this description.*

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on paper records in file folders, audio or audiovisual tapes, microimaging, optical digital data disk, computers, and computer output products.

RETRIEVABILITY:

By name, aliases, or title in combination with social security number or regular dossier number, military service number for prisoners of war and U.S. service persons declared missing in action, date and or place of birth. For those subjects who have no identifying data other than the name, the name only index is searched. Additionally, a nonstandard search is required. The name only index will provide a subject's name and dossier number only. The nonstandard search will provide a listing of all subjects with identifying data. In some instances, some other identifying data must be furnished such as address. Dossiers possibly identical with the subject may be forwarded to the requester.

SAFEGUARDS:

Buildings employ alarms, security guards, and or rooms are security controlled areas accessible only to authorized persons. Paper and microform records are maintained in General Service Administration approved security containers. Paper and microform records in the IRR are stored in security controlled areas accessible only to authorized persons. Electronically and optically stored records are maintained in 'fail-safe' system software with password protected access. Records are accessible only to authorized persons with a need-to-know who are properly screened, cleared, and trained.

RETENTION AND DISPOSAL:

Personnel security/adjudicative records on non-DoD persons who are considered for affiliation with DoD are destroyed after 1 year if affiliation is not completed.

Personnel security investigations and adjudicative records of a routine nature are retained in the active file until no longer needed; retired to the U.S. Army Investigative Records Repository (IRR) and retained for 15 years after last action reflected in the file, except that files which contain significant derogatory information and or resulted in adverse action(s) against the individual are destroyed after 25 years. However, once affiliation is terminated, acquiring and adding material to the file is prohibited unless affiliation is renewed. Records determined to be of historical value, of wide spread value, or Congressional interest and investigations of treason, spying, espionage, sabotage, sedition, and subversion or other major investigations or operations of a counterintelligence or security nature are permanent. They will be retained in the IRR for 25 years after the date of the last action reflected in the file and then permanently transferred to the National Archives.

Records pertaining to U.S. persons declared POW, missing, or detainees will be maintained in the active file until no longer needed, retired to the IRR and retained for 50 years after the

date of the last action reflected in the file or the subject is declared Killed in Action or dead and then permanently transferred to the National Archives.

Records pertaining to counterintelligence polygraph technical files will be maintained in the active file until no longer needed and then disposed of after the final quality control review as follows: (1) For counterintelligence scope cases, 90 days for favorably resolved cases or 15 years for other than favorably resolved cases, (2) for counterintelligence investigative cases, 15 years, and (3) for offensive counterintelligence operations and Human Intelligence cases, material is transferred to the IRR, incorporated into an operational dossier, and disposed of according to the disposition guidance for the operational file under system notice A0381–100aDAMI.

Security, suitability, and criminal incident information that is collected in the performance of the counterintelligence mission and which is not within the U.S. Army counterintelligence jurisdiction to investigate is retained at the location only so long as necessary to transmit it to the appropriate law enforcement or investigative agency having jurisdiction for this incident.

Summarized records pertaining to local intelligence, counterintelligence or incidents of interest to the local military intelligence activity are reviewed annually and destroyed when determined to be of no further operational value.

Destruction of records will be by shredding, burning, or pulping for paper records; magnetic erasing for computerized records. Optical digital data records should not be destroyed pending the development of a satisfactory destruction method.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff for Intelligence, Headquarters, Department of the Army, 1001 Army Pentagon, Washington, DC 20310–1001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Central Security Facility, Freedom of Information and Privacy Office, 4552 Pike Road, Fort Meade, MD 20755–5995.

Individual should provide their full name, aliases, date and place of birth, Social Security Number, service number(s), or other information verifiable from the records in written request.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Central Security Facility, Freedom of Information and Privacy Office, 4552 Pike Road, Fort Meade, MD 20755–5995.

Individual should provide their full name, aliases, date and place of birth, Social Security Number, service number(s), current address, and telephone number in written request.

Visits are limited to Building 4552, Fort Meade, MD 20755–5995.

Visitors must provide acceptable identification (e.g., valid driver's license, employing office's identification card) and verbal information that can be verified with his/her case folder.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From individual, DoD and Military Department records; Federal Agency records; foreign law enforcement, security, intelligence, investigatory, or administrative authorities; state, county, and municipal records; employment records of public schools, colleges, universities, technical and trade schools; hospital records; real estate agencies; credit bureaus; financial institutions which maintain credit information on individuals such as loan and mortgage companies, credit unions, banks, etc.; transportation companies (airlines, railroad, etc.); other private records sources deemed necessary in order to complete an investigation; miscellaneous records such as: telephone directories, city directories; Who's Who in America; Who's Who in Commerce and Industry; Who Knows What, a listing of experts in various fields; American Medical Directory; Martindale-Hubbell Law Directory; U.S. Postal Guide; Insurance Directory; Dunn and Bradstreet; and the U.S. Army Register; any other type of miscellaneous record deemed necessary to complete the U.S. Army Intelligence investigation or inquiry; the interview of individuals who have knowledge of the subject's background and activities; the interview of witnesses, victims, confidential sources, and of other individuals deemed necessary to complete the U.S. Army Intelligence investigation.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k)(1), (k)(2), or (k)(5), as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 505. For additional information contact the system manager.

A0381–45bDAMI

SYSTEM NAME:

Department of the Army Operational Support Activities *(February 22, 1993, 58 FR 10125).*

CHANGES:

SYSTEM IDENTIFIER:

Delete entry and replace with 'A0614–115DAMI.'

SYSTEM LOCATION:

Delete entry and replace with 'Investigative Records Repository, U.S. Army Central Security Facility, U.S. Army Intelligence and Security Command, 902d Military Intelligence Group, ATTN: IAMG-CSF-R, Fort Meade, MD 20755–5995.

U.S. Army Field Support Center, U.S. Army Intelligence and Security Command, Fort George G. Meade, MD 20755–5905.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete 'and civilian employees of the Department of the Army' from entry.

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace 'Personnel files containing information such as autobiographies, financial statements, psychological test results, photographs of the applicants and spouse, and probationary/tenure reports with automated index of individuals who have received support from DA in completing specialized duties within the Army's intelligence and counterintelligence activities. Files and duplicate automated files of individuals indicating any identity and other data which may be used to identify them in their support of the Department of the Army's intelligence and counterintelligence activities.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Add 'E.O. 12333, United States Intelligence Activities, paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6;' to entry.

* * * * *

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Delete the second paragraph.

* * * * *

RETENTION AND DISPOSAL:

Delete entry and replace with 'Records are retained in active file until release, separation, transfer, retirement or resignation by individual; retained in inactive file for 5 years; and retired to the IRR where file is destroyed 15 years after date of last action by shredding, burning or pulping, and magnetic erasing for computerized records.'

* * * * *

A0614–115DAMI

SYSTEM NAME:

Department of the Army Operational Support Activities.

SYSTEM LOCATION:

Investigative Records Repository, U.S. Army Central Security Facility, U.S. Army Intelligence and Security Command, 902d Military Intelligence Group, ATTN: IAMG-CSF-R, Fort Meade, MD 20755–5995.

U.S. Army Field Support Center, U.S. Army Intelligence and Security Command, Fort George G. Meade, MD 20755–5905.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Selected members of the U.S. Army who participate in and have received support for conducting U.S. Army intelligence and counterintelligence duties. Included are personnel of other Federal agencies who request and receive support from appropriate authority.

CATEGORIES OF RECORDS IN THE SYSTEM:

Personnel files containing information such as autobiographies, financial statements, psychological test results, photographs of the applicants and spouse, and probationary/tenure reports with automated index of individuals who have received support from DA in completing specialized duties within the Army's intelligence and counterintelligence activities. Files and duplicate automated files of individuals indicating any identity and other data which may be used to identify them in their support of the DA's intelligence and counterintelligence activities.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013(b), (c), (g); National Security Act of 1947, as amended; E.O. 10450, Security Requirements for Government Employees, sections 2, 3, 4, 5, 6, 7, 8, 9, and 14; E.O. 12333, United States Intelligence Activities, paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6; and E.O. 9397.

PURPOSE(S):

To identify and manage the careers of individuals performing duties in the Department of the Army specialized intelligence and counterintelligence assignments.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as routine uses pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Army's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on paper records in file folders, computers, and computer output products.

RETRIEVABILITY:

By name, date and place of birth, and Social Security Number.

SAFEGUARDS:

Buildings employ alarms, security guards and or rooms are security controlled areas accessible only to authorized persons. Paper records are maintained in General Service Administration approved security containers. Electronically stored records are maintained in 'fail-safe' system software with password protected access. Records are accessible only to authorized persons who are properly screened, cleared, and trained.

RETENTION AND DISPOSAL:

Records are retained in active file until release, separation, transfer, retirement or resignation by individual; retained in inactive file for 5 years; and retired to the IRR where file is destroyed 15 years after date of last action by shredding, burning or pulping, and magnetic erasing for computerized records.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff for Intelligence, Headquarters, Department of the Army, 1001 Army Pentagon, Washington, DC 20310–1001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Central Security Facility, Freedom of Information and Privacy Office, 4552 Pike Road, Fort Meade, MD 20755–5995.

Individuals should provide their full name, Social Security Number, or other information verifiable from the record itself in written request.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Central Security Facility, Freedom of Information and Privacy Office, 4552 Pike Road, Fort Meade, MD 20755–5995.

Individual should provide their full name, Social Security Number, address, and telephone number in written request.

Visits are limited to Building 4552, Fort Meade, MD 20755–5995. Visitors must provide acceptable identification (e.g., valid driver's license, employing office's identification card) and verbal information that can be verified with his/her case folder.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From the individual and investigative reports of Defense Investigative Service, U.S. Army Intelligence and Security Command, and other Federal and Department of Defense investigative and law enforcement agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k)(1), (k)(2), or (k)(5) as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 505. For additional information contact the system manager.

A0318–100aDAMI

SYSTEM NAME:

Intelligence Collection Files *(February 22, 1993, 58 FR 10127).*

CHANGES:

* * * * *

SYSTEM NAME:

Delete entry and replace with 'Intelligence/Counterintelligence Source Files'.

SYSTEM LOCATION:

Delete entry and replace with 'U.S. Army Intelligence and Security Command, 8825 Beulah Street, Fort Belvoir, VA 22060–5246.

Decentralized segments are located at U.S. Army Intelligence brigades, groups, battalions, companies, detachments, and field offices and resident offices worldwide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.'

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Delete entry and replace with 'Selected individuals who qualify and may be accepted as an intelligence or counterintelligence source for the U.S. Army.'

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with 'Record consists of agreements; contracts; information reports; financial reports; operational correspondence; requests for, technical files, and results of polygraph examinations; audiovisual products and similar documents necessary to confirm operational use of source or future claims against the Army by source or heirs of the source. Administrative records required by the U.S. Army Investigative Records Repository (IRR) for records management purposes such as form transmitting operational material to the IRR and providing instructions for indexing the record in the Defense Central Index of Investigations [Defense Clearance and Investigations Index] (System Notice V5–02) and release of material contained therein, form indicating dossier has been reviewed and all material therein conforms to Department of Defense (DoD) policy regarding retention criteria, form pertaining to the release of information pertaining to controlled records, cross reference sheet to indicate the removal of investigative documents requiring limited access, form identifying material that has been segregated and or is exempt from release, and records accounting for the disclosure of operational information made outside of the DoD.'

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with '10 U.S.C. 3013(b),(c),(g); National Security Act of 1947, as amended; E.O. 10450, Security Requirements for Government Employment, paragraphs 2, 3, 4, 5, 6, 7, 8, 9, and 14; E.O. 12333, United States Intelligence Activities, paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6; the National Security Act of 1947, as amended; the Intelligence Authorization Act of 1995, title V, section 503 and title VIII, sections 801–811 and E.O. 9397.'

PURPOSE(S):

Delete entry and replace with 'To support contingency planning and military operations, to conduct counterintelligence and intelligence operations, to confirm claims against the Army by source or heirs of source, and to document source operations pertaining to the U.S. Army's responsibilities for intelligence and counterintelligence.'

* * * * *

STORAGE:

Delete entry and replace with 'Maintained on paper records in file folders, audio or audiovisual tapes, microimaging, optical digital data disk, computers, and computer output products.

RETRIEVABLY:

Delete entry and replace with 'By individual name or source/project name, date and place of birth, Social Security Number, and numerically by source or project number.'

SAFEGUARDS:

Delete entry and replace with 'Buildings employ alarms, security guards and/or rooms are security controlled areas accessible only to authorized persons. Paper and microform records are maintained in General Service Administration approved security containers. Paper and microfilm records in the IRR are stored in security controlled areas accessible only to authorized persons. Electronically and optically stored records are maintained in 'fail-safe' system software with password protected access. Records are accessible only to authorized persons with a need-to-know who are properly screened, cleared, and trained.'

RETENTION AND DISPOSAL:

Delete entry and replace with 'Records are retained in active file until no longer needed; then retired to the IRR where they are destroyed 75 years after date of last action. Destruction is by shredding, burning, or pulping for paper records and magnetic erasing for computerized records. Optical digital data records should not be destroyed pending the development of a satisfactory destruction method.'

* * * * *

RECORD SOURCE CATEGORIES:

Delete entry and replace with 'From individual; Federal and Department of Defense investigative, intelligence and law enforcement agencies; and foreign investigative, intelligence, and law enforcement agencies.'

* * * * *

A0381–100aDAMI

SYSTEM NAME:

Intelligence/Counterintelligence Source Files.

SYSTEM LOCATION:

U.S. Army Intelligence and Security Command, 8825 Beulah Street, Fort Belvoir, VA 22060–5246.

Decentralized segments are located at U.S. Army Intelligence brigades, groups, battalions, companies, detachments, and field offices and resident offices worldwide. Official mailing addresses are published as an appendix to the Army's compilation of systems of records notices.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Selected individuals who qualify and may be accepted as an intelligence or counterintelligence source for the U.S. Army.

CATEGORIES OF RECORDS IN THE SYSTEM:

Record consists of agreements; contracts; information reports; financial reports; operational correspondence; requests for, technical files, and results of polygraph examinations; audiovisual products and similar documents necessary to confirm operational use of source or future claims against the Army by source or heirs of the source. Administrative records required by the U.S. Army Investigative Records Repository (IRR) for records management purposes such as form transmitting operational material to the IRR and providing instructions for indexing the record in the Defense Central Index of Investigations [Defense Clearance and Investigations Index] (System Notice V5–02) and release of material contained therein, form indicating dossier has been reviewed and all material therein conforms to Department of Defense (DoD) policy regarding retention criteria, form pertaining to the release of information pertaining to controlled records, cross reference sheet to indicate the removal of investigative documents requiring limited access, form identifying material that has been segregated and or is exempt from release, and records accounting for the disclosure of operational information made outside of the DoD.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 3013(b),(c),(g); National Security Act of 1947, as amended; E.O. 10450, Security Requirements for Government Employment, paragraphs 2, 3, 4, 5, 6, 7, 8, 9, and 14; E.O. 12333, United States Intelligence Activities, paragraphs 1.1(c), 1.1(d), 1.12(d), 2.3, 2.4, and 2.6; the National Security Act of 1947, as amended; the Intelligence Authorization Act of 1995, title V, section 503 and title VIII, sections 801–811 and E.O. 9397.

PURPOSE(S):

To support contingency planning and military operations, to conduct counterintelligence and intelligence operations, to confirm claims against the Army by source or heirs of source, and to document source operations pertaining to the U.S. Army's responsibilities for intelligence and counterintelligence.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as routine uses pursuant to 5 U.S.C. 552a(b)(3) as follows:

The 'Blanket Routine Uses' published at the beginning of the Army's compilation of systems of records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on paper records in file folders, audio or audiovisual tapes, microimaging, optical digital data disk, computers, and computer output products.

RETRIEVABILITY:

By individual name or source/project name, date and place of birth, Social Security Number, and numerically by source or project number.

SAFEGUARDS:

Buildings employ alarms, security guards and or rooms are security controlled areas accessible only to authorized persons. Paper and microform records are maintained in General Service Administration approved security containers. Paper and microfilm records in the IRR are stored in security controlled areas accessible only to authorized persons. Electronically and optically stored records are maintained in 'fail-safe' system software with password protected access. Records are accessible only to authorized persons with a need-to-know who are properly screened, cleared, and trained.

RETENTION AND DISPOSAL:

Records are retained in active file until no longer needed; then retired to the IRR where they are destroyed 75 years after date of last action. Destruction is by shredding, burning, or pulping for paper records and magnetic erasing for computerized records. Optical digital data records should not be destroyed pending the development of a satisfactory destruction method.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Chief of Staff for Intelligence, Headquarters, Department of the Army, 1001 Army Pentagon, Washington, DC 20310–1001.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Central Security Facility, Freedom of Information and Privacy Office, 4552 Pike Road, Fort George G. Meade, MD 20755–5995.

Individual should provide their full name, Social Security Number, current address, and telephone number.

RECORD ACCESS PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the U.S. Army Central Security Facility,Freedom of Information and Privacy Office, 4552 Pike Road, Fort George G. Meade, MD 20755–5995.

Individual should provide their full name, Social Security Number, current address, and telephone number.

Visits are limited to Building 4552, Fort Meade, MD 20755–5995. Visitors must provide acceptable identification (e.g., valid driver's license, employing office's identification card) and verbal information that can be verified from his/her case folder.

CONTESTING RECORD PROCEDURES:

The Army's rules for accessing records, contesting contents, and appealing initial agency determinations are contained in Army Regulation 340–21; 32 CFR part 505; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

From individual; Federal and Department of Defense investigative, intelligence and law enforcement agencies; and foreign investigative, intelligence, and law enforcement agencies.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Parts of this system may be exempt under 5 U.S.C. 552a(k)(1), (k)(2), or (k)(5) as applicable.

An exemption rule for this system has been promulgated in accordance with requirements of 5 U.S.C. 553(b)(1), (2), and (3), (c), and (e) and published in 32 CFR part 505. For additional information contact the system manager.

[FR Doc. 95–24665 Filed 10–3–95; 8:45 am]

BILLING CODE 5000–04–F

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2586–018 Alabama]

Alabama Electric Cooperative, Inc.; Notice of Availability of Environmental Assessment

September 28, 1995.

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 486, 52 FR 47897), the Commission's Office of Hydropower Licensing has reviewed an application to amend the license and for a non-project use of project lands and waters for the Conecuh River Project, located on the Conecuh River, in Convington County, Alabama. The application's major proposed change is: Temporary drawdown of the Point A Reservoir. An Environmental Assessment (EA) was prepared for the plan. The EA finds that approving the plan 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 3104, of the Commission's offices at 941 North Capitol Street, N.E., Washington, D.C. 20426. For further information, please contact Jon Cofrancesco at (202) 219–0079.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24630 Filed 10–3–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. ER95–1478–000]

Kentucky Utilities Company; Notice of Filing

September 28, 1995.

Take notice that on September 22, 1995, Kentucky Utilities Company tendered for filing an amendment in the above-referenced docket.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before October 12, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a 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. 95–24632 Filed 10–03–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–446–000]

Northwest Pipeline Corporation; Notice of Petition for Grant of Limited Waiver of Tariff

September 28, 1995.

Take notice that on September 25, 1995, pursuant to Rule 207(a) of the Commission's Rules of Practice and Procedure, 18 CFR 385.207(a)(5), Northwest Pipeline Corporation (Northwest) tendered for filing a Petition for Grant of Limited Waiver of Tariff.

Northwest seeks waiver of Sections 17.5(c) and 26 of the General Terms and Conditions and Section 1 of Rate Schedule TF–1 of Northwest's FERC Gas Tariff, Third Revised Volume No. 1, and any other applicable provisions of Northwest's Tariff, to provide Petro-Canada Hydrocarbons, Inc. with a portion of the capacity rights that will become available in November at the Stanfield Receipt/Delivery Point. Petro-Canada Hydrocarbons, Inc. will extend the primary term of its Agreement No. F–107 to December 20, 2003 in exchange for such capacity rights.

Northwest states that a copy of this filing has been served upon Northwest's jurisdictional customers and upon affected state regulatory commissions.

Any person desiring to be heard or protest said 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 Sections 385.214 and 385.211 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before October 5, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in that Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24629 Filed 10–3–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. GT95–67–000]

Paiute Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

September 28, 1995.

Take notice that on September 26, 1995, Paiute Pipeline Company (Paiute) tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1–A, Fourth Revised Sheet No. 161, with a proposed effective date of November 1, 1995.

Paiute indicates that the purpose of its filing is to comply with the Commission's order issued June 1, 1995 in Docket Nos. RP95–55–001 and RP95–269–000, by which the Commission approved an offer of settlement filed by Paiute. Paiute states that pursuant to the settlement, the monthly billing determinants pertaining to Paiute's firm transportation service under Rate Schedule FT–1 are to be revised periodically as of certain specified dates, including November 1, 1995.

Paiute states that the tendered tariff sheet reflects the monthly billing determinants for each of Paiute's firm transportation shippers that are to be effective November 1, 1995 under the terms of the settlement.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before October 5, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–24631 Filed 10–31–95; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP95–447–000]

Williams Natural Gas Company; Notice of Proposed Changes in FERC Gas Tariff

September 28, 1995.

Take notice that on September 26, 1995, Williams Natural Gas Company (WNG) tendered for filing to become part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Original Sheet Nos. 8A and 8B

The proposed effective date of these tariff sheets is October 27, 1995.

WNG states that this filing is being made pursuant to Article II, Section 10 of the Stipulation and Agreement dated November 24, 1992 (November 24 S & A), approved by Commission Order dated March 12, 1993 (61 FERC ¶ 61,240) and Article 14 of the General Terms and Conditions of its FERC Gas Tariff, Second Revised Volume No. 1. WNG hereby submits a further report of take-or-pay buyout, buydown and contract reformation costs and the application or distribution of those costs and refunds.

WNG states that a copy of its filing was served on all participants listed on the service lists maintained by the Commission in the dockets referenced above and on all of WNG's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Section 385.211 or 385.214 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before October 5, 1995. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. 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 in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 95–34633 Filed 10–03–95; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5311–9]

Proposed Settlement; Acid Rain Allowance Allocations and Reserves Rule Litigation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act (''Act''), notice is hereby given of a proposed settlement of *International Fabricare Institute* v. *U.S. Environmental Protection Agency*, No. 93–1773 (D.C. Cir.).

This case involves a challenge to the final rule, entitled ''National Emission Standards for Hazardous Air Pollutants for Perchloroethylene Dry Cleaning Facilities,'' which, *inter alia*, established limits for emissions of perchloroethylene from categories and subcategories of perchloroethylene dry cleaning facilities under section 112(d) of the Act. 58 FR 49,376 (Sept. 22, 1993).

For a period of thirty (30) days following the date of publication of this notice, the Environmental Protection Agency will receive written comments relating to the settlement from persons who were not named as parties to the litigation in question. The Agency or the Department of Justice may withhold or withdraw consent to the proposed settlement if the comments disclose facts or circumstances that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Copies of the settlement are available from Samantha Hooks, Air and Radiation Division (2344), Office of General Counsel, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 260–7606. Written comments should be sent to Jon Averback at the above address and must be submitted on or before November 3, 1995.

Dated: September 19, 1995.

Jonathan Z. Cannon,

Assistant Administrator (General Counsel).

[FR Doc. 95–24653 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5311–5]

Public Water System Supervision Program; Program Revision for the State of Nevada

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice of decision and opportunity for hearing.

SUMMARY: Notice is hereby given that the State of Nevada is revising its approved State Public Water System Supervision Program. Nevada has adopted new regulations to address new/revised organic and inorganic compounds in drinking water. The state regulations correspond to National Primary Drinking Water Regulations promulgated by EPA on July 17, 1992 (57 FR 31776). EPA has determined that the state program revision is no less stringent than the corresponding federal rule. Therefore, EPA has tentatively decided to approve the state program revision.

All interested parties are invited to request a public hearing. A request for a public hearing must be submitted by November 3, 1995, to the Regional Administrator at the address shown below. Insubstantial requests for a hearing may be denied by the Regional Administrator. If no timely and appropriate request for a hearing is received and the Regional Administrator does not elect to hold a hearing on her own motion, this determination shall be effective November 3, 1995.

Any request for a public hearing shall include the following: (1) The name, address, and telephone number of the individual, organization, or other entity requesting a hearing; (2) a brief statement of the requesting person's interest in the Regional Administrator's determination and of information that the requesting person intends to submit at such hearing; and (3) the signature of the individual making the request, or, if the request is made on behalf of an organization or other entity, the signature of a responsible official of the organization or entity.

ADDRESSES: All documents relating to this determination are available for inspection between the hours of 9:00 and 4:00 p.m., Monday through Friday, at the following offices: Department of Human Resources, State Health Division, Bureau of Health Protection Services, 505 E. King Street, Carson City, Nevada 89710; and EPA, Region IX, Water Management Division, Drinking Water Protection Branch, Drinking Water Section (W–6–1), 75 Hawthorne Street, San Francisco, CA 94105.

FOR FURTHER INFORMATION CONTACT: Corine Li, EPA, Region IX at the San Francisco address given above or by telephone at (415) 744–1858.

(Sec. 1413 of the Safe Drinking Water Act as amended (1986); and 40 CFR 142.10 of the National Primary Drinking Water Regulations)

Dated: September 25, 1995.

Felicia Marcus,

Regional Administrator.

[FR Doc. 95–24654 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–P

[FRL–5311–8]

Montana Board of Oil and Gas Conservation; Underground Injection Control; Primacy Application

AGENCY: Environmental Protection Agency.

ACTION: Notice of public comment period and of public hearing.

SUMMARY: The purpose of this notice is to announce that: (1) The Environmental Protection Agency (EPA) has received an application from the Montana Board of Oil and Gas Conservation requesting primary enforcement responsibility for the Underground Injection Control (UIC) Program for Class II injection wells; (2) determined the application contains all the required elements; (3) the application is available for inspection and copying; (4) public comments are requested; and (5) a public hearing will be held.

Section 1422 (b)(4) of the Safe Drinking Water Act (SDWA) requires that prior to approving, disapproving, or approving in part, a State's UIC program, the Administrator provide opportunity for a public hearing. This notification advises the public of the date, time and location of the required public hearing.

The proposed comment period and public hearing will provide EPA the breadth of information and public opinion necessary to approve, disapprove, or approve in part the application from the Montana Board of Oil and Gas Conservation to regulate Class II injection wells under provisions of Section 1425 of the SDWA.

DATES: Requests to present oral testimony must be filed by November 8, 1995; the public hearing will be held on November 14, 1995, at 7:00 p.m. Written comments must be received by November 21, 1995.

ADDRESSES: Comments and requests to testify should be mailed to Dan Jackson, Ground Water Unit (8P2–GW), Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500,

Denver, Colorado, 80202–2466. The hearing will be held in the Galletin meeting room in the Holiday Inn, 5500 Midland Road, Billings, Montana. Copies of the application and pertinent materials are available between 8:30 a.m. and 4:00 p.m. Monday through Friday at the following locations:

Environmental Protection Agency, Region VIII, Ground Water Unit, 4th Floor Terrace, 999 18th Street, Suite 500, Denver, CO 80202–2466, PH: (303) 293–1434

Montana Board of Oil and Gas Conservation, 2535 St. Johns Avenue, Billings, MT 59102, PH: (406) 656–0040

Environmental Protection Agency, Region VIII, Montana Office Building, Federal Office Building, 301 S. Park, Helena MT 59626–0026, PH: (406) 449–5486

FOR FURTHER INFORMATION CONTACT: Paul S. Osborne, Ground Water Unit (8P2–GW), Environmental Protection Agency, Region VIII, 999 18th Street, Suite 500, Denver, CO 80202–2466, (303) 293–1418 (Voice Mail) or (303) 294–1183.

SUPPLEMENTARY INFORMATION: The UIC program was implemented to prevent contamination of all Underground Sources of Drinking Water (USDW's), which are aquifers capable of yielding a significant amount of water containing less than 10,000 mg/liter of total dissolved solids. If the application by the Montana Board of Oil and Gas Conservation is approved, the State would be responsible for preventing endangerment of USDWs by the following activities: (1) Disposal (via injection wells) of fluids produced in conjunction with primary oil and gas development and production, including gas plant waste; (2) injection for the purpose of storing liquid hydrocarbons; and (3) injection of fluids for the purpose of enhanced recovery of oil and gas. The program proposed by the State will regulate Class II injection activities by establishing state permits which will include technical requirements for the protection of USDW's. Such requirements include criteria for construction, testing, operation, monitoring, and abandonment of injection wells.

At present, there are approximately 1,232 Class II injection wells in Montana. The USEPA has held primary enforcement authority for the UIC program in Montana since the program was implemented in 1984. The application from the Montana Board of Oil and Gas Conservation requests that EPA delegate to the State, primary enforcement authority for the regulation of all Class II injection wells on all lands subject to the State's police power and taxing authority and all lands owned or under the jurisdiction of the United States, except those wells located within the exterior boundaries on an Indian Reservation pursuant to 40 CFR 144.3. The application includes program description, copies of all applicable rules and forms, a quality assurance plan, a statement of legal authority and appropriate memoranda of agreement.

Dated: September 27, 1995.

Max H. Dodson,

Director, Region VIII, Water Management Division.

[FR Doc. 95–24656 Filed 10–3–95; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Privacy Act of 1974; Amendment to an Existing System of Records

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice of amendment to an existing system of records—''Financial Institutions Investigative and Enforcement Records System''.

SUMMARY: As part of an ongoing examination of the FDIC's systems of records, the Financial Institutions Investigative and Enforcement Records System has been reviewed for compliance with the Privacy Act of 1974, 5 U.S.C. 552a. Numerous amendments have been made to the existing system notice that will update the following elements in this system of records: System location, safeguards, retention and disposal, system manager(s) and address, and notification procedure. Some of the changes reflect the FDIC's intention to maintain a portion of the records in this system of records in a computerized database to be managed by the Financial Crimes Enforcement Network (FinCEN), Department of the Treasury, pursuant to an inter-agency support agreement. Other changes reflect organizational changes within the FDIC. Finally, a portion of the notification procedure has been amended in light of *Summers* v. *United States Department of Justice,* 999 F. 2d 570 (D.C. Cir. 1993).

DATES: Comments on the amendment of this system must be submitted by November 13, 1995. The system will become effective November 28, 1995, unless a superseding notice to the contrary is published before that date.

ADDRESSES: Comments should be addressed to Jerry L. Langley, Executive Secretary, Federal Deposit Insurance Corporation, 550–17th Street, NW, Washington, DC 20429, or hand-delivered to Room F–400 at 1776 F Street, NW, Washington, DC, Monday through Friday, between the hours of 8:30 a.m. and 5 p.m. [FAX number: (202) 898–3838; Internet E-mail: comments@fdic.gov]

FOR FURTHER INFORMATION CONTACT: Frederick N. Ottie, Attorney, FDIC, 550–17th Street, NW, Washington, DC 20429,(202) 898–6679.

SUPPLEMENTARY INFORMATION: The FDIC's system of records entitled Financial Institutions Investigative and Enforcement Records System is being amended. The modifications include updating descriptions in the system location as well as the system manager and address elements to reflect both organizational changes within the FDIC and the FDIC's intention that criminal referral reports and status updates, currently maintained in this system of records, henceforth be managed by FinCEN pursuant to an inter-agency support agreement.

In this regard, the FDIC has entered into an agreement with FinCEN, the Board of Governors of the Federal Reserve System, the Office of Thrift Supervision, the Office of the Comptroller of the Currency, and the National Credit Union Administration (the participating agencies). Under the agreement, FinCEN will manage a computerized database containing criminal referral reports and status updates, information currently collected and/or maintained separately by the participating agencies. The participating agencies are currently revising or issuing published rules to simplify the reporting requirements for financial institutions by prescribing a single form to be filed with FinCEN.

For purposes of the Privacy Act, only those records generated under the jurisdiction of the FDIC are considered to be FDIC records contained in this database. Authority to access and use these FDIC records by other agencies, as well as by the participating agencies, is neither created nor increased by this agreement. Access to and use of these FDIC records by all other agencies will continue to be governed by the existing published routine uses for the FDIC's Financial Institutions Investigative and Enforcement Records System. The computerized augmentation of this existing system of records facilitates access by the participating agencies pursuant to existing routine uses and in accordance with the terms of the inter-agency support agreement. It also enables the FDIC to expand internal access to regional offices of the FDIC's Division of Supervision and Legal Division. All of these changes are noted in the system location element of the amended system notice.

Additionally, the safeguards element is amended to add that on-line access to the computerized database managed by FinCEN is limited to authorized individuals who have been specified by each participating agency and who have been issued a nontransferable identifier or password.

The retention and disposal element is amended to indicate: (1) That hard-copy records maintained by the FDIC are retained until no longer needed; (2) that the computerized database managed by FinCEN will be retained until no longer needed; and (3) that the criminal referral reports and status updates received by FinCEN for data entry will be retained by FinCEN for 30 days after receipt and thereafter destroyed by FinCEN.

Finally, in accordance with the court decision in *Summers* v. *United States Department of Justice,* 999 F. 2d 570 (D.C. Cir. 1993), the notification procedure element is amended to delete the requirement that requesters must establish proof of identity solely by the production of a notarized statement. The FDIC's existing Privacy Act regulation, 12 CFR 310.4, will be used in determining individual identity.

Accordingly, the Board of Directors of the FDIC amends the Financial Institutions Investigative and Enforcement Records System to read as follows:

FDIC 30–64–0002

SYSTEM NAME:

Financial Institutions Investigative and Enforcement Records System.

(Complete text appears at 53 FR 7358, March 8, 1988).

SYSTEM LOCATION:

Division of Supervision, FDIC, 550 17th Street, NW., Washington, DC 20429. Computerized records of criminal referral reports and status updates are managed by the Financial Crimes Enforcement Network (FinCEN), Department of the Treasury, 2070 Chain Bridge Road, Vienna, Virginia 22182, and stored in Detroit, Michigan. The Special Activities Section, Division of Supervision, FDIC, the regional offices thereof, and the Legal Division, FDIC, have on-line access to the computerized database managed by FinCEN through individual work stations that are linked to the database central computer.

* * * * *

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

* * * * *

SAFEGUARDS:

Index cards and file folders are maintained in lockable metal file cabinets. Computer discs maintained at the FDIC are accessed only by authorized personnel. On-line access to the database managed by FinCEN is limited to authorized individuals who have been specified by each participating agency and who have been issued a nontransferable identifier or password.

RETENTION AND DISPOSAL:

Hard-copy records maintained at the FDIC are retained until no longer needed. Records maintained at the FDIC on computer discs are retained until no longer needed. The computerized database managed by FinCEN are retained until no longer needed. The criminal referral reports and status updates received by FinCEN for data entry are retained by FinCEN for 30 days after receipt and thereafter destroyed by FinCEN.

* * * * *

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Supervision, FDIC, 550 17th Street, NW., Washington, DC 20429.

NOTIFICATION PROCEDURE:

Requests must be in writing and addressed to the Office of the Executive Secretary, FDIC, 550 17th Street, NW., Washington, DC 20429.

* * * * *

By direction of the Board of Directors.

Dated at Washington, DC, this 26th day of September, 1995.

Federal Deposit Insurance Corporation.

Jerry L. Langley,

Executive Secretary.

[FR Doc. 95–24646 Filed 10–3–95; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement(s) Filed

The Federal Maritime Commission hereby gives notice that the following agreement(s) has been filed with the Commission pursuant to section 15 of the Shipping Act, 1916, and section 5 of the Shipping Act of 1984.

Interested parties may inspect and obtain a copy of each agreement at the Washington, D.C. Office of the Federal Maritime Commission, 800 North Capitol Street NW., 9th Floor. Interested parties may submit protests or comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, within 10 days after the date of the Federal Register in which this notice appears. The requirements for comments and protests are found in § 560.602 and/or 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.

Any person filing a comment or protest with the Commission shall, at the same time, deliver a copy of that document to the person filing the agreement at the address shown below.

Agreement No.: 003–010071–024.

Title: The Cruise Lines International Association Agreement

Parties:

American Hawaii Cruises
Carnival Cruise Line
Celebrity Cruises, Inc.
Commodore Cruise Line, Ltd.
Costa Cruise Lines
Crystal Cruises
Cunard Crown Cruises
Cunard Europamerica River Cruises
Cunard Queen Elizabeth 2
Cunard Royal Viking Line
Delta Queen Steamboat Co.
Diamond Cruise
Dolphin Cruise Line
Epirotiki Lines, Inc.
Holland America Line
Majesty Cruise Line
Norwegian Cruise Line
Oceanic Cruises
Orient Lines, Inc.
Pearl Cruises
Premier Cruise Lines
Princess Cruises
Regency Cruises
Royal Caribbean Cruises, Ltd.
Royal Cruise Line
Seabourn Cruise Line
Seawind Cruise Line
Seven Seas Cruise Line, Ltd.
Silversea Cruises
Sun Line Cruises
Windstar Cruises
World Explorer Cruises

Synopsis: The proposed amendment adds Radisson Seven Seas Cruises and deletes Diamond Cruise and Seven Seas Cruise Line, Ltd. It also reflects the current annual agency fee for Independent Travel Agency affiliates and makes other non-substantive changes to the Agreement.

Dated: September 28, 1995.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24647 Filed 10–3–95; 8:45 am]

BILLING CODE 6730–01–M

Notice of 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, D.C. Office of the Federal Maritime Commission, 800 North Capitol Street NW., 9th Floor. Interested parties may submit comments on each agreement to the Secretary, Federal Maritime Commission, Washington, D.C. 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.: 203–011515.

