

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

#### 7 CFR Part 905

[Docket No. FV02-905-1C]

#### Oranges, Grapefruit, Tangerines, and Tangelos Grown in Florida; Continuance Referendum; Correction

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Referendum order; correction.

**SUMMARY:** The Agricultural Marketing Service published in the **Federal Register** on March 14, 2002, a Referendum Order to conduct a continuance referendum for marketing agreement and order 905. This document corrects the ballot postmark deadline date, changing it from May 6, 2002 to April 26, 2002 in the **SUPPLEMENTARY INFORMATION** section of the Notice.

**FOR FURTHER INFORMATION CONTACT:** Melissa Schmaedick, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs; Agricultural Marketing Service, Department of Agriculture, 1400 Independence Avenue, SW STOP 0237, Washington, DC 20250-0237; telephone: (202) 720-2491, or Fax: (202) 720-8938.

#### SUPPLEMENTARY INFORMATION:

##### Background

The referendum order that is the subject of this correction provides that a referendum be conducted among eligible producers of Florida citrus to determine whether they favor continuance of the marketing order regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in the production area.

##### Need for Correction

As published, the ballot postmark deadline date in the **SUPPLEMENTARY INFORMATION** section is incorrect. The ballot postmark deadline date needs to

be changed from May 6, 2002 to April 26, the ending date of the referendum period.

#### Correction of Publication

The publication of the referendum order (Docket No. FV02-905-1), which was the subject of FR Doc. 02-6108 published on March 14, 2002 (67 FR 11450) is corrected as follows:

On page 11450, column two, under **SUPPLEMENTARY INFORMATION**, the date "May 6, 2002" for ballots to be postmarked by is corrected to read "April 26, 2002."

Authority:  
7 U.S.C. 601-674.

Dated: March 27, 2002.

**A.J. Yates,**  
*Administrator, Agricultural Marketing Service.*

[FR Doc. 02-7905 Filed 3-28-02; 12:04 pm]

**BILLING CODE 3410-02-P**

## DEPARTMENT OF ENERGY

### Office of Security

#### 10 CFR Part 824

[Docket No. SO-RM-00-01]

RIN 1992-AA28

#### Procedural Rules for the Assessment of Civil Penalties for Classified Information Security Violations

**AGENCY:** Office of Security, Department of Energy.

**ACTION:** Notice of proposed rulemaking and public hearing.

**SUMMARY:** The Department of Energy (DOE) proposes regulations to implement section 234B of the Atomic Energy Act of 1954 (Section 234B) which was added to that act by section 3147 of the National Defense Authorization Act for Fiscal Year 2000. Section 234B subjects contractors and others working for DOE to civil penalties for violations of DOE rules, regulations and orders regarding the safeguarding and security of Restricted Data and other classified information.

**DATES:** Written comments (7 copies) may be submitted by July 1, 2002. Public hearings will be held in Las Vegas, Nevada on May 22, 2002, and in Washington, DC on May 29, 2002. Requests to speak at the Las Vegas

hearing must be submitted on or before May 15, 2002, or at the Washington, DC hearing on or before May 22, 2002.

**ADDRESSES:** Comments should be addressed to: GERALYN C. PRASKIEVICZ, Office of Security, SO-1, Docket No. SO-RM-00-01, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, (202) 586-4451.

The following two public hearings will be held: May 22, 2002, from 9:30 a.m. until 12:30 p.m. at the U.S. Department of Energy, National Nuclear Security Administration, Nevada Operations Office, 232 Energy Way, Las Vegas, Nevada, room A107, and May 29, 2002, from 9:30 a.m. until 12:30 p.m., at the U.S. Department of Energy, James Forrestal Building, 1000 Independence Avenue SW, Washington, DC, room GE-086.

The envelope and written comments should indicate the above docket number. Written comments and hearing testimony may be examined between 9 a.m. and 4 p.m., Monday through Friday at: U.S. Department of Energy, Freedom of Information Reading Room, room 1E-190, Docket No. SO-RM-00-01, 1000 Independence Avenue S.W., Washington, D.C. 20585, (202) 586-3142.

#### FOR FURTHER INFORMATION CONTACT:

GERALYN PRASKIEVICZ, Office of Security, SO-1, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, (202) 586-4451; Jo Ann Williams, Office of General Counsel, GC-53, U.S. Department of Energy, 1000 Independence Ave. SW., Washington, DC 20585, (202) 586-6899.