Title: Steamship Line Co-operative Chassis Pool Agreement.

Parties:

Atlantic Container Line, A.B.
Columbus Line
Mediterranean Shipping Company, S.A.
Polish Ocean Lines
United Arab Agencies, Inc.

Synopsis: The proposed Agreement would permit the parties to interchange equipment among themselves and to lease equipment on a commercial basis to non-agreement parties.

Dated: September 28, 1995.

By Order of the Federal Maritime Commission.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24648 Filed 10–3–95; 8:45 am]

BILLING CODE 6730–01–M

Security for the Protection of the Public Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages; Notice of Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Cunard Line Limited and Cunard Steamship Company Plc, 555 Fifth Avenue, New York, NY 10017

Vessels: Cunard Countess and Vistafjord

Dated: September 28, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24609 Filed 10–3–95; 8:45 am]

BILLING CODE 6730–01–M

Security for the Protection of the Public Indemnification of Passengers for Nonperformance of Transportation; Notice of Issuance of Certificate (Performance)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Public Law 89–777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR Part 540, as amended:

Cunard Line Limited, 555 Fifth Avenue, New York, NY 10017

Vessel: Cunard Countess

Dated: September 28, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24610 Filed 10–3–95; 8:45 am]

BILLING CODE 6730–01–M

Secretary for the Protection of the Public Financial Responsibility To Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages

Notice of Issuance of Certificate (Casualty)

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of Section 2, Public Law 89–777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR Part 540, as amended:

New Commodore Cruise Lines Limited and Azure Investments, Inc., 4000 Hollywood Blvd., Suite #385, South Tower, Hollywood, Florida 33021

Vessel: Enchanted Seas

Dated: September 28, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 95–24635 Filed 10–3–95; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Bridgeport Financial Corporation, et al.; Notice of Applications to Engage de novo in Permissible Nonbanking Activities

The companies listed in this notice have 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.

Each 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 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.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 18, 1995.

A. Federal Reserve Bank of Dallas (Genie D. Short, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. Bridgeport Financial Corporation, Bridgeport, Texas, and Bridgeport Bancshares, Inc., Dover, Delaware; to engage *de novo* through their subsidiary, First National Bridgeport Securities Corporation, Bridgeport, Texas, in providing portfolio investment advice to any other person, pursuant to § 225.25(4)(iii) of the Board's Regulation

Y, and securities brokerage services, pursuant to § 225.25(15) of the Board's Regulation Y. The geographic scope for these activities is Wise County, Texas.

Board of Governors of the Federal Reserve System, September 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24659 Filed 10–3–95; 8:45 am]

BILLING CODE 6210–01–F

JDOB, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have 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 225.14) 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)).

Each 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 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.

Unless otherwise noted, comments regarding each of these applications must be received not later than October 27, 1995.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. JDOB, Inc., Sandstone, Minnesota; to acquire 80 percent of the voting shares of Prairie National Bank of Belle Plaine, Belle Plaine, Minnesota, a *de novo* bank.

B. Federal Reserve Bank of San Francisco (Kenneth R. Binning, Director, Bank Holding Company) 101 Market Street, San Francisco, California 94105:

1. BankWest Nevada Corporation, Las Vegas, Nevada; to become a bank holding company by acquiring 100 percent of the voting shares of BankWest of Nevada, Las Vegas, Nevada.

Board of Governors of the Federal Reserve System, September 28, 1995.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 95–24658 Filed 10–3–95; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–3973–D–01]

Office of the Assistant Secretary for Public and Indian Housing; Order of Succession

AGENCY: Office of the Assistant Secretary for Public and Indian Housing (PIH), HUD.

ACTION: Notice of order of succession for the Assistant Secretary for Public and Indian Housing.

SUMMARY: In this notice, the Assistant Secretary for Public and Indian Housing designates the Order of Succession for the position of Assistant Secretary for PIH, and revokes the prior Order of Succession for this position.

EFFECTIVE DATE: September 22, 1995.

FOR FURTHER INFORMATION CONTACT: Brenda L. Earle, Staff Assistant to the Assistant Secretary, Office of Public and Indian Housing, Room 4100, Department of Housing and Urban Development, 451 7th Street, SW, Washington, DC 20410, 202–708–0950. A telecommunications device for hearing impaired persons (TDD) is available at 202–708–0850. [These are not toll-free numbers.].

SUPPLEMENTARY INFORMATION: In this document, the Assistant Secretary for Public and Indian Housing is issuing the Order of Succession of officials authorized to serve as Acting Assistant Secretary for PIH when, by reason of absence, disability, or vacancy in office, the Assistant Secretary for PIH is not available to exercise the powers or perform the duties of the office. Succession to act for and exercise the powers of the Assistant Secretary for PIH pursuant to this order shall be subject to the time limitations specified in the Vacancies Act, 5 U.S.C. 3348. This notice also revokes the prior Order of Succession for the Assistant Secretary for PIH.

Accordingly, the Assistant Secretary for PIH designates the following officials in the order specified to act for and assume the powers of the Assistant Secretary for PIH:

Section A. Order of Succession

During any period when, by reason of absence, disability, or vacancy in office, the Assistant Secretary for Public and Indian Housing is not available to exercise the powers or perform the duties of the office of the Assistant Secretary for PIH, the following are hereby designated to serve as Acting Assistant Secretary for PIH:

(1) Deputy Assistant Secretary, Office of Distressed and Troubled Housing Recovery;

(2) General Deputy Assistant Secretary;

(3) Director, Office of Assisted Housing.

These officials shall serve as Acting Assistant Secretary for PIH in the order specified herein and no official shall serve unless all the other officials, whose position titles precede his/hers in this order, are unable to act by reason of absence, disability, or vacancy in office.

Authorization to serve as Acting Assistant Secretary for PIH shall not exceed the time limitations imposed by the Vacancies Act, 5 U.S.C. 3348.

Section B. Authority Revoked

The Order of Succession of the Assistant Secretary for PIH, published in the Federal Register on April 2, 1990, at 55 FR 12291, is hereby revoked.

Authority: Sec. 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: September 22, 1995.

Joseph Shuldiner,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 95–24620 Filed 10–3–95; 8:45 am]

BILLING CODE 4210–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AK–963–4230–05–P; AA–6648–A]

Alaska Native Claims Selection; Notice for Publication

In accordance with Departmental regulation 43 CFR 2650.7(d), notice is hereby given that a decision to issue conveyance under the provisions of Sec. 14(a) of the Alaska Native Claims Settlement Act of December 18, 1971, 43 U.S.C. 1601, 1613(a), will be issued to Aleknagik Natives Limited for 1.74 acres. The lands involved are located in T. 10 S., R. 56 W., Seward Meridian, in the vicinity of the Native village of Aleknagik, Alaska; further described as Lots 1 and 2, U.S. Survey No. 4927, Alaska.

A notice of the decision will be published once a week, for four (4) consecutive weeks, in the Anchorage

Daily News. Copies of the decision may be obtained by contacting the Alaska State Office of the Bureau of Land Management, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513–7599 ((907) 271–5960).

Any party claiming a property interest which is adversely affected by the decision, an agency of the Federal government or regional corporation, shall have until November 3, 1995 to file an appeal. However, parties receiving service by certified mail shall have 30 days from the date of receipt to file an appeal. Appeals must be filed in the Bureau of Land Management at the address identified above, where the requirements for filing an appeal may be obtained. Parties who do not file an appeal in accordance with the requirements of 43 CFR Part 4, Subpart E, shall be deemed to have waived their rights.

Katherine L. Flippen,

Acting Chief, Branch of Southwest Adjudication.

[FR Doc. 95–24670 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–JA–P

[ES–930–05–1320–020241A]

Amendment to the List of Affected States Under Federal Coalbed Methane Recovery Regulations

AGENCY: Bureau of Land Management, Interior.

ACTION: Removal of Pennsylvania from the list of affected States.

SUMMARY: The Energy Policy Act of 1992 (the Act) Pub. L. 102–486) requires that the Secretary of the Interior (Secretary) administer a Federal program to regulate coalbed methane development in states where coalbed methane development has been impeded by disputes or uncertainty over ownership of coalbed methane gas. As required by the Act, the Department of the Interior, with the participation of the Department of Energy, developed a List of Affected States to which this program would apply (58 FR 21589, April 22, 1993). The List of Affected States is currently comprised of the States of Illinois, Indiana, Kentucky, Pennsylvania, and Tennessee.

The legislative body of the Commonwealth of Pennsylvania in the form of a resolution passed on June 28, 1995, petitioning the Secretary of the Interior for removal from the List of Affected States. The resolution stated that the General Assembly of the Commonwealth of Pennsylvania request the Secretary of the Interior to remove and delete Pennsylvania from the list of ''Affected States'' that will be subject to Federal regulations implementing section 1339 of the Energy Policy Act of 1992. Section 1339 of the Act provides three mechanisms by which a state may be removed from the List of Affected States:

1. A state may pass a law or resolution requesting removal;
2. The governor of a state may petition for removal, but only after giving the legislature six months notice, during a legislative session, of his intention to submit the petition; or
3. The state legislature implements a law or regulation permitting and encouraging the development of coalbed methane.

Since the Commonwealth of Pennsylvania has met the condition for removal from the List of Affected States by passing a resolution requesting removal, the Commonwealth of Pennsylvania is officially removed from the List of Affected States.

FOR FURTHER INFORMATION CONTACT: David R. Stewart, Chief, Branch of Resources Planning and Protection, Bureau of Land Management, Eastern States, 7450 Boston Boulevard, Springfield, Virginia 22153, or telephone (703) 440–1728; or Charles W. Byrer, U.S. Department of Energy, 3610 Collins Ferry Road, Morgantown, West Virginia 26507, or telephone (304) 291–4547.

Dated: September 25, 1995.

Gary D. Bauer,

Acting State Director.

[FR Doc. 95–24615 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–GJ–M

[NV–1990–01; N46–83–004P]

Final Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability, final environmental impact statement for the Placer Dome U.S. Bald Mountain Mine Expansion Project.

SUMMARY: Pursuant to requirements of the National Environmental Policy Act, the Bureau of land Management has prepared, by a third party contractor, and made available for a 30-day public review, the Final Environmental Impact Statement for the Placer Dome U.S. Bald Mountain Mine Expansion Project, located in White Pine County, Nevada.

DATES: The Final Environmental Impact Statement will be distributed and made available to the public on September 29, 1995. The period of availability for public review for the Final Environmental Impact Statement ends on October 30, 1995. At that time a Record of Decision will be issued regarding the Proposed Action.

ADDRESSES: A copy of the Final Environmental Impact Statement can be obtained from: Bureau of Land Management, Ely District Office, 702 N. Industrial Way, HC 33 Box 33500, Ely, NV 89301. The Final Environmental Impact Statement is available for inspection at the following locations: Bureau of Land Management Nevada State Office (Reno); Bureau of Land Management Ely District; Eureka, White Pine, and Elko County Libraries; and the University of Nevada libraries in Reno and Las Vegas.

FOR FURTHER INFORMATION CONTACT: Daniel Netcher, EIS Team Leader, at the above address or telephone (702 289–1872.

SUPPLEMENTARY INFORMATION: The Final Environmental Impact Statement analyses the potential environmental impacts from the expansion of the current gold mining operations at Bald Mountain Mine and development of the Horseshoe/Galaxy Mine (Proposed Action) and reasonable alternatives. Alternatives analyzed consist of: No Action; haul road design; waste rock dump configurations; and reclamation options. The Bureau of Land Management's preferred alternative is described within the The Final Environmental Impact Statement. The Final Environmental Impact Statement also responds to the issues raised during the scoping period and comments received on the Draft Environmental Impact Statement. Issues analyzed of major concern involve potential impacts to groundwater, visual resources, wildlife habitat, the economy and social services of White Pine and Elko Counties, and cumulative impacts. Twelve letters and two oral comments regarding the Draft Environmental Impact Statement were received. All substantive comments were incorporated for improving document clarity, further defining issues, and improving analysis of potential impacts in the Final Environmental Impact Statement. The primary concerns and issues presented in these comments involved mine reclamation, long term monitoring for toxic substances, and impacts to groundwater.

The Bald Mountain Mine expansion would consist of modification of the processing circuit with a wet crushing that would produce a split flow of ore. This processing facility would consist of both heap leaching and carbon-in-leach facilities with associated tailings. The Bald Mountain Mine expansion would also consist of expansion of the current

Top Pit and development of the Sage Flats Pit with corresponding waste rock dumps. The Horseshoe/Galaxy mine would involve construction and operation of a new mine with open pits, crushing facilities, waste dumps, conventional heap leaching facilities, and several ancillary facilities.

Dated: September 19, 1995.

Gene A. Kolkman,

Ely District Manager.

[FR Doc. 95–24614 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–HC–M

[UT–920–05–1330–00]

Classification Standards for Establishing Known Leasing Areas for Gilsonite

SUMMARY: The Secretary of the Interior, through Secretarial Orders 3071 and 3087, transferred the authority under 43 U.S.C. 21 to classify public lands for leasable minerals to the Director, Bureau of Land Management. On May 22, 1986, regulations were finalized at 43 CFR part 3500 which provided for prospecting permits for gilsonite on lands that were not known to contain valuable deposits of gilsonite. Lands with known gilsonite deposits will be subject to competitive leasing procedures only. On January 20, 1995, a notice was published in the Federal Register inviting comments on a proposed standard which would be used to determine whether lands will be subject to competitive leasing for gilsonite. A total of two comments were submitted on the proposed standard within the 60-day comment period identified in the notice. The first commenter suggested that the standard was too restrictive and should be broadened to include lands beyond the mappable surface exposure of a gilsonite vein. We recognize that some gilsonite veins continue to be minable at depth even though they are not exposed on the surface, but that is not always the case. Under the proposed standard, if a mappable gilsonite vein occurs in any part of a legal subdivision (generally a 40-acre tract), all of the lands within the tract will be considered as a known gilsonite area. This has the effect of extending the vein as much as 1,320 feet beyond any surface expression. The second commenter suggested that the Bureau of Land Management (BLM) use a more restrictive standard which would require a vein to exhibit consistent surface exposures of at least 18 inches in width. This commenter further stated that application of the broad standard identified in the January 20, 1995, Federal Register notice would eliminate prospecting permits for gilsonite because all prospective gilsonite areas have mappable gilsonite veins exposed at the surface. BLM has determined that the more restrictive standard suggested by this commenter places a more rigorous standard for determining whether lands should be leased competitively than the gilsonite industry places on itself before making a decision to open a mine. Furthermore, the regulations at 43 CFR part 3554 provide for an exploration license which enables interested parties to further explore unleased deposits of gilsonite. This allows a prospective lessee to obtain any necessary information about the deposit before obtaining a lease. Lands not known to contain gilsonite veins or extensions of existing veins where no gilsonite is mappable at the surface would still be available for prospecting through a prospecting permit. However, issuing prospecting permits on lands containing clearly defined veins of gilsonite imposes an unnecessary administrative burden on the BLM to process both a prospecting permit and a preference-right lease application when the existence of a gilsonite vein is known in advance. The public interest is best served by leasing such gilsonite deposits through a competitive process, ensuring a fair return for the public's resources.

The Director, Bureau of Land Management, has determined that the following standard will be used to define Known Gilsonite Leasing Areas: Lands will be defined as a Known Gilsonite Area and subject to competitive leasing if they contain a gilsonite vein that can be mapped as a continuous vein based on surface exposures and other indications of a continuous linear feature using generally accepted geologic mapping techniques. The Known Gilsonite Leasing Area shall be described by aliquot parts generally no smaller than a quarter-quarter section or, when appropriate, a lot. If any part of the lot or quarter-quarter section contains a portion of a mapped vein meeting the classification standard, that subdivision shall be included within the Known Gilsonite Leasing Area.

FOR FURTHER INFORMATION CONTACT: Bureau of Land Management, Division of Mineral Resources, Attn: James Kohler, P.O. Box 45155, Salt Lake City, Utah 84145–0155.

Dated: August 14, 1995.

Mat Millenbach,

Utah State Director.

[FR Doc 95–24611 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–DQ–M

[NV–930–1430–01; N–60040]

Notice of Realty Action: Non-Competitive Sale of Public Lands

AGENCY: Bureau of Land Management, Interior.

ACTION: Non-competitive sale of public lands in Clark County, Nevada.

SUMMARY: The following described public land in Clark County, Nevada, has been examined and found suitable for sale utilizing non-competitive procedures, at not less than the fair market value. Authority for the sale is Section 203 and Section 209 of P.L. 94–579, the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1719).

Mount Diablo Meridian, Nevada

T. 25 S., R. 59 E.,
Sec. 11: SW¼SE¼NW¼, NW¼NE¼SW¼.

Containing 20 acres, more or less.

This parcel of land, situated in Clark County, NV, is being offered as non-competitive sale to Consolidated Freightways Corporation.

The land is not required for any Federal purposes. The sale is consistent with current Bureau planning for this area and would be in the public interest.

The patent, when issued, will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890 (43 U.S.C. 945).
2. All minerals.

and will be subject to:

1. Those rights for a road granted to the Nevada Department of Transportation by right-of-way CC–020583 under the Act of 11–09–1921 (042 Stat. 0216).
2. Those rights for transmission line purposes granted to Nevada Power Company by right-of-way Nev-055383 under the Act of 10–21–1976 (090 Stat. 2776; 43 U.S.C. 1761).

Upon publication of this notice in the Federal Register, the above described land will be segregated from all forms of appropriation the public land laws, including the general mining laws, except for sales and disposals under the mineral disposal laws. This segregation will terminate upon issuance of a patent or 270 days from the date of this publication, whichever occurs first. For a period of 45 days from the date of publication of this notice in the Federal Register, interested parties may submit comments to the District Manager, Las Vegas District, 4765 West Vegas Drive, Las Vegas, NV 89108. Any adverse comments will be reviewed by the State

Director who may sustain, vacate or modify this realty action. In the absence of any adverse comments, this realty action will become the final determination of the Department of the Interior. The Bureau of Land Management may accept or reject any or all offers, or withdraw any land or interest in the land from sale, if, in the opinion of the authorized officer, consummation of the sale would not be fully consistent with Public Law 94–579, or other applicable laws. The land will not be offered for sale until at least 60 days after the date of publication of this notice in the Federal Register.

Dated: September 22, 1995.

Michael F. Dwyer,

District Manager, Las Vegas, NV.

[FR Doc. 95–24619 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–HC–P

[MT–020–1610–00]

Notice of Intent To Conduct Further Planning, Miles City, MT

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Further planning will be conducted for the Calypso Trail in the Big Dry Resource Area of the Miles City District. The purpose of this planning is to propose future management for the Calypso Trail and is scheduled for completion by December 1995.

EFFECTIVE DATE: Any comments, concerns, or information to be considered for this planning on the Calypso Trail should be submitted to BLM on or before November 13, 1995.

ADDRESSES: All submissions should be sent to the following address: David D. Swogger, Bureau of Land Management, P.O. Box 940, Miles City, Montana 59301.

FOR FURTHER INFORMATION CONTACT: Mary Bloom, Team Leader, Big Dry Resource Area Office, P.O. Box 940, Miles City, Montana 59301, 406–232–4331.

SUPPLEMENTARY INFORMATION: The proposed Big Dry Resource Management Plan and Final Environmental Impact Statement was issued in February of 1995. One decision protested by the public was the closure of Calypso Trail to motorized vehicles. Located west of Terry, Montana, the Calypso Trail is a road that separates two roadless areas that make up the Terry Badlands Wilderness Study Area. The trail experiences a high amount of erosion each year making the trail hazardous at times and difficult to maintain. For those reasons, the BLM proposed closure of the trail to motorized vehicles.

To ensure that all available data have been considered, the public is asked to assist the BLM in identifying impacts from leaving the Calypso Trail open or closing the trail to motorized vehicles. Written comments will be accepted until November 13, 1995. Comments may also be submitted at an open house meeting to be held October 19, 1995, from 1 p.m. to 7 p.m. in Room 106 of the Miles Community College in Miles City, Montana.

Dated: September 27, 1995.

Howard A. Lemm,

Acting Deputy State Director, Division of Resources.

[FR Doc. 95–24639 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–DN–P

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

The following applicants have applied for a permit to conduct certain activities with endangered species. This notice is provided pursuant to Section 10(c) of the Endangered Species Act of 1973, *as amended* (16 U.S.C. 1531, *et seq.*):

PRT–806882

Applicant: Duke University Primate Center, Durham, NC.

The applicant requests a permit to import two male and three female wild caught golden-crowned sifaka (*Propithecus tattersalli*) from Dariana, Madagascar for the purpose of enhancement of survival of the species through captive propagation.

PRT–806924

Applicant: Aryon Roest, California Polytechnic State University, San Luis Obispo, CA.

The applicant requests a permit to export up to ten dead captive-born Morro Bay Kangaroo Rats (*Dipodomys heermanni morroensis*) to Institute for Zoology, Martin Luther University, Halle, Germany for the purposes of enhancement of survival of the species through scientific research.

PRT–806875

Applicant: Waimea Arboretum Foundation, Haleiwa, HI.

The applicant requests a permit to export and re-import endangered and threatened plants cultivated within the Waimea Arboretum for the purposes of propagation and scientific research. This notification covers activities conducted by the applicant for a five year period.

PRT–806668

Applicant: Commonwealth Zoological Corporation, Franklin Park Zoo, Boston, MA.

The applicant requests a permit to import two male and one female captive-born Siberian cranes (*Grus leucogeranus*) from Vogelpark Walsrode, Walstrode, Germany for the purposes of enhancement of the species through captive propagation.

PRT–807144

Applicant: Ralph Lang, Tarpon Springs, FL.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from the captive herd maintained by Mr. E. Pringle, Huntly Glen, Bedford, South Africa for the purpose of enhancement of the survival of the species.

PRT–807171

Applicant: Henry Beech, c/o Jefferey Beech, Lutcher, LA.

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygarcus dorcas*) culled from the captive herd maintained by J.B. Pohl, ''Shenfield'', Riebeeck East, Republic of South Africa, for the purpose of enhancement of the survival of the species.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 420(c), Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

Documents and other information submitted with these applications are available for review, *subject to the requirements of the Privacy Act and Freedom of Information Act*, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Office of Management Authority, 4401 North Fairfax Drive, Room 420(c), Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: September 29, 1995.

Mary Ellen Amtower,

Acting Chief, Branch of Permits, Office of Management Authority.

[FR Doc. 95–24667 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–55–P

Notice of Intent To Prepare an Environmental Impact Statement on the Protection of Important Seabird Nesting Islands on Maine's Coast

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice.

SUMMARY: This notice advises the public that the Fish and Wildlife Service (Service) intends to gather information necessary for the preparation of an Environmental Impact Statement (EIS) on the protection of important seabird, wading bird, shorebird and bald eagle nesting islands on Maine's coast. This notice is being furnished as required by the National Environmental Policy Act (NEPA) regulations (40 CFR 1501.7) to obtain suggestions and information from other agencies and the public on the scope of issues to be addressed in the EIS.

SCOPING INFORMATION: Private island owners, other individuals, organizations of all sorts and other interested parties are encouraged to participate in the scoping process in order to identify and discuss the major issues that should be addressed in the EIS. A series of public scoping meetings (meetings) will be held in Ellsworth, Machias, Rockland, Brunswick, Wells and Augusta in November, 1995. These meetings will (1) provide a brief description of the project, (2) solicit advice about the scope of issues that should be addressed, what the significant issues are, and potential alternative courses of action, (3) seek input about review, consultation, coordination, clearance or permit requirements, and (4) describe the role of the Service in the planning and decision-making process. The major tool used to collect public comment will be an issues workbook which will be available at the meetings. The dates, times and locations of these meetings will be announced in area newspapers and through direct mailings. Those who are unable to attend one of the meetings can request a copy of the issues workbook from the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Mr. Stan Skutek, Refuge Manager, Petit Manan National Wildlife Refuge, P.O. Box 279, Milbridge, Maine 04658 or telephone (207) 546–2124.

WRITTEN COMMENTS INFORMATION: All written comments and completed workbooks should be sent to the contact person listed above by January, 1996, or no later than 30 days after the last meeting is held.

SUPPLEMENTARY INFORMATION: Petit Manan National Wildlife Refuge has been acquiring islands in Maine over the past decade, through donations and purchases from willing sellers. The majority of the Refuge islands support nesting seabirds habitat. In addition, the Service has been actively involved in providing technical assistance and promoting efforts to protect coastal nesting island habitat in partnership with private landowners, non-governmental organizations (e.g. land trusts and statewide conservative groups) and state agencies. During the last two years, the Service has worked with partners to discuss the importance of island nesting birds and to explore voluntary tools available to promote island wildlife habitat protection. In recent years, the number of landowners interested in selling their islands to the Service has increased, and the Service has recognized the need to solicit public input in directing future habitat protection work on coastal nesting islands. In order for the Service to continue to acquire seabird, wading bird, shorebird and eagle habitat on Maine's coastal islands, the Service has decided to pursue an EIS. The EIS process will allow the public to continue to provide input and direction to the Service for protection of these important habitats.

A range of alternative actions—including no action, the Service's proposed action, and other reasonable actions—will be presented in the EIS. All viable actions, including those that may be taken by others outside the federal government, are open for consideration. No final decision will be made until all interested parties, organizations and individuals have had the opportunity to review and comment on the EIS. The environmental review of the project will be conducted in accordance with the requirements of NEPA as amended (42 U.S.C. 4371 et seq.), NEPA regulations (40 CFR 1300–1508), other appropriate federal regulations and Service procedures for compliance with those regulations. It is estimated that a Draft EIS will be available for public review and comment in April 1995.

Ronald E. Lambertson,

Regional Director.

[FR Doc. 95–22918 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–55–M

Marine Mammals; Stock Assessment Reports

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of completion and availability of final marine mammal stock assessments and guidelines for preparing stock assessments.

SUMMARY: Section 117 of the 1994 amendments to the Marine Mammal Protection Act (MMPA) requires the Fish and Wildlife Service (Service) and the National Marine Fisheries Service (NMFS) to prepare stock assessments for each marine mammal stock that occurs in waters under the jurisdiction of the United States. The Service made draft stock assessments and preliminary guidelines available for public review and comment on August 23, 1994. Comments received from the public and from scientific review groups (established according to section 117) were reviewed and incorporated into the reports and guidelines, as appropriate. Final stock assessments have been completed and are now available for polar bears, walrus, and northern sea otters in Alaska; southern sea otters in California and northern sea otters in Washington State; and two West Indian manatee stocks in the southeastern United States and Puerto Rico. Final guidelines for preparing these stock assessments are also available.

ADDRESSES: Copies of these final stock assessments and final guidelines are available from the Division of Fish and Wildlife Management Assistance, U.S. Fish and Wildlife Service, Mail Stop 840–ARLSQ, 1849 C Street NW., Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Jeff Horwath, Division of Fish and Wildlife Management Assistance, Arlington, Virginia, at 703/358–1718. For specific information about stock assessments for polar bears, walrus, and northern sea otters in Alaska, contact David McGillivary in the Service's Office of Marine Mammals Management, Anchorage, Alaska, at 907/786–3800. For specific information about stock assessments for southern sea otters in California and northern sea otters in Washington State, contact Carl Benz in the Service's field office in Ventura, California, Telephone 805/644–1766. For specific information about stock assessments for West Indian manatees in the southeastern United States and Puerto Rico, contact Robert Turner in the Service's field office in Jacksonville, Florida, Telephone 904/232–2580.

SUPPLEMENTARY INFORMATION: On April 30, 1994, the MMPA Amendments of 1994 were enacted into law (Public Law 103–238). New section 117 of the MMPA required the Service and the NMFS (as appropriate) to prepare and periodically revise stock assessments for marine mammals that occur in waters

under the jurisdiction of the United States. These reports must contain information regarding the distribution and abundance of the stocks, population growth rates and trends, estimates of annual human-caused mortality from all sources, descriptions of the fisheries with which the stocks interact, and the status of each stock.

Although many of the items included in the reports were described explicitly in the MMPA, many elements, including a quantitative definition of the parameters used in calculating Potential Biological Removal (PBR) levels, were defined only in general terms. To promote consistent interpretation of the provisions of the law, the NMFS convened a workshop composed of NMFS and FWS scientists in June 1994 to develop preliminary guidelines to be used in preparing draft stock assessments.

On August 23, 1994, the Service published in the Federal Register a notice of availability of draft guidelines and stock assessments (59 FR 43353) for polar bears, Pacific walrus, and Alaska sea otters in Alaska, southern sea otters in California and northern sea otters in Washington State, and West Indian manatees in the southeastern United States and Puerto Rico. A 90-day public comment period expired on November 21, 1994. Substantial background information was provided in that notice, and is not repeated at this time. On November 16, 1994, the Service, in response to public concerns, extended the public comment period through December 1, 1994 (59 FR 59243). This new expiration date provided several additional days for public comment while reducing public confusion by aligning the Service's cut-off date with that of the NMFS; that agency was developing their own stock assessments and had also extended their comment period to December 1, 1994. The Service also concluded that it would allow a reasonable amount of time for the Alaska Scientific Review Group (see next two paragraphs) to review public comments prior to the Group's scheduled meeting of December 12–13, 1994.

In addition to the requirements to develop stock assessments, section 117 of the amendments to the MMPA also required the NMFS, in consultation with the Service and others, to establish three independent regional Scientific Review Groups (SRG) representing Alaska, the Pacific Coast (including Hawaii), and the Atlantic Coast (including the Gulf of Mexico). These SRG's were charged with providing advice on the stock assessments and other issues appropriate for pursuing the goals of the MMPA.

Subsequent to the close of the comment period for the draft stock assessments, the Service provided copies of public comments, as appropriate, to members of the Alaska, Pacific, and Atlantic SRG's for review and consideration. All public comments and the input of the appropriate SRG's was considered by the Service in producing the final stock assessments announced by this Federal Register notice. Final guidelines have also been completed. Following is a brief summary of comments received and the Service's response to those comments.

Comments

Polar Bear

Multiple stock assessment versus single stock assessment. *Comment:* Public comment favored development of two independent stock assessments versus one combined stock assessment for both the Beaufort Sea and Chukchi/Bearing Seas stocks. *Response:* The Service agrees and has recognized the information on the two stocks contained in the initial draft stock assessment into two individual final stock assessments.

Minimum population estimate. *Comment:* Public comment was not received on the minimum population estimate for the Beaufort Sea stock or lack of an estimate for the Chukchi/Bearing Seas stock. However, a reanalysis of Service/National Biological Service mark and recapture data for the Beaufort Sea stock resulted in a revised $N_{(min)}$ estimate of 1,717 animals.

Maximum productivity rates. *Comment:* One organization, and an observer at the Alaska SRG commented that the initial $R_{(max)}$ value of 10 percent was greater than observed rates and suggested that a review of data used for the calculation be conducted. *Response:* The $R_{(max)}$ from the draft stock assessment was revised based on modeling of observed reproduction and survival rates for polar bears in the Beaufort Sea stock. A 6 percent value is now used.

Mortality. *Comment:* Several commenters suggested that the Service should present the harvest averages for the last 5-year period instead of the longer-term averages. *Response:* The Service concurs and has modified the stock assessments accordingly. A common concern was that modeling the effects of mortality did not account nor make adjustment for the skewed sex ratio of the harvest. The final estimate of the Potential Biological Removal (PBR) level for the Beauford Sea stock includes the appropriate adjustment for the sex of harvested animals.

Status of stock. *Comment:* One comment stated that polar bear stocks in Alaska should be designated as ''strategic'' because of the lack of information regarding population size and status, inherently low reproductive capability, and threats emanating from the harvest rates and industry. *Response:* The Service has concluded that the stocks are ''non-strategic.'' The rationale for these decisions are described in detail within the stock assessment and the calculations of PBR.

Pacific Walrus

Minimum population estimate. *Comment:* Several groups believed this estimate should be based on the estimated population size obtained during the last range-wide aerial survey (1990). They pointed out the survey was conducted during an ice minimum period when only a few walrus were counted along the ice edge. While many walrus were counted on land, presumably many more were in the water and were not counted. *Response:* The stock assessment report follows guidelines outlined in the NMFS Workshop Report to use the best available scientific information to calculate the minimum population estimate, (N_{min}), not the total estimated population, (N_{best}). The minimum estimate obtained is based on a sum of the direct counts of the walrus observed on land, plus the adjusted estimate of that portion of the population observed on the ice.

Maximum productivity rates. *Comment:* Several groups suggested the 0.06 value for R_{max} in the draft stock assessment was too low; one group believed it to be too high. *Response:* Commenting groups typically confused the term maximum net productivity, as defined by the amended MMPA and the PBR Workshop, with maximum productivity. The available data for maximum growth at a small population size for the Pacific walrus are scant. Estimated values of R_{max} derived from population models are equivocal. In our reassessment, the Service consulted with experts from several agencies and the Alaska SRG. Recognizing the limitations of the best available data and that the R_{max} value proposed in the draft stock assessment may not fully account for a skewed sex ratio in the population, the Service chose to follow the recommendation of the Alaska SRG to tentatively adopt 0.08 as a more plausible estimate of R_{max}. The Service is in the process of reviewing available information and is open to revision of

this value when and if it becomes appropriate.

Mortality. *Comment:* Several groups questioned the use of calculating the estimated average annual mortality due to subsistence harvest on the basis of a 30 year data set. Some groups believed the estimate of struck and lost was too high. *Response:* The Service agrees that using the most recent 5-year period to calculate average annual mortality is an approach which more accurately reflects current harvest trends and levels; the value was recalculated using new information from Russian colleagues obtained since publication of the draft stock assessment. While the available information on struck and lost rates is somewhat dated (collected during the late 1960's–early 1970's), it is the only sound scientific information collected to date. The Service believes it is appropriate to use these data until such time as newer scientifically rigorous data can be obtained.

Status of stock. *Comment:* Several groups objected to the draft stock assessment's categorization of the Pacific walrus stock as ''strategic.'' *Response:* Using the new, updated, and adjusted information discussed above and presented in the final stock assessment, the Service has concluded the stock is ''non-strategic.''

Northern Sea Otter in Alaska

Single species focus. *Comment:* The stock assessment inappropriately focused on a single species. It should have included Alaska Natives in its focus. *Response:* The stock assessment was developed based on the MMPA requirements and guidance developed for all stock assessments which focused on the status, incidental fisheries take, and other human take of marine mammal species.

Multiple stocks vs. single stock. *Comment:* The Service was inconsistent on the treatment of single versus multiple stocks. Several commenters suggested that sea otters should be treated as multiple stocks, while others agreed with a single Alaska stock. *Response:* The Service will continue to consider splitting the Alaska stock of sea otters into multiple stocks if the scientific data supports such a split.

Minimum population estimate. *Comment:* Several commenters suggested that the minimum population estimate was too low since they believed that sea otter populations in Alaska have been growing rapidly. Others concurred with the minimum population estimate. *Response:* The Service is aware of the uncertainty of the population abundance of Alaska sea otters. This is based on the fact that survey results are dated and variable. The stock assessment followed the guidelines and used the best available information to calculate the minimum population estimate, not the total estimated population. Additional language was added to clarify the variability of survey results. Additionally, the table in the stock assessment was updated to include more recent data that had become available.

Potential Biological Removal. *Comment:* Commenters suggested that the Potential Biological Removal level should not be determined because of the uncertainty associated with the minimum population estimate and the lack of current survey information. *Response:* See ''Minimum population estimate'' discussion above.

Maximum productivity rate. *Comment:* Several commenters suggested that the maximum productivity rate was too high, while another believed it to be accurate. *Response:* After reviewing public comments and the comments of the Alaska Scientific Review Group, the maximum productivity rate was increased to 20 percent based on information in the scientific literature.

Incidental take. *Comment:* Comments were received describing the incidental take of sea otters by commercial fisheries as insignificant, while another commenter suggested that our incidental take data was inadequate to evaluate commercial fishery interactions. *Response:* The best available information was used by the Service. If more information becomes available, future stock assessments will be modified accordingly.

Native harvest. *Comment:* One commenter believed that too much information was provided on Native harvest while another suggested expanding the section to describe geographic patterns of Native harvest. *Response:* Because the focus of the stock assessment was to be commercial fisheries incidental take, other human-caused mortality was generally described. In the case of human-caused mortality to sea otters, this includes Native harvest.

Other human-caused mortality. *Comment:* The comment was received that the section on human-caused mortality should be expanded to include historic information. *Response:* This section was expanded.

Southern Sea Otter in California

Annual human-caused mortality. *Comment:* Sentiment was expressed that the Service needs to clarify that southern sea otter mortality attributable to drowning in lobster pots is unknown, but may be a significant contributor to the lack of population growth at San Nicolas Island. It was further stated that this information should be included in the ''Fisheries Information'' section of the stock assessment. *Response:* The Service agrees; comments were incorporated into the final stock assessment.

Potential Biological Removal (PBR). *Comment:* Comment was received that the stock assessment should clarify that the NMFS will defer to the opinion of the Service regarding PBR for this species, and that the option of the Service is that incidental take should remain at zero. *Response:* This comment was noted but not incorporated into the final stock assessment. The section on PBR has been expanded and retains the clarification that the 1994 amendments to the MMPA do not pertain to the southern sea otter. No take is allowed.

Endangered Species Act (ESA) listing, recovery plan, and translocation effort. *Comment:* Comments were received that the final stock assessment should: (1) Note the date and reason for listing this stock as threatened under the ESA; (2) indicate that a recovery plan has been developed and is being revised; (3) explain that the Service has attempted to establish a reserve population at San Nicolas Island, California; (4) discuss Public Law 99–625 and the closely associated Management Zone to prohibit range expansion and protect fishery resources; (5) indicate that a number of otters have entered the Management Zone and have died, or may have died, as a consequence of efforts to capture and remove them; and (6) discuss that an uncertain number of sea otters may have been killed in recent years by small oil spills and unusual diseases. *Response:* These comments were incorporated into the final stock assessment.