#### SUPPLEMENTARY INFORMATION:

- I. Introduction.
- II. Procedural Requirements.
  - A. Review Under Executive Order 12866.
  - B. Review Under the Regulatory Flexibility Act.
  - C. Review Under the Paperwork Reduction Act.
  - D. Review Under the National Environmental Policy Act.
  - E. Review Under Executive Order 12988.
  - F. Review Under Executive Order 13132.
  - G. Review Under the Treasury and General Appropriations Act, 1999.
  - H. Review under Executive Order 13084.
- III. Public Comment Procedures.
  - A. Written Comments.
  - B. Public Hearings.

#### I. Introduction.

On October 5, 1999, Congress enacted section 3147 of the National Defense

Authorization Act for Fiscal Year 2000 (Pub.L. 106–65, October 5, 1999) that adds a new section 234B to the Atomic Energy Act of 1954, 42 U.S.C. 2282b. Subsection a. of section 234B provides that any person who: (1) Has entered into a contract or agreement with DOE, or a subcontract or subagreement thereto, and (2) violates (or whose employee violates) any applicable rule, regulation, or order prescribed or otherwise issued by the Secretary of Energy pursuant to the Atomic Energy Act relating to the safeguarding or security of Restricted Data or other classified or “sensitive information,” shall be subject to a civil penalty not to exceed \$100,000 for each such violation. Subsection b. of section 234B requires that each DOE contract contain provisions which provide an appropriate reduction in the fees or amounts paid to the contractor under the contract in the event of a violation by the contractor or contractor employee of any rule, regulation or order relating to the safeguarding or security of Restricted Data or other classified or sensitive information.

On February 1, 2001, DOE published a Notice of Proposed Rulemaking (66 FR 8560) to implement subsection b. of section 234B, concerning reductions in fees or amounts paid to contractors in the event of a security violation. DOE received numerous comments in response to that notice of proposed rulemaking. Some of the commenters assumed that the procurement rulemaking was intended to address all of the provisions in section 234B. Two separate rulemakings, one establishing procedural rules similar to the procedural rules to achieve compliance with DOE nuclear safety requirements found at 10 CFR Part 820 and the other establishing a procurement clause like Conditional payment of fee, profit or incentives, 48 CFR (DEAR) 970.5204–86, were always contemplated and deemed necessary by DOE. The February 1, 2001, notice of proposed rulemaking was only intended to address subsection b. of 234B.

DOE in this rulemaking proposes to establish a new Part 824 to Chapter III of Title 10 of the Code of Federal Regulations (CFR) to implement all subsections of section 234B of the Atomic Energy Act, except subsection b., with respect to contractors of DOE, including those of the National Nuclear Security Administration (NNSA). To a large extent these proposed regulations are self-explanatory. There are, however, several features that require explanation.

In this rulemaking action, DOE proposes applying civil penalties only

to violations of requirements for the protection of classified information. Classified information is “Restricted Data” or “Formerly Restricted Data” protected against unauthorized disclosure pursuant to the Atomic Energy Act of 1954, and “National Security Information” protected against unauthorized disclosure pursuant to Executive Order 12958 (April 17, 1995) or any predecessor or successor order. Although section 234B refers to “sensitive information,” DOE does not employ this term in the proposal because: (1) Neither the statute nor its legislative history defines the term; (2) there is no commonly accepted definition of “sensitive information” within DOE or the Executive Branch; (3) the legislative history indicates that the Congress was concerned with unauthorized disclosures of classified information; and (4) the only category of unclassified information that might merit inclusion in a regulation imposing civil penalties is Unclassified Controlled Nuclear Information (UCNI), a category of unclassified government information concerning atomic energy defense programs established by section 148 of the Atomic Energy Act of 1954 (42 U.S.C. 2168). Section 148 provides that any person who violates a regulation or order issued under that section shall be subject to a civil penalty not to exceed \$100,000. DOE implemented the provisions of section 148 in regulations contained in 10 CFR Part 1017. Since Part 1017 already imposes a civil monetary penalty for unauthorized dissemination of UCNI comparable to the penalty specified in section 3147, we determined that it is unnecessary to include UCNI in regulations implementing section 3147.