Maximum productivity rate. *Comment:* Comment was received that $R_{(max)}$ for the southern sea otter appeared to be closer to 4 percent or 5 percent rather than the 6 percent rate used in the stock assessment and that this should be explained. *Response:* The 6 percent rate continues to be used in the final stock assessment. The Service believes that adequate data is presented in the ''Current and Maximum Net Productivity Rates'' section to justify use of the 6 percent rate.

Comment: One commenter believed that the Service should note that before 1985, when such fisheries were prohibited, the take of southern sea otters was far above the estimates of PBR. Therefore, if restrictions on gill nets were lifted, then the southern sea

otter would be designated as a ''strategic stock,'' requiring formation of a Take Reduction Team to advise on measures that should be taken to ensure that incidental take does not exceed the PBR. *Response:* The final stock assessment was modified to incorporate these comments.

Northern Sea Otter in Washington State

Annual human-caused mortality. *Comment:* The Service should elucidate Indian treaty rights, particularly in relation to MMPA recovery objectives. It was further stated that this information should be included in the ''Fisheries Information'' section of the stock assessment. *Response:* The ''Annual Human-Caused Mortality'' section of the stock assessment was changed to acknowledge the tribal rights claim. However, until this issue is legally clarified, the Service is unable to provide better information and guidance.

Comment: A comment was received that the Service should identify the number and source(s) of animals translocated to Washington State. *Response:* These comments were incorporated into the final stock assessment.

Maximum Productivity Rate. *Comment:* One commenter stated that the Service should describe and discuss data used to determine that $R_{(max)}$ is 12 percent for the Alaska sea otter in Washington State. *Response:* The ''Population Size'' section was modified slightly and now describes the type of data and survey techniques used. However, actual survey counts were not included in the final stock assessment.

Sea otter/fishery interaction. *Comment:* One commenter indicated that the Service should include information on sea otter/fishery interactions in Washington State. *Response:* This suggestion was incorporated into the final stock assessment.

Comment: One commenter stated that the Service should indicate the present distributions of sea otters and gil-net fisheries in Washington State coastal waters. *Response:* The Service agrees and has incorporated the comment into the final stock assessment.

West Indian Manatees

Annual mortality data. *Comment:* Comments was received that the Service should use the most recent mortality data for the Florida manatee. *Response:* The Service concurs. Summary data through December 1994, as provided by the Florida Department of Environmental Protection, has been incorporated into the final stock assessment.

Stock definition and range. *Comment:* One commenter questioned the Service's definition of a single stock of Florida manatees and suggested that an Atlantic coast stock and a Gulf coast stock would be more appropriate. *Response:* The Service considered the merits of delineating two stocks of Florida manatees, but prefers to retain a single stock classification, noting that genetic studies published to date do not strongly support the definition of clearly distinct stocks. Furthermore, intensive studies of far south Florida manatee movements are lacking, and it may be premature to conclude that no genetic exchange between Atlantic coast and Gulf coast animals. Should new information become available, the Service will re-evaluate the stock definition as needed. Such re-evaluations will be easily accommodated, especially in light of section 117 of the MMPA that requires annual review and, if appropriate, revision of stock assessments for strategic stocks. West Indian manatees, in light of their endangered status, are classified as strategic animals.

Potential Biological Removal. *Comment:* Concerns were raised about the designation of a PBR level for manatees and the implications for Section 7 consultations under ESAct and incidental take policy regarding manatees. *Response:* The Service has already addressed these concerns in the narrative of the assessments.

Summary of Final Stock Assessments

Along with the requirement of section 117(b)(3) of the 1994 amendments to the MMPA that require publication in the Federal Register of a notice of availability of final stock assessments, a summary of those final stock assessments must also be published. Appropriately, the following table lists summary information for the Service's final stock assessments for polar bears, walrus, and northern sea otters in Alaska, southern sea otters in California and northern sea otters in Washington State; and two West Indian manatee stocks in the southeastern United States and Puerto Rico.

Dated: September 20, 1995.

John G. Rogers, Jr.,

Acting Director, U.S. Fish and Wildlife Service.

SUMMARY OF MARINE MAMMAL STOCK ASSESSMENTS FOR SPECIES OF MARINE MAMMALS UNDER FISH AND WILDLIFE SERVICE MANAGEMENT AUTHORITY

Species	Stock area	SRG region	FWS region	$N_{(min)}$	$R_{(max)}$	$F_{(r)}$	PBR	Annual estimated average human-caused mortality	Annual fishing-caused mortality	Strategic status
Polar bear-Chukchi/Bering Sea stock.	Chukchi and Bering Seas-Alaska and Russia.	AKA	7	[1] N/AV	[1] N/AV	1.0	[1] N/AV	55	0	No.
Polar bear-Beaufort Sea stock.	Beaufort Sea-Alaska and Canada.	AKA	7	1,579	0.06	1.0	[2] 72	63	0	No.
Sea otter-Alaska stock.	Alaska	AKA	7	100,000	0.2	1.0	10,000	506	<1	No.
Pacific walrus	Alaska and Russia.	AKA	7	188,316	0.08	1.0	7,533	5,895	16	No.
West Indian manatee-Florida stock.	Southeastern U.S.A.	ATL	4	1,822	0.04	0.1	3	[3] 49	<1	Yes.

SUMMARY OF MARINE MAMMAL STOCK ASSESSMENTS FOR SPECIES OF MARINE MAMMALS UNDER FISH AND WILDLIFE SERVICE MANAGEMENT AUTHORITY—Continued

Species	Stock area	SRG region	FWS region	$N_{(min)}$	$R_{(max)}$	$F_{(r)}$	PBR	Annual estimated average human-caused mortality	Annual fishing-caused mortality	Strategic status
West Indian manatee-Antillean stock.	Puerto Rico	ATL	4	86	0.04	0.1	0	2	Unknown .	Yes.
Southern sea otter-California stock.	Central California and San Nicolas Island.	PAC	1	2,376	0.06	0.1	[4] N/AP	[5] Unknown	[6] Unknown	Yes.
Sea otter-Washington stock.	Neah Bay to Destruction Island, WA.	PAC	1	360	0.12	0.5	11	[7] Unknown	[6] Unknown	No.

[1] N/AV indicates Not Available.
[2] Adjusted upwards to 72 animals from the calculated PBR of 48 to reflect the approximate 2 male:1 female sex ratio of the harvest. See stock assessment for additional information.
[3] Estimated average human-caused mortality for the West Indian manatee—Florida stock from 1984–1992. The estimated average annual human caused mortality from 1974–1992 is 36 animals.
[4] N/AP indicates Not Applicable. Although the PBR level for the southern sea otter—California stock was calculated to be 7, their incidental take is not governed under Section 118 of the 1994 amendments to the marine Mammal Protection Act.
[5] Unknown. Human caused mortalities of sea otters have been attributed to drowning in gill nets and lobster/crab pots, shootings, boat collisions, disease, and oil spills. However, data are insufficient for estimating annual losses. See stock assessment for additional information.
[6] Unknown. Observer coverage is inadequate to estimate annual fishery mortality.
[7] Sea otters in Washington State ares susceptible to the same sources of human-caused mortality as they are in California.

[FR Doc. 95–24622 Filed 10–3–95; 8:45 am]
BILLING CODE 4310–55–M

Aquatic Nuisance Species Task Force Ruffe Control Committee Meeting

AGENCY: Department of the Interior, Fish and Wildlife Service.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Ruffe Control Committee, a committee of the Aquatic Nuisance Species Task Force. The Committee will meet to discuss the following items: ruffe surveillance in 1995; ballast water management; population investigations; ruffe movement and distribution in the Iron and Sand Rivers; round goby in the Great Lakes; and, developments in the implementation of the aspects of the Ruffe Control Program.

TIME AND DATE: The Ruffe Control Committee will meet from 8:00 a.m. to 4:00 p.m. on Thursday, November 9, 1995. The meeting will be held at the Clarion Inn, 31200 Detroit Industrial Expressway, Romulus, Michigan, 48174 (near Detroit Metro Airport).

STATUS: The meeting is open to the public. Interested persons may make oral statements to the Committee or may file written statements for consideration.

CONTACT PERSON FOR MORE INFORMATION: Tom Busiahn, Ruffe Control Committee Chairperson, U.S. Fish and Wildlife Service, Fishery Resources Office, 2800 Lake Shore Drive East, Ashland, Wisconsin 54806 at (715) 682–6185.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.A. App. I), this notice announces a meeting of the Ruffe Control Committee, a committee of the Aquatic Nuisance Species Task Force established under the authority of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101–646, 104 Stat. 4761, 16 U.S.C. 4701 *et seq.*, November 29, 1990). Minutes of meeting will be maintained by Coordinator, Aquatic Nuisance Species Task Force, Room 840, 4401 North Fairfax Drive, Arlington, Virginia 22203 and the Chairperson, Ruffe Control Committee, U.S. Fish and Wildlife Service, Fishery Resources Office, 2800 Lake Shore Drive East, Ashland, Wisconsin 54806, and will be available for public inspection during regular business hours, Monday through Friday within 30 days following the meeting.

Dated: September 28, 1995.

Rowan W. Gould,

Deputy Assistant Director—Fisheries.

[FR Doc. 95–24623 Filed 10–3–95; 8:45 am]
BILLING CODE 4310–55–M

National Park Service

Jimmy Carter National Historic Site

AGENCY: National Park Service.

ACTION: Notice of Advisory Commission meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Commission Act that a meeting of the Jimmy Carter National Historic Site Advisory Commission will be held at 8:30 a.m. to 4:00 p.m., at the following location and date.

DATES: October 27, 1995.

ADDRESSES: The Windsor Hotel, Windsor Avenue, Americus, Georgia 31709.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Boyles, Superintendent, Jimmy Carter National Historic Site, Route 1, Box 800, Andersonville, Georgia 31711, (912) 924–0343.

SUPPLEMENTARY INFORMATION: The purpose of the Jimmy Carter National Historic Site Advisory Commission is to advise the Secretary of the Interior or his designee on achieving balanced and accurate interpretation of the Jimmy Carter National Historic Site.

The members of the Advisory Commission are as follows: Dr. Steven Hochman, Dr. James Sterling Young, Dr. Donald B. Schewe, Dr. Henry King Stanford, Dr. Barbara Fields, Director, National Park Service, Ex-Officio member.

The matters to be discussed at this meeting include the status of park development and planning activities. This meeting will be open to the public. However, facilities and space for accommodating members of the public are limited. Any member of the public may file with the commission a written statement concerning the matters to be discussed. Written statements may also

be submitted to the Superintendent at the address above. Minutes of the meeting will be available at Park Headquarters for public inspection approximately 4 weeks after the meeting.

Dated: September 27, 1995.

W. Thomas Brown,

Acting Field Director, Southeast Field Area.

[FR Doc. 95–24691 Filed 10–3–95; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF JUSTICE

[AAG/A Order No. 109–95]

Privacy Act of 1974; New System of Records

Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), notice is given that the Federal Bureau of Prisons (''Bureau'') proposes to establish a new system of records entitled, ''Access Control Entry/Exit System'' (JUSTICE/BOP–010).

Title 5 U.S.C. 552a(e)(4) and (11) provide that the public be provided a 30-day period in which to comment on the routine uses of a new system. The Office of Management and Budget (OMB), which has oversight responsibilities under the Privacy Act, requires that it be given a 40-day period in which to review the system.

Therefore, please submit any comments by November 3, 1995. The public, OMB, and the Congress are invited to send written comments to Patricia E. Neely, Program Analyst, Systems Policy Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (Room 850, WCTR).

A description of the system of records is provided below. In addition, the Department has provided a report to OMB and the Congress in accordance with 5 U.S.C. 552a(r).

Dated: September 22, 1995.

Stephen R. Colgate,

Assistant Attorney General for Administration.

Justice/BOP–010

SYSTEM NAME:

Access Control Entry/Exit System.

SYSTEM LOCATION:

Records may be retained at the Central Office, Regional Offices, and at any of the Bureau of Prison (Bureau) facilities. A list of these system locations may be found at 28 CFR part 503.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current and former staff, inmates now or formerly under the custody of the Attorney General or the Bureau, and all visitors to Bureau facilities, including law enforcement personnel, contractors, volunteers, and inmate visitors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information retrieved and stored by the system may include any information relative to providing safe and secure prison facilities, to protecting the prison population and/or the general public, and/or, where appropriate, to otherwise promoting the interests of effective law enforcement. Examples include:

(a) Identification data (much of which is collected from the individual) such as the person's name, current residence, social security number, employer, place and date of birth, age, height, weight, digital image, biometric identifier information, alien registration number, driver's license number, telephone number, passport number, system-generated number, hair color, eye color, sex, race, escort of visitor into institution, and system classification of individual;

(b) Other data collected from the visitor and/or from law enforcement to enable prison officials to determine the suitability/acceptability of a visitor such as: The purpose of the visit, relationship to the inmate and information indicating whether the visitor is under investigation by law enforcement and/or has ever been convicted of a crime, probation and/or parole status, name of supervising probation/parole officer, etc.;

(c) Records generated by the system to report entry/exit activity e.g., date and time of entry/exit, entry/exit locations used; and location data, including location in the institution visited and/or movement within the institution;

(d) Any related law enforcement or investigatory data, provided by third parties such as inmates, courts, and other Federal, State, local, and foreign law enforcement agencies, e.g., criminal history and/or investigatory data relating to potential visitors; investigatory data otherwise developed by Bureau officials regarding any activity, or suspicious activity, which may threaten the safe and secure operation of Federal correctional facilities, e.g., remarks describing a possible introduction of contraband; and any other information that may enable the Bureau to pursue an internal investigation on a record subject.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

This system is established and maintained under the authority of 18 U.S.C. 3621, 4003, 4042, 4082.

PURPOSE OF THE SYSTEM:

The records in this system are maintained to better ensure the safety, security and good order of Bureau facilities; to improve staff ability to quickly account for all persons (inmates, visitors, and staff) within an institution in the event of an emergency, such as an institution disturbance or a natural disaster; to identify and, where appropriate, determine the suitability of visitors with respect to entering prison facilities; and, to more effectively prevent violation of institution policy and/or criminal activities such as inmate escapes and the introduction of contraband. Where these efforts fail to prevent such violations, and/or where otherwise appropriate, records may be collected and used by the Bureau for internal investigations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Relevant data from this system will be disclosed as follows:

(a) To Federal, State, local and foreign law enforcement agencies who have a need for the information to perform their duties, e.g., in the course of apprehensions, investigations, possible criminal prosecutions, civil court actions, regulatory proceedings, inmate disciplinary hearings, parole hearings, responding to emergencies, or other law enforcement activity;

(b) To Federal, State, local and foreign law enforcement agencies in order to solicit or obtain data needed by prison officials for law enforcement purposes, e.g., to determine whether a visitor may be under investigation, have a criminal record, or otherwise be unsuitable to visit; or to obtain any information that may enable the Bureau to pursue an internal investigation pertaining to any record subject based on information developed by the Bureau;

(c) To the news media and the public pursuant to 28 CFR § 50.2 unless it is determined that release of the specific information in the context of a particular case would constitute an unwarranted invasion of personal privacy;

(d) To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of and at the request of the individual who is the subject of the record;

(e) To the National Archives and Records Administration and the General

Services Administration in records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906;

(f) To a court or adjudicative body before which the Department of Justice or the Bureau is authorized to appear when any of the following is a party to litigation or has an interest in litigation and such records are determined by the Bureau to be arguably relevant to the litigation: (1) The Bureau, or any subdivision thereof, or (2) any Department or Bureau employee in his or her official capacity, or (3) any Department or Bureau employee in his or her individual capacity where the Department has agreed to provide representation for the employee, or (4) the United States, where the Bureau determines that the litigation is likely to affect it or any of its subdivisions;

(g) To an administrative forum which may or may not include an Administrative Law Judge, or which may or may not convene public hearings/proceedings, or to other established adjudicatory or regulatory agencies, professional licensing and disciplinary boards and commissions, or other appropriate entities with similar or related responsibilities, statutory or otherwise, to assist in the adjudication of decisions affecting individuals who are the subject of Bureau investigations, including decisions to effect any necessary remedial actions, e.g., disciplinary and/or other appropriate personnel actions, and/or other law enforcement related actions, where appropriate; (To protect the privacy of the individual, information provided will be sanitized as warranted and/or a protective order may be requested to prevent further dissemination.)

(h) To contractors and subcontractors to the extent necessary to perform administrative tasks and/or technical installation and/or maintenance operations or other similar contractual duties; and

(i) To any person or entity to the extent necessary to prevent immediate loss of life or serious bodily injury.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information maintained in the system is stored in electronic media in Bureau facilities via a configuration of personal computer, client/server, and mainframe systems architecture. Computerized records are maintained on hard disk, floppy diskettes, magnetic tape and/or optical disks. Documentary records are maintained in manual file folders and/or on index card files.

RETRIEVABILITY:

Records are retrievable by identifying data, including last name, inmate register number, system classification category, Social Security number, alien registration number, system-generated identification number, passport number, employee badge number and/or miscellaneous identification number as provided by the visitor and/or other law enforcement agencies.

SAFEGUARDS:

Information is safeguarded in accordance with Bureau rules and policy governing automated information systems security and access. These safeguards include the maintenance of records and technical equipment in restricted areas, and the required use of proper passwords and user identification codes to access the system. Similarly, paper records are stored in secured areas to prevent unauthorized access. Only those Bureau personnel who require access to perform their official duties may access the records described in this system of records.

RETENTION AND DISPOSAL:

Records generated by the system to report entry/exit and internal movement activities are retained in accordance with General Records Schedule (GRS) 19, All other records in the system of records are retained until such time as the records no longer serve the purpose described by this system of records. At such time, these records (including investigatory records and/or records relating to disciplinary hearings and/or other appropriate personnel actions) may be incorporated into an appropriate, published system of records with an approved retention schedule, or otherwise destroyed. Computerized records are destroyed by shredding, degaussing, etc., and documentary records are destroyed by shredding.

SYSTEM MANAGER AND ADDRESS:

Assistant Director, Information, Policy, and Public Affairs Division, Federal Bureau of Prisons, 320 First Street NW., Washington, DC 20534.

NOTIFICATION PROCEDURE:

Inquiries concerning this system should be directed to the System Manager listed above.

RECORD ACCESS PROCEDURES:

All requests for records may be made by writing to the Director, Federal Bureau of Prisons, 320 First Street NW., Washington, DC 20534, and should be clearly marked ''Privacy Act Request.'' This system is exempt, under 5 U.S.C. 552a(j)(2) and (k)(2), from some access. A determination as to exemption shall be made at the time a request for access is received.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Individuals covered by the system; and Federal, State, local and foreign law enforcement agencies, and Federal and State probation and judicial offices.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Pursuant to 5 U.S.C. 552a(j)(2), the Attorney General has exempted this system from subsections (c) (3) and (4), (d), (e)(1), (e)(2), (e)(3), (e) (5), and (8), and (g) of the Privacy Act. In addition, pursuant to 5 U.S.C. 552a(k)(2), the Attorney General has exempted this system from subsections (c)(3), (d), and (e)(1). Rules have been promulgated in accordance with the requirements of 5 U.S.C. 553 (b), (c) and (e) and have been published in the Federal Register.

[FR Doc. 95–24612 Filed 10–3–95; 8:45 am]

BILLING CODE 4410–05–M

Antitrust Division

United States v. HealthCare Partners, Inc., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h), that a proposed Final Judgment, Stipulation, and a Competitive Impact Statement have been filed with the United States District Court for the District of Connecticut in *United States* v. *Healthcare Partners, Inc., et al.*, Civil No. 395–CV–01946–RNC as to HealthCare Partners, Inc., Danbury Area IPA, Inc., and Danbury Health Systems, Inc.

The Complaint alleges that defendants entered into an agreement with the purpose and effect of restraining competition unreasonably among physicians in the Danbury, Connecticut area, in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. The Complaint also alleges that Danbury Health Systems, Inc. willfully maintained its monopoly in general acute inpatient services in the Danbury, Connecticut area, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

The proposed Final Judgment eliminates the continuance or recurrence of defendants' unlawful agreement and of the additional acts of Danbury Health Systems, Inc. that gave rise to the violation of Section 2.

Public comment on the proposed Final Judgment is invited within the statutory 60-day comment period. Such comments and responses thereto will be published in the Federal Register and filed with the Court. Comments should be directed to call Gail Kursh, Chief, Professions and Intellectual Property Section/Health Care Task Force; United States Department of Justice; Antitrust Division; 600 E Street, NW., Room 9300; Washington, DC 20530 (telephone: 202/307–5799).

Rebecca P. Dick,

Deputy Director of Operations.

[Civil Action No. 395CV01946RNC.]

Stipulation

United States of America and State of Connecticut, ex rel., Richard Blumenthal, Attorney General, Plaintiffs, vs. HealthCare Partners, Inc., Danbury Area IPA, Inc., and Danbury Health Systems, Inc., Defendants.

It is stipulated by and between the undersigned parties, by their respective attorneys, that:

1. The Court has jurisdiction over the subject matter of this action and over each of the parties hereto, and venue of this action is proper in the District of Connecticut;

2. The parties consent that a Final Judgment in the form hereto attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16), and without further notice to any party or other proceedings, provided that plaintiffs have not withdrawn their consent, which they may do at any time before the entry of the proposed Final Judgment by serving notice thereof on defendants and by filing that notice with the Court; and

3. Defendants agree to be bound by the provisions of the proposed Final Judgment pending its approval by the Court. If plaintiffs withdraw their consent, or if the proposed Final Judgment is not entered pursuant to the terms of the Stipulation, this Stipulation shall be of no effect whatsoever, and the making of this Stipulation shall be without prejudice to any party in this or in any other proceeding.

For Plaintiff United States of America:

Lawrence R. Fullerton,

Acting Assistant Attorney General.

Rebecca P. Dick,

Deputy Director, Office of Operations.

Gail Kursh,

Chief, Professions & Intellectual Property Section.

Mark J. Botti,

Pamela C. Girardi,

Attorneys, U.S. Department of Justice, Antitrust Division, Professions & Intellectual Property Section, Room 9320, BICN Bldg., 600 E Street, NW., Washington, DC 20530, (202) 307–0827.

Plaintiff State of Connecticut

Richard Blumenthal,

Attorney General.

By:

William M. Rubenstein,

Assistant Attorney General, Federal Bar No. CT08834, 110 Sherman Street, Hartford, Connecticut 06105, (203) 566–5374.

For Defendants HealthCare Partners, Inc. and Danbury Health Systems, Inc.

David Marx, Jr.,

Jillisa Brittan,

McDermott, Will & Emery, 227 West Monroe Street, Chicago, Illinois 60606–5096, (312) 372–2000.

For Defendant Danbury Area IPA, Inc.

James Sicilian,

Day, Berry & Howard, CityPlace, Hartford, CT 06103, (203) 275–0100.

Final Judgment

Plaintiffs, the United States of America and the State of Connecticut, having filed their Complaint on September 13, 1995, and plaintiffs and defendants, by their respective attorneys, having consented to the entry of this Final Judgment without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or an admission by any party with respect to any issue of fact or law;

And Whereas defendants have agreed to be bound by the provisions of this Final Judgment pending its approval by the Court;

Now, Therefore, before the taking of any testimony, and without trial or adjudication of any issue of fact or law, and upon consent of the parties, it is hereby Ordered, Adjudged, and Decreed:

I

Jurisdiction

This Court has jurisdiction over the subject matter of and each of the parties to this action. The Complaint states claims upon which relief may be granted against the defendants under Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

II

Definitions

As used in this Final Judgment:

(A) *Competing physicians* means physicians in separate medical practices in the same relevant physician market;

(B) *Control* means either:

(1) holding 50 percent or more of the outstanding voting securities of an issuer;

(2) in the case of an entity that has no outstanding voting securities, having the right to 50 percent or more of the profits of an entity, or having the right in the event of dissolution to 50 percent or more of the assets of the entity; or

(3) having the contractual power to designate 50 percent or more of the directors of a corporation, or in the case of unincorporated entities, of individuals exercising similar functions.

(C) *DAIPA* means Danbury Area IPA, Inc., each of its directors, officers, agents, representatives, and employees (in such capacity only), its successors and assigns, and each entity over which it has control.

(D) *DHS* means Danbury Health Systems, Inc., each of its directors, officers, agents, representatives, and employees (in such capacity only), its successors and assigns, and each entity over which it has control.

(E) *DHS Affiliated Physician* means any physician employed, or whose practice is owned, by DHS or DOPS at the time of the filing of the Complaint in this action.

(F) *DOPS* means Danbury Office of Physician Services, P.C., each of its directors, officers, agents, representatives, and employees (in such capacity only), its successors and assigned, and each entity over which it has control.

(G) *HealthCare Partners* means HealthCare Partners, Inc., each of its directors, officers, agents, representatives, and employees (in such capacity only), its successors and assigns, and each entity over which it has control.

(H) Messenger model means the use of an agent or third party to convey to payers any information obtained from individual providers about the prices or other competitive terms and conditions each provider is willing to accept from payers, and to convey to providers any contract offer made by a payer, where each provider makes a separate, independent, and unilateral decision to accept or reject a payer's offer; the information on prices or other competitive terms and conditions conveyed to payers is obtained separately from each individual provider; and the agent or third party

does not negotiate collectively for the providers, disseminate to any provider the agent's or third party's or any other provider's views or intentions as to the proposal, or otherwise serve to facilitate any agreement among providers on prices or other competitive terms and conditions.

The agent or third party, so long as it acts consistently with the foregoing, may:

(1) Convey to a provider objective information about proposed contract terms, including comparisons with terms offered by other payers;

(2) solicit clarifications from a payer of proposed contract terms, or engage in discussions with a payer regarding contract terms other than prices and other competitive terms and conditions, except that the agent or third party (a) must tell the payer that the payer may refuse to respond or may terminate discussions at any time and (b) may not communicate to the providers regarding, or comment on, the payer's refusal to offer a clarification or decision not to enter into or to terminate discussions except to providers who requested the clarification;

(3) convey to a provider any response made by a payer to information conveyed or clarifications sought;

(4) convey to a payer the acceptance or rejection by a provider of any contract offer made by the payer;

(5) at the request of a payer, provide the individual response, information, or views of each provider concerning any contract offer made by such payer; and

(6) charge a reasonable fee to convey contract offers, by applying preexisting objective criteria, not involving prices or other competitive terms and conditions, in a nondiscriminatory manner.

Additionally, the agent or third party must communicate each contract offer made by a payer unless the payer refuses to pay the fee for delivery of that offer; the offer is the payer's first offer and lacks material terms such that it could not be considered a bona fide offer, or the agent or third party applies preexisting objective criteria, not involving prices or other competitive terms and conditions, in a nondiscriminatory manner (for example, refusing to convey offers of payers whose plans do not cover a certain minimum number of people, or offers made after the agent or messenger has conveyed a stated maximum number of offers for a given time period).

(I) *Pre-existing practice group* means a physician practice group existing as of the date of the filing of the Complaint in this action. All DHS affiliated physicians at the time of the filing of the Complaint in this action constitute a single pre-existing practice group. DAIPA does not constitute a pre-existing physician practice group. A pre-existing practice group may add any physician to the group after the filing of the Complaint, without losing the status of ''pre-existing'' under this definition for any relevant physician market, so long as each additional physician is not currently offering services in the relevant physician market and would not have entered that market but for the group's efforts to recruit the physician into the market.

(J) *Prices or other competitive terms and conditions* means all material terms of the contract, including information relating to fees or other aspects of reimbursement, outcomes data, practice parameters, utilization patterns, credentials, and qualifications.

(K) *Provider panel* means those health care providers with whom an organization contracts to provide care to its enrollees.

(L) *Qualified managed care plan* means an organization:

(1) Whose members or owners share substantial financial risk and either directly or through membership or ownership in another organization, comprise, (a) where membership or ownership is non-exclusive, no more than 30% of the physicians in any relevant physician market, except that it may include any single physician or pre-existing practice group, or (b) where membership or ownership is exclusive, no more than 20% of the physicians in any relevant physician market; and

(2) Whose provider panel, does not have more than where non-exclusive 30% or where exclusive 20% of the physicians in any relevant physician market, unless, for those subcontracting physicians whose participation increases the panel beyond the 20% or 30% limitations, the organization bears significant financial risk for payments to and the utilization practices of the subcontracting physicians and does not compensate those subcontracting physicians in a manner that substantially replicates membership or ownership in the organization.

The organization may not facilitate an agreement between any subcontracting physician and any other physician on their charges to payers not contracting with the organization. The organization may at any given item exceed the 20% or 30% limitations as a result of (a) any physician exiting any relevant physician market or (b) the addition of any physician not previously offering services in a relevant physician market who would not have entered that market but for the organization's efforts to recruit the physician into the market; however, the organization may not exceed the 20% or 30% limitation by any greater degree than is directly caused by such exit or entry.

(M) *Relevant physician market* means, unless defendants obtain plaintiffs' prior written approval of a different definition, each of the following groups of physicians with active staff privileges other than courtesy privileges at Danbury Hospital:

(1) Physicians who are: (a) Board-certified only in general internal medicine or family practice; (b) listed only under family practice or internal medicine on the attached medical staff lists of Danbury Hospital; or (c) generally-recognized, and in fact practicing more than a third of the time as a family practitioner or general internist (for purposes of determining the percentage of physicians applicable to a qualified managed care plan, each physician included in a relevant physician market pursuant to this clause (c) of Paragraph (II)(M)(1) of this Final Judgment shall count as only one-third of a physician);

(2) Physicians who are board-certified in, or board-eligible and actually practicing in, obstetrics or gynecology;

(3) Physicians who are board-certified in, or board-eligible and actually practicing in, pediatrics; and

(4) Any other group of physicians who offer services in a relevant product market as defined applying federal antitrust principles.

(N) *Subcontracting physician* means any physician who provides services to an organization or to persons receiving healthcare services from that physician pursuant to an agreement by that organization to provide such services, but who does not hold, directly or indirectly, any ownership interest in that organization.

(O) *Substantial financial risk* means financial risk achieved through capitation or the creation of significant financial incentives for the group to achieve specified cost-containment goals, such as withholding from all members or owners of a qualified managed care plan a substantial amount of the compensation due to them, with distribution of that amount to the members or owners only if the cost-containment goals are met.

III

Applicability

This Final Judgment applies to DHS, DAIPA, and HealthCare Partners, and to all other persons who receive actual notice of this Final Judgment by personal service or otherwise and then act or participate in active concert with any or all of the defendants.

IV

Injunctive Relief

(A) DAIPA and HealthCare Partners are enjoined from, directly or through any agent or other third party, setting, or expressing views on, the prices or other competitive terms and conditions or negotiating for competing physicians, regardless of whether those physicians are subcontracting physicians or owners or members of DAIPA or HealthCare Partners, unless done as part of the operation of a qualified managed care plan; provided that, nothing in this Final Judgment shall prohibit DAIPA or HealthCare Partners from acting as or using a messenger model.

(B) DAIPA, HealthCare Partners, and DHS are enjoined from:

(1) Precluding or discouraging any physician from contracting with any payer, providing incentives for any physician to deal exclusively with DAIPA, HealthCare Partners, or any payer, or agreeing to any priority among themselves as to which will have the right to first negotiate with any payer, provided that, nothing is in this paragraph shall prohibit a physician from agreeing to exclusivity in connection with an ownership interest or membership in a qualified managed care plan, or prohibit DHS from participant in contracting decisions of DHS-affiliated physicians;

(2) Disclosing to any physician any financial or other competitively sensitive business information about any competing physician, except as is reasonably necessary for the operation of any qualified managed care plan, or requiring any physician to disclose any financial or other competitively sensitive business information about any payer or other competitor of DAIPA or HealthCare Partners; provided that, nothing in this Final Judgment shall prohibit the disclosure of information already generally available to the medical community or the public or the provision of information pursuant to the Antitrust Safety Zones delineated in the attached Statements 5 and 6 of the 1994 Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust;

(3) Owning an interest in any organization (including DAIPA and HealthCare Partners) that, directly or through any agent or other third party, sets, or expresses views on, prices or other competitive terms and conditions or negotiates for competing physicians, regardless of whether those physicians are subcontracting physicians or owners or members of that organization, unless that organization is a qualified managed care plan and complies with Paragraphs IV (B)(1) and (B)(2) of the Final Judgment as if those Paragraphs applied to that organization; provided that, nothing in this Final Judgment shall prohibit owning an interest in an organization that acts as or uses a messenger model.

(C) DHS is enjoined from:

(1) Exercising its control over staff privileges with the purpose of reducing competition with DHS in any line of business, including managed care, outpatient surgery or radiology, and physician services; provided that nothing in this Final Judgment shall limit DHS's authority to make staff decisions for the purpose of assuring quality of care;

(2) Conditioning the provision of inpatient hospital services to individuals covered by any payer on:

(a) The purchase or use of DHS's utilization review program, any DHS qualified managed care plan, DHS's ancillary or outpatient services, or any physician's services unless such services are intrinsically related to the provision of acute inpatient care (as, for example, are radiology, anesthesiology, emergency room, and pathology services deemed to be for purposes of this Final Judgment where these services are performed in connection with an inpatient admission), or

(b) A contract or other agreement to deal through HealthCare Partners or any other organization; provided that, nothing in this Paragraph IV(C)(2) shall limit the terms and conditions on which DHS may contract with any payer pursuant to which DHS bears substantial financial risk for the delivery of the services or products identified in Subparagraphs (1) and (2); and

(3) Conditioning rates to any payer for inpatient hospital services on the exclusive use of DHS outpatient services, provided that nothing in this Paragraph IV(C)(3) shall (a) limit the terms and conditions on which DHS may contract with any payer pursuant to which DHS bears substantial financial risk for the delivery of outpatient services; or (b) prohibit DHS from entering into exclusive contracts that require payers to use DHS's outpatient services where rates for those services are not tied to discounts on inpatient rates.

V

Additional Provisions

(A) DAIPA and HealthCare Partners shall:

(1) Inform each participating physician annually in writing that the physician is free to contract separately with any payer on any terms, except with regard to physicians who have agreed to exclusivity in connection with an ownership interest or membership in a qualified managed care plan; and

(2) Notify in writing each payer with which HealthCare Partners currently has or is negotiating a contract, or which subsequently inquires about contracting with HealthCare Partners, that each provider on HealthCare Partners' provider panel is free to contract separately with such payer on any terms, without consultation with DAIPA or HealthCare Partners.

(B) DHS shall file with plaintiffs each year on the anniversary of the filing of the Complaint in this action a written report disclosing the rates for inpatient hospital services to any payer, including any plan affiliated with DHS, or in lieu of such a report, documents sufficient to disclose those rates for each payer (other than Medicare and Medicaid). Plaintiffs agree not to disclose this information unless in connection with a proceeding to enforce this Final Judgment or pursuant to a court or congressional order.

VI

Compliance Program

Each defendant shall maintain an antitrust compliance program (unless the defendant dissolves without any successors or assigns), which shall include:

(A) Distributing within 60 days from the entry of this Final Judgment, a copy of the Final Judgment and Competitive Impact Statement to all officers and directors;

(B) Distributing in a timely manner a copy of the Final Judgment and Competitive Impact Statement to any person who succeeds to a position described in Paragraph VI(A);

(C) Briefing annually in writing or orally those persons designated in Paragraphs VI (A) and (B) on the meaning and requirements of this Final Judgment and the antitrust laws, including penalties for violation thereof;

(D) Obtaining from those persons designated in Paragraphs (VI) (A) and (B) annual written certifications that they (1) have read, understand, and agree to abide by this Final Judgment, (2) understand that their noncompliance with this Final Judgment may result in conviction for criminal contempt of court and imprisonment and/or fine, and (3) have reported violations, if any, of this Final Judgment of which they are aware to counsel for the respective defendant; and

(E) Maintaining for inspection by plaintiffs a record of recipients to whom this Final Judgment and Competitive

Impact Statement have been distributed and from whom annual written certifications regarding this Final Judgment have been received.

VII

Certifications

(A) Within 75 days after entry of this Final Judgment, each defendant shall certify to plaintiffs that it has made the distribution of the Final Judgment and Competitive Impact Statement as required by Paragraph VI(A); and

(B) For 10 years, unless the defendant dissolves without any successors or assigns, after the entry of this Final Judgment, on or before its anniversary date, each defendant shall certify annually to plaintiffs whether it has complied with the provisions of Section VI applicable to it.

VIII

Plaintiffs' Access

For the sole purpose of determining or securing compliance with this Final Judgment, and subject to any recognized privilege, authorized representatives of the United States Department of Justice or the Office of the Attorney General of the State of Connecticut, upon written request of the Assistant Attorney General in charge of the Antitrust Division or the Connecticut Attorney General, respectively, shall on reasonable notice be permitted:

(A) Access during regular business hours of any defendant to inspect and copy all records and documents in the possession or under the control of that defendant relating to any matters contained in this Final Judgment;

(B) To interview officers, directors, employees, and agents of any defendant, who may have counsel present, concerning such matters; and

(C) To obtain written reports from any defendant, under oath if requested, relating to any matters contained in this Final Judgment.

IX

Notifications

Each defendant shall notify the plaintiffs at least 30 days prior to any proposed (1) dissolution of that defendant, (2) sale or assignment of claims or assets of that defendant resulting in the emergence of a successor corporation, or (3) change in corporate structure of that defendant that may affect compliance obligations arising out of Section IV of this Final Judgment.

X

Jurisdiction Retained

This Court retains jurisdiction to enable any of the parties to this Final Judgment, but no other person, to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify or terminate any of its provisions, to enforce compliance, and to punish violations of its provisions.

XI

Expiration of Final Judgment

This Final Judgment shall expire ten (10) years from the date of entry.

XII

Public Interest Determination

Entry of this Final Judgment is in the public interest.

Dated: _____.

_____

United States District Judge

Note: The Danbury Hospital Medical Staff List by Department, Statement of Department of Justice and Federal Trade Commission Enforcement Policy on Providers' Collective Provision of the Related Information to Purchasers of Health Care Services, and Statement of Department of Justice and Federal Trade Commission Enforcement Policy on Provider Participation in Exchanges of Price and Cost Information are attachments to the proposed Final Judgment filed with the Court. A copy of the attachments may be obtained from the Department of Justice, Legal Procedures Unit.

Competitive Impact Statement

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b)–(h) (''APPA''), the United States files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I

Nature and Purpose of the Proceeding

On September 13, 1995, the United States and the State of Connecticut filed a civil antitrust complaint alleging that defendant HealthCare Partners, Inc. (''HealthCare Partners''), defendant Danbury Area IPA, Inc. (''DAIPA''), and defendant Danbury Health Systems, Inc. (''DHS''), with others not named as defendants, entered into an agreement and took other actions, the purpose and effect of which were, among other things, to restrain competition unreasonably by preventing or delaying the development of managed care in the Danbury, Connecticut area (''Danbury''), to willfully maintain DHS' market power in acute, inpatient care, and to gain an unfair advantage in markets for outpatient services, in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2. The Complaint seeks injunctive relief to enjoin continuance or recurrence of these violations.

The United States and the State of Connecticut filed with the Complaint a proposed Final Judgment intended to settle this matter. Entry of the proposed Final Judgment by the Court will terminate this action, except that the Court will retain jurisdiction over the matter for further proceedings that may be required to interpret, enforce, or modify the Judgment, or to punish violations of any of its provisions.

Plaintiffs and all defendants have stipulated that the Court may enter the proposed Final Judgment after compliance with the APPA, unless prior to entry plaintiffs have withdrawn their consent. The proposed Final Judgment provides that its entry does not constitute any evidence against, or admission by, any party concerning any issue of fact or law.

The present proceeding is designed to ensure full compliance with the public notice and other requirements of the APPA. In the Stipulation to the proposed Final Judgment, defendants have also agreed to be bound by the provisions of the proposed Final Judgment pending its entry by the Court.

II

Practices Giving Rise To The Alleged Violations

DHS's 450-bed acute care facility, Danbury Hospital, is the sole source of acute inpatient care in the Danbury area. It faces no competition from other general acute care hospitals in the market for these services and, accordingly, possesses a monopoly in general acute inpatient care. The Hospital also provides outpatient surgical care and other services.

By 1992, managed care organizations had recruited a sufficient number of physicians with active staff privileges at Danbury Hospital to offer managed care plans to employers and individuals in the Danbury area. The introduction of managed care plans into the Danbury area reduced the Hospital's market power in inpatient services by decreasing the number of hospital admissions and the length of hospital stays, thereby causing the Hospital to lose significant inpatient volume. Additionally, the introduction of managed care plans resulted in increased competition among doctors and reduced referrals to specialists in

DOPS (Danbury Hospital's affiliated multispecialty practice group).

In 1993, DHS took steps to form an alliance with virtually every doctor on its Hospital's medical staff to protect the economic interests of both the Hospital and the doctors and forestall the continued development of managed care plans in Danbury. On May 6, 1994, HealthCare Partners was incorporated to represent jointly Danbury Hospital and physicians in negotiations with managed care organizations, and DAIPA was created as the vehicle for physician ownership in HealthCare Partners. Danbury Hospital and DAIPA jointly own HealthCare Partners, and each appoints six of the twelve directors of HealthCare Partners' board of directors.

Only active members of Danbury Hospital's medical staff could be owners of DAIPA. Over 98% of the doctors on Danbury Hospital's medical staff joined DAIPA. Each paid a small fee. None committed to any integration of their practices.

Each doctor who joined DAIPA contracted with HealthCare Partners and authorized it to negotiate fees on the doctor's behalf. The doctors authorized HealthCare Partners to enter into non-risk-bearing contracts in one of two ways.[1]

First, it could prepare a minimum fee schedule and present it to each doctor for approval. A doctor's approval would then authorize HealthCare Partners to enter into non-risk-bearing contracts on behalf of the doctor without further consultation so long as the resulting fees equalled or exceeded the minimum fee schedule.

Alternatively, HealthCare Partners could negotiate fees on behalf of all the doctors and then present each doctor with the collectively negotiated fee schedule. Each doctor would then have the opportunity to accept this jointly negotiated fee schedule.

HealthCare Partners negotiated two contracts using this latter approach and succeeded in obtaining generous fees for the DAIPA doctors. Indeed, one of the contracting managed care plans was forced to increase its fees to doctors outside of the Danbury area to avoid the excessive administrative costs it would have incurred to administer one fee schedule for Danbury and a separate schedule for the other areas in which it operated.

The Hospital's goal in forming HealthCare Partners was to eliminate competition among physicians in order to further its broader goal of reducing or limiting the impact of managed care plans on its monopoly in acute inpatient services. In furtherance of these goals, the Hospital also used its control over admitting privileges to reduce competition in physician and outpatient services markets. The Hospital adopted a Medical Staff Development Plan in part to limit the size and mix of its medical staff. This Plan effectively controlled the entry of new physicians into Danbury and thereby insulated HealthCare Partners from competition. The Hospital also announced a policy that required its doctors to perform at least 30% of their procedures at the Hospital. This announcement caused a reduction in the use of a competing outpatient surgery center.

Based on the facts described above, the Complaint alleges (1) that the defendants entered into a contract, combination, or conspiracy that eliminated competition among physicians, reduced or limited the development of managed care plans, and reduced or limited competition among outpatient service providers, all in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1 and (2) that HDS took exclusionary acts that had the purpose and effect of maintaining Danbury Hospital's market power in acute inpatient hospital services and gaining an unfair advantage in markets for outpatient services, in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

III

Explanation of The Proposed Final Judgment

The proposed Final Judgment is intended to prevent the continuance or recurrence of defendants' agreement to eliminate competition among doctors and reduce or limit the development of managed care in the Danbury area. The proposed Final Judgment is also intended to prevent the continuance or recurrence of DHS's exclusionary conduct. The overarching goal of the proposed Final Judgment is to enjoin defendants from engaging in any activity that unreasonably restrains competition among physicians, outpatient service providers, or managed care plans in the Danbury area, or that willfully maintains Danbury Hospital's market power in acute inpatient services, or gains Danbury hospital an unfair advantage in markets for outpatient services, while still permitting defendants to market a provider-controlled managed care plan.[2]

A. *Scope of the Proposed Final Judgment*

Section III of the proposed Final Judgment provides that the Final Judgment shall apply to defendants and to all other persons who receive actual notice of this proposed Final Judgment by personal service or otherwise and then participate in active concert with any defendant. The proposed Final Judgment applies to DHS, DAIPA, and HealthCare Partners.

B. Prohibitions and Obligations

Sections IV and V of the proposed Final Judgment contain the substantive provisions of the Judgment.

In Section IV(A), DAIPA and HealthCare Partners are enjoined from setting or expressing views on the prices or other competitive terms and conditions or negotiating entity is a Qualified Managed Care Plan (''QMCP''—as defined in the proposed Final Judgment and discussed below). However, DAIPA and HealthCare Partners are permitted to use a messenger model, as discussed below.

Section IV(B)(1) enjoins DHS, DAIPA, and HealthCare Partners from precluding or discouraging any physician from contracting with any payer, providing incentives for any physician to deal exclusively with DAIPA, HealthCare Partners, or any payer, or agreeing to any priority among themselves as to which will have the right to negotiate first with any payer. Nothing in Section IV(B), however, prohibits physicians from agreeing to exclusivity in connection with an ownership interest or membership in a QMCP.

Section IV(B)(2) prohibits the sharing of competitively sensitive information. DHA, DAIPA, and HealthCare Partners are enjoined from disclosing to any physician any financial or other competitively sensitive business information about any competing physician and from requiring any physician to disclose any financial or other competitively sensitive information about any payer. An exception permits any defendant to

[1] While the doctors also authorized HealthCare Partners to enter into risk-bearing contracts, HealthCare Partners has not exercised this authority. Even if it had, or does in the future, the negotiation of risk-bearing contracts would not justify the unlawful negotiation of non-risk-bearing contracts that occurred here. *See* Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust (''Health Care Policy Statements'') that the U.S. Department of Justice and the Federal Trade Commission issued jointly on September 27, 1994, 4 Trade Reg. Rep. (CCH) ¶ 13,152, at 20,794 n.35.

[2] This relief comports with the Health Care Policy Statements, and in particular with the principles enunciated therein that a provider network (1) should not prevent the formation of rival networks and (2) may not negotiate on behalf of providers, unless those providers share substantial financial risk or offer a new product to the market place. Statement 8, 4 Trade Reg. Rep. (CCH) ¶ 13,152, at 20,788–89; Statement 9, *id.* at 20,793–94, 20,796.

disclose such information if disclosure is reasonably necessary for the operation of a QMCP in which that defendant has an ownership interest, or if the information is already generally available to the medical community or the public.

Section IV(B)(3) enjoins DHS, DAIPA, and HealthCare Partners from owning an interest in any organization that directly or through an agent or other third party sets fees or other terms of reimbursement, or negotiates for competing physicians, unless that organization is a QMCP and complies with Sections IV (B)(1) and (B)(2). However, defendants may own an interest in an organization that uses a messenger model.

Section IV(C)(1) enjoins DHS from exercising its control over staff privileges with the purpose of reducing competition with DHS in any line of business, including managed care, outpatient services, and physician services. Nothing in the Final Judgment limits DHS' authority to make staff decisions for assuring quality of care.

Section IV(C)(2) prohibits DHS from conditioning the provision of inpatient hospital services to individuals covered by any payer on the purchase or use of DHS' utilization review program, qualified managed care plan, ancillary or outpatient services, or any physician's services, unless the physician services are intrinsically related to the provision of inpatient care. (These prohibitions, however, do not apply to any organization or any contract in which DHS has a substantial financial risk.)

Section IV(C)(3) prohibits DHS from conditioning rates to any payer for inpatient hospital services on the exclusive use of the Hospital's outpatient services. Nothing in this Section limits the terms and conditions on which DHS may contract with any payer pursuant to which DHS bears substantial financial risk for the delivery of outpatient services.

Section V of the proposed Final Judgment contains additional provisions with respect to DAIPA and HealthCare Partners. Section V(A) requires DAIPA and HealthCare Partners to notify participating physicians annually that they are free to contract separately with any payer on any terms, except with regard to those physicians who have agreed to exclusivity in connection with an ownership interest or membership in a QMCP. Similarly, DAIPA and HealthCare Partners must notify in writing each payer with whom HealthCare Partners has or is negotiating a contract, or which subsequently inquires about contracting, that each of its participating physicians is free to contract separately with such payer on any terms and without consultation with DAIPA or HealthCare Partners.

Under Section V(B), DHS must file with plaintiffs annually on the anniversary of the filing of the Complaint a written report disclosing the rates for inpatient hospital services to any payer, including any plan affiliated with DHS. In lieu of a report, DHS may file documents disclosing the rates for each payer other than Medicare and Medicaid.

Section VI of the proposed Final Judgment requires defendants to implement a judgment compliance program. Section VI(A) requires that within 60 days of entry of the Final Judgment, defendants must provide a copy of the proposed Final Judgment and the Competitive Impact Statement to all officers and directors. Sections VI (B) and (C) require defendants to provide a copy of the proposed Final Judgment and Competitive Impact Statement to persons who assume those positions in the future and to brief such persons annually on the meaning and requirements of the proposed Final Judgment and the antitrust laws, including penalties for violating them. Section VI(D) requires defendants to maintain records of such persons' written certifications indicating that they (1) have read, understand, and agree to abide by the terms of the proposed Final Judgment, (2) understand that their noncompliance with the proposed Final Judgment may result in conviction for criminal contempt of court, and imprisonment, and/or fine, and (3) have reported any violation of the proposed Final Judgment of which they are aware to counsel for defendants. Section VI(E) requires defendants to maintain for inspection by plaintiffs a record of recipients to whom the proposed Final Judgment and Competitive Impact Statement have been distributed and from whom annual written certifications regarding the proposed Final Judgment have been received.

The proposed Final Judgment also contains provisions in Section VII requiring defendants to certify their compliance with specified obligations of Section VI(A) of the proposed Final Judgment. Section VIII of the proposed Final Judgment sets forth a series of measures by which plaintiffs may have access to information needed to determine or secure defendants' compliance with the proposed Final Judgment. Section IX provides that each defendant must notify plaintiffs of any proposed change in corporate structure at least 30 days before that change to the extent the change may affect compliance obligations arising out of the proposed Final Judgment.

Finally, Section XI states that the Judgment expires ten years from the date of entry.

C. Effect of the Proposed Final Judgment on Competition

1. The Prohibitions on Setting and Negotiating Fees and Other Contract Terms

The prohibitions on setting or expressing views on prices and other contract terms or negotiating for competing physicians, set forth in Section IV(A), provide defendants with essentially two options for complying with the proposed Final Judgment. First, HealthCare Partners and DAIPA may change their manner of operation and no longer set or negotiate fees on behalf of competing physicians, for example by using a ''messenger model,'' a term defined in the proposed Final Judgment. Second, HealthCare Partners and DAIPA may restructure their ownership and provider panels to become a QMCP.[3]

DAIPA jointly owns HealthCare Partners with DHS and appoints six of HealthCare Partners directors. DAIPA includes competing physicians among its owners on whose behalf HealthCare Partners negotiates fees and other competitively sensitive terms and conditions. These physicians do not share financial risk. The proposed Final Judgment prevents HealthCare Partners and DAIPA, under their present structures, from continuing to set or negotiate fees or other terms of reimbursement collectively on behalf of the competing physicians. (Section IV(A)) Such conduct would constitute naked price fixing. *Arizona* v. *Maricopa County Medical Soc'y,* 457 U.S. 332, 356–57 (1982).

The proposed Final Judgment does not, however, prohibit HealthCare Partners and DAIPA, as presently structured, from engaging in activities that are not anticompetitive. In particular, while the proposed Judgment enjoins HealthCare Partners and DAIPA from engaging in price fixing or similar anticompetitive conduct, it permits HealthCare Partners and DAIPA to use an agent or third party to facilitate the transfer of information between individual physicians and purchasers of physician services. Appropriately designed and administered, such messenger models rarely present substantial competitive concerns and indeed have the potential to reduce the transaction costs of negotiations

[3] Of course, HealthCare Partners and DAIPA could simply cease operations and dissolve.

between health plans and numerous physicians.

The proposed Final Judgment makes clear that the critical feature of a properly devised and operated messenger model is that individual providers make their own separate decisions about whether to accept or reject a purchaser's proposal, independent of other physicians' decisions and without any influence by the messenger. (Section II(H)) The messenger may not, under the proposed Judgment, coordinate individual providers' responses to a particular proposal, disseminate to physicians the messenger's or other physicians' views or intentions concerning the proposal, act as an agent for collective negotiation and agreement, or otherwise serve to facilitate collusive behavior.[4] The proper role of the messenger is simply to facilitate the transfer of information between purchasers of physician services and individual physicians or physician group practices and not to coordinate or otherwise influence the physicians' decision-making process.[5]

If, on the other hand, HealthCare Partners or DAIPA wants to negotiate on behalf of competing physicians, it must restructure itself to meet the requirements of a QMCP as set forth in the proposed Final Judgment. To comply, (1) the owners or members of HealthCare Partners or DAIPA (to the extent they compete with other owners or members or compete with physicians on their provider panels) must share substantial financial risk, and comprise no more than 30% on a nonexclusive basis, or 20% on an exclusive basis, of the physicians in any relevant market; *and* (2) to the extent HealthCare Partners or DAIPA has a provider panel that exceeds either of these limits in any relevant market, there must be a divergence of economic interest between the owners and the subcontracting physicians, such that the owners have the incentive to bargain down the fees of the subcontracting physicians. (See II(L) (1) and (2)) As explained below, the requirements of a QMCP are necessary to avoid the creation of a physician cartel while at the same time allowing payers access to larger physician panels.

a. QMCP Ownership Requirements

The financial risk-sharing requirement of a QMCP ensures that the physician owners in the venture share a clear economic incentive to achieve substantial cost savings and provide better services at lower prices to consumers. This requirement is applicable to all provider-controlled organizations since without this requirement a network of competing providers would have both the incentive and the ability to increase prices for health care services.

The requirement that a QMCP not include more than 30% on a nonexclusive basis, and 20% on an exclusive basis, of the local physicians in certain instances is designed to ensure that there are available sufficient remaining physicians in the market with the incentive to contract with competing managed care plans or to form their own plans.[6] These limitations are particularly critical in this case in view of defendants' prior conduct in forming negotiating groups with nearly every physician with active staff privileges at Danbury Hospital.

The 20% and 30% limitations will prevent defendants from aggregating market power to pursue and achieve the same type of anticompetitive effects that led to this action. Consistent with the reasons for these limitations, the proposed Final Judgment permits recruitment of new physicians, and thus an increase in the supply of physicians in the Danbury area, even if that recruitment causes a QMCP to exceed the 20% or 30% limitation. Similarly, defendants will not violate the proposed Final Judgment if these limits are exceeded as a result of a physician exiting any relevant market.

In addition, the 30% limitation does not apply where a QMCP includes any single physician or pre-existing practice group that already has more than a 30% market share. In these circumstances, no aggregation of market power could occur as a result of the practice group joining the QMCP. To quality for this exemption, the pre-existing practice group must exist as of the date of the filing of the Complaint in this action (Section II(I)) For example, Danbury Hospital would violate the Final Judgment if it owns an interest in a QMCP in which DOPS participates as an owner on a nonexclusive basis and, after the filing of the complaint, DOPS acquires physician practices that cause it to exceed the 30% limitation or increase its market share in markets where it already exceeds 30%.[7]

b. OMCP Subcontracting Requirements

Many employers and payers may want managed care products with panels larger than permitted by the 20% and 30% limitations. The QMCP's subcontracting requirements are designed to permit a larger physician panel, but with restrictions to avoid the risk of competitive harm. To offer panels above the 20% and 30% limits, a QMCP must operate with the same incentives as a nonprovider-controlled plan. Specifically, the owners of a QMCP must bear significant financial risk for the payments to, and utilization practices of, the panel physicians in excess of the 20% and 30% limitations. These requirements significantly reduce the incentives for a QMCP to use the subcontracts as a mechanism for increasing fees for physician services.

Consequently, the proposed Final Judgment permits a QMCP to subcontract with any number of physicians in a market provided important safeguards are met. Under Section II(L)(2) of the proposed Final Judgment, the subcontracting physician panel may exceed the 20% or 30% limitation if the organization bears significant financial risk for payments to and the utilization practices of the subcontracting physicians and does not compensate those subcontracting

[4] For example, it would be a violation of the proposed Final Judgment if the messenger were to select a fee for a particular procedure from a range of fees previously authorized by the individual physician, or if the messenger were to convey collective price offers from physicians to purchasers or negotiate collective agreements with purchasers on behalf of physicians. This would be so even if individual physicians were given the opportunity to ''opt in'' to any agreement. In each instance, it would in fact be the messenger, not the individual physician, who would be making the critical decision, and the purchaser would be faced with the prospect of a collective response.

[5] For example, the messenger may convey to a physician objective or empirical information about proposed contract terms, convey to a purchaser any individual physician's acceptance or rejection of a contract offer, canvass member physicians for the rates at which each would be willing to contract even before a purchaser's offer is made, and charge a reasonable, non-discriminatory fee for messenger services. The proposed Final Judgment gives guidelines for these and other activities that a messenger may undertake without violating the Final Judgment. (Section II(H))

[6] The proposed Final Judgment embodies the parties' stipulation that only physicians with active staff privileges (not including those with just courtesy privileges) at Danbury Hospital are in any relevant physician market. One anticompetitive effect remedied by the proposed Final Judgment was the reduction in competition among these physicians, which allowed both the exercise of horizontal market power in physician markets and the willful maintenance of the Hospital's market power in acute inpatient hospital service. Accordingly, the 20% and 30% limitations apply to this universe of doctors. The proposed Final Judgment specifies three separate product markets to which these limitations apply: adult primary care doctors (Section II(M)(1)), OB/GYNs (Section II(M)(2)), and pediatricians (Section IIM)(3). The limitations also apply to any other relevant product market for physician services. (Section II(M)(4)) The proposed Final Judgment permits plaintiffs to give written approval of relevant markets differing from those specified.

[7] In contrast, the 20% limitation does not have an exception for pre-existing practice groups because in an exclusive arrangement such practice groups could have the incentives and ability to create the same type of cartel that the proposed Final Judgment is intended to break up.

physicians in a manner that substantially replicates ownership. These requirements will assure that there is a sufficient divergence of economic interest between those subcontracting physicians and the owners such that the owners have the incentive to bargain down the fees of the subcontracting physicians. Indeed, without these requirements, the organization could serve as a cartel manager for all members of Danbury Hospital's active medical staff by, for example, passing through directly to payers substantial liability for making payments to the subcontracting physicians.

A QMCP would meet the subcontracting requirements if, for example, a QMCP were compensated on a capitated, per diem, or diagnostic related group basis and, in turn, reimbursed subcontracting physicians pursuant to a fee schedule. In such a situation, an increase in the fee schedule to subcontracting physicians during the term of a QMCP's contract with the particular payer would not be directly passed through to the payer but rather would be borne by a QMCP itself. This would provide a substantial incentive for a QMCP to bargain down its fees to the subcontracting physicians.

On the other hand, the subcontracting requirements would *not* be met if a QMCP's contract with a payer were structured so that significant changes in the payments by a QMCP to its physicians directly affected payments from the payer to a QMCP, or if the payer directly bears the risk for paying the panel physicians or pays the panel physicians pursuant to a fee-for-service schedule. The requirements would also not be satisfied if contracts between a QMCP and the subcontracting physicians provided that payments to the physicians depended on, or varied in response to, the terms and conditions of a QMCP's contracts with payers.[8] Any of these scenarios would permit a QMCP to pass through to payers, rather than bear, the risk that its provider panel will charge fees that are too high or deliver services inefficiently.[9]

2. Prohibitions Against Exclusionary Acts

In addition to helping to organize HealthCare Partners and DAIPA, DHS used other exclusionary acts to maintain its market power in acute impatient hospital services and to gain an unfair advantage in markets for outpatient services. The proposed Final Judgment eliminates the continuance or recurrence of such exclusionary acts.

Section IV(C) of the proposed Final Judgment prohibits Danbury Hospital from exercising its control over staff privileges with the purpose of reducing competition with the Hospital in any line of business, tying the availability of inpatient services to any other service, or conditioning favorable inpatient rates on exclusive use of Danbury Hospital's outpatient services. These prohibitions are crafted to permit Danbury Hospital to assure the quality of care delivered at the Hospital, participate in managed care plans, retain freedom to contract on acceptable terms, and compete aggressively in outpatient markets, while at the same time ensure that Danbury Hospital does not unlawfully abuse its monopoly in acute inpatient services. The Hospital is also required to report annually its inpatient rates to payers. (Section V(B))

3. Other Substantive Provisions

Section IV(B)(2) of the proposed Final Judgment enjoins the disclosure to any physician of any financial or competitively sensitive business information about any competing physician. It also enjoins defendants' requiring any physician to disclose competitively sensitive information about any payer. This provision will ensure that defendants do not exchange information that could facilitate price fixing or other anticompetitive harm.

Section V(A) requires DAIPA and HealthCare Partners to give notice to doctors and managed care plans that each doctor currently under contract with HealthCare Partners is free to contract separately from DAIPA and HealthCare Partners. This will help abate any continuing effect from the unlawful conspiracy.

4. Conclusion

The Department of Justice believes that the proposed Final Judgment contains adequate provisions to prevent further violations of the type upon which the Complaint is based and to remedy the effects of the alleged conspiracy and DHS' exclusionary acts. The proposed Final Judgment's injunctions will restore the benefits of free and open competition in the Danbury area and will provide consumers with a broader selection of competitive health care plans.

IV

Alternative to the Proposed Final Judgment

The alternative to the proposed Final Judgment would be a full trial on the merits of the case. In the view of the Department of Justice, such a trial would involve substantial costs to the United States, the State of Connecticut, and defendants and is not warranted because the proposed Final Judgment provides all of the relief necessary to remedy the violations of the Sherman Act alleged in the Complaint.

V

Remedies Available to Private Litigants

Section 4 of the Clayton Act, 15 U.S.C. § 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages suffered, as well as costs and a reasonable attorney's fee. Entry of the proposed Final Judgment will neither impair nor assist in the bringing of such actions. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. § 16(a), the proposed Final Judgment has no *prima facie* effect in any subsequent lawsuits that may be brought against one or more defendants in this matter.

VI

Procedures Available for Modification of the Proposed Final Judgment

As provided by Sections 2 (b) and (d) of the APPA, 15 U.S.C. § 16 (b) and (d), any person believing that the proposed Final Judgment should be modified may submit written comments to Gail Kursh, Chief; Professions & Intellectual Property Section/Health Care Task Force; United States Department of Justice; Antitrust Division; 600 E Street, N.W.; Room 9300; Washington, D.C. 20530, within the 60-day period provided by the Act. Comments received, and the Government's responses to them, will be filed with the Court and published in the Federal Register. All comments will be given due consideration by the Department of Justice, which remains free, pursuant to Paragraph 2 of the Stipulation, to withdraw its consent to the proposed Final Judgment at any time before its entry, if the Department should

[8] Nothing in the proposed Final Judgment prohibits a QMCP from entering into arrangements that shift risk to subcontracting physicians, such as may be desirable to create cost-reducing incentives, so long as those arrangements are consistent with the criteria for a QMCP set forth in Section II(L) of the Judgment.

[9] Similarly, a QMCP would fail the ownership replication restriction of Section II(L) of the proposed Final Judgment if, for example, the owners paid themselves a dividend and then, through declaration of a bonus, paid the same or similar amount to the subcontracting physicians. The same would be true if the owners otherwise structured dividends, bonuses, and incentive payments in such a way that ensures that subcontracting and owning physicians receive equal overall compensation.

determine that some modification of the Final Judgment is necessary for the public interest. Moreover, the proposed Final Judgment provides in Section X that the Court will retain jurisdiction over this action, and that the parties may apply to the Court for such orders as may be necessary or appropriate for the modification, interpretation, or enforcement of the proposed Final Judgment.

VII

Determinative Documents

No materials and documents of the type described in Section 2(b) of the APPA, 15 U.S.C. § 16(b), were considered in formulating the proposed Final Judgment. Consequently, none are filed herewith.

Dated: September 13, 1995.

Respectfully submitted,

Mark J. Botti,

Pamela C. Girardi,

Attorneys, Antitrust Division, U.S. Dept. of Justice, 600 E Street, N.W., Room 9320, Washington, D.C. 20530, (202) 307–0827.

Christopher F. Droney,

United States Attorney.

Carl J. Schuman,

Assistant U.S. Attorney, Federal Bar No. CT 05439, 450 Main Street, Hartford, Connecticut 06103, (203) 240–3270.

Certificate of Service

I, Carl J. Schuman, hereby certify that copies of the Complaint, Stipulation, Competitive Impact Statement, and Notice of Lodging in *U.S.* v. *HealthCare Partners, Inc., et. al.* were served on the 13th day of September 1995 by first class mail to counsel as follows:

David Marx, Jr.,

McDermott, Will & Emery, 227 West Monroe Street, Chicago, Illinois 60606–5096.

James Sicilian,

Day, Berry & Howard, CityPlace, Hartford, Connecticut 06103.

Carl J. Schuman

[FR Doc. 95–24596 Filed 10–3–95; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF LABOR

Labor Advisory Committee for Trade Negotiations and Trade Policy; Meeting Notice

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463 as amended), notice is hereby given of a meeting of the Labor Advisory Committee for Trade Negotiations and Trade Policy.

Date, Time and Place: October 12, 1995, 10:00 am–12:00 noon, U.S. Department of Labor, Room S–1011, 200 Constitution Ave., NW., Washington, DC 20210.

Purpose: The meeting will include a review and discussion of current issues which influence U.S. trade policy. Potential U.S. negotiating objectives and bargaining positions in current and anticipated trade negotiations will be discussed. Pursuant to section 9(B) of the Government in the Sunshine Act, 5 U.S.C. 552b(c)(9)(B), it has been determined that the meeting will be concerned with matters the disclosure of which would seriously compromise the Government's negotiating objectives or bargaining positions. Accordingly, the meeting will be closed to the public.

For further information contact: Fernand Lavallee, Director, Trade Advisory Group, Phone: (202) 219–4752.

Signed at Washington, D.C. this 25th day of September, 1995.

Joaquin Otero,

Deputy Under Secretary, International Affairs.

[FR Doc. 95–24668 Filed 10–3–95; 8:45 am]

BILLING CODE 4510–28–M

Bureau of Labor Statistics

Business Research Advisory Council; Notice of Meetings and Agenda

The regular Fall meetings of the Business Research Advisory Council and its Committees will be held on October 25 and 26, 1995. All of the meetings will be held in the Conference Center of the Postal Square Building, 2 Massachusetts Avenue, NE., Washington, DC.

The Business Research Advisory Council and its committees advise the Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs. Membership consists of technical officers from American business and industry.

The schedule and agenda for the meetings are as follows:

Wednesday, October 25, 1995

8:30–10:00 a.m.—Committee on Price Indexes

1. Consumer Price Index
   a. Current measurement issues
   b. CPI Revision
2. Producer Price Indexes
3. Other committee business

10:30–12:00 p.m.—Committee on Compensation and Working Conditions

1. Update on COMP2000
2. Highlights from the Temporary Help Services Workers News Release
3. Highlights from the Employee Benefits Surveys of Small Establishments and State and Local Governments
4. Other business

1:30–3:00 p.m.—Committee on Occupational Safety and Health Statistics

1. 1994 Census of Fatal Occupational Injuries report
2. How to access BLS safety and health data
3. Report on the Fiscal Year 1996 budget for the program
4. Election of Vice-chairperson
5. Status of the Survey of Employer-Provided Training

3:30–5:00 p.m.—Committee on Employment Projections

1. Status of on-going work
2. Publication plans for the 1994–2005 projections
3. Plans for research and analysis in Fiscal Year 1996
4. Proposal for scenario building

Thursday, October 26, 1995

8:30–10:00 a.m.—Committee on Productivity and Foreign Labor Statistics

1. Report on recent developments in the Office of Productivity and Technology
2. Measurement of productivity growth in U.S. manufacturing
3. Comparison of multifactor productivity growth in manufacturing in the U.S., Germany, and France
4. International comparisons of unemployment indicators: trends and levels

10:30–12:30 p.m.—Council Meeting

1. Chairperson's opening remarks
2. Commissioner Abraham's address and discussion
3. BLS data on the Internet
4. Chairperson's closing remarks

2:00–3:30 p.m.—Committee on Employment and Unemployment Statistics

Discussion

1. Current Employment Survey redesign issues
2. BLS and the new workforce legislation

Updates

1. New directions in the Mass Layoff Statistics program
2. The National Wage Record Database

The meetings are open to the public. Persons with disabilities wishing to attend should contact Constance B. DiCesare, Liaison, Business Research Advisory Council, at (202) 606–5903, for appropriate accommodations.

Signed at Washington, D.C. the 26th day of September 1995.

Katharine G. Abraham,

Commissioner.

[FR Doc. 95–24669 Filed 10–3–95; 8:45 am]

BILLING CODE 4510–24–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 95–091]

NASA Advisory Council (NAC), Aeronautics Advisory Committee, Subcommittee on Materials and Structures; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, as amended, the National Aeronautics and Space Administration announces an NAC, Aeronautics Advisory Committee, Subcommittee on Materials and Structures meeting.

DATES: November 2, 1995, 8:30 a.m. to 4:30 p.m.

ADDRESSES: National Aeronautics and Space Administration, Lewis Research Center, Room 215, Building 3, Cleveland, OH 44135.

FOR FURTHER INFORMATION CONTACT: Dr. Hugh R. Gray, National Aeronautics and Space Administration, Lewis Research Center, Cleveland, OH 44135 (216/433–3230).

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

—Objectives of NASA's Materials and Structures Program
—Restructuring of Aero Base/Disciplines
—NASA's Implementation Plans of Zero Base Review
—Major Changes in Focused Technology Programs

It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

Dated: September 27, 1995.

Timothy M. Sullivan,

Advisory Committee Management Officer.

[FR Doc. 95–24624 Filed 10–3–95; 8:45 am]

BILLING CODE 7510–01–M

NATIONAL SCIENCE FOUNDATION

Directorate for Social, Behavioral, and Economic Sciences; Proposed Data Collection Available for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Science Foundation (NSF) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, call the NSF Clearance Officer on (703) 306–1243.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Estimation of the expenditures on research and development performed within the United States by industrial firms—A mail survey, the Survey of Industrial Research and Development, has been conducted annually since 1953. The survey is the industrial component of the NSF statistical program that seeks to ''provide a central clearinghouse for the collection, interpretation, and analysis of data on the availability of, and the current and projected need for, scientific and technical resources in the United States, and to provide a source of information for policy formulation by other agencies of the Federal government'' as mandated in the National Science Foundation Act of 1950. The proposed project will continue the survey for three years. The survey will be mailed to a statistical sample of approximately 23,300 companies to collect information on the amount and sources of funds for and character of R&D performed and contracted out by industrial firms, and information on sales and employment of the firms themselves. Industry accounts for over 70 percent of total U.S. R&D each year and since its inception, the survey has provided continuity of statistics on R&D expenditures by major industry groups and by source of funds. Statistics from the survey are published in NSF's annual publication series Research and Development in Industry.

The survey will be mailed to R&D executives of large companies and to planning or accounting executives in smaller companies. To minimize burden, over 90-percent of the companies selected for the Survey of Industrial R&D are asked to respond to the Form RD–1A, the abbreviated version of the basic survey questionnaires, Form RD–1L (used in odd-numbered years) and Form RD–1S (used in even-numbered years). Further, only companies with five paid employees or more are asked to participate in the survey and extensive use is made of the descriptive codes and information on the establishment list that is the source of the survey sample to avoid sampling firms in industries that traditionally do not perform R&D. Burden estimates are as follows:

1995 23,300 respondents, 61,300 total burden hours
1996 23,300 respondents, 32,300 total burden hours
1997 23,300 respondents, 61,300 total burden hours

Send comments to Herman Fleming, Clearance Officer, National Science Foundation, National Science Foundation, 4201 Wilson Boulevard, Suite 485, Arlington, VA 22230. Written comments should be received by December 1, 1995.

Dated: September 29, 1995.

Herman G. Fleming,

NSF Clearance Officer.

[FR Doc. 95–24679 Filed 10–3–95; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL TRANSPORTATION SAFETY BOARD

Continuation of Public Hearing in Springfield, VA: Aviation Accident

In connection with its investigation of USAir Inc., Flight 427, Boeing 737–300, Aliquippa, Pennsylvania, September 8, 1994, accident, the National Transportation Safety Board will convene a public hearing at 9:00 a.m., (est) on November 15, 1995, in the Caribbean Ballroom at the Springfield Hilton Hotel, located at 6550 Loisdale Road, Springfield, Virginia 22150. For more information, contact Mike Benson, Office of Public Affairs, Washington, D.C. 20594, telephone (202) 382–0660.

Dated: September 29, 1995.

Bea Hardesty,

Federal Register Liaison Officer.

[FR Doc. 95–24651 Filed 10–3–95; 8:45 am]

BILLING CODE 7533–01–P

SMALL BUSINESS ADMINISTRATION

Hartford District Advisory Council Meeting; Public Meeting

The U.S. Small Business Administration Hartford District Advisory Council will hold a public meeting on Monday, December 11, 1995 at 8:30 a.m. at 2 Science Park Haven, New Haven, Connecticut 06511, to

discuss matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Ms. Jo-Ann Van Vechten, District Director, U.S. Small Business Administration, 330 Main Street, Hartford, Connecticut, (203) 240–4670.

Dated: September 28, 1995.

Art DeCoursey,

Director, Office of Advisory Council.

[FR Doc. 95–24627 Filed 10–3–95; 8:45 am]

BILLING CODE 8025–01–P

Atlanta District Advisory Council Meeting; Public Meeting

The U.S. Small Business Administration Atlanta District Advisory Council will hold a public meeting on Thursday, November 9, 1995 from 8:30 a.m. to 5:00 p.m. and Friday, November 10, 1995 from 8:30 a.m. to 12:00 noon at the Best Western Motel, Tifton, GA, to discuss matters as may be presented by members, staff of the U.S. Small Business Administration, or others present.

For further information, write or call Ms. Laura A. Brown, Acting District Director, U.S. Small Business Administration, 1720 Peachtree Road, NE, Suite 600, Atlanta, GA 30309 (404) 347–4147, Ext. 46.

Dated: September 28, 1995.

Art DeCoursey,

Director, Office of Advisory Council.