DOE proposes to assess civil penalties only for violations described in proposed section 824.4. These are violations of: (1) Specified DOE regulations related to classified information security presently in the CFR, (2) any other DOE rule, regulation or order relating to the safeguarding or security of Restricted Data or other classified information that specifically indicates that violation of its provisions may result in a civil penalty pursuant to section 234B, and (3) compliance orders issued pursuant to proposed part 824.

With respect to compliance orders, section 161 of the Atomic Energy Act grants DOE broad authority to prescribe regulations and orders deemed necessary to protect the common defense and security, 42 U.S.C. 2201. Pursuant to this authority, the Secretary may issue a compliance order requiring a person to take corrective action if a person by act or omission jeopardizes

the security of classified information even if that person has not violated a regulation listed in the proposed part. Violation of the compliance order may result in the assessment of a civil penalty. Compliance orders would not be subject to the DOE Acquisition Regulations or require any authorization by a contracting officer. While the recipient of a compliance order may request the Secretary to rescind or modify the compliance order, the request does not stay the effectiveness of the order unless the Secretary issues a new order to that effect. The compliance order provisions of today’s proposed regulations are modeled after a similar mechanism in 10 CFR Part 820, the regulations implementing procedures for section 234A of the Atomic Energy Act of 1954 with respect to nuclear safety.

It is important to note that this proposed rule would only apply to contractors and others who have entered into agreements or subagreements with DOE. Subsection a. of section 234B clearly provides that the contractor or other entity that has entered into an agreement or subagreements thereto with DOE is liable for violations of its employees. Consequently, no civil penalties would be assessed against individual employees under Part 824 as proposed.

Subsection d. of section 234B sets limitations on civil penalties assessed against certain non-profit entities specified at subsection d. of section 234A. As to each of these seven named entities working at named sites, the statute provides that no civil penalty may be assessed until the entity enters into a new contract with DOE or an extension of a current contract with DOE. The statute also limits the total amount of civil penalties assessed against these entities in any fiscal year to the total amount of fees paid to that entity in that fiscal year. It should be noted that the limitations applicable to these seven entities at the named sites also apply to their subcontractors and suppliers regardless of whether they are for-profit or non-profit.

DOE has determined as a matter of discretion under section 234B.c. and section 234A.b.(2) to extend the cap on civil penalties assessed on non-profits provided in section 234B.d.(2) to any non-profit educational institution under the United States Internal Revenue Code. DOE exercised similar discretionary authority for educational non-profit institutions in Part 820 with respect to automatic remission from civil penalties for nuclear safety violations. DOE continues to believe these other non-profit entities should

receive uniform treatment concerning civil penalties. However, the for-profit subcontractors and suppliers of these other non-profits would not have their civil penalties limited to fee as in the case of the for-profit subcontractors and for-profit suppliers of the seven named entities at sites named in section 234A. Also, as a matter of discretion, these other non-profit entities would not be subject to civil penalties until they enter into a new contract with DOE or an extension of a current contract.

The fee that represents the cap for civil penalties of non-profits will be determined pursuant to the provisions of the specific contracts covered by the limitation on non-profits.

## II. Procedural Requirements

### A. Review Under Executive Order 12866

Today's regulatory action has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, today's action is not subject to review under the Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

### B. Review Under the Regulatory Flexibility Act

These proposed rules were reviewed under the Regulatory Flexibility Act of 1980, Pub. L. 96-354, which requires preparation of an initial regulatory flexibility analysis for any rule that is likely to have significant economic impact on a substantial number of small entities. This rulemaking will apply principally to large entities who are management and operating contractors with cost reimbursement contracts. Therefore, DOE certifies that this regulation will not have a significant economic impact on a substantial number of small entities and, therefore, no regulatory flexibility analysis has been prepared.

### C. Review Under the Paperwork Reduction Act

The proposed information and reporting requirements are not substantially different from existing reporting requirements contained in DOE contracts with the Department's prime contractors covered by these rules. DOE will submit any new information collection requests concerning these proposed rules to the Office of Management and Budget for approval in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. 3501.1 *et seq.*, and the

procedures implementing that Act, 5 CFR Part 1320.