[FR Doc. 95–24628 Filed 10–3–95; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice No. 2258]

Shipping Coordinating Committee Assembly and Associated Bodies; Notice of Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 10:30 a.m. on Friday, October 27, 1995, in Room 3317, at U.S. Coast Guard Headquarters, 2100 Second Street, SW, Washington, DC 20593–0001. The purpose of the meeting is to finalize preparations for the 19th Session of the Assembly and the 19th Extraordinary and the 75th session of the Council of the International Maritime Organization (IMO), which are scheduled during the period November 10 through November 24, 1995 at IMO Headquarters in London. At the meeting, discussions will focus on the papers received and the draft U.S. positions. Among other things, the items of particular interest are:

a. Reports of the IMO committees
b. Reports on diplomatic conferences
c. Work program and budget for 1996–1997
d. Proposed amendments to various conventions
e. Review of the IMO technical cooperation activities

Members of the public may attend the meeting up to the capacity of the room. Interested persons may seek information by writing: Mr. Gene F. Hammel, U.S. Coast Guard Headquarters (G–CI), 2100 Second Street, SW, Room 2114, Washington, DC 20593–0001, by calling: (202) 267–2280, or by faxing: (202) 267–4588.

Dated: September 26, 1995.

Charles A. Mast,

Chairman, Shipping Coordinating Committee.

[FR Doc. 95–24616 Filed 10–3–95; 8:45 am]

BILLING CODE 4710–07–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Aircraft Certification Procedures Issues

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration's Aviation Rulemaking Advisory Committee to discuss aircraft certification procedures issues.

DATES: The meeting will be held on October 26, 1995, at 9:00 a.m. Arrange for oral presentations by October 20, 1995.

ADDRESSES: The meeting will be held at the Aerospace Industries Association of America, Inc., Suite 1100, 1250 Eye Street, NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Jeanne Trapani, Office of Rulemaking (ARM–208), 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–7624.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. II), notice is hereby given of a meeting of the Aviation Rulemaking Advisory Committee to be held on October 26, 1995, at the Aerospace Industries Association of America, Inc., Suite 1100, 1250 Eye Street, NW., Washington, DC 20005. The agenda for the meeting will include:

- Opening Remarks
- Working Group Reports
  Delegation System
  ELT
  Parts
  Production Certification
  ICPTF
- New Business

Attendance is open to the interested public, but will be limited to the space available. The public must make arrangements by October 20, 1995, to present oral statements at the meeting. The public may present written statements to the committee at any time by providing 25 copies to the Assistant Executive Director for Aircraft Certification Procedures or by bringing the copies to him at the meeting. Arrangements may be made by contacting the person listed under the heading **FOR FURTHER INFORMATION CONTACT.**

Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting.

Issued in Washington, DC, on September 28, 1995.

Ava L. Robinson,

Assistant Executive Director, Aviation Rulemaking Advisory Committee for Aircraft Certification Procedures Issues.

[FR Doc. 95–24683 Filed 10–3–95; 8:45 am]

BILLING CODE 4910–13–M

RTCA, Inc.; Technical Management Committee; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (P.L. 92–463, 5 U.S.C. Appendix 2), notice is hereby given for the RTCA Technical Management Committee meeting to be held October 20, 1995, starting at 9:00 a.m. The meeting will be held at RTCA, Inc., 1140 Connecticut Avenue, NW., Suite 1020, Washington, DC, 20036.

The agenda will include: (1) Chairman's Remarks: (2) Review and Approval of Summary of August 21 Meeting; (3) Consider and Approve: a. Proposed Final Draft, Minimum Operational Performance Standards for Airborne Radio Communications Equipment Operating Within the Radio Frequency Range 117.975–137.000 MHz (RTCA Paper No. 463–95/TMC–187); b. Proposed Final Draft, Minimum Operational Performance Standards for Global Navigation Satellite System (GNSS) Airborne Antenna Equipment (RTCA Paper No. 468–95/TMC–191); c. Proposed Final Draft, Minimum Operational Performance Standards for Global Positioning System/Wide Area Argumentation System Airborne

Equipment (RTCA Paper No. 469–95/TMC–192); (4) Take Action on Open Items from Previous Meeting: a. Report on Integration of RTCA Response to 1994 Symposium Recommendations; b. White Paper on RNP Issues and Recommendations; c. Report from FAA Concerning Cockpit Moving Map Displays; (5) Other Business; (6) Date and Place of Next Meeting.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the RTCA Secretariat, 1140 Connecticut Avenue, NW., Suite 1020, Washington, D.C. 20036; (202) 833–9339 (phone) or (202) 833–9434 (fax). Members of the public may present a written statement to the committee at any time.

Issued in Washington, D.C., on September 28, 1995.

Janice L. Peters,

Designated Official.

[FR Doc. 95–24684 Filed 10–3–95; 8:45 am]

BILLING CODE 4810–13–M

Notice of Intent To Rule on Application To Impose a Passenger Facility Charge (PFC) at Greater Buffalo International Airport, Buffalo, New York and Use the Revenue From Such PFC at Greater Buffalo International Airport (BUF), Buffalo, New York and Niagara Falls International Airport (IAG), Niagara Falls, New York

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Intent to Rule on Application.

SUMMARY: The FAA proposes to rule and invites public comment on the application to impose a PFC at BUF and use the revenue from such PFC at BUF and IAG under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR Part 158).

DATES: Comments must be received on or before November 3, 1995.

ADDRESSES: Comments on this application may be mailed or delivered in triplicate to the FAA at the following address: Mr. Philip Brito, Manager New York Airports District Office, 600 Old Country Road, suite 446, Garden City, New York 11530.

In addition, one copy of any comments submitted to the FAA must be mailed or delivered to Richard T. Swist, Executive Director of the Niagara Frontier Transportation Authority (NFTA) at the following address: 181 Elliot Street, Buffalo, New York 14203.

Air carriers and foreign air carriers may submit copies of written comments previously provided to the Niagara Frontier Transportation Authority under § 158.23 of Part 158.

FOR FURTHER INFORMATION CONTACT: Mr. Philip Brito, Manager New York Airports District Office, 600 Old Country Road, suite 446, Garden City, New York 11530. The application may be reviewed in person at this same location.

SUPPLEMENTARY INFORMATION: The FAA proposes to rule and invites public comment on the application to impose a PFC at BUF and use the revenue from such PFC at BUF and IAG under the provisions of the Aviation Safety and Capacity Expansion Act of 1990 (Title IX of the Omnibus Budget Reconciliation Act of 1990) (Public Law 101–508) and Part 158 of the Federal Aviation Regulations (14 CFR part 158).

On August 28, 1995, the FAA determined that the application to impose and use the revenue form a PFC submitted by Niagara Frontier Transportation Authority was substantially complete within the requirements of section 158.25 of Part 158. The FAA will approve or disapprove the application, in whole or in part, no later than November 25, 1995.

The following is a brief overview of the application.

Level of the proposed PFC: $3.00

Proposed charge effective date: August 1, 1992

Proposed charge expiration date: April 30, 2006

Total estimated PFC revenue: $62,669,139

Brief description of proposed projects:

BUF Projects

Acquisition and Demolition of Airways Hotel (use only)

Demolition of the American Airlines Hanger and Cargo Building (use only)

Construction of a New Passenger Terminal Facility (use only)

Schematic Design of Overall Airport Development (use only)

Value Engineering for Overall Airport Development (use only)

Environmental Assessment for Overall Development (use only)

Rehabilitate North Concourse Ramps and Apron (use only)

Purchase Two Snow Blowers and One Roadway Salter (use only)

Replace 6 Foot Security Fence (use only)

Construct New Passenger Facility D1 (Impose and Use)

Purchase One Dump Truck (Impose and Use)

Install Radio System Expansion (Impose and Use)

Purchase Rubber-Blade Snowplow (Impose and Use)

Purchase One Front Loader (Impose Only)

Pavement Strengthening for Taxiway C and Perimeter Road (Impose Only)

Pavement Reconstruction for Aprons and Taxiways (Impose Only)

Pavement Overlays for Taxiways D and F (Impose Only)

Pavement Study (Impose Only)

Rehabilitation and Overlay of Runway 14/32 (Impose Only)

Replacement of Airfield Vehicles (Impose Only)

IAG Projects

Replace Runway 28R/10L HIRL (Use only)

Purchase Bucket Loader with Blade (Use only)

Purchase Snow Removal Truck and Blade (Use only)

Airport Runway Broom (Use only)

Snow and Ice Control Equipment Building (Use only)

Class or classes of air carriers which the public agency has requested not be required to collect PFC's: Air Taxi, Except commuter air carriers.

Any person may inspect the application in person at the FAA office listed above under **FOR FURTHER INFORMATION CONTACT** and at the FAA regional Airports office located at: Fitzgerald Federal Building, John F. Kennedy International Airport, Jamaica, New York, 11430.

In addition, any person may, upon request, inspect the application, notice and other documents germane to the application in person at the Niagara Frontier Transportation Authority.

Issued in Jamaica, New York State on September 27, 1995.

Anthony P. Spera,

Manager, Airports Division, Eastern Region.

[FR Doc. 95–24682 Filed 10–3–95; 8:45 am]

BILLING CODE 4910–13–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301–94 and 301–100]

Termination of Investigation; Initiation of New Investigation and Request for Public Comment: European Union Banana Regime

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of termination and initiation, request for comment.

SUMMARY: The United States Trade Representative (USTR) has terminated an investigation under section 302(a) of the Trade Act of 1974, (Trade Act) concerning the European Union's (EU) practices with respect to the importation of bananas. Pursuant to section 302(b)(1) of the Trade Act, the USTR has initiated a second investigation concerning the EU's acts, policies and practices relating to the importation, sale and distribution of bananas and, pursuant to section 303(a) of the Trade Act, has requested consultations with the EU pursuant to the World Trade Organization's (WTO) Understanding on Rules and Procedures Concerning the Settlement of Disputes (DSU). USTR invites public comment concerning the matter under investigation.

DATES: Investigation 301–94 was terminated on September 27, 1995, and investigation 301–100 was initiated on September 27, 1995. Written comments from the public are due on or before November 1, 1995.

ADDRESSES: Office of the United States Trade Representative, 600 17th Street, NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Edward Kaska, Director for European Services and Agriculture, (202) 395–4620; or Rachel Shub, Assistant General Counsel, (202) 395–7305.

SUPPLEMENTARY INFORMATION: On September 2, 1994, Chiquita Brands International, Inc. and the Hawaii Banana Industry Association filed a petition pursuant to section 302(a) of the Trade Act (19 U.S.C. 2412(a)) alleging that various policies and practices of the EU, Colombia, Costa Rica, Nicaragua and Venezuela concerning trade in bananas are discriminatory, unreasonable and burden or restrict United States commerce. On October 17, 1994, pursuant to section 302(a) of the Trade Act, the USTR initiated an investigation of the following practices of the EU: (1) Council Regulation (EEC) No. 404/93 and related rules implementing a EU banana policy discriminating against U.S. banana marketing companies importing bananas from Latin America, including a restrictive and discriminatory licensing scheme designed to transfer market share to firms traditionally trade bananas from Africa, Caribbean and Pacific (ACP) sources and from EU overseas territories and dependencies; and (2) the March 29, 1994, Framework Agreement on Bananas between the EU and Colombia, Costa Rica, Nicaragua and Venezuela.

Upon initiation and again in January of 1995, the USTR requested public comment on the issues raised in the petition, the actionability under section 301 of the EU practices under investigation and what action would be appropriate under subsections (a) or (b) of section 301 of the Trade Act (19 U.S.C. 2411 (a) or (b)) if the practices were determined to be actionable. (See 59 FR 53495 of October 24, 1994, and 60 FR 3285 of January 13, 1995.) Numerous comments were received in response to both requests (Docket No. 301–94).

Since initiation of investigation 301–94, the USTR has conducted numerous consultations and bilateral discussions with the EU concerning the issues in the petition. These efforts have failed to bring about reform of the EU practices.

On the basis of the consultations with the EU, the comments received and consultations with the petitioner and with the relevant private sector advisory committees established pursuant to section 135 of the Trade Act, the USTR decided that issues raised in the investigation involve agreements annexed to the Agreement Establishing the WTO, including the General Agreement on Tariffs and Trade, the Agreement on Import Licensing Procedures and the General Agreement on Trade in Services, and should most appropriately be addressed by resort to the procedures of the DSU. In light of the foregoing and the consent of the petitioners, the USTR on September 27 terminated the section 301 investigation of the EU banana regime initiated on October 17, 1994 (Docket No. 301–94) and, based on information obtained in the prior investigation, decided to initiate a second investigation of the EU's regime for the importation, sale and distribution of bananas (Docket No. 301–100).

Investigation and Consultations

On September 27, 1995, pursuant to section 302(b)(1) of the Trade Act (19 U.S.C. 2412(b)(1)), the USTR initiated an investigation of the acts, policies and practices of the EU concerning the importation, sale and distribution of bananas. The investigation will be conducted in accordance with the regulations set forth in 15 CFR part 2006. Pursuant to section 304 of the Trade Act (19 U.S.C. 2414), the USTR will be required to make a determination on actionability under section 301 in this investigation by no later than 30 days after the conclusion of WTO dispute settlement procedures or March 27, 1997, whichever is earlier.

On September 27, 1995, the USTR also requested consultations with the EU, as required by section 303(a) of the Trade Act. These consultations were requested in accordance with DSU procedures. In preparing for such consultations, USTR will seek information and advice from the appropriate committees established pursuant to section 135 of the Trade Act, as provided in section 303(a)(3) of that Act.

Public Comment

Interested persons are invited to submit written comments concerning the acts, policies and practices of the EU which are the subject of this investigation, the amount of burden or restriction on U.S. commerce caused by these acts, policies and practices and the determinations required under section 304 of the Trade Act. Comments must be filed in accordance with the requirements set forth in 15 CFR 2006.8(b) (55 FR 20593) and must be filed no later than 12 noon, Wednesday, November 1, 1995. Comments must be in English and provided in twenty copies to: Sybia Harrison, Staff Assistant to the Section 301 Committee, Room 223, Office of the U.S. Trade Representative, 600 17th Street, NW, Washington, DC 20508.

Comments will be placed in a file (Docket 301–100) open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15. Confidential business information submitted in accordance with 15 CFR 2006.15 must be clearly marked ''BUSINESS CONFIDENTIAL'' in a contrasting color ink at the top of each page on each of 20 copies, and must be accompanied by a nonconfidential summary of the confidential information. The nonconfidential summary shall be placed in the file that is open to public inspection. An appointment to review the docket (Docket No. 301–100) may be made by calling Brenda Webb (202) 395–6186. The USTR Reading Room is open to the public from 10 a.m. to 12 noon and 1 p.m. to 4 p.m., Monday through Friday, and is located in Room 101.

Irving A. Williamson,

Chairman, Section 301 Committee.

[FR Doc. 95–24677 Filed 10–3–95; 8:45 am]

BILLING CODE 3190–01–M

Report on Identification of Trade Expansion Priorities Pursuant to Section 310 of the Trade Act of 1974

AGENCY: Office of United States Trade Representative.

ACTION: Notice.

SUMMARY: Notice is hereby given that the United States Trade Representative (USTR) transmitted on September 28, 1995, the report published herein to the Committee on Finance of the United States Senate and the Committee on Ways and Means of the United States House of Representatives identifying trade expansion priorities pursuant to the provisions in section 310 of the Trade Act of 1974 (''Super 301'') (19 U.S.C. 2420). Section 310 was last amended by section 314(f) of the Uruguay Round Agreements Act.

FOR FURTHER INFORMATION CONTACT: Irving Williamson, Chairman, Section 301 Committee, Office of the U.S. Trade Representative, 600 17th Street, NW., Washington, DC 20506, (202) 395–3432.

SUPPLEMENTARY INFORMATION: The text of the USTR report is as follows:

Identification of Trade Expansion Priorities Pursuant to Section 310 of the Trade Act of 1974

This report is submitted pursuant to the provisions in section 310 of the Trade Act of 1974. Section 310 requires the United States Trade Representative (USTR) to ''review United States trade expansion priorities and identify priority foreign country practices, the elimination of which is likely to have the most significant potential to increase United States exports, either directly or through the establishment of a beneficial precedent.''

In identifying priority foreign country practices, the USTR must take into account all relevant factors, including:

(a) The major barriers and trade distorting practices described in the National Trade Estimate Report;

The trade agreements to which a country is a party and its compliance with those agreements;

The medium- and long-term implications of foreign government procurement plans; and

The international competitive position and export potential of U.S. products and services.

Section 310 permits the USTR to include, if appropriate, ''a description of foreign country practices that may in the future warrant identification as priority foreign country practices that may in the future warrant identification as priority foreign country practices.'' The USTR may also include ''a statement about other foreign country practices that were not identified because they are already being addressed by provisions of United States trade law, by existing bilateral trade agreements, or as part of trade negotiations with other countries and progress is being made toward the elimination of such practices.''

Trade Expansion Priorities

We remain committed to ensuring that our trade policies support our effort to promote U.S. economic growth, competitiveness, and high-wage jobs. The principal components of U.S. trade policy remain enforcement of U.S. trade laws and U.S. rights under trade agreements and securing increasing and reciprocal access to the markets of our trading partners.

We are dedicated to achieving our trade policy goals by using all mechanisms at our disposal: multilateral fora such as the World Trade Organization (WTO); regional or bilateral agreements; and our trade laws.

In the multilateral context, the United States will continue to push for full and rapid implementation of the results of the Uruguay Round. The Round produced the most comprehensive trade agreement in history and provided for significant reductions in tariff and non-tariff barriers, the establishment of the WTO and a new and effective dispute resolution mechanism. We will continue to make maximum use of the WTO to require our trading partners to accept their share of responsibility for global growth and maintenance of the global trading system and to open their markets to competitive U.S. exports.

In the regional and bilateral context, we are continuing our pursuit of U.S. trade interests under the historic North American Free Trade Agreement (NAFTA) and the NAFTA dispute settlement procedures, and are committed to negotiating Chile's accession to the NAFTA. In the Americas, we are committed to achieving a Free Trade Area of the Americas (FTAA) by 2005. In the Pacific, we are pursuing market opening objectives under the Asia Pacific Economic Cooperation (APEC) forum. With Europe, we are exploring market opening through the Trans Atlantic Agreement (TAA) initiative.

Finally, we will continue to make maximum use of our trade laws to advance U.S. interests. Section 301 remains a key tool for enforcing U.S. rights under existing trade agreements and, where necessary, for addressing foreign unfair trade barriers not covered by trade agreements. In this regard, we have used the review of our trade expansion priorities required by Super 301 to ensure that we are pursuing effectively the elimination of trade barriers that inhibit the growth of U.S. exports and the growth in employment resulting from increased exports.

Priority Foreign Country Practices

As a result of the review of the United States trade expansion priorities under section 310 and recent negotiations, the USTR has decided not to identify any priority foreign country practices at this time.

Other Practices

A. The following practices may in the future warrant identification as priority foreign country practices:

- Japan Market Access for Paper & Paper Products: In the April 1992 U.S.-Japan paper agreement, Japan, agreed to take GATT-consistent measures to increase substantially market access in Japan for foreign paper and paperboard products. Nevertheless, structural barriers such as exclusionary business practices and a closed distribution system continue to impede U.S. paper companies' access to the Japanese paper and paper products market. In addition, the U.S. remains concerned about lax Japanese implementation of the measures contained in the paper agreement and inadequate enforcement of Japan's Anti-Monopoly Act. The United States and Japan have consulted on ways to strengthen and enhance implementation of the agreement. Further consultations are planned later this year with a view to reaching agreement on ways to strengthen and enhance implementation.
- Japan Market Access for Wood Products: In the 1990 U.S.-Japan Wood Products Agreement, Japan agreed to reduce tariffs substantially, to reduce subsidies, to speed up product certification, and to adopt performance-based standards and building codes. Although Japan has made progress in implementing the agreement, barriers continue to impede market access. Tariffs, although reduced in the Uruguay Round, remains a significant impediment. Adoption of performance-based standards and building codes continues to be slow, and Japan still maintains a parallel unliberalized set of building standards for housing loans. Subsidies to the wood products industry still appear to be rising. The United States has consulted with Japan on these issues, and further consultations are planned later this year with a view to reaching agreement on ways to strengthen and enhance implementation.

• China Market Access for Agricultural Products: China continues to apply to U.S. exports of citrus fruit and Pacific Northwest wheat phytosanitary standards that are not based on scientific principles and which act as a virtual ban on these exports. Under the 1992 U.S.-China Market Access Memorandum of Understanding, China committed to remove by October 1993 any unscientific phytosanitary standards on a number of agricultural items, including citrus and wheat. China is a major potential market for U.S. citrus and what producers. Despite further commitments on the part of China and repeated efforts by the U.S. to negotiate a resolution of these issues, China has yet to remove these unscientific restrictions. The United States and China are continuing bilateral discussions.

B. The following practices were determined not to be appropriate for identification because they are already being addressed by other provisions of U.S. trade law, existing bilateral or multilateral agreements, or in trade negotiations with other countries, and progress is being made in addressing them. These practices do, however, remain significant trade negotiating objectives of the United States.

• Korea Market Access for Autos: The United States has had serious concerns regarding access to the Korean market for automobiles. Korea has maintained a number of barriers to market access for foreign autos, including taxes that particularly burden imports, measures which have created anti-import sentiments, and standards barriers. As a result of recent negotiations, the United States has reached agreement with Korea on measures to improve access to the Korean auto market and will be consulting with Korea on further steps to open that market to foreign competition. The United States will monitor closely progress in implementing the agreement and the results of ongoing consultations with a report due to the USTR on June 1, 1996.

• Korea Market Access for Medical Devices: Korean Government regulations impede market access for U.S. medical devices. The regulations require unwarranted local testing for certain products. For example, for eleven categories of medical devices that Korea classifies as ''sensitive,'' testing is required for each piece, even if the product has been previously imported. Korea also requires disclosure of proprietary and other product information without adequate protection from disclosure to local competitors. Competition from imports is further limited by a requirement that a local medical equipment trade association monitor each import shipment for product, volume and price information. The United States is continuing to negotiate with Korea to resolve outstanding issues.

• Korea Market Access for Agricultural Products: The United States has reached agreement with Korea to address the adverse impact of government-mandated shelf-life standards on imports of meat and other agricultural products, but market access barriers to other agricultural products, including citrus and almonds, continue to exist. Korea has designated a cooperative, which produces and markets Korea's only citrus product, to manage the tariff rate quota on U.S. oranges. Consumer acceptance of U.S. fruit is discouraged because the cooperative allows entry of only low-quality fruit. Also, market access is inhibited by Korean delays in clearing incoming agricultural products. Cumbersome commercial import procedures, such as government-required approval on letters of credit, have a further adverse effect on market access for almonds and other agricultural products.

• EU Utilities—Telecommunications Procurement: The European Union (EU) member states continue to apply discriminatory requirements under the EU Utilities Directive to procurements of telecommunications equipment. The Directive requires telecommunications utilities to penalize bids of equipment with less than 50 percent EU content by a 3 percent margin and allows them to reject such bids altogether at their discretion. In 1993, the United States implemented sanctions against the EU under Title VII of the 1988 Trade Act. These sanctions remain in force and were recently extended to the three new member states—Austria, Finland and Sweden. The United States continues to work toward a liberalized telecommunications market in the EU through fora such as the WTO Negotiating Group on Basic Telecommunications Services.

• German Market Access for Power Generation Equipment: Power generation utilities in EU member states are covered by the 1993 U.S.-EU Memorandum of Understanding (MOU) on Government Procurement, which expires at the end of 1995, and the U.S.-EU Marrakesh Agreement on Government Procurement, which will be implemented through the new WTO Government Procurement Code beginning January 1, 1996. Germany has failed to fully adhere to its obligations under two EU directives that implement EU obligations under the 1993 MOU (the Utilities Directive and the Remedies for Utilities Directive) with respect to a steam turbine procurement associated with the Lippendorf project undertaken by the German utility, VEAG. A German review body, the BVS, concluded on September 14 that the contract for the steam turbine procurement had been awarded illegally but declined to overturn the contract. Therefore, the United States will continue to monitor developments in the case and Germany efforts to provide transparent award procedures and rapid and effective remedy procedures for other pending and future procurements. The United States also will work with the EU Commission to ensure that the WTO Government Procurement Agreement is fully implemented when it enters into force on January 1, 1996.

• EU Ecolabeling Directive: The EU Ecolabeling Directive sets forth a scheme whereby EU member states will develop voluntary criteria for granting environmental labels with respect to products in specific sectors. Without objecting to the concept of Ecolabeling, the United States has expressed concern about potential adverse impacts on U.S. exports. In particular, the United States is concerned that the process for developing criteria in certain industry sectors has been insufficiently transparent and has failed to provide for adequate participation by U.S. and other non-EU interests. The United States has also urged that the criteria not reflect a single approach to environmental protection without adequate attention having been given to other potentially comparable approaches and that the EU Ecolabeling program provide sufficient and accurate information to consumers regarding the relative environmental impacts of competing products. The United States is currently negotiating with the EU to ensure that the foregoing concerns are adequately addressed.

• WTO and NAFTA Dispute Settlement Proceedings: The United States continues to make vigorous use of the dispute settlement provisions of the World Trade Organization (WTO) and the North American Free Trade Agreement (NAFTA) to address significant foreign trade barriers.

The United States is addressing the following barriers in the WTO:

EU/Bananas—The EU has implemented as part of its single market exercise a banana import regime that discriminates against U.S. banana marketing firms in favor of EU firms. Moreover, in April 1994, the EU reached agreement with four Latin American banana exporting countries on a Framework Agreement on Bananas that

contains provisions that further discriminate against U.S. firms.

EU/Grains—The EU has implemented its Uruguay Round market access commitments on grains using a reference price rather than transaction value. This system does not allow for quality differences and is protective in effect.

EU/Scallops—Until recently, scallops of all species have been sold in France under the traditional name ''coquilles St. Jacques.'' French legislation now requires that scallops of certain species occurring outside French waters be sold under the unappealing name ''pétoncles.''

Japan/Alcohol—Japan imposes specific excise taxes on distilled spirits at significantly lower rates on the domestic spirit shochu than on whiskey or other Western-type spirits.

Korea/Residue Testing Requirements—Korean residue testing requirements have delayed imports of perishable agricultural products.

The U.S. is addressing the following barriers under NAFTA:

Canada/Dairy & Poultry—In the Uruguay Round, Canada tariffied its supply-management import quotas on dairy, poultry, eggs and barley. Canada has been applying these tariffs on imports from the U.S. in spite of the prohibition in NAFTA against imposition of new or increased tariffs.

Mexico/Small Package Delivery—Mexico has denied a U.S. firm the ability to operate large trucks in its small package delivery service even though Mexican firms engaged in the same business can do so and Mexico in the NAFTA agreed to accord U.S. firms national treatment in this service sector.

• WTO Accession Negotiations: The United States will continue to seek market openings for goods and services in negotiations with the 28 countries and customs territories currently seeking membership in the WTO. As part of their accession package, all countries must agree to subject their trade practices to the disciplines of the WTO. The agreement establishing the WTO also requires that all members provide market access commitments for industrial and agricultural goods, and services. The United States is committed to gaining appropriate market access commitments and adherence to WTO disciplines from every membership applicant.

Irving A. Williamson,

Chairman, Section 301 Committee.

[FR Doc. 95–24676 Filed 10–3–95; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

Voluntary Service National Advisory Committee; Availability of Annual Report

Under section 10(d) of Public Law 92–463 (Federal Advisory Committee Act) notice is hereby given that the Annual Report of the Department of Veterans Affairs Voluntary Service (VAVS) National Advisory Committee has been issued. The Report is a summary of the 48th Annual Meeting of the VAVS National Advisory Committee. It is available for public inspection at two locations:

Federal Document Section, Exchange and Gift Division, LM 632, Library of Congress, Washington, D.C. 20540

and

Department of Veterans Affairs, Voluntary Service Office, Techworld Plaza—Room 643, 801 I Street, N.W., Washington, D.C. 20001

Dated: September 26, 1995.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 95–24634 Filed 10–3–95; 8:45 am]

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federal register

Wednesday
October 4, 1995

Part II

Environmental Protection Agency

Proposed Guidelines for Neurotoxicity Risk Assessment; Notice

ENVIRONMENTAL PROTECTION AGENCY

[FRL–5306–2]

Proposed Guidelines for Neurotoxicity Risk Assessment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed guidelines for Neurotoxicity Risk Assessment and request for comments.

SUMMARY: The U.S. Environmental Protection Agency (EPA; Agency) is today issuing proposed guidelines for assessing the risks for neurotoxicity from exposure to environmental agents. As background information for this guidance, this notice describes the scientific basis for concern about exposure to agents that cause neurotoxicity and outlines the general process for assessing potential risk to humans because of environmental contaminants.

These proposed Guidelines for Neurotoxicity Risk Assessment (hereafter ''Guidelines'') are intended to guide Agency evaluation of agents that are suspected to cause neurotoxicity in line with the policies and procedures established in the statutes administered by the EPA. The Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Risk Assessment Forum, within EPA's Office of Research and Development. Draft Guidelines were developed by an Agency work group composed of scientists from throughout the Agency, and selected drafts were peer reviewed internally and by experts from universities, environmental groups, industry, and other governmental agencies. A subsequent draft has undergone peer review in a workshop held on June 2–3, 1992, and has received internal review by the Concordance and Oversight Subcommittees of the Risk Assessment Forum. Most recently, the Committee on the Environment and Natural Resources of the Office of Science and Technology Policy reviewed the guidelines at a meeting held on August 15, 1995. The proposed Guidelines are based, in part, on recommendations derived from these reviews and on those made at various scientific meetings and workshops on neurotoxicology.

The public is invited to comment, and public comments will be considered in EPA decisions in formulating the final Guidelines. Commenters are asked to focus on several special issues, particularly, (1) the issue of compensation and recovery of function in neurotoxicological studies and how to account for compensation in neurotoxicology risk assessment; (2) the use of blood and/or brain acetylcholinesterase activity as an indication of neurotoxicity for risk assessment; (3) endpoints indicative of neurotoxicity that may not be covered by these guidelines, i.e., endocrine disruption or neuroendocrine-mediated neurotoxicity; and (4) the possibility of no threshold for some neurotoxic agents.

The EPA Science Advisory Board (SAB) also will review these proposed Guidelines at a meeting to be announced in a future Federal Register. Agency staff will prepare summaries of the public and SAB comments, analyses of major issues presented by commenters, and Agency responses to those comments. Appropriate comments will be incorporated, and the revised Guidelines will be submitted to the Risk Assessment Forum for review. The Agency will consider comments from the public, the SAB, and the Risk Assessment Forum in its recommendations to the EPA Administrator.

DATES: The Proposed Guidelines are being made available for a 120-day public review and comment period. Comments must be in writing and must be postmarked by February 1, 1996. Please submit one unbound original with pages consecutively numbered, and three copies. If there are attachments, include an index numbered consecutively with comments, and three copies.

FOR FURTHER INFORMATION CONTACT: Dr. Hugh A. Tilson, Tel: 919–541–2671; Fax: 919–541–4849.

ADDRESSES: Comments on the proposed Guidelines may be mailed or delivered to: Dr. Hugh A. Tilson, Neurotoxicology Division (MD–74B), National Health and Environmental Effects Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, NC 27711. Please note that all comments received in response to this notice will be placed in a public record. Commenters should not send any item of personal information, such as medical information or home address, if they do not wish it to be part of the public record.

SUPPLEMENTARY INFORMATION: In its 1983 book, Risk Assessment in the Federal Government: Managing the Process, the National Academy of Sciences recommended that Federal regulatory agencies establish ''inference guidelines'' (1) to promote consistency and technical quality in risk assessment, and (2) to ensure that the risk assessment process is maintained as a scientific effort separate from risk management. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

In 1984, EPA scientists began work on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures, and exposure assessment. Following extensive scientific and public review, these first five guidelines were issued on September 24, 1986 (51 FR 33992–34054). Since 1986, additional risk assessment guidelines have been proposed for male and female reproductive risk (53 FR 24834–847; 53 FR 24850–869), and two of the 1986 guidelines, suspect developmental toxicants (56 FR 63798–826) and exposure assessment (57 FR 22888–938), have been revised, reproposed, and finalized.

The Guidelines proposed today continue the guidelines development process initiated in 1984. These Guidelines set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments and to inform Agency decision makers and the public about these procedures. In particular, the Guidelines emphasize that risk assessments will be conducted on a case-by-case basis, giving full consideration to all relevant scientific information. This case-by-case approach means that Agency experts study scientific information on each chemical under review and use the most scientifically appropriate interpretation to assess risk. The Guidelines also stress that this information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

The Guidelines are formulated in part to bridge gaps in risk assessment methodology and data. By identifying these gaps and the importance of the missing information to the risk assessment process, EPA wishes to encourage research and analysis that will lead to new risk assessment methods and data.

Dated: September 25, 1995.

Carol M. Browner,

Administrator.

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I. Introduction

These proposed Guidelines describe the principles, concepts, and procedures that the U.S. Environmental Protection Agency (EPA; Agency) would follow in evaluating data on potential neurotoxicity associated with exposure to environmental toxicants. The Agency's authority to regulate substances that have the potential to interfere with human health is derived from a number of statutes that are implemented through multiple offices within the EPA. The procedures outlined here are intended to help develop a sound scientific basis for neurotoxicity risk assessment, promote consistency in the Agency's assessment of toxic effects on the nervous system, and inform others of the approaches used by the Agency in those assessments.

A. Organization of These Guidelines

This Introduction (section I) summarizes the purpose of these proposed Guidelines within the overall framework of risk assessment at the EPA. It also outlines the organization of the guidance and describes several default assumptions to be used in the risk assessment process as discussed in the recent National Research Council report ''Science and Judgment in Risk Assessment (NRC, 1994).''

Section II sets forth definitions of particular terms widely used in the field of neurotoxicology. These include ''neurotoxicity'' and ''behavioral alterations.'' Also included in this section are discussions concerning reversible and irreversible effects and direct versus indirect effects.

Risk assessment is the process by which scientific judgments are made concerning the potential for toxicity to occur in humans. The National Research Council (NRC, 1983) has defined risk assessment as including some or all of the following components (paradigm): hazard identification, dose-response assessment, exposure assessment, and risk characterization. In its 1994 report ''Science and Judgment in Risk Assessment'' the NRC extended its view of the paradigm to include characterization of each component (NRC, 1994). In addition, it noted the importance of an approach that is less fragmented and more holistic, less linear and more interactive, and one that deals with recurring conceptual issues that cut across all stages of risk assessment. These Guidelines propose a more interactive approach by organizing the process around components that focus on evaluation of the toxicity data (hazard characterization), the quantitative dose-response analysis, the exposure assessment, and the risk characterization. This is done because, in practice, hazard identification for neurotoxicity and other noncancer health effects is usually done in conjunction with an evaluation of dose-response relationships in the studies used to identify the hazard. Determining a hazard often depends on whether a dose-response relationship is present (Kimmel et al., 1990). Thus, the hazard characterization provides an evaluation of a hazard within the context of the dose, route, duration, and timing of exposure. This approach combines the information important in comparing the toxicity of a chemical to potential human exposure scenarios (Section V). Secondly, it avoids the potential for labeling chemicals as ''neurotoxicants'' on a purely qualitative basis. This organization of the risk assessment process is similar to that discussed in the Guidelines for Developmental Toxicity Risk Assessment (56 FR 63798), the main difference being that the quantitative dose-response analysis is discussed under a separate section in these guidelines.

Hazard characterization involves examining all available experimental animal and human data and the associated doses, routes, timing, and durations of exposure to determine if an agent causes neurotoxicity in that species and under what conditions. From the hazard characterization and criteria provided in these Guidelines, the health-related data base can be characterized as sufficient or insufficient for use in risk assessment (section III.C). Combining hazard identification and some aspects of dose-response evaluation into hazard characterization does not preclude the evaluation and use of data when quantitative information for setting reference doses (RfDs) and reference concentrations (RfCs) are not available.

The next step, the dose-response analysis (section IV) is the quantitative analysis, and includes determining the no-observed-adverse-effect-level (NOAEL) and/or the lowest-observed-adverse-effect-level (LOAEL) for each study and type of effect. Because of the limitations associated with the use of the NOAEL, the Agency is beginning to use an additional approach, i.e., the

benchmark dose approach (Crump, 1984; U.S. EPA, 1995a), for more quantitative dose-response evaluation when sufficient data are available. The benchmark dose approach takes into account the variability in the data and the slope of the dose-response curve, and provides a more consistent basis for calculation of the RfD or RfC. If data are considered sufficient for risk assessment, and if neurotoxicity is the effect occurring at the lowest dose level (i.e., the critical effect), an oral or dermal RfD or an inhalation RfC, based on neurotoxic effects, is then derived. This RfD or RfC is derived using the NOAEL or benchmark dose divided by uncertainty factors to account for interspecies differences in response, intraspecies variability and other factors of study design or the data base. A statement of the potential for human risk and the consequences of exposure can come only from integrating the hazard characterization and dose-response analysis with the human exposure estimates in the final risk characterization.

The section on exposure assessment (section V) identifies human populations exposed or potentially exposed to an agent, describes their composition and size, and presents the types, magnitudes, frequencies, and durations of exposure to the agent. The exposure assessment provides an estimate of human exposure levels for particular populations from all potential sources.

In risk characterization (section VI), the hazard characterization, dose-response analysis, and the exposure assessment for given populations are combined to estimate some measure of the risk for neurotoxicity. As part of risk characterization, a summary of the strengths and weaknesses of each component of the risk assessment is given along with major assumptions, scientific judgments, and, to the extent possible, qualitative and quantitative estimates of the uncertainties. This characterization of the health-related data base is always presented in conjunction with information on the dose, route, duration and timing of exposure as well as the dose-response analysis including the RfD or RfC. If human exposure estimates are available, the exposure basis used for the risk assessment is clearly described, e.g., highly exposed individuals or highly sensitive or susceptible individuals. The NOAEL may be compared to the various estimates of human exposure to calculate the margin(s) of exposure (MOE). The considerations for judging the acceptability of the MOE are similar to those for determining the appropriate size of the uncertainty factor for calculating the RfD or RfC.

The Agency recently issued a policy statement and associated guidance for risk characterization (U.S. EPA, 1995b, 1995c), which is currently being implemented throughout EPA. This policy statement is designed to ensure that critical information from each stage of a risk assessment is used in forming conclusions about risk and that this information is communicated from risk assessors to risk managers (policy makers), from middle to upper management, and from the Agency to the public. Additionally, the policy provides a basis for greater clarity, transparency, reasonableness, and consistency in risk assessments across Agency programs. Final neurotoxicity risk assessment guidelines may reflect additional changes in risk characterization practices resulting from implementation activities.

Risk assessment is just one component of the regulatory process and defines the potential adverse health consequences of exposure to a toxic agent. The other component, risk management, combines risk assessment with statutory directives regarding socioeconomic, technical, political, and other considerations, to decide whether to control future exposure to the suspected toxic agent and, if so, the nature and level of control. One major objective of these risk assessment Guidelines is to help the risk assessor determine whether the experimental animal or human data indicate the potential for a neurotoxic effect. Such information can then be used subsequently to categorize evidence to identify and characterize neurotoxic hazards as described in section III.3.C, Characterization of the Health-Related Data Base, and Table 8 of these Guidelines. Risk management is not dealt with directly in these Guidelines because the basis for decision making goes beyond scientific considerations alone, but the use of scientific information in this process is discussed. For example, the acceptability of the MOE is a risk management decision, but the scientific bases for establishing this value are discussed here.

B. The Role of Environmental Agents in Neurotoxicity

Chemicals are an integral part of life, with the capacity to improve as well as endanger health. The general population is exposed to chemicals with neurotoxic properties in air, water, foods, cosmetics, household products, and drugs used therapeutically or illicitly. Naturally occurring neurotoxins, such as animal and plant toxins, present additional hazards. During daily life, a person experiences a multitude of exposures, both voluntary and unintentional, to neuroactive substances, singly and in combination. Levels of exposure vary and may or may not pose a hazard depending on dose, route, and duration of exposure.

A link between human exposure to some chemical substances and neurotoxicity has been firmly established (Anger, 1986; OTA, 1990). Because many natural and synthetic chemicals are present in today's environment, there is growing scientific and regulatory interest in the potential for risks to humans from exposure to neurotoxic agents. If sufficient exposure occurs, the effects resulting from such exposures can have a significant adverse impact on human health. It is not known how many chemicals may be neurotoxic in humans (Reiter, 1987). The EPA's inventory of toxic chemicals is greater than 65,000 and increasing yearly. An overwhelming majority of the materials in commercial use have not been tested for their neurotoxic potential (NRC, 1984). Estimates of the number of chemicals with neurotoxic properties have been made for subsets of substances. For instance, a large percentage of the more than 500 registered active pesticide ingredients are neurotoxic to varying degrees. Of 588 chemicals listed by the American Conference of Governmental Industrial Hygienists, 167 affected the nervous system or behavior at some exposure level (Anger, 1984). Anger (1990) estimated that of the approximately 200 chemicals to which one million or more American workers are exposed, more than one-third may have adverse effects on the nervous system, if sufficient exposure occurs. Anger (1984) also recognized neurotoxic effects as one of the 10 leading workplace disorders. A number of therapeutic substances, including some anticancer and antiviral agents and abused drugs, can cause adverse or neurotoxicological side effects at therapeutic levels (OTA, 1990). Thus, estimating the risks of exposure to chemicals with neurotoxic potential is of concern with regard to the overall impact of these exposures on human health.

C. Neurotoxicity Risk Assessment

In addition to its primary role in cognitive functions, the nervous system controls most, if not all, other bodily processes. It is sensitive to perturbation from various sources and has limited ability to regenerate. There is evidence that even small anatomical, biochemical, or physiological insults to the nervous system may result in

adverse effects on human health. Therefore, there is a need for consistent guidance on how to evaluate data on neurotoxic substances and assess to what degree, if any, they have the potential to cause transient or persistent, direct or indirect effects on human health.

To help address these needs, these Guidelines develop principles and concepts in several areas. First, these Guidelines outline the scientific basis for evaluating effects due to exposure to neurotoxicants and discuss principles and methods for evaluating data from human and animal studies on behavior, neurochemistry, neurophysiology, and neuropathology. This guidance document also discusses adverse effects on neurological development and function in infants and children following prenatal and perinatal exposure to chemical agents. Other sections of these Guidelines outline the method for calculating reference doses or reference concentrations when neurotoxicity is the critical effect, discuss the availability of alternative mathematical approaches to dose-response analyses, characterize the health-related data base for neurotoxicity risk assessment, and discuss integration of exposure information with the results of the dose-response assessment to characterize risks of exposures of concern. These Guidelines do not advocate developing reference doses specific for neurotoxicity, but rather the use of neurotoxicity as one possible end point to develop reference doses.

EPA offices have published guidelines for neurotoxicity testing in animals (U.S. EPA, 1986, 1987, 1988a, 1991a). The testing guidelines address the development of new data for use in risk assessment. These proposed neurotoxicity risk assessment Guidelines provide the Agency's first comprehensive guidance on the use and interpretation of neurotoxicity data. These proposed Guidelines are part of the Agency's risk assessment guidelines development process, which was initiated in 1984. As part of its neurotoxicity guidelines development program, the EPA has sponsored or participated in several conferences on relevant issues (Tilson, 1990); these and other sources (see references) provide the scientific basis for these proposed risk assessment Guidelines. This guidance is intended for use by Agency risk assessors and is separate and distinct from the recently published document on principles of neurotoxicity risk assessment (U.S. EPA, 1993). The document on principles was prepared under the auspices of the Subcommittee on Risk Assessment of the Federal Coordinating Council for Science, Engineering, and Technology and was not intended to provide specific directives for how neurotoxicity risk assessment should be performed.

It is expected that, like other EPA risk assessment guidelines (U.S. EPA, 1991b), this document will encourage research and analysis leading to new risk assessment methods and data, which in turn would be used to revise and improve the Guidelines and better guide Agency risk assessors.

D. Assumptions

There are a number of unknowns in the extrapolation of data from animal studies to humans. Therefore, a number of default assumptions are made that are generally applied in the absence of data on the relevance of effects to potential human risk. Default assumptions should not be applied indiscriminantly. First, all available mechanistic and pharmacokinetic data should be considered. If these data indicate that an alternative assumption is appropriate or obviate the need for applying an assumption, such information should be used in the risk assessment of that agent. The following default assumptions form the basis of the approaches taken in these Guidelines.

It is assumed that an agent that produces detectable adverse neurotoxic effects in experimental animal studies will pose a potential hazard to humans. This assumption is based on the comparisons of data for known human neurotoxicants (Anger, 1990; Kimmel et al., 1990; Spencer and Schaumburg, 1980), which indicate that experimental animal data are frequently predictive of a neurotoxic effect in humans.

It is assumed that behavioral, neurophysiological, neurochemical, and neuroanatomical manifestations are of concern. In the past, the tendency has been to consider only neuropathological changes as end points of concern. Based on the data on agents that are known human neurotoxicants (Anger, 1990; Kimmel et al., 1990; Spencer and Schaumberg, 1980), there is usually at least one experimental species that mimics the types of effects seen in humans, but in other species tested, the type of neurotoxic effect may be different or absent. Thus, a biologically significant increase in any of the manifestations is considered indicative of an agent's potential for disrupting the structure or function of the human nervous system.

It is assumed that the types of neurotoxic effects seen in animal studies may not always be the same as those produced in humans. Therefore, it may be difficult to determine which will be the most appropriate species in terms of predicting the specific types of effects seen in humans. The fact that every species may not react in the same way is probably due to species-specific differences in maturation of the nervous system, differences in timing of exposure, metabolism, or mechanisms of action.

It is assumed that the most appropriate species will be used when data are available to estimate human risk. In the absence of such data, the most sensitive species is used, based on the fact that for the majority of known human neurotoxicants, humans are as sensitive or more so than the most sensitive animal species tested.

In general, a threshold is assumed for the dose-response curve for most neurotoxicants. This is based on the known capacity of the nervous system to compensate for or to repair a certain amount of damage at the cellular, tissue, or organ level. In addition, because of the multiplicity of cells in the nervous system, multiple insults at the molecular or cellular level may be required to produce an effect on the whole organism.

These assumptions are ''plausibly conservative'' (NRC, 1994) in that they are protective of public health and are also well-founded in scientific knowledge about the effects of concern.

II. Definitions and Critical Concepts

This section defines the key terms and concepts that the EPA will use in the identification and evaluation of neurotoxicity. The various health effects that fall within the broad classification of neurotoxicity are described and examples are provided.

Adverse effects include alterations from baseline that diminish an organism's ability to survive, reproduce, or adapt to the environment. Neurotoxicity is an adverse change in the structure or function of the central and/or peripheral nervous system following exposure to a chemical, physical, or biological agent (Tilson, 1990). Neurotoxic effects include changes in somatic/autonomic, sensory, motor, and/or cognitive function. Structural effects are defined as neuroanatomical changes occurring at any level of nervous system organization; functional changes are defined as neurochemical, neurophysiological, or behavioral alterations. Changes in function can also result from toxicity to other specific organ systems, and these indirect changes may be considered adverse but not necessarily neurotoxic.

The risk assessor also should know that there are different levels of concern based on the magnitude of effect and reversibility of some neurotoxic effects. Neurotoxic effects may be irreversible, i.e., cannot return to the state prior to exposure, resulting in a permanent change in the organism, or reversible, i.e., can return to the pre-exposure condition, allowing the organism to return to its state prior to exposure. Clear or demonstrable irreversible change in either the structure or function of the nervous system causes greater concern than do reversible changes. If neurotoxic effects are observed at some time during the life span of the organism but are slowly reversible, the concern is also high. There is lesser concern for effects that are rapidly reversible or transient, i.e., measured in minutes, hours, or days, and appear to be associated with the pharmacokinetics of the causal agent and its presence in the body. Reversible changes that occur in the occupational setting or environment, however, may be of high concern if, for example, exposure to a short-acting solvent interferes with operation of heavy equipment in an industrial plant. The context of the exposure should be considered in evaluating reversible effects. The risk assessor should note that once damaged, neurons, particularly in the central nervous system, have a limited capacity for regeneration. Reversibility of effects resulting from cell death or from the destruction of cell processes may represent an activation of repair capacity, decreasing future potential adaptability. Therefore, even reversible neurotoxic changes should be of concern. Evidence of progressive effects, i.e., those that continue to worsen even after the causal agent has been removed; or delayed effects, i.e., those that occur at a time distant from the last contact with the causal agent; or residual effects, i.e., those that persist beyond a recovery period; or latent effects, i.e., those that become evident only after an environmental challenge or aging, have a high level of concern. Environmental challenges can include stress, increased physical or cognitive workload, pharmacological manipulations, and nutritional deficiency or excess.

Neurotoxic effects can be observed at various levels of organization of the nervous system, including neurochemical, anatomical, physiological, or behavioral. At the neurochemical level, for example, an agent that causes neurotoxicity might inhibit macromolecule or transmitter synthesis, alter the flow of ions across cellular membranes, or prevent release of neurotransmitter from the nerve terminals. Anatomical changes may include alterations of the cell body, the axon, or the myelin sheath. At the physiological level, a chemical might change the thresholds for neural activation or reduce the speed of neurotransmission. Behavioral alterations can include significant changes in sensations of sight, hearing, or touch; alterations in simple or complex reflexes and motor functions; alterations in cognitive functions such as learning, memory or attention; and changes in mood, such as fear or rage, disorientation as to person, time, or place, or distortions of thinking and feeling, such as delusions and hallucinations. At present, relatively few neurotoxic syndromes have been thoroughly characterized in terms of the initial neurochemical change, structural alterations, physiological consequence, and behavioral effects. Knowledge of exact mechanisms of action is not, however, necessary to conclude that a chemically induced change is a neurotoxic effect.

Neurotoxic effects can be produced by chemicals that do not require metabolism prior to interacting with their target sites in the nervous system, i.e., primary neurotoxic agents, or those that require metabolism prior to interacting with their target sites in the nervous system, i.e., secondary neurotoxic agents. Chemically induced neurotoxic effects can be direct, i.e., due to an agent or its metabolites acting directly on target sites in the nervous system, or indirect, i.e., due to agents or metabolites that produce their effects primarily by interacting with target sites outside the nervous system, which subsequently affect target sites in the nervous system. Excitatory amino acids such as domoic acid damage specific neurons directly by activating excitatory amino acid receptors in the nervous system, while carbon monoxide decreases oxygen availability, which indirectly kills neurons. Other examples of indirect effects of chemicals that could lead to altered structure and/or function of the nervous system include cadmium-induced spasms in blood vessels supplying the nervous system, dichloroacetate-induced perturbation of metabolic pathways, and chemically induced alterations in skeletomuscular function or structure and effects on the endocrine system. Professional judgment may be required in making determinations about direct versus indirect effects.

The interpretation of data as indicative of a potential neurotoxic effect involves the evaluation of the validity of the data base. This approach and these terms have been adapted from the literature on human psychological testing (Sette, 1987; Sette and MacPhail, 1992) where they have long been used to evaluate the level of confidence in different measures of intelligence or other abilities, aptitudes, or feelings. There are four principal questions that should be addressed: whether the effects result from exposure (content validity); whether the effects are adverse or toxicologically significant (construct validity); whether there are correlative measures among behavioral, physiological, neurochemical, and morphological end points (concurrent validity); and whether the effects are predictive of what will happen under various conditions (predictive validity). Addressing these issues can provide a useful framework for evaluating either human or animal studies or the weight of evidence for a chemical (Sette, 1987; Sette and MacPhail, 1992). The next sections indicate the extent to which chemically induced changes can be interpreted as providing evidence of neurotoxicity.

III. Hazard Characterization

A. Neurotoxicological Studies: End Points and Their Interpretation

Identification and characterization of neurotoxic hazard can be based on either human or animal data (Anger, 1984; Reiter, 1987; U.S. EPA, 1993). Such data can result from accidental, inappropriate, or controlled experimental exposures. This section describes many of the general and some of the specific characteristics of human studies and reports of neurotoxicity. It then describes some features of animal studies of neuroanatomical, neurochemical, neurophysiological, and behavioral effects relevant to risk assessment. The process of characterizing the sufficiency or insufficiency of neurotoxic effects for risk assessment is described in section III.C. Additional sources of information relevant to hazard characterization, such as comparisons of molecular structure among compounds and in vitro screening methods, are also discussed.

The hazard characterization should:

a. Identify strengths and limitations of the database:

—Epidemiological studies (case reports, cross-sectional, case-control, cohort, or human laboratory exposure studies);

—Animal studies including (structural or neuropathological, neurochemical, neurophysiological, behavioral or neurological, or developmental end points).

b. Evaluate the validity of the database:

—Content validity (effects result from exposure);
—Construct validity (effects are adverse or toxicologically significant);
—Concurrent validity (correlative measures among behavioral, physiological, neurochemical, or morphological end points);
—Predictive validity (effects are predictive of what will happen under various conditions).

c. Identify and describe key toxicological studies.

d. Describe the type of effects:

—Structural (neuroanatomical alternations);
—Functional (neurochemical, neurophysiological, behavioral alterations).

e. Describe the nature of the effects (irreversible, reversible, transient, progressive, delayed, residual, or latent effects).

f. Describe how much is known about how (through what biological mechanism) the chemical produces adverse effects.

g. Discuss other health end points of concern.

h. Comment on any non-positive data in humans or animals.

i. Discuss the dose-response data (epidemiological or animal) available for further dose-response analysis.

j. Discuss the route, level, timing, and duration of exposure in studies demonstrating neurotoxicity as compared to expected human exposures.

k. Summarize the hazard characterization:

—Confidence in conclusions;
—Alternative conclusions also supported by the data;
—Significant data gaps; and
—Highlight of major assumptions.

1. Human Studies

It is well established that information from the evaluation of human exposure can identify neurotoxic hazards (Anger and Johnson, 1985; Anger, 1990). Prominent among historical episodes of neurotoxicity in human populations are the outbreaks of methylmercury poisoning in Japan and Iraq and the neurotoxicity seen in miners of metals, including mercury, manganese, and lead (Carson et al., 1987; Silbergeld and Percival, 1987; OTA, 1990). In the last decade, lead poisoning in children has been a prominent issue of concern (Silbergeld and Percival, 1987). Neurotoxicity in humans has been studied and reviewed for many pesticides (Hayes, 1982; NRDC, 1989; Ecobichon and Joy, 1982; Ecobichon et al., 1990). Organochlorines, organophosphates, carbamates, pyrethroids, certain fungicides, and some fumigants are all known neurotoxicants. They may pose occupational risks to manufacturing and formulation workers, pesticide applicators and farm workers, and consumers through home application or consumption of residues in foods. Families of workers may also be exposed by transport into the home from workers' clothing. Data on humans can come from a number of sources, including clinical evaluations, case reports, and epidemiologic studies. A more extensive description of issues concerning human neurotoxicology and risk assessment has been published elsewhere (U.S. EPA, 1993).

a. Clinical Evaluations. Clinical methods are used extensively in neurology and neuropsychology to evaluate patients suspected of having neurotoxicity. An extensive array of examiner-administered and paper-and-pencil tasks are used to assess sensory, motor, cognitive, and affective functions and personality states/traits. Neurobehavioral data are synthesized with information from neurophysiologic studies and medical history to derive a working diagnosis. Brain imaging techniques based on magnetic resonance imaging or emission tomography may also be useful in helping diagnose neurodegenerative disorders following chemical exposures in humans (Omerod et al., 1994; Callender et al., 1994). Clinical diagnostic approaches have provided a rich conceptual framework for understanding the functions (and malfunctions) of the central and peripheral nervous systems and have formed the basis for the development of methods for measuring the behavioral expression of nervous system disorders. Human neurobehavioral toxicology has borrowed heavily from neurology and neuropsychology for concepts of nervous system impairment and functional assessment methods. Neurobehavioral toxicology has adopted the neurologic/neuropsychologic model, using adverse changes in behavioral function to assist in identifying chemically or drug-induced changes in nervous system processes.

Neurologic and neuropsychologic methods have long been employed to identify the adverse health effects of environmental workplace exposures (Sterman and Schaumburg, 1980). Peripheral neuropathies (with sensory and motor disturbances), encephalopathies, organic brain syndromes, extrapyramidal syndromes, demyelination, autonomic changes, and dementia are well-characterized consequences of acute and chronic exposure to chemical agents. The range of exposure conditions that produce clinical signs of neurotoxicity also has been defined by these clinical methods. It is very important to make external/internal dose measurements in humans to determine the actual dose(s) that can cause unwanted effects.

Aspects of the neurologic examination approach limit its usefulness for neurotoxicologic risk assessment. Information obtained from the neurologic exam is mostly qualitative and descriptive rather than quantitative. Estimates of the severity of functional impairment can be reliably placed into only three or four categories (for example, mild, moderate, severe). Much of the assessment depends on the subjective judgment of the examiner. For example, the magnitude and symmetry of muscle strength are often judged by having the patient push against the resistance of the examiner's hands. The end points are therefore the absolute and relative amount of muscle load sensed by the examiner in his or her arms.

Compared with other methods, the neurologic exam may be less sensitive in detecting early neurotoxicity in peripheral sensory and motor nerves. While clinicians' judgments are equal in sensitivity to quantitative methods in assessing the amplitude of tremor, tremor frequency is poorly quantified by clinicians. Thus, important aspects of the clinical neurologic exam may be insufficiently quantified and lack sufficient sensitivity for detecting early neurobehavioral toxicity produced by environmental or workplace exposure conditions. However, a neurologic evaluation of persons with documented neurobehavioral impairment would be helpful for identifying nonchemical causes of neurotoxicity, such as diabetes and cardiovascular insufficiency.

Administration of a neuropsychological battery also requires a trained technician, and interpretation requires a trained and experienced neuropsychologist. Depending on the capabilities of the patient, 2 to 4 hours may be needed to administer a full battery; 1 hour may be needed for the shorter screening versions. These practical considerations may limit the usefulness of neuropsychological assessment in large field studies of suspected neurotoxicity.

In addition to logistical problems in administration and interpretation, neuropsychological batteries and neurologic exams share two disadvantages with respect to neurotoxicity risk assessment. First,

neurologic exams and neuropsychological test batteries are designed to confirm and classify functional problems in individuals selected on the basis of signs and symptoms identified by the patient, family, or other health professionals. Their usefulness in detecting low base-rate impairment in workers or the general population is generally thought to be limited, decreasing the usefulness of clinical assessment approaches for epidemiologic risk assessment.

Second, neurologic exams and neuropsychologic test batteries were developed to assess the functional correlates of the most common forms of nervous system dysfunction: brain trauma, focal lesions, and degenerative conditions. The clinical tests were validated against these neurologic disease states. With a few notable exceptions, chemicals are not believed to produce impairment similar to that from trauma or lesions; neurotoxic effects are more similar to the effects of degenerative disease. There has been insufficient research to demonstrate which tests designed to assess functional expression of neurologic disease are useful in characterizing the modes of central nervous system impairment produced by chemical agents and drugs.

b. Case reports. The first type of human data available is often the case report or case series, which can identify cases of a disease and are reported by clinicians or discerned through active or passive surveillance, usually in the workplace. However, case reports where exposure involved a single neurotoxic agent, although informative, are rare in the literature; for example, farmers are likely to be exposed to a wide variety of potentially neurotoxic pesticides. Careful case histories assist in identifying common risk factors, especially when the association between the exposure and disease is strong, the mode of action of the agent is biologically plausible, and clusters occur in a limited period of time.

Case reports are inexpensive compared with epidemiologic studies and can be obtained more quickly than more complex studies. However, they provide little information about disease frequency or population at risk, but their importance has been clearly demonstrated, particularly in accidental poisoning or acute exposure to high levels of toxicant. They remain an important source of index cases of new diseases and for surveillance.

c. Epidemiologic Studies. Epidemiology has been defined as ''the study of the distributions and determinants of disease and injuries in human populations'' (Mausner and Kramer, 1985). Knowing the frequency of illness in groups and the factors that influence the distribution is the tool of epidemiology that allows the evaluation of causal inference with the goal of prevention and cure of disease (Friedlander and Hearn, 1980). Epidemiologic studies are a means of evaluating the effects of neurotoxic substances on human populations, but such studies are limited because they must be performed shortly after exposure if the effect is acute. Most often these effects are suspected to be a result of occupational exposures due to the increased opportunity for exposure to industrial and other chemicals. Frequently, determining the precise dose or exposure concentration can be difficult in epidemiological studies.

(1) Cross-sectional studies. In cross-sectional studies or surveys, both the disease and suspected risk factors are ascertained at the same time, and the findings are useful in generating hypotheses. A group of people are interviewed, examined, and tested at a single point in time to ascertain a relationship between a disease and a neurotoxic exposure. This study design does not allow the investigator to determine whether the disease or the exposure came first, rendering it less useful in estimating risk. These studies are intermediate in cost and time required to complete compared with case reports and more complex analytical studies but should be augmented with additional data.

(2) Case-control (retrospective) studies. Last (1986) defines a case-control study as one that ''starts with the identification of persons with the disease (or other outcome variable) of interest, and a suitable control population (comparison, reference group) of persons without the disease.'' He states that the relationship of an ''attribute'' to the disease is measured by comparing the diseased with the nondiseased with regard to how frequently the attribute is present in each of the groups. The cases are assembled from a population of persons with and without exposure, and the comparison group is selected from the same population; the relative distribution of the potential risk factor (exposure) in both groups is evaluated by computing an odds ratio that serves as an estimate of the strength of the association between the disease and the potential risk factor. The statistical significance of the ratio is determined by calculating a p-value and is used to approximate relative risk.

The case-control approach to the study of potential neurotoxicants in the environment provides a great deal of useful information for the risk assessor. In his textbook, Valciukas (1991) notes that the case-control approach is the strategy of choice when no other environmental or biological indicator of neurotoxic exposure is available. He further states: ''Considering the fact that for the vast majority of neurotoxic chemical compounds, no objective biological indicators of exposure are available (or if they are, their half-life is too short to be of any practical value), the case-control paradigm is a widely accepted strategy for the assessment of toxic causation.'' The case-control study design, however, can be very susceptible to bias. The potential sources of bias are numerous and can be specific to a particular study. Many of these biases also can be present in cross-sectional studies. For example, recall bias or faulty recall of information by study subjects in a questionnaire-based study can distort the results of the study. Analysis of the case-comparison study design assumes that the selected cases are representative persons with the disease—either all cases with the disease or a representative sample of them have been ascertained. It further assumes that the control or comparison group is representative of the nondiseased population (or that the prevalence of the characteristic under study is the same in the control group as in the general population). Failure to satisfy these assumptions may result in selection bias, but violation of assumptions does not necessarily invalidate the study results.

An additional source of bias in case-control studies is the presence of confounding variables, i.e., factors known to be associated with the exposure and causally related to the disease under study. These must be controlled either in the design of the study by matching cases to controls on the basis of the confounding factor or in the analysis of the data by using statistical techniques such as stratification or regression. Matching requires time to identify an adequate number of potential controls to distinguish those with the proper characteristics, while statistical control of confounding factors requires a larger study.

The definition of exposure is critical in epidemiologic studies. In occupational settings, exposure assessment often is based on the job assignment of the study subjects, but can be more precise if detailed company records allow the development of exposure profiles. Positive results from a properly controlled retrospective

study should weigh heavily in the risk assessment process.

(3) Cohort (prospective, followup) studies. In a prospective study design, a healthy group of people is assembled and followed forward in time and observed for the development of disease. Such studies are invaluable for determining the time course for development of disease (e.g., followup studies performed in various cities on the effects of lead on child development). This approach allows the direct estimate of risks attributed to a particular exposure since disease incidence rates in the cohort can be determined. Prospective study designs also allow the study of chronic effects of exposure. One major strength of the cohort design is that it allows the calculation of rates to determine the excess risk associated with an exposure. Also, biases are reduced by obtaining information before the disease develops. This approach, however, can be very time-consuming and costly.

In cohort studies information bias can be introduced when individuals provide distorted information about their health because they know their exposure status and may have been told of the expected health effects of the exposure under study.

A special type of cohort study is the retrospective cohort study in which the investigator goes back in time to select the study groups and traces them over time, often to the present. The studies usually involve specially exposed groups and have provided much assistance in estimating risks due to occupational exposures. Occupational retrospective cohort studies rely on company records of past and current employees that include information on the dates of employment, age at employment, date of departure, and whether diseased (or dead in the case of mortality studies). Workers can then be classified by duration and degree of exposure. Positive results from a properly controlled prospective study should weigh heavily in the risk assessment process.

d. Human Laboratory Exposure Studies. Neurotoxicity assessment has an advantage not afforded the evaluation of other toxic end points, such as cancer or reproductive toxicity, in that the effects of some chemicals are short in duration and reversible. This makes it ethically possible to perform human laboratory exposure studies and obtain data relevant to the risk assessment process. Information from experimental human exposure studies has been used to set occupational exposure limits, mostly for organic solvents that can be inhaled. Laboratory exposure studies have contributed to risk assessment and the setting of exposure limits for several solvents and other chemicals with acute reversible effects.

Human exposure studies sometime offer advantages over epidemiologic field studies. Combined with appropriate sampling of biologic fluids (urine or blood), it is possible to calculate body concentrations, examine toxicokinetics, and identify metabolites. Bioavailability, elimination, dose-related changes in metabolic pathways, individual variability, time course of effects, interactions between chemicals, and interactions between chemical and environmental/biobehavioral processes (stressors, workload/respiratory rate) are factors that are generally easier to collect under controlled conditions.

Other goals of laboratory studies include the indepth characterization of effects, the development of new assessment methods, and the examination of the sensitivity, specificity, and reliability of neurobehavioral assessment methods across chemical classes. The laboratory is the most appropriate setting for the study of environmental and biobehavioral variables that affect the action of chemical agents. The effects of ambient temperature, task difficulty, rate of ongoing behavior, conditioning variables, tolerance/sensitization, sleep deprivation, motivation, and so forth are sometimes studied.

From a methodologic standpoint, human laboratory studies can be divided into two categories—between-subjects and within-subjects designs. In the former, the neurobehavioral performance of exposed volunteers is compared with that of nonexposed participants. In the latter, preexposure performance is compared with neurobehavioral function under the influence of the chemical or drug. Within-subjects designs have the advantage of requiring fewer participants, eliminating individual differences as a source of variability, and controlling for chronic mediating variables, such as caffeine use and educational achievement. A disadvantage of the within-subjects design is that neurobehavioral tests must be administered more than once. Practice on many neurobehavioral tests often leads to improved performance that may confound the effect of the chemical/drug. There should be a sufficient number of test sessions in the pre-exposure phase of the study to allow performance on all tests to achieve a relatively stable baseline level.

Participants in laboratory exposure studies may have been recruited from populations of persons already exposed to the chemical/drug or from naive populations. Although the use of exposed volunteers has ethical advantages, can mitigate against novelty effects, and allows evaluation of tolerance/sensitization, finding an accessible exposed population in reasonable proximity to the laboratory is difficult. Naive participants are more easily recruited but may differ significantly in important characteristics from a representative sample of exposed persons. Naive volunteers are often younger, healthier, and better educated than the populations exposed environmentally, in the workplace, or pharmacotherapeutically.

Compared with workplace and environmental exposures, laboratory exposure conditions can be controlled more precisely, but exposure periods are much shorter. Generally only one or two relatively pure chemicals are studied for several hours while the population of interest may be exposed to multiple chemicals containing impurities for months or years. Laboratory studies are therefore better at identifying and characterizing effects with acute onset and the selective effects of pure agents.

Neurobehavioral test methods may have been selected according to several strategies. A test battery that examines multiple neurobehavioral functions may be more useful for screening and the initial characterization of acute effects. Selected neurobehavioral tests that measure a more limited number of functions in multiple ways may be more useful for elucidating mechanisms or validating specific effects.

Both chemical and behavioral control procedures are valuable for examining the specificity of the effects. A concordant effect among different measures of the same neurobehavioral function (e.g., reaction time) and a lack of effect on some other measures of psychomotor function (e.g., untimed manual dexterity) would increase the confidence in a selective effect on motor speed and not on attention or nonspecific motor function. Likewise, finding concordant effects among similar chemical or drug classes along with different effects from dissimilar classes would support the specificity of chemical effect. For example, finding that the effects of a solvent were similar to those of ethanol but not caffeine would support the specificity of solvent effects on a given measure of neurotoxicity.

2. Animal Studies

This section provides an overview of the major types of end points that may be evaluated in animal neurotoxicity

studies, describes the kinds of effects that may be observed and some of the tests used to detect and quantify these effects, and provides guidance for interpreting data. Compared with human studies, animal studies are more often available for specific chemicals, provide more precise exposure information, and control environmental factors better (Anger, 1984). For these reasons, risk assessments tend to rely heavily on animal studies.

Many tests that can measure some aspect of neurotoxicity have been used in the field of neurobiology in the last 50 years. The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has published animal testing guidelines that were developed in cooperation with the Office of Research and Development (U.S. EPA, 1991a). While the test end points included serve as a convenient focus for this section, there are many other end points for which there are no current EPA guidelines. The goal of this document is to provide a framework for interpreting data collected with tests frequently used by neurotoxicologists.

Five categories of end points will be described: Structural or neuropathological, neurophysiological, neurochemical, behavioral, and developmental end points. Table 1 lists a number of end points in each of these categories.

Table 1.—Examples of Possible Indicators of a Neurotoxic Effect

I. Structural or Neuropathological End Points
1. Gross changes in morphology, including brain weight
2. Hemorrhage in nerve tissue
3. Breakdown of neurons, glial cells
4. Accumulation, proliferation, or rearrangement of structural elements
5. Glial fibrillary acidic protein increases (in adults)

II. Neurochemical End Points
1. Alterations in synthesis, release, uptake, degradation of neurotransmitters
2. Alterations in second messenger associated signal transduction
3. Alterations in membrane-bound enzymes regulating neuronal activity
4. Inhibition of neuropathy target enzyme (≥40%)

III. Neurophysiological End Points
1. Change in velocity, amplitude, or refractory period of nerve conduction
2. Change in latency or amplitude of sensory-evoked potential
3. Change in electroencephalographic pattern

IV. Behavioral and Neurological End Points
1. Increases or decreases in motor activity
2. Changes in touch, sight, sound, taste, or smell sensations
3. Changes in motor coordination, weakness, paralysis, abnormal movement or posture, tremor, ongoing performance
4. Absence or decreased occurrence, magnitude, or latency of sensorimotor reflex
5. Altered magnitude of neurological measurement, including grip strength, hindlimb splay
6. Seizures
7. Changes in rate or temporal patterning of schedule-controlled behavior
8. Changes in learning, memory, intelligence, attention

V. Developmental End Points
1. Chemically induced changes in the time of appearance of behaviors during development
2. Chemically induced changes in the growth or organization of structural or neurochemical elements.

a. *Structural End Points of Neurotoxicity.* Structural end points are typically defined as neuropathological changes measured through gross observation or with the aid of a microscope. Gross changes in morphology can include discrete or widespread lesions in nerve tissue. Changes in brain size (weight, width, or length) are considered to be indicative of neurotoxic events. This is true regardless of changes in body weight, because brain size is generally protected during undernutrition or weight loss, unlike many other organs or tissues. It is inappropriate to express brain weight changes as a ratio of body weight and thereby dismiss changes in absolute brain weight. The risk assessor should be aware that a unit of measurement that is biologically meaningful should be used for analysis. Brain length measurements, for example, expressed to 1 or 10 micron units is biologically meaningless. The same is true for brain width.

Neurons are composed of a neuronal body, axon, and dendritic processes. Various types of neuropathological lesions may be classified according to the site where they occur (WHO, 1986; Krinke, 1989; Griffin, 1990). Neurodegenerative lesions in the central or peripheral nervous system may be classified as a neuronopathy (changes in the neuronal cell body), axonopathy (changes in the axons), myelinopathy (changes in the myelin sheaths), or terminal degeneration. For axonopathies, a more precise location of the changes may also be described (i.e., proximal, central, or distal axonopathy). In the case of some developmental exposures, a neurotoxic chemical might delay or accelerate the differentiation or proliferation of cells or cell types. Alteration in the axonal termination site might also occur with exposure. In an aged population, exposure to some neurotoxicants might accelerate the normal loss of neurons associated with aging (Reuhl, 1991). In rare cases, neurotoxic agents have been reported to produce neuropathic conditions resembling neurodegenerative disorders in humans such as Parkinson's disease (WHO, 1986). Table 2 lists examples of such neurotoxic chemicals, their putative site of action, the type of neuropathology produced, and the disease or condition that each typifies.

TABLE 2.—NEUROTOXICANTS AND DISEASES WITH SPECIFIC NEURONAL TARGETS

Site of action	Neuropathology	Neurotoxicant	Corresponding neurodegenerative disease or condition
Neuron cell body	Neuronopathy	Methylmercury Quinolinic acid 3-Acetylpyridine.	Minamata disease, Huntington's disease, Cerebellar ataxia.
Nerve terminal	Terminal destruction	1-Methyl-4-phenyl-1,2,3,6-tetrahydropyridine (dopaminergic).	Parkinson's disease.
Schwann cell Myelin	Myelinopathy	Hexachlorophene	Congenital hypomyelinogenesis.
Central-peripheral distal axon.	Distal axonopathy	Acrylamide Carbon disulfide n-Hexane	Peripheral neuropathy.
Central axons	Central axonopathy	Clioquinol	Subacute myeloopticoneuropathy.
Proximal axon	Proximal axonopathy	B,B′-iminodipropionitrile	Motor neuron disease.

Alterations in the structure of the nervous system (i.e., neuronopathy, axonopathy, myelinopathy, terminal degeneration) are regarded as evidence of a neurotoxic effect. The risk assessor should note that pathological changes in many cases require time for the perturbation to become observable, especially with evaluation at the light

microscopic level. Neuropathological studies should control for potential differences in the area(s) and section(s) of the nervous system sampled, in the age, sex, and body weight of the subject, and in fixation artifacts (WHO, 1986). Concern for the structural integrity of nervous system tissues derives from its functional specialization and the lack of regenerative capacity in the central nervous system.

In general, chemical effects can lead to two types of structural alteration at the cellular level: the breakdown of cells, in whole or in part, or the accumulation, proliferation, or rearrangement of structural elements (e.g., intermediate filaments, microtubules) or organelles (e.g., mitochondria). Some changes may be associated with regenerative processes that reflect adaptive changes associated with exposure to a toxicant.

Chemically induced injury to the central nervous system may be associated with astrocytic hypertrophy. Such changes may be seen using immunocytochemical techniques visualized by light microscopy or quantified more precisely by radioimmunoassay (RIA) procedures. Assays of glial fibrillary acidic protein (GFAP), the major intermediate filament protein of astrocytes, have been proposed as a biomarker of this response (O'Callaghan, 1988). The interpretation of a chemical-induced change in GFAP is facilitated by corroborative data from the neuropathology or neuroanatomy evaluation. A number of chemicals known to injure the central nervous system, including trimethyltin, methylmercury, cadmium, 3-acetylpyridine, and methylphenyltetrahydropyridine (MPTP), have been shown to increase levels of GFAP. Measures of GFAP are now included in the Neurotoxicity Test Battery testing guidelines (U.S. EPA, 1991a).

Increases in GFAP above control levels may be seen at dosages below those necessary to produce damage seen by standard microscopic or histopathological techniques. Because increases in GFAP reflect an astrocyte response in adults, treatment-related increases in GFAP are considered to be evidence that a neurotoxic effect has occurred. Decreases in GFAP are not clearly interpretable as indicative of neurotoxicity. The absence of a change in GFAP following exposure does not necessarily mean that the chemical is devoid of neurotoxic potential. Known neurotoxicants such as cholinesterase-inhibiting pesticides, for example, would not be expected to increase brain levels of GFAP. Interpretation of GFAP changes prior to weaning is confounded by the possibility that chemically induced increases in GFAP may be masked by changes in the concentration of this protein associated with maturation of the central nervous system, and these data may be difficult to interpret.

b. *Neurophysiological End Points of Neurotoxicity.* Neurophysiological studies are those that measure the electrical activity of the nervous system. The term ''neurophysiology'' is often used synonymously with ''electrophysiology'' (Dyer, 1987). Neurophysiological techniques provide information on the integrity of defined portions of the nervous system. Several neurophysiological procedures are available for application to neurotoxicological studies. Examples of neurophysiological measures of neurotoxicity are listed in Table 3. They range in scale from procedures that employ microelectrodes to study the function of single nerve cells or restricted portions of them, to procedures that employ macroelectrodes to perform simultaneous recordings of the summed activity of many cells. Microelectrode procedures typically are used to study mechanisms of action and are frequently performed in vitro. Macroelectrode procedures are generally used in studies to detect or characterize the potential neurotoxic effects of agents of interest because of potential environmental exposure. The present discussion concentrates on macroelectrode neurophysiological procedures because it is more likely that they will be the focus of decisions regarding critical effects in risk assessment. All of the procedures described below for use in animals also have been used in humans to determine chemically induced alterations in neurophysiological function.

TABLE 3.—EXAMPLES OF NEUROPHYSIOLOGICAL MEASURES OF NEUROTOXICITY

System/function	Procedure	Representative agents
Retina	Electroretinography (ERG)	Developmental lead.
Visual pathway	Flash evoked potential (FEP)	Carbon disulfide.
Visual function	Pattern evoked potential (PEP) pattern size and contrast).	Carbon disulfide.
Auditory pathway	Brain stem auditory evoked potential (BAER) (clicks).	Aminoglycoside, Antibiotics, Toluene, styrene.
Auditory function	BAER (tones)	Aminoglycoside, Antibiotics, Toluene, styrene.
Somatosensory pathway	Somatosensory evoked potential (SEP) (shocks).	Acrylamide, n-Hexane.
Somatosensory function	SEP (tactile)	Acrylamide n-Hexane.
Spinocerebellar pathway	SEP recorded from cerebellum	Acrylamide n-Hexane.
Mixed nerve	Peripheral nerve compound action potential (PNAP).	Triethyltin.
Motor axons	PNAP isolate motor components	Triethyltin.
Sensory axons	PNAP isolate sensory components	Triethyltin.
Neuromuscular	Electromyography (EMG), H-reflex, M-response.	Dithiobiuret.
General central nervous system/level of arousal.	Electroencephalography (EEG)	Anesthetics.

(1) Nerve conduction studies. Nerve conduction studies, generally performed on peripheral nerves, can be useful in investigations of possible peripheral neuropathy. Most peripheral nerves contain mixtures of individual sensory and motor nerve fibers, which may or may not be differentially sensitive to neurotoxicants. It is possible to distinguish sensory from motor effects in peripheral nerve studies by measuring activity in purely sensory

nerves such as the sural nerve or by measuring the muscle response evoked by nerve stimulation to measure motor effects. While a number of end points can be recorded, the most critical variables are (1) nerve conduction velocity, (2) response amplitude, and (3) refractory period.

Nerve conduction measurements are influenced by a number of factors, the most important of which is temperature. An adequate nerve conduction study will either measure the temperature of the limb under study and mathematically adjust the results according to well-established temperature factors or control limb temperature within narrow limits. Studies that measure peripheral nerve function without regard for temperature are not adequate for risk assessment.

In well-controlled studies, statistically significant decreases in nerve conduction velocity are indicative of a neurotoxic effect. While a decrease in nerve conduction velocity is indicative of demyelination, it frequently occurs later in the course of axonal degradation because normal conduction velocity may be maintained for some time in the face of axonal degeneration. For this reason, a measurement of normal nerve conduction velocity does not rule out peripheral axonal degeneration if other signs of peripheral nerve dysfunction are present.

Decreases in response amplitude reflect a loss of active nerve fibers and may occur prior to decreases in conduction velocity in the course of peripheral neuropathy. Hence, changes in response amplitude may be more sensitive measurements of axonal degeneration than conduction velocity. Measurements of response amplitude, however, can be more variable and require careful application of experimental techniques, a larger sample size, and greater statistical power than measurements of velocity to detect changes. The refractory period refers to the time required after stimulation before a nerve can fire again and provides a measure reflecting the functional status of nerve membrane ion channels. Chemically induced changes in refractory periods in a well-controlled study indicate a neurotoxic effect.

In summary, alterations in peripheral nerve response amplitude and refractory period in studies that are well controlled for temperature are indicative of a neurotoxic effect. Alterations in peripheral nerve function are frequently associated with clinical signs such as numbness, tingling, or burning sensations or with motor impairments such as weakness. Examples of compounds that alter peripheral nerve function in humans or experimental animals include acrylamide, carbon disulfide, n-hexane, lead, and some organophosphates.

(2) Sensory, motor, and other evoked potentials. Evoked potential studies are electrophysiological procedures that measure the response elicited from a defined stimulus such as a tone, a light, or a brief electrical pulse. Evoked potentials reflect the function of the system under study, including visual, auditory, or somatosensory; motor involving motor nerves and innervated muscles; or other neural pathways in the central or peripheral nervous system (Rebert, 1983; Dyer, 1985; Mattsson and Albee, 1988; Mattsson et al., 1992; Boyes, 1992, 1993). Evoked potential studies should be interpreted with respect to the known or presumed neural generators of the responses, and their likely relationships with behavioral outcomes, when such information is available. Such correlative information strengthens the confidence in electrophysiological outcomes. In the absence of such supportive information, the extent to which evoked potential studies provide convincing evidence of neurotoxicity is a matter of professional judgment on a case-by-case basis. Judgments should consider the nature, magnitude, and duration of such effects, along with other factors discussed elsewhere in this document.

Data are in the form of a voltage record collected over time and can be quantified in several ways. Commonly, the latency (time from stimulus onset) and amplitude (voltage) of the positive and negative voltage peaks are identified and measured. Alternative measurement schemes may involve substitution of spectral phase or template shifts for peak latency and spectral power, spectral amplitude, root-mean-square, or integrated area under the curve for peak amplitude. Latency measurements are dependent on both the velocity of nerve conduction and the time of synaptic transmission. Both of these factors depend on temperature, as discussed in regard to nerve conduction, and similar caveats apply for sensory evoked potential studies. In studies that are well controlled for temperature, increases in latencies or related measures can reflect deficits in nerve conduction, including demyelination or delayed synaptic transmission, and are indicators of a neurotoxic effect.

Decreases in peak latencies, like increases in nerve conduction velocity, are unusual, but the neural systems under study in sensory evoked potentials are complex, and situations that might cause a peak measurement to occur earlier are conceivable. Two such situations are a reduced threshold for spatial or temporal summation of afferent neural transmission and a selective loss of cells responding late in the peak, thus making the measured peak occur earlier. Decreases in peak latency should not be dismissed outright as experimental or statistical error, but should be examined carefully and perhaps replicated to assess possible neurotoxicity. A decrease in latency is not conclusive evidence of a neurotoxic effect.

Changes in peak amplitudes or equivalent measures reflect changes in the magnitude of the neural population responsive to stimulation. Both increases and decreases in amplitude are possible following exposure to chemicals. Whether excitatory or inhibitory neural activity is translated into a positive or negative deflection in the sensory evoked potential is dependent on the physical orientation of the electrode with respect to the tissue generating the response, which is frequently unknown. Comparisons should be based on the absolute change in amplitude. Therefore, either increases or decreases in amplitude may be indicative of a neurotoxic effect.

Within any given sensory system, the neural circuits that generate various evoked potential peaks differ as a function of peak latency. In general, early latency peaks reflect the transmission of afferent sensory information. Changes in either the latency or amplitude of these peaks are considered convincing evidence of a neurotoxic effect that is likely to be reflected in deficits in sensory perception. The later-latency peaks, in general, reflect not only the sensory input but also the more nonspecific factors such as the behavioral state of the subject, including such factors as arousal level, habituation, or sensitization (Dyer, 1987). Thus, changes in later-latency evoked potential peaks must be interpreted in light of the behavioral status of the subject and would generally be considered evidence of a neurotoxic effect.

(3) Seizures/convulsions. Neurophysiological recordings of brain electrical activity that demonstrate seizure-like activity are indicative of a neurotoxic effect. Occasionally, behaviors resembling convulsions might follow actions outside the nervous system, such as direct effects on muscle. When convulsion-like behaviors are observed, as described in the behavioral section, neurophysiological recordings can determine if these behaviors

originate from seizure activity in the brain.

In addition to producing seizures directly, neurotoxicants also may alter the frequency, severity, duration, or threshold for eliciting seizures produced through other means. Such changes can occur after acute exposure or after repeated exposure to dose levels below the acute threshold and are considered to be neurotoxic effects. Examples of agents that produce convulsions include lindane, DDT (dichloro-diphenyl-trichloroethane), pyrethroids, and trimethyltin.

(4) Electroencephalography (EEG). EEG analysis is used widely in clinical settings for the diagnosis of neurological disorders and less often for the detection of subtle toxicant-induced dysfunction (WHO, 1986; Eccles, 1988). The basis for using EEG in either setting is the relationship between specific patterns of EEG waveforms and specific behavioral states. Because states of alertness and stages of sleep are associated with distinct patterns of electrical activity in the brain, it is generally thought that arousal level can be evaluated by monitoring the EEG.

Dissociation of EEG activity and behavior can, however, occur after exposure to certain chemicals. Normal patterns of transition between sleep stages or between sleeping and waking states are known to remain disturbed for prolonged periods of time after exposure to some chemicals. Changes in the pattern of the EEG can be elicited by stimuli producing arousal (e.g., lights, sounds) and anesthetic drugs. In studies with toxicants, changes in EEG pattern can sometimes precede alterations in other objective signs of neurotoxicity (Dyer, 1987).

EEG studies must be done under highly controlled conditions, and the data must be considered on a case-by-case basis. Chemically induced seizure activity detected in the EEG pattern is evidence of a neurotoxic effect.

c. *Neurochemical End Points of Neurotoxicity*. Many different neurochemical end points have been measured in neurotoxicological studies, and some have proven useful in advancing the understanding of mechanisms of action of neurotoxic chemicals (Bondy, 1986; Mailman, 1987; Morell and Mailman, 1987; Costa, 1988). Normal functioning of the nervous system depends on the synthesis and release of specific neurotransmitters and activation of their receptors at specific presynaptic and postsynaptic sites. Chemicals can interfere with the ionic balance of a neuron, act as a cytotoxicant after transport into a nerve terminal, block reuptake of neurotransmitters and their precursors, act as a metabolic poison, overstimulate receptors, block transmitter release, and inhibit transmitter synthetic or catabolic enzymes. Table 4 lists several chemicals that produce neurotoxic effects at the neurochemical level (Bondy, 1986; Mailman, 1987; Morell and Mailman, 1987; Costa, 1988).

TABLE 4.—EXAMPLES OF NEUROTOXICANTS WITH KNOWN NEUROCHEMICAL MECHANISMS

Site of action	Examples
1. Neurotoxicants Acting on Ionic Balance:	
A. Inhibit sodium entry	Tetrodotoxin.
B. Block closing of sodium channel	p,p′-DDT, pyrethroids.
C. Increase permeability to sodium	Batrachotoxin.
D. Increase intracellular calcium	Chlordecone.
2. Cytotoxicants—Depend on uptake into nerve terminal	MPTP.
3. Uptake blockers	Hemicholinium.
4. Metabolic poisons	Cyanide.
5. Hyperactivation of receptors	Domoic acid.
6. Blocks transmitter release (Acetylcholine [ACh])	Botulinum toxin.
7. Inhibition of transmitter degradation (ACh)	Pesticides of the organophosphate and carbamate classes.
8. Blocks axonal transport	Acrylamide.

As stated previously, any neurochemical change is potentially neurotoxic, but each determination requires professional judgment. Persistent or irreversible chemically induced neurochemical changes are indicative of neurotoxicity. Because the ultimate functional significance of some biochemical changes is not known at this time, neurochemical studies should be interpreted with reference to the presumed neurotoxic consequence(s) of the neurochemical changes. For example, many neuroactive agents can increase or decrease neurotransmitter levels, but such changes are not necessarily indicative of a neurotoxic effect. If, however, these neurochemical changes may be expected to have neurophysiological, neuropathological, or neurobehavioral correlates, then the neurochemical changes could be classified as neurotoxic effects.

Some neurotoxicants, such as the organophosphate and carbamate pesticides, are known to inhibit the activity of a specific enzyme, acetylcholinesterase (for a review see Costa, 1988), which hydrolyzes the neurotransmitter acetylcholine. Inhibition of the enzyme prolongs the action of the acetylcholine at the neuron's synaptic receptors and is responsible for the autonomic stimulation and death that these agents cause.

Within EPA and elsewhere, questions have arisen as to whether inhibition of cholinesterase activity constitutes an adverse effect for defining hazard potential and evaluating risk. There is agreement among scientists that statistically significant inhibition of cholinesterase activity in multiple organs and tissues accompanied by clinical effects constitutes a hazard. However, there is scientific uncertainty and related controversy about the risk assessment implications of data describing inhibition of cholinesterase enzyme activity in the absence of observable clinical effects. While there is agreement that such inhibition is a biomarker of exposure, there is continued disagreement over whether cholinesterase inhibition, especially in blood, constitutes an adverse effect.

At this point, it can be stated that there is general agreement among scientists that objective clinical measures of dysfunction/impairment can be overt manifestations of inhibition of cholinesterase in the nervous system. On the basis of clinical manifestations, e.g., muscle weakness, tremor, blurred vision, one should be able to evaluate dose-response and dose-effect relationships and define the presence and absence of given effects. A relationship between the effect and cholinesterase inhibition should be

confirmed by biochemical measures of reduced cholinesterase activity.

In addition, a reduction in brain cholinesterase activity may or may not be accompanied by clinical manifestations. Most experts in the field acknowledge that when significant reductions in brain cholinesterase activity alone occur, reduced cholinesterase levels either are themselves toxic or would lead to a neurotoxic effect if exposure were to persist over time or increase in magnitude. Therefore, statistically significant decreases in brain cholinesterase could be considered to be a biologically significant effect.

A reduction in RBC and/or plasma cholinesterase activity also may or may not be accompanied by clinical manifestations. At this time, there is general agreement that the observation of inhibition of RBC and/or plasma cholinesterase contributes to the overall hazard identification of cholinesterase inhibiting agents by serving as biomarkers. As such, these enzyme parameters can provide information that will help scientists evaluate whether reported clinical effects are associated with cholinesterase inhibition. There remains, however, a lack of consensus as to whether RBC and/or plasma cholinesterase represent biologically significant events. Discussions on this topic are continuing within the Agency.

A subset of organophosphate agents also produces organophosphate-induced delayed neuropathy (OPIDN) after acute or repeated exposure. Prolonged inhibition (i.e., aging) of neurotoxic esterase (or neuropathy target enzyme) has been associated with agents that produce OPIDN (Johnson, 1990), a clear neurotoxic effect.

d. *Behavioral End Points of Neurotoxicity.* EPA's testing guidelines developed for the Toxic Substances Control Act and the Federal Insecticide, Fungicide and Rodenticide Act describe the use of functional observational batteries (FOB), motor activity, and schedule-controlled behavior for assessing neurotoxic potential (U.S. EPA, 1991a). There are many other measures of behavior, including specialized tests of motor and sensory function and of learning and memory (Tilson, 1987; Anger, 1984). Examples of behavioral end points that have been used to detect neurotoxicity are included in Table 1. The risk assessor should know that the literature is clear that a number of other behaviors besides those listed in Tables 1 and 5 could be affected by chemical exposure. For example, alterations in food and water intake, reproduction, sleep, temperature regulation, and circadian rhythmicity are controlled by specific regions of the brain and chemical-induced alterations in these behaviors could be indicative of neurotoxicity. It is reasonable to assume that a NOAEL or LOAEL could be based on one or more of these end points.

TABLE 5.—SUMMARY OF MEASURES IN A REPRESENTATIVE FUNCTIONAL OBSERVATIONAL BATTERY, AND THE TYPE OF DATA PRODUCED BY EACH

Home cage and open field	Manipulative	Physiologic
Posture (D)	Ease of removal (R)	Body temperature (I).
Convulsions, tremors (D)	Handling reactivity (R)	Body weight (I).
Palpebral closure (R)	Palpebral closure (R).	
Lacrimation (R)	Approach response (R).	
Piloerection (Q)	Click response (R).	
Salivation (R)	Touch response (R).	
Vocalizations (Q)	Tail pinch response (R).	
Rearing (C)	Righting reflex (R).	
Urination (C)	Landing foot splay (I).	
Defecation (C)	Forelimb grip strength (I).	
Gait (D, R)	Hindlimb grip strength (I).	
Arousal (R)	Pupil response (Q).	
Mobility (R).		
Stereotypy (D).		
Bizarre behavior (D)		

D—descriptive data; R—rank order data; Q—quantal data; I—interval data; C—count data.

Behavior is an indication of the overall well-being of the organism. Changes in behavior can arise from a direct effect of a toxicant on the nervous system or indirectly from its effects on other physiological systems. Understanding the interrelationship between systemic toxicity and behavioral changes is extremely important (e.g., the relationship between liver damage and motor activity). The presence of systemic toxicity may complicate, but does not necessarily preclude, interpretation of behavioral changes as evidence of neurotoxicity. In addition, a number of behaviors (e.g., schedule-controlled behavior) may require a motivational component for successful completion of the task. In such cases, experimental paradigms designed to assess the motivation of an animal during behavior might be necessary to interpret the meaning of some chemical-induced changes in behavior.

The following sections describe in general behavioral tests and their uses and offer guidance on interpreting data.

(1) Functional observational battery. A functional observational battery is designed to detect and quantify major overt behavioral, physiological, and neurological signs (Gad, 1982; O'Donoghue, 1989; Moser, 1989). A number of batteries have been developed, each consisting of tests generally intended to evaluate various aspects of sensorimotor function (Tilson and Moser, 1992). Many FOB tests are essentially clinical neurological examinations that rate the presence or absence, and in many cases the severity, of specific neurological signs. Some FOBs in animals are similar to clinical neurological examinations used with human patients. Most FOBs have several components or tests. A typical FOB is summarized in Table 5 and evaluates several functional domains, including neuromuscular (i.e., weakness, incoordination, gait, and tremor), sensory (i.e., audition, vision, and somatosensory), and autonomic (i.e., pupil response and salivation) function. FOB data may be in the form of interval, ordinal, or continuous measurements.

The relevance of statistically significant test results from an FOB is judged according to the number of signs affected, the dose(s) at which effects are observed, and the nature, severity, and persistence of the effects and their

incidence in relation to control animals. If only a few unrelated measures in the FOB are affected, or the effects are unrelated to dose, the results are not considered evidence of a neurotoxic effect. If several neurological signs are affected but only at the high dose and in conjunction with other overt signs of toxicity, including systemic toxicity, large decreases in body weight, decreases in body temperature, or debilitation, there is no conclusive evidence of a direct neurotoxic effect. In cases where several related measures in a battery of tests are affected and the effects appear to be dose dependent, the data are considered to be evidence of a neurotoxic effect, especially in the absence of systemic toxicity. Recently, it was proposed that data from FOB studies be grouped into several neurobiological domains, including neuromuscular (i.e., weakness, incoordination, abnormal movements, gait), sensory (i.e, auditory, visual, somatosensory), and autonomic functions (Tilson and Moser, 1992). This statistical technique is useful when separating changes that occur on the basis of chance or in conjunction with systemic toxicity from those treatment-related changes indicative of neurotoxic effects. In the case of the developing organism, chemicals may alter the maturation or appearance of sensorimotor reflexes. Significant alterations in or delay of such reflexes is evidence of a neurotoxic effect.

Examples of chemicals that affect neuromuscular function are 3-acetylpyridine, acrylamide, and triethyltin. Organophosphate and carbamate insecticides produce autonomic dysfunction, while organochlorine and pyrethroid insecticides increase sensorimotor sensitivity, produce tremors, and in some cases, cause seizures and convulsions (Spencer and Schaumberg, 1980).

(2) Motor activity. Motor activity represents a broad class of behaviors involving coordinated participation of sensory, motor, and integrative processes. Assessment of motor activity is noninvasive and has been used to evaluate the effects of acute and repeated exposure to neurotoxicants (MacPhail et al., 1989). An organism's level of activity can, however, be affected by many different types of environmental agents, including nonneurotoxic agents. Motor activity measurements also have been used in humans to evaluate disease states, including disorders of the nervous system (Goldstein and Stein, 1985).

Motor activity is usually quantified as the frequency of movements over a period of time. The total counts generated during a test period will depend on the recording mechanism and size and configuration of the testing apparatus. Effects of agents on motor activity can be expressed as absolute activity counts or as a percentage of control values. In some cases, a transformation (e.g., square root) may be used to achieve a normal distribution of the data. The frequency of motor activity within a session usually decreases and is reported as the average number of counts occurring in each successive block of time. The EPA's Office of Prevention, Pesticides and Toxic Substances guidelines (U.S. EPA, 1991a), for example, call for test sessions of sufficient duration to allow motor activity to approach steady-state levels during the last 20 percent of the session for control animals. A sum of the counts in each epoch will add up to the total number of counts per session.

In the adult, neurotoxic agents generally decrease motor activity (MacPhail et al., 1989). Examples include many pesticides (e.g., carbamates, chlorinated hydrocarbons, organophosphates, and pyrethroids), heavy metals (lead, tin, and mercury), and other agents (3-acetylpyridine, acrylamide, and 2,4-dithiobiuret). Some neurotoxicants (e.g., toluene, xylene, triadimefon) produce transient increases in activity by presumably stimulating neurotransmitter release, while others (e.g., trimethyltin) produce persistent increases in motor activity by destroying specific regions of the brain (e.g., hippocampus).

Following developmental exposures, neurotoxic effects are often observed as a change in the developmental profile or maturation of motor activity patterns. Frequently, developmental exposure to neurotoxic agents will produce an increase in motor activity that persists into adulthood or that results in changes in other behaviors. This type of effect is evidence of a neurotoxic effect. Like other organ systems, the nervous system may be differentially sensitive to toxicants in groups such as the young. For example, toxicants introduced to the developing nervous system may kill stem cells and thus cause profound effects on adult structure and function. Moreover, toxicants may have greater access to the developing nervous system before the blood-brain barrier is completely formed or before metabolic detoxifying systems are functional.

Motor activity measurements are typically used with other tests (e.g., FOB) to help detect neurotoxic effects. Agent-induced changes in motor activity associated with other overt signs of toxicity (e.g., loss of body weight, systemic toxicity) or occurring in non-dose-related fashion are of less concern than changes that are dose dependent, related to structural or other functional changes in the nervous system, or occur in the absence of life-threatening toxicity.

(3) Schedule-controlled operant behavior. Schedule-controlled operant behavior (SCOB) involves the maintenance of behavior (e.g., performance of a lever-press or key-peck response) by reinforcement. Different rates and patterns of responding are controlled by the relationship between response and subsequent reinforcement. SCOB provides a measure of performance of a learned behavior (e.g., lever press or key peck) and involves training and motivational variables that must be considered in evaluating the data. Agents may interact with sensory processing, motor output, motivational variables (i.e., related to reinforcement), training history, and baseline characteristics (Rice, 1988; Cory-Slechta, 1989). Rates and patterns of SCOB display remarkable species and experimental generality.

In laboratory animals, SCOB has been used to study a wide range of neurotoxicants, including methylmercury, many pesticides, carbon disulfide, organic and inorganic lead, and triethyl and trimethyltin (MacPhail, 1985; Tilson, 1987; Rice, 1988). The primary SCOB end points for evaluation are response rate and the temporal pattern of responding. These end points may vary as a function of the contingency between responding and reinforcement presentation (i.e., schedule of reinforcement). While most chemicals decrease the efficiency of responding at some dose, some agents may increase response efficiency on schedules requiring high response rates due to a stimulant effect or an increase in central nervous system excitability. Agent-induced changes in responding between reinforcements (i.e., the temporal pattern of responding) may occur independently of changes in the overall rate of responding. Chemicals may also affect the reaction time to respond following presentation of a stimulus. Agent-induced changes in response rate or temporal patterning associated with other overt signs of toxicity (e.g., body weight loss, systemic toxicity, or occurring in a non-dose-related fashion) are of less concern than changes that are dose dependent, related to structural or other functional changes in the nervous system, or occur in the absence of life-threatening toxicity.

(4) Convulsions. Observable convulsions in animals are indicative of an adverse effect. These events can

reflect central nervous system activity comparable to that of epilepsy in humans and could be defined as neurotoxicity. Occasionally, other toxic actions of compounds, such as direct effects on muscle, might mimic some convulsion-like behaviors. In some cases, convulsions or convulsion-like behaviors may be observed in animals that are otherwise severely compromised, moribund, or near death. In such cases, convulsions might reflect an indirect effect of systemic toxicity and are less clearly indicative of neurotoxicity. As discussed in the section on neurophysiological measures, electrical recordings of brain activity could be used to determine specificity of effects on the nervous system.

(5) Specialized tests for neurotoxicity. Several procedures have been developed to measure agent-induced changes in specific neurobehavioral functions such as motor, sensory, or cognitive function (Tilson, 1987; Cory-Slechta, 1989). Table 6 lists several well-known behavioral tests, the neurobehavioral functions they were designed to assess, and agents known to affect the response. Many of these tests in animals have been designed to assess neural functions in humans using similar testing procedures.

TABLE 6.—EXAMPLES OF SPECIALIZED BEHAVIORAL TESTS TO MEASURE NEUROTOXICITY

Function	Procedure	Representative agents
Neuromuscular:		
Weakness	Grip strength; swimming endurance; suspension rod; discriminative motor function.	n-Hexane, methl n-butylketone, carbaryl.
Incoordination	Rotorod, gait measurements; righting reflex	3-Acetylpyridine, ethanol.
Tremor	Rating scale, spectral analysis	Chlordecone, Type I pyrethroids, DDT.
Myoclonia spasms	Rating scale, spectral analysis	DDT, Type II pyrethroids.
Sensory:		
Auditory	Discrimination conditioning Reflex modification	Toluene, trimethyltin.
Visual	Discrimination conditioning	Methylmercury.
Somatosensory	Discrimination conditioning	Acrylamide.
Pain sensitivity	Discrimination conditioning (titration); functional observational battery.	Parathion.
Olfactory	Discrimination conditioning	3-Methylindole, methylbromide.
Learning/Memory:		
Habituation	Startle reflex	Diisopropyl-fluorophosphate (DFP) Pre/neonatal methylmercury.
Classical conditioning	Nictitating membrane	Aluminum.
	Conditioned flavor aversion	Carbaryl.
	Passive avoidance	Trimethyltin, IDPN.
	Olfactory conditioning	Neonatal trimethyltin.
Operant conditioning	One-way avoidance	Chlordecone.
	Two-way avoidance	Pre/neonatal lead.
	Y-maze avoidance	Hypervitaminois A.
	Biel water maze	Styrene.
	Morris water maze	DFP.
	Radial arm maze	Trimethyltin.
	Delayed matching to sample	DFP.
	Repeated acquisition	Carbaryl.
	Visual discrimination	Lead.

A statistically significant chemically induced change in any measure in Table 6 is presumptive evidence of adverse effect. Judgments of neurotoxicity may involve not only the analysis of changes seen but the structure and class of the chemical and other available neurochemical, neurophysiological, and neuropathological evidence. In general, behavioral changes seen across broader dose ranges indicate more specific actions on the systems underlying those changes, i.e., the nervous system. Changes that are not dose dependent or that are confounded with body weight changes and/or other systemic toxicity may be more difficult to interpret as neurotoxic effects.

(a) Motor function: Neurotoxicants commonly affect motor function. These effects can be categorized generally into (1) weakness or decreased strength, (2) tremor, (3) incoordination, and (4) spasms, myoclonia, or abnormal motor movements (Tilson, 1987; Cory-Slechta, 1989). Specialized tests used to assess weakness include measures of grip strength, swimming endurance, suspension from a hanging rod, and discriminative motor function. Rotarod and gait assessments are used to measure incoordination, while rating scales and spectral analysis techniques can be used to quantify tremor and other abnormal movements.

(b) Sensory function: Gross perturbations of sensory function can be observed in simple neurological assessments such as the FOB. However, these tests may not be sufficiently sensitive to detect subtle sensory changes. Psychophysical procedures that study the relationship between a physical dimension (e.g., intensity, frequency) of a stimulus and behavior may be necessary to quantify agent-induced alterations in sensory function. Examples of psychophysical procedures include discriminated conditioning and startle reflex modification.

(c) Cognitive function: Alterations in learning and memory in experimental animals must be inferred from changes in behavior following exposure when compared with that either seen prior to exposure or with a nonexposed control group. Learning is defined as a relatively lasting change in behavior due to experience, and memory is defined as the persistence of a learned behavior over time. Table 6 lists several examples of learning and memory tests and representative neurotoxicants known to affect these tests. Measurement of changes in learning and memory must be separated from other changes in behavior that do not involve cognitive or associative processes (i.e., motor function, sensory capabilities, motivational factors). In addition, any apparent toxicant-induced change in learning or memory should ideally be

demonstrated over a range of stimulus and response conditions and testing conditions. In developmental exposures, it should be shown that the animals have matured enough to perform the specified task. Developmental neurotoxicants can accelerate or delay the ability to learn a response or interfere with cognitive function at the time of testing. Older animals frequently perform poorly on some types of tests, and it must be demonstrated that control animals in this population are capable of performing the procedure. Neurotoxicants might accelerate age-related dysfunction or alter motivational variables that are important for learning to occur. Further, it is not necessarily the case that a decrease in responding on a learning task is adverse while an increase in performance on a learning task is not. It is well known that lesions in certain regions of the brain can facilitate the acquisition of certain types of behaviors by removing preexisting response tendencies (e.g., inhibitory responses due to stress) that moderate the rate of learning under normal circumstances. Examples of learning and memory procedures include simple habituation, classical conditioning, and operant (or instrumental) conditioning, including tests for spatial learning and memory.

e. Developmental Neurotoxicity. Although the previous discussion of various neurotoxicity end points and tests applies to studies in which developmental exposures are used, there are particular issues of importance in the evaluation of developmental neurotoxicity studies. Exposure to chemicals during development can result in a spectrum of effects, including death, structural abnormalities, altered growth, and functional deficits (U.S. EPA, 1991b). Children are often differentially sensitive to chemical exposure. A number of agents have been shown to cause developmental neurotoxicity when exposure occurred during the period between conception and sexual maturity (e.g., Riley and Vorhees, 1986; Vorhees, 1987). Table 7 lists several examples of agents known to produce developmental neurotoxicity in experimental animals. Animal models of developmental neurotoxicity have been shown to be sensitive to several environmental agents known to produce developmental neurotoxicity in humans, including lead, ethanol, x-irradiation, methylmercury, and polychlorinated biphenyls (PCBs) (Kimmel et al., 1990; Needleman, 1990; Jacobson et al., 1985; Needleman, 1986). In many of these cases, functional deficits are observed at dose levels below those at which other indicators of developmental toxicity are evident or at minimally toxic doses in adults. Such effects may be transient, but generally are considered to be adverse effects.

TABLE 7.—EXAMPLES OF DEVELOPMENTAL NEUROTOXICANTS

Alcohols	Methanol, ethanol.
Antimitotics	X-radiation, azacytidine.
Insecticides	DDT, kepone.
Metals	Lead, methylmercury, cadmium.
Polyhalogenated hydrocarbons.	PCBs, PBBs.
Solvents	Carbon disulfide, toluene.

Testing for developmental neurotoxicity has not been required routinely by regulatory agencies in the United States, but is required by the EPA when other information indicates the potential for developmental neurotoxicity (U.S. EPA, 1986, 1988a, 1988b, 1989, 1991a, 1991b). Useful data for decision making may be derived from well-conducted adult neurotoxicity studies, standard developmental toxicity studies, and multigeneration studies, although the dose levels used in the latter may be lower than that in studies with shorter term exposure.

Important design issues to be evaluated for developmental neurotoxicity studies are similar to those for standard developmental toxicity studies (e.g., a dose-response approach with the highest dose producing minimal overt maternal or perinatal toxicity, number of litters large enough for adequate statistical power, randomization of animals to dose groups and test groups, litter generally considered as the statistical unit). In addition, the use of a replicate study design provides added confidence in the interpretation of data. A pharmacological/physiological challenge may also be valuable in evaluating neurologic function and ''unmasking'' effects not otherwise detectable. For example, a challenge with a psychomotor stimulant such as d-amphetamine may unmask latent developmental neurotoxicity (Hughes and Sparber, 1978; Adams and Buelke-Sam, 1981; Buelke-Sam et al., 1985).

Direct extrapolation of developmental neurotoxicity to humans is limited in the same way as for other end points of toxicity, i.e., by the lack of knowledge about underlying toxicological mechanisms and their significance (U.S. EPA, 1991b). However, comparisons of human and animal data for several agents known to cause developmental neurotoxicity in humans showed many similarities in effects (Kimmel et al., 1990). Comparisons at the level of functional category (sensory, motivational, cognitive, and motor function and social behavior) showed close agreement across species for the agents evaluated, even though the specific end points used to assess these functions varied considerably across species (Stanton and Spear, 1990). Thus, it can be assumed that developmental neurotoxicity effects in animal studies indicate the potential for altered neurobehavioral development in humans, although the specific types of developmental effects seen in experimental animal studies will not necessarily be the same as those that may be produced in humans. Therefore, when data suggesting adverse effects in developmental neurotoxicity studies are encountered for particular agents, they should be considered in the risk assessment process.

Functional tests with a moderate degree of background variability (e.g., a coefficient of variability of 20 percent or less) may be more sensitive to the effects of an agent on behavioral end points than are tests with low variability that may be impossible to disrupt without using life-threatening doses. A battery of functional tests, in contrast to a single test, is usually needed to evaluate the full complement of nervous system functions in an animal. Likewise, a series of tests conducted in animals in several age groups may provide more information about maturational changes and their persistence than tests conducted at a single age.

It is a well-established principle that there are critical developmental periods for the disruption of functional competence, which include both the prenatal and postnatal periods to the time of sexual maturation, and the effect of a toxicant is likely to vary depending on the time and degree of exposure (Rodier, 1978, 1990). It is also important to consider the data from studies in which postnatal exposure is included, as there may be an interaction of the agent with maternal behavior, milk composition, pup suckling behavior, as well as possible direct exposure of pups via dosed food or water (Kimmel et al., 1992).

Agents that produce developmental neurotoxicity at a dose that is not toxic to the maternal animal are of special concern. However, adverse developmental effects are often produced at doses that cause maternal toxicity (e.g., <20 percent reduction in weight gain during gestation and lactation). In these cases, the

developmental effects are still considered to represent neurotoxicity and should not be discounted as being secondary to maternal toxicity. At doses causing moderate maternal toxicity (i.e., ≥20 percent reduction in weight gain during gestation and lactation), interpretation of developmental effects may be confounded. Current information is inadequate to assume that developmental effects at doses causing minimal maternal toxicity result only from maternal toxicity; rather, it may be that the mother and developing organism are equally sensitive to that dose level. Moreover, whether developmental effects are secondary to maternal toxicity or not, the maternal effects may be reversible while the effects on the offspring may be permanent. These are important considerations for agents to which humans may be exposed at minimally toxic levels either voluntarily or involuntarily, because several agents are known to produce adverse developmental effects at minimally toxic doses in adult humans (e.g., alcohol) (Coles et al., 1991).

Although interpretation of developmental neurotoxicity data may be limited, it is clear that functional effects must be evaluated in light of other toxicity data, including other forms of developmental toxicity (e.g., structural abnormalities, perinatal death, and growth retardation). For example, alterations in motor performance may be due to a skeletal malformation rather than nervous system change. Changes in learning tasks that require a visual cue might be influenced by structural abnormalities in the eye. The level of confidence that an agent produces an adverse effect may be as important as the type of change seen, and confidence may be increased by such factors as reproducibility of the effect either in another study of the same function or by convergence of data from tests that purport to measure similar functions. A dose-response relationship is an extremely important measure of a chemical's effect; in the case of developmental neurotoxicity both monotonic and biphasic dose-response curves are likely, depending on the function being tested. The EPA Guidelines for Developmental Toxicity Risk Assessment (U.S. EPA, 1991b) may be consulted for more information on interpreting developmental toxicity studies. The endpoints frequently used to assess developmental neurotoxicity in exposed children was recently reviewed by Winneke (1995).

3. Other Considerations

a. Pharmacokinetics. Extrapolation of test results between species can be aided considerably by data on the pharmacokinetics of a particular agent in the species tested and, if possible, in humans. Information on a toxicant's half-life, metabolism, absorption, excretion, and distribution to the peripheral and central nervous system may be useful in predicting risk. Of particular importance for the pharmacokinetics of neurotoxicants is the blood-brain barrier, which ordinarily excludes ionic and nonlipid soluble chemicals from the central nervous system. The brain contains circumventricular organs whose purpose seems to be to sense the chemical composition of the peripheral circulation and activate mechanisms to bring the composition of the blood back to equilibrium if disturbed. These areas are technically inside the brain, but they lie outside of the blood-brain-barrier. Therefore, chemicals from the periphery can pass directly into the brain at these sites. The majority of these structures are located within or near the hypothalamus, an area that is crucial for maintenance of neuroendocrine function. Pharmacokinetic data may be helpful in defining the dose-response curve, developing a more accurate basis for comparing species sensitivity (including that of humans), determining dosimetry at target sites, and comparing pharmacokinetic profiles for various dosing regimens or routes of administration. The correlation of pharmacokinetic parameters and neurotoxicity data may be useful in determining the contribution of specific pharmacokinetic processes to the effects observed.

b. Comparisons of Molecular Structure. Comparisons of the chemical or physical properties of an agent with those of known neurotoxicants may provide some indication of the potential for neurotoxicity. Such information may be helpful for evaluating potential toxicity when only minimal data are available. The structure-activity relationships (SAR) of some chemical classes have been studied, including hexacarbons, organophosphates, carbamates, and pyrethroids. Therefore, class relationships or SAR may help predict neurotoxicity or interpret data from neurotoxicological studies. Under certain circumstances (e.g., in the case of new chemicals), this procedure is one of the primary methods used to evaluate the potential for toxicity when little or no empirical toxicity data are available. It should be recognized, however, that effects of chemicals in the same class can vary widely. Moser (1994), for example, reported that the behavioral effects of prototypic cholinesterase-inhibiting pesticides differed qualitatively in a battery of behavioral tests.

c. Statistical Considerations. Properly designed studies on the neurotoxic effects of compounds will include appropriate statistical tests of significance. In general, the likelihood of obtaining a significant effect will depend jointly on the magnitude of the effect and the variability obtained in control and treated groups. A number of texts are available on standard statistical tests (e.g., Siegel, 1956; Winer, 1971; Sokal and Rohlf, 1969; Salsburg, 1986; Gad and Weil, 1988).

Neurotoxicity data present some unique features that must be considered in selecting statistical tests for analysis. Data may involve several different measurement scales, including categorical (affected or not), rank (more or less affected), and interval and ratio scales of measurement (affected by some percentage). For example, convulsions are usually recorded as being present or absent (categorical), whereas neuropathological changes are frequently described in terms of the degree of damage (rank). Many tests of neurotoxicity involve interval or ratio measurements (e.g., frequency of photocell interruptions or amplitude of an evoked potential), which are the most powerful and sensitive scales of measurement. In addition, measurements are frequently made repeatedly in control and treated subjects, especially in the case of behavioral and neurophysiological end points. For example, OPPTS guidelines for FOB assessment call for evaluations before exposure and at several times during exposure in a subchronic study (U.S. EPA, 1991a).

Descriptive data (categorical) and rank order data can be analyzed using standard nonparametric techniques (Siegel, 1956). In some cases, if it is determined that the data fit the linear model, the categorical modeling procedure can be used for weighted least-squares estimation of parameters for a wide range of general linear models, including repeated-measures analyses. The weighted least-squares approach to categorical and rank data allows computation of statistics for testing the significance of sources of variation as reflected by the model. In the case of studies assessing effects in the same animals at several time points, univariate analyses can be carried out at each time point when the overall dose effect or the dose-by-time interaction is significant.

Continuous data (e.g., magnitude, rate, amplitude), if found to be normally distributed, can be analyzed with general linear models using a grouping factor of dose and, if necessary, repeated measures across time (Winer, 1971). Univariate analyses of dose, comparing dose groups to the control group at each time point, are performed when there is a significant overall dose effect or a dose-by-time interaction. Post hoc comparisons between control and treatment groups can be made following tests for overall significance. In the case of multiple end points within a series of evaluations, some type of correction for multiple observations is warranted (Winer, 1971).

d. In Vitro Data in Neurotoxicology. Methods and procedures that fall under the general heading of short-term tests include an array of in vitro tests that have been proposed as alternatives to whole-animal tests (Goldberg and Frazier, 1989). In vitro approaches use animal or human cells, tissues, or organs and maintain them in a nutritive medium. Various types of in vitro techniques produce data for evaluating potential and known neurotoxic substances, including primary cell cultures, cell lines, and cloned cells. While such procedures are important in studying the mechanism of action of toxic agents, their use in hazard identification in human health risk assessment has not been explored to any great extent.

Data from in vitro procedures are generally based on simplified approaches that require less time to yield information than do many in vivo techniques. However, in vitro methods generally do not take into account the distribution of the toxicant in the body, the route of administration, or the metabolism of the substance. It also is difficult to extrapolate in vitro data to animal or human neurotoxicity end points, which include behavioral changes, motor disorders, sensory and perceptual disorders, lack of coordination, and learning deficits. In addition, data from in vitro tests cannot duplicate the complex neuronal circuitry characteristic of the intact animal.

Many in vitro systems are now being evaluated for their ability to predict the neurotoxicity of various agents seen in intact animals. This validation process requires considerations in study design, including defined end points of toxicity and an understanding of how a test agent would be handled in vitro as compared to the intact organism. Demonstrated neurotoxicity in vitro in the absence of in vivo data is suggestive but inadequate evidence of a neurotoxic effect. In vivo data supported by in vitro data enhance the reliability of the in vivo results.

B. Dose-Response Evaluation

Dose-response evaluation is a critical part of hazard characterization and involves the description of the dose response relationship in the available data. Human studies covering a range of exposures are rarely available and therefore animal data are typically used for estimating exposure levels likely to produce adverse effects in humans. Evidence for a dose-response relationship is an important criterion in establishing a neurotoxic effect, although this analysis may be limited when based on standard studies using three dose groups or fewer. The evaluation of dose-response relationships includes identifying effective dose levels as well as doses associated with no increase in incidence of adverse effects when compared with controls. Much of the focus is on identifying the critical effect(s) observed at the lowest-observed-adverse-effect-level and the no-observed-adverse-effect-level associated with that effect. The NOAEL is defined as the highest dose at which there is no statistically or biologically significant increase in the frequency of an adverse neurotoxic effect when compared with the appropriate control group in a data base characterized as having sufficient evidence for use in a risk assessment (see section C). Although a threshold is assumed for neurotoxic effects, the existence of a NOAEL in an animal study does not prove or disprove the existence or level of a biological threshold. Alternatively, mathematical modeling of the dose-response relationship may be performed to determine a quantitative estimate of responses in the experimental range. This approach can be used to determine a BMD, which may be used in place of the NOAEL (Crump, 1994) (see Dose-Response Analysis, Section IV).

In addition to identifying the NOAEL/LOAEL or BMD, the dose-response evaluation defines the range of doses that are neurotoxic for a given agent, species, route of exposure, and duration of exposure. In addition to these considerations, pharmacokinetic factors and other aspects that might influence comparisons with human exposure scenarios should be taken into account. For example, dose-response curves may exhibit not only monotonic but also U-shaped or inverted U-shaped functions (Davis and Svendsgaard, 1990). Such curves are hypothesized to reflect multiple mechanisms of action, the presence of homeostatic mechanisms, and/or activation of compensatory or protective mechanisms. In addition to considering the shape of the dose-response curve, it should also be recognized that neurotoxic effects vary in terms of nature and severity across dose or exposure level. At high levels of exposure, frank lesions accompanied by severe functional impairment may be observed. Such effects are widely accepted as adverse. At progressively lower levels of exposure, however, the lesions may become less severe and the impairments less obvious. At levels of exposure near the NOAEL and LOAEL, the effects will often be mild, possibly reversible, and inconsistently found. In addition, the end points showing responses may be at levels of organization below the whole organism (e.g., neurochemical or electrophysiological end points). The adversity of such effects can be contentious (e.g., cholinesterase inhibition), yet it is such effects that are likely to be the focus of risk assessment decisions. To the extent possible, this document provides guidance on determining the adversity of neurotoxic effects. However, the identification of a critical adverse effect often requires considerable professional judgment and should consider factors such as the biological plausibility of the effect, the evidence of a dose-effect continuum, and the likelihood for progression of the effect with continued exposure.

C. Characterization of the Health-Related Data Base

This section describes a scheme for characterizing the sufficiency of evidence for neurotoxic effects. This scheme defines two broad categories: sufficient and insufficient (Table 8). Categorization is aimed at providing certain criteria for the Agency to use to define the minimum evidence necessary to define hazards and to conduct dose-response analyses. It does not address the issues related to characterization of risk, which requires analysis of potential human exposures and their relation to potential hazards to estimate the risks of those hazards from anticipated or estimated exposures.

Table 8.—Characterization of the Health-Related Database

Sufficient Evidence

The sufficient evidence category includes data that collectively provide enough information to judge whether or not a human neurotoxic hazard could exist. This category may include both human and experimental animal evidence.

Sufficient Human Evidence

This category includes agents for which there is sufficient evidence from

epidemiologic studies, e.g., case control and cohort studies, to judge that some neurotoxic effect is associated with exposure. A case series in conjunction with other supporting evidence may also be judged ''sufficient evidence.'' Epidemiologic and clinical case studies should discuss whether the observed effects can be considered biologically plausible in relation to chemical exposure. (Historically, much often has been made of the notion of causality in epidemiologic studies. Causality is a more stringent criterion than association and has become a topic of scientific and philosophical debate. See Susser [1986], for example, for a discussion of inference in epidemiology.)

Sufficient Experimental Animal Evidence/ Limited or No Human Data

This category includes agents for which there is sufficient evidence from experimental animal studies and/or limited human data to judge whether a potential neurotoxic hazard may exist. Generally, agents that have been tested according to current test guidelines would be included in this category. The minimum evidence necessary to judge that a potential hazard exists would be data demonstrating an effect in a single appropriate, well-executed study in a single experimental animal species, whereas the minimum evidence needed to judge that a potential hazard does not exist would include data from appropriate, well-executed laboratory animal studies that evaluated a variety of the potential manifestations of neuroxtoxicity and showed no effects at doses that were at least minimally toxic. Information on pharmacokinetics, mechanisms, or known properties of the chemical class may also strengthen the evidence.

Insufficient Evidence

This category includes agents for which there is less than the minimum evidence sufficient for identifying whether or not a neurotoxic hazard exists, such as agents for which there are no data on neurotoxicity or agents with data bases from studies in animals or humans that are limited by study design or conduct (e.g., inadequate conduct or report of clinical signs). Many general toxicity studies, for example, are considered insufficient in terms of the conduct of clinical neurobehavioral observations or the number of samples taken for histopathology of the nervous system. Thus, a battery of negative toxicity studies with these shortcomings would be regarded as providing insufficient evidence of the lack of a neurotoxic effect of the test material. Further, most screening studies based on simple observations involving autonomic and motor function provide insufficient evaluation of many sensory or cognitive functions. Data, which by itself would likely fall in this category, would also include information on structure-activity relationships or data from in vitro tests. While such information would be insufficient by itself to proceed further in the assessment it could be used to support the need for additional testing.

Data from all potentially relevant studies, whether indicative of potential hazard or not, should be included in this characterization. The primary sources of data are human studies and case reports, experimental animal studies, other supporting data, and in vitro and/or structure-activity relationship data. Because a complex interrelationship exists among study design, statistical analysis, and biological significance of the data, a great deal of scientific judgment, based on experience with neurotoxicity data and with the principles of study design and statistical analysis, is required to adequately evaluate the data base on neurotoxicity. In many cases, interaction with scientists in specific disciplines either within or outside the field of neurotoxicology (e.g., epidemiology, statistics) may be appropriate.

The adverse nature of different neurotoxicity end points may be a complex judgment. In general, most neuropathological and many neurobehavioral changes are regarded as adverse. However, there are adverse behavioral effects that may not reflect a direct action on the nervous system. Neurochemical and electrophysiological changes may be regarded as adverse as a function of their known or presumed relation to neuropathological and/or neurobehavioral consequences. In the absence of supportive information, a professional judgment must be made regarding the adversity of such outcomes, considering factors such as the nature, magnitude, and duration of the effects reported. Thus, correlated measures of neurotoxicity strengthen the evidence for a hazard. Correlations between functional and morphological effects, such as the correlation between leg weakness and paralysis and peripheral nerve damage from exposure to tri-ortho-cresyl phosphate, are the most common and striking example of this form of validity. Correlations support a coherent and logical link between behavioral effects and biochemical mechanisms. Replication of a finding also strengthens the evidence for a hazard. Some neurotoxicants cause similar effects across most species. Many chemicals shown to produce neurotoxicity in laboratory animals have similar effects in humans. Some neurologic effects may be considered adverse even if they are small in magnitude, reversible, or the result of indirect mechanisms.

Because of the inherent difficulty in ''proving any negative,'' it is more difficult to document a finding of no apparent adverse effect than a finding of an adverse effect. Neurotoxic effects (and most kinds of toxicity) can be observed at many different levels, so that only a single end point needs to be found to demonstrate a hazard, but many end points need to be examined to demonstrate no effect. For example, to judge that a hazard for neurotoxicity could exist for a given agent, the minimum evidence sufficient would be data on a single adverse end point from a well-conducted study. In contrast, to judge that an agent is unlikely to pose a hazard for neurotoxicity, the minimum evidence would include data from a host of end points that revealed no neurotoxic effects. This may include human data from appropriate studies that could support a conclusion of no evidence of a neurotoxic effect. With respect to clinical signs and symptoms, human exposures can reveal far more about the absence of effects than animal studies, which are confined to the signs examined.

In some cases, it may be that no individual study is judged sufficient to establish a hazard, but the total available data may support such a conclusion. Pharmacokinetic data and structure-activity considerations, data from other toxicity studies, as well as other factors may affect the strength of the evidence in these situations. For example, given that gamma diketones are known to cause motor system neurotoxicity, a marginal data set on a candidate gamma diketone, e.g., 1/10 animals affected, might be more likely to be judged sufficient than equivalent data from a member of a chemical class about which nothing is known.

A judgment that the toxicology data base is sufficient to indicate a potential neurotoxic hazard is not the end of analysis. The circumstances of expression of hazard are essential to describing human hazard potential. Thus, reporting should contain the details of the circumstances under which effects have been observed, e.g., ''long-term oral exposures of adult rodents to compound X at levels of roughly 1 mg/kg have been associated with ataxia and peripheral nerve damage.''

IV. Dose-Response Analysis

This section describes several approaches (including the LOAEL/ NOAEL and BMD) for determining the reference dose or reference concentration. The NOAEL or BMD/ uncertainty factor approach results in a RfD or RfC, which is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

The dose-response analysis characterization should:

a. Describe how the RfD/RfC was calculated;

b. Discuss the confidence in the estimates;

c. Describe the assumptions or uncertainty factors used; and

d. Discuss the route and level of exposure observed, as compared to expected human exposures. (Specifically, are the available data from the same route of exposure as the expected human exposures? How many orders of magnitude do you need to extrapolate from the observed data to environmental exposures?)

A. LOAEL/NOAEL and Benchmark Dose (BMD) Determination

As indicated earlier, the LOAEL and NOAEL are determined for endpoints that are seen at the lowest dose level (so-called critical effect). Several limitations in the use of the NOAEL have been identified and described (e.g., Barnes and Dourson, 1988; Crump, 1984). For example, the NOAEL is derived from a single end point from a single study (the critical study) and

ignores both the slope of the dose-response function and baseline variability in the end point of concern. Because the baseline variability is not taken into account, the NOAEL from a study using small group sizes may be higher than the NOAEL from a similar study in the same species that uses larger group sizes. The NOAEL is also directly dependent on the dose spacing used in the study. Finally, and perhaps most importantly, use of the NOAEL does not allow estimates of risk or extrapolation of risk to lower dose levels.

Because of these and other limitations in the NOAEL approach, mathematical curve-fitting techniques (Crump, 1984; Gaylor and Slikker, 1990; Glowa, 1991; U.S. EPA, 1995a) are beginning to be used with, or as an alternative to, the NOAEL in calculating the RfD or RfC. The Agency is in the process of implementing these newer techniques and strongly encourages the calculation of BMDs for neurotoxicity and other health effect end points. These techniques typically apply a mathematical function that describes the dose-response relationship and then interpolate to a level of exposure associated with a small increase in effect over that occurring in the control group or under baseline conditions. The BMD has been defined as a lower confidence limit on the effective dose associated with some defined level of effect, e.g., a 5 percent or 10 percent increase in response (i.e., a BMD_{05} or BMD_{10} for a particular effect). Because the model is only used to interpolate within the dose range of the study, no assumptions about the existence (or nonexistence) of a threshold are needed. Thus, any model that fits the data well is likely to provide a reasonable estimate of the BMD.

Many neurotoxic end points provide continuous measures of response, such as response speed, nerve conduction velocity, IQ score, degree of enzyme inhibition, or the accuracy of task performance. Although it is possible to impose a dichotomy on a continuous effects distribution and to classify some level of response as ''affected'' and the remainder as ''unaffected,'' it may be very difficult and inappropriate to establish such clear distinctions, because such a dichotomy would misrepresent the true nature of the neurotoxic response. Alternatively, quantitative models designed to analyze continuous effect variables may be preferable. Other techniques that allow this approach, with transformation of the information into estimates of the incidence or frequency of affected individuals in a population, have been proposed (Crump, 1984; Gaylor and Slikker, 1990). Categorical regression analysis has been proposed since it can evaluate different types of data and derive estimates for short-term exposures (Rees and Hattis, 1994). Decisions about the most appropriate approach require professional judgment, taking into account the biological nature of the continuous effect variable and its distribution in the population under study.

Although dose-response functions in neurotoxicology are generally linear or monotonic, curvilinear functions, especially U-shaped or inverted U-shaped curves, have been reported as noted earlier (Section III B). Dose-response analyses should consider the uncertainty that U-shaped dose-response functions might contribute to the estimate of the NOAEL/LOAEL or BMD. Typically, estimates of the NOAEL/LOAEL are taken from the lowest part of the dose-response curve associated with impaired function or adverse effect.

B. Determination of the Reference Dose or Reference Concentration

Since the availability of dose-response data in humans is limited, extrapolation of data from animals to humans usually involves the application of uncertainty factors to the NOAEL/LOAEL or BMD. The NOAEL or BMD/uncertainty factor approach results in a RfD or RfC, which is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The oral RfD and inhalation RfC are applicable to chronic exposure situations and are based on an evaluation of all the noncancer health effects, including neurotoxicity data. RfDs and RfCs in the Integrated Risk Information System (IRIS–2) data base for several agents are based on neurotoxicity end points and include a few cases in which the RfD or RfC is calculated using the BMD approach (e.g., methylmercury, carbon disulfide). The size of the final uncertainty factor used will vary from agent to agent and will require the exercise of scientific judgment, taking into account interspecies differences, the shape of the dose-response curve, and the neurotoxicity end points observed. Default uncertainty factors are typically multiples of 10 and are used to compensate for human variability in sensitivity, the need to extrapolate from animals to humans, and the need to extrapolate from less than lifetime (e.g., subchronic) to lifetime exposures. An additional factor of up to 10 may be included when only a LOAEL (and not a NOAEL) is available from a study, or depending on the completeness of the data base, a modifying factor of up to 10 may be applied, depending on the confidence one has in the data base. Barnes and Dourson (1988) provide a more complete description of the calculation, use, and significance of RfDs in setting exposure limits to toxic agents by the oral route. Jarabek et al. (1990) provide a more complete description of the calculation, use, and significance of RfCs in setting exposure limits to toxic agents in air. Neurotoxicity can result from acute, shorter term exposures, and it may be appropriate in some cases, e.g., for air pollutants or water contaminants, to set shorter term exposure limits for neurotoxicity as well as for other noncancer health effects.

V. Exposure Assessment

Exposure assessment describes the magnitude, duration, frequency, and routes of exposure to the agent of interest. This information may come from hypothetical values, models, or actual experimental values, including ambient environmental sampling results. Guidelines for exposure assessment have been published separately (U.S. EPA, 1992) and will, therefore, be discussed only briefly here.

The exposure assessment should include an exposure characterization that:

a. Provides a statement of the purpose, scope, level of detail, and approach used in the exposure assessment;

b. Presents the estimates of exposure and dose by pathway and route for individuals, population segments, and populations in a manner appropriate for the intended risk characterization;

c. Provides an evaluation of the overall level of confidence in the estimate of exposure and dose and the conclusions drawn; and

d. Communicates the results of the exposure assessment to the risk assessor, who can then use the exposure characterization, along with the characterization of the other risk assessment elements, to develop a risk characterization.

A number of considerations are relevant to exposure assessment for neurotoxicants. An appropriate evaluation of exposure should consider the potential for exposure via ingestion, inhalation, and dermal penetration from relevant sources of exposures, including multiple avenues of intake from the same source. On-going Agency activities that support neurotoxicity exposure

assessment include characterizing cumulative risk and revising the Guidelines for the Health Risk Assessment of Chemical Mixtures.

In addition, neurotoxic effects may result from short-term (acute), high-concentration exposures as well as from longer term (subchronic), lower level exposures. Neurotoxic effects may occur after a period of time following initial exposure or be obfuscated by repair mechanisms or apparent tolerance. The type and severity of effect may depend significantly on the pattern of exposure rather than on the average dose over a long period of time. For this reason, exposure assessments for neurotoxicants may be much more complicated than those for long-latency effects such as carcinogenicity. It is rare for sufficient data to be available to construct such patterns of exposure or dose, and professional judgment may be necessary to evaluate exposure to neurotoxic agents.

VI. Risk Characterization

A. Overview

Risk characterization, the culmination of the risk assessment process, consists of an integrative analysis and a risk characterization summary. The integrative analysis (a) involves integration of the toxicity information from the hazard characterization and dose-response analysis with the human exposure estimates, (b) provides an evaluation of the overall quality of the assessment and the degree of confidence in the estimates of risk and conclusions drawn, and (c) describes risk in terms of the nature and extent of harm. The risk characterization summary communicates the results of the risk assessment to the risk manager.

This summary should include but is not limited to a discussion of the following elements:

a. Quality of and confidence in the available data;

b. Uncertainty analysis;

c. Justification of defaults or assumptions;

d. Related research recommendations;

e. Contentious issues and extent of scientific consensus;

f. Effect of reasonable alternative assumptions on conclusions and estimates;

g. Highlight reasonable plausible ranges;

h. Reasonable alternative models; and

i. Perspective through analogy.

The risk manager can then use the risk assessment, along with other risk management elements, to make public health decisions.

An effective risk characterization must fully, openly, and clearly characterize risks and disclose the scientific analyses, uncertainties, assumptions, and science policies that underlie decisions throughout the risk assessment and risk management processes. The risk characterization must feature values such as transparency in the decision-making process; clarity in communicating with each other and the public regarding environmental risk and the uncertainties associated with assessments of environmental risk; and consistency across program offices in core assumptions and science policies, which are well grounded in science and reasonable.

The following sections describe these four aspects of the risk characterization in more detail.

B. Integration of Hazard Characterization, Dose-Response Analysis and Exposure Assessment

In developing the hazard characterization, dose-response analysis and exposure portions of the risk assessment, the assessor must take into account many judgments concerning human relevance of the toxicity data, including the appropriateness of the various animal models for which data are available and the route, timing, and duration of exposure relative to expected human exposure. These judgments should be summarized at each stage of the risk assessment process (e.g., the biological relevance of anatomical variations may be established in the hazard characterization process, or the influence of species differences in metabolic patterns in the dose-response analysis). In integrating the information from the assessment, the risk assessor must determine if some of these judgments have implications for other portions of the assessment and whether the various components of the assessment are compatible.

The risk characterization should not only examine the judgments but also explain the constraints of available data and the state of knowledge about the phenomena studied in making them, including (1) the qualitative conclusions about the likelihood that the chemical may pose a specific hazard to human health, the nature of the observed effects, under what conditions (route, dose levels, time, and duration) of exposure these effects occur, and whether the health-related data are sufficient to use in a risk assessment; (2) a discussion of the dose-response characteristics of the critical effects(s), data such as the shapes and slopes of the dose-response curves for the various end points, the rationale behind the determination of the NOAEL and LOAEL and calculation of the benchmark dose, and the assumptions underlying the estimation of the RfD or RfC; and (3) the estimates of the magnitude of human exposure; the route, duration, and pattern of the exposure; relevant pharmacokinetics; and the number and characteristics of the population(s) exposed.

If data to be used in a risk characterization are from a route of exposure other than the expected human exposure, then pharmacokinetic data should be used, if available, to make extrapolations across routes of exposure. If such data are not available, the Agency makes certain assumptions concerning the amount of absorption likely or the applicability of the data from one route to another (U.S. EPA, 1992).

The level of confidence in the hazard characterization should be stated to the extent possible, including the appropriate category regarding sufficiency of the health-related data. A comprehensive risk assessment ideally includes information on a variety of end points that provide insight into the full spectrum of potential neurotoxicological responses. A profile that integrates both human and test species data and incorporates a broad range of potential adverse neurotoxic effects provides more confidence in a risk assessment for a given agent.

The ability to describe the nature of the potential human exposure is important to predict when certain outcomes can be anticipated and the likelihood of permanence or reversibility of the effect. An important part of this effort is a description of the nature of the exposed population and the potential for sensitive, highly susceptible, or highly exposed populations. For example, the consequences of exposure to the developing individual versus the adult can differ markedly and can influence whether the effects are transient or permanent. Other considerations relative to human exposures might include the likelihood of exposures to other agents, concurrent disease, and nutritional status.

The presentation of the integrated results of the assessment should draw from and highlight key points of the individual characterizations of component analyses performed under these Guidelines. The overall risk characterization represents the integration of these component characterizations. If relevant risk assessments on the agent or an analogous agent have been done by EPA or other Federal agencies, these should

be described and the similarities and differences discussed.

C. Quality of the Data Base and Degree of Confidence in the Assessment

The risk characterization should summarize the kinds of data brought together in the analysis and the reasoning on which the assessment is based. The description should convey the major strengths and weaknesses of the assessment that arise from availability of data and the current limits of our understanding of the mechanisms of toxicity.

Health risk is a function of the hazard characterization, dose-response analysis, and exposure assessment. Confidence in the results of a risk assessment is, thus, a function of confidence in the results of the analysis of these elements. Each of these elements should have its own characterization as a part of the assessment. Within each characterization, the important uncertainties of the analysis and interpretation of data should be explained, and the risk manager should be given a clear picture of consensus or lack of consensus that exists about significant aspects of the assessment. Whenever more than one view is supported by the data and choosing between them is difficult, all views should be presented. If one has been selected over the others, the rationale should be given; if not, then all should be presented as plausible alternative results.

D. Descriptors of Neurotoxicity Risk

There are a number of ways to describe risks. Several ways that are relevant to describing risks for neurotoxicity are as follows:

1. Estimation of the Number of Individuals

The RfD or RfC is taken to be a chronic exposure level at or below which no significant risk occurs. Therefore, presentation of the population in terms of those at or below the RfD or RfC (''not at risk'') and above the RfD or RfC (''may be at risk'') may be useful information for risk managers. This method is particularly useful to a risk manager considering possible actions to ameliorate risk for a population. If the number of persons in the at-risk category can be estimated, then the number of persons removed from the at-risk category after a contemplated action is taken can be used as an indication of the efficacy of the action.

2. Presentation of Specific Scenarios

Presenting specific scenarios in the form of ''what if?'' questions is particularly useful to give perspective to the risk manager, especially where criteria, tolerance limits, or media quality limits are being set. The question being asked in these cases is, at this proposed limit, what would be the resulting risk for neurotoxicity above the RfD or RfC?

3. Risk Characterization for Highly Exposed Individuals

This measure is one example of the just-discussed descriptor. This measure describes the magnitude of concern at the upper end of the exposure distribution. This allows risk managers to evaluate whether certain individuals are at disproportionately high or unacceptably high risk.

The objective of looking at the upper end of the exposure distribution is to derive a realistic estimate of a relatively highly exposed individual or individuals. This measure could be addressed by identifying a specified upper percentile of exposure in the population and/or by estimating the exposure of the highest exposed individual(s). Whenever possible, it is important to express the number of individuals who comprise the selected highly exposed group and discuss the potential for exposure at still higher levels.

If population data are absent, it will often be possible to describe a scenario representing high-end exposures using upper percentile or judgment-based values for exposure variables. In these instances caution should be used not to compound a substantial number of high-end values for variables if a ''reasonable'' exposure estimate is to be achieved.

4. Risk Characterization for Highly Sensitive or Susceptible Individuals

This measure identifies populations sensitive or susceptible to the effect of concern. Sensitive or susceptible individuals are those within the exposed population at increased risk of expressing the toxic effect. All stages of nervous system maturation might be considered highly sensitive or susceptible, but certain subpopulations can sometimes be identified because of critical periods for exposure, for example, pregnant or lactating women, infants, children.

In general, not enough is understood about the mechanisms of toxicity to identify sensitive subgroups for all agents, although factors such as nutrition, personal habits (e.g., smoking, alcohol consumption, illicit drug abuse), or preexisting disease (e.g., diabetes, sexually transmitted diseases) may predispose some individuals to be more sensitive to the neurotoxic effects of various agents.

5. Other Risk Descriptors

In risk characterization, dose-response information and the human exposure estimates may be combined either by comparing the RfD or RfC and the human exposure estimate or by calculating the margin of exposure (MOE). The MOE is the ratio of the NOAEL from the most appropriate or sensitive species to the estimated human exposure level. If a NOAEL is not available, a LOAEL may be used in calculating the MOE. Alternatively, a benchmark dose may be compared with the estimated human exposure level to obtain the MOE. Considerations for the evaluation of the MOE are similar to those for the uncertainty factor applied to the LOAEL/NOAEL or the benchmark dose. The MOE is presented along with a discussion of the adequacy of the data base, including the nature and quality of the hazard and exposure data, the number of species affected, and the dose-response information.

The RfD or RfC comparison with the human exposure estimate and the calculation of the MOE are conceptually similar but are used in different regulatory situations. The choice of approach depends on several factors, including the statute involved, the situation being addressed, the data base used, and the needs of the decision maker. The RfD or RfC and the MOE are considered along with other risk assessment and risk management issues in making risk management decisions, but the scientific issues that must be taken into account in establishing them have been addressed here.

If the MOE is equal to or more than the uncertainty factor × any modifying factor used as a basis for an RfD or RfC, then the need for regulatory concern is likely to be small. Although these methods of describing risk do not actually estimate risks per se, they give the risk manager some sense of how close the exposures are to levels of concern.

E. Communicating Results

Once the risk characterization is completed, the focus turns to communicating results to the risk manager. The risk manager uses the results of the risk characterization along with other technological, social, and economic considerations in reaching a regulatory decision. Because of the way in which these risk management factors

may affect different cases, consistent but not necessarily identical risk management decisions must be made on a case-by-case basis. These Guidelines are not intended to give guidance on the nonscientific aspects of risk management decisions.

F. Summary and Research Needs

These Guidelines summarize the procedures that the U.S. Environmental Protection Agency would use in evaluating the potential for agents to cause neurotoxicity. These Guidelines discuss the general default assumptions that should be made in risk assessment for neurotoxicity because of gaps in our knowledge about underlying biological processes and how these compare across species. Research to improve the risk assessment process is needed in a number of areas. For example, research is needed to delineate the mechanisms of neurotoxicity and pathogenesis, provide comparative pharmacokinetic data, examine the validity of short-term in vivo and in vitro tests, elucidate the functional modalities that may be altered, develop improved animal models to examine the neurotoxic effects of exposure during the premating and early postmating periods and in neonates, further evaluate the relationship between maternal and developmental toxicity, provide insight into the concept of threshold, develop approaches for improved mathematical modeling of neurotoxic effects, improve animal models for examining the effects of agents given by various routes of exposure, and address the synergistic or antagonistic effects of mixtures of chemicals and neurotoxic response. Such research will aid in the evaluation and interpretation of data on neurotoxicity and should provide methods to assess risk more precisely.

VII. References

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federal register

Wednesday
October 4, 1995

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 330

Labeling of Drug Products for Over-the-Counter Human Use; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 330

[Docket No. 92N–0454]

RIN 0905–AA06

Labeling of Drug Products for Over-the-Counter Human Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is modifying a proposed rule that proposed to amend the general labeling policy for over-the-counter (OTC) drug products to allow for interchangeable use of the terms ''Drug interaction precaution,'' ''Avoid mixing drugs,'' or ''Do not mix drugs'' in labeling required by an OTC drug monograph. This modification provides for one additional alternative term, ''Do not use with * * *.''

DATES: Written comments by January 2, 1996; written comments on the agency's economic impact determination by January 2, 1996. The agency is proposing that any final rule that may issue based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD–810), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5000.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 3, 1994 (59 FR 39499), the agency proposed to amend its general labeling policy for OTC drug products to allow for the interchangeable use of the terms ''Drug interaction precaution'' or ''Avoid mixing drugs'' or ''Do not mix drugs.'' The agency stated its belief that the phrase ''Avoid mixing drugs'' or ''Do not mix drugs'' may be better understood by consumers than ''Drug interaction precaution.'' The agency specifically invited comments on whether the terms ''Avoid mixing drugs'' or ''Do not mix drugs'' could be used interchangeably with the term ''Drug interaction precaution.'' Further, the agency requested comments on whether it would be desirable to change negatively worded warnings to more positive phraseology (e.g., ''Do not use more than 7 days'' to ''Use only 7 days''). The agency also asked for comment concerning the desirability of identical warning language for similar OTC drug products.

The agency received a number of comments in response to the proposed rule. Those comments are being evaluated. The agency is modifying the proposal to include another alternative term and reopening the administrative record to allow for comments on this alternative term.

II. The Additional Term

The agency believes that there may be a simpler way to alert consumers to this type of information. The agency is proposing an additional term, ''Do not use with * * *,'' as an alternative to the proposed interchangeable terms. For example, the current drug interaction precaution in § 341.76(c)(4) (21 CFR 341.76(c)(4)) begins with the words ''Do not use this product * * * '' following the words ''*Drug interaction precaution*.'' If this new approach were used, the words ''Drug interaction precaution'' would no longer be needed and the precaution would begin with ''*Do not use with*'' and could be followed by ''a prescription drug for * * *.'' This approach would shorten the required labeling without changing the meaning. The agency would like comment on this approach and whether this term would be desirable for all OTC drug product labeling.

III. Analysis of Impacts

The economic impact and the environmental impact statements remain the same as stated in the proposed rule (59 FR 39499 at 39500).

Interested persons may, on or before January 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this amended proposal. Written comments on the agency's economic impact determination may be submitted on or before January 2, 1996. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 330

Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 330 be amended as follows:

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND EFFECTIVE AND NOT MISBRANDED

1. The authority citation for 21 CFR part 330 continues to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. Section 330.1 is amended by redesignating paragraphs (i)(7), (i)(8), and (i)(9) as paragraphs (i)(8), (i)(9), and (i)(10), respectively, and by adding new paragraph (i)(7) to read as follows:

§ 330.1 General conditions for general recognition as safe, effective and not misbranded.

* * * * *

(i) * * *

(7) ''Drug interaction precaution'' or ''Avoid mixing drugs'' or ''Do not mix drugs'' or ''Do not use with * * *''.

* * * * *

Dated: September 25, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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federal register

Wednesday
October 4, 1995

Part IV

The President

Memorandum of September 29, 1995

Federal Register
Vol. 60, No. 192
Wednesday, October 4, 1995

Presidential Documents

Title 3—

The President

Memorandum of September 29, 1995

Delegation of Authority Under Section 103(a) of the North American Free Trade Agreement Implementation Act and Section 115 of the Uruguay Round Agreements Act

Memorandum for the United States Trade Representative

By virtue of the authority vested in me as President by the Constitution and laws of the United States, including section 301 of title 3 of the United States Code, you are hereby delegated the authority set forth in section 103(a) of the North American Free Trade Agreement Implementation Act (''NAFTA Act'') and section 115 of the Uruguay Round Agreements Act (''Uruguay Round Act'') to perform certain functions in order to fulfill the consultation and layover requirements set forth in those provisions, including:

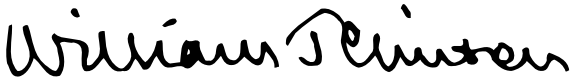
(1) obtaining advice from the appropriate advisory committees and the U.S. International Trade Commission on the proposed implementation of an action by Presidential proclamation;

(2) submitting a report on such action to the House Ways and Means and Senate Finance Committees; and

(3) consulting with such committees during the 60-day period following the date on which the requirements under (1) and (2) have been met.

The President retains the sole authority under the NAFTA Act and Uruguay Round Act to implement an action by proclamation after the consultation and layover requirements set forth in section 103(a)(1) through (4) and section 115 of such Acts, respectively, have been met.

You are authorized and directed to publish this memorandum in the Federal Register.



THE WHITE HOUSE,
Washington, September 29, 1995.

[FR Doc. 95–24863
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H.R. 2399/P.L. 104–29

Truth in Lending Act Amendments of 1995. (Sept. 30, 1995; 109 Stat. 271; 6 pages)

H.R. 2404/P.L. 104–30

To extend authorities under the Middle East Peace Facilitation Act of 1994 until November 1, 1995, and for other purposes. (Sept. 30, 1995; 109 Stat. 277; 1 page)

H.J. Res. 108/P.L. 104–31

Making continuing appropriations for the fiscal year 1996, and for other purposes. (Sept. 30, 1995; 109 Stat. 278; 5 pages)

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