### D. Review Under the National Environmental Policy Act

DOE has reviewed the promulgation of this proposed rule with respect to its responsibilities under the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*) and the Council on Environmental Quality regulations for implementing NEPA (40 CFR Parts 1500-1508). The proposed rulemaking specifies procedures and standards for DOE enforcement actions under section 3147 of the Defense Authorization Act for Fiscal Year 2000. As noted in the CEQ regulations, major Federal actions "do not include bringing judicial or administrative civil or criminal enforcement actions" (40 CFR 1508.18(a)). Therefore, DOE has concluded that the proposed rulemaking is not a major Federal action with significant effects on the human environment within the meaning of NEPA and that no further review under NEPA is required.

### E. Review Under Executive Order 12988

With respect to the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996) imposes on Executive agencies the general duty to: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and to promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that a regulation: (1) Clearly specifies its preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies its retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of the applicable standards in section 3(a) and 3(b) to determine whether they are met or if it is unreasonable to meet one or more of them. The DOE has completed the required reviews and has determined that, to the extent allowed by law, the proposed regulations meet

the relevant standards of Executive Order 12988.

### F. Review Under Executive Order 13132

Executive Order 13132 (64 FR 43255, August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined today's proposed rule and has determined that it does not preempt State law and does 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. No further action is required by Executive Order 13132.

### G. Review Under Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105-277) requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family well-being. Today's proposal would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a family policymaking assessment.

### H. Review Under Executive Order 13084

Under Executive Order 13084 (Consultation and Coordination with Indian Tribal Governments), DOE may not issue a discretionary rule that significantly or uniquely affects Indian tribal governments and imposes substantial direct compliance costs. This proposed rulemaking would not have such effects. Accordingly, Executive Order 13084 does not apply to this rulemaking.

## III. Public Comment Procedures

### A. Written Comments

Interested persons are invited to participate by submitting data, views, or arguments with respect to the proposed rule set forth in this notice. Seven copies of written comments should be submitted to the address indicated in the **ADDRESSES** section of this notice. All comments will be available for public inspection in the DOE Freedom of Information Reading Room, room 1E-190, 1000 Independence Avenue, SW., Washington, DC 20585, between the

hours of 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays. Written comments received by the date indicated in the **DATES** section of this notice of proposed rulemaking will be assessed and considered prior to publication of the final rule. Any information that a commenter considers to be confidential must be so identified and submitted in writing, one copy only. DOE reserves the right to determine the appropriateness of confidential status for the information and to treat it in accordance with its determination. See 10 CFR Part 1004.11.

DOE is interested in comments concerning the potential costs and benefits of this regulation, either to the general public, the Department's contractors, or the Department itself.

#### *B. Public Hearing.*

Requests to speak at the hearings must be submitted to the address and by the date indicated in the **DATES** section of this notice of proposed rule making. Requests for oral presentations should contain a telephone number where the requester may be contacted prior to the hearing. Speakers are requested to submit seven copies of their statement to DOE at the hearings.

DOE reserves the right to select the persons to be heard at the hearings, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearings. The length of each presentation is limited to fifteen minutes. The hearings will begin at 9:30 a.m. A DOE official will be designated to preside at each hearing. These will not be judicial-type hearings. Questions may be asked only by those conducting the hearing. Any further procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer. A transcript of the hearing will be made available to the public. The entire record of each hearing, including the transcript, will be retained by DOE and made available for inspection in the DOE Freedom of Information Reading Room. Transcripts may be purchased from the hearing transcriber/reporter.

#### **List of Subjects in 10 CFR Part 824**

Classified information, Government contracts, Nuclear security, Penalties, Security measures.

Issued in Washington, DC on March 19, 2002.

**Spencer Abraham,**  
*Secretary of Energy.*

For the reasons set forth in the preamble, DOE proposes to amend Chapter III of Title 10 of the Code of

Federal Regulations by adding a new part 824 as set forth below.

### **PART 824—PROCEDURAL RULES FOR THE ASSESSMENT OF CIVIL PENALTIES FOR CLASSIFIED INFORMATION SECURITY VIOLATIONS**

Sec.

- 824.1 Purpose and scope.
- 824.2 Applicability.
- 824.3 Definitions.
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- 824.12 Initial decision.
- 824.13 Final order.
- 824.14 Special procedures.
- 824.15 Collection of civil fines.

**Authority:** 42 U.S.C. 2201, 2282b, 7101 *et seq.*, 50 U.S.C. 2401 *et seq.*

### **PART 824—PROCEDURAL RULES FOR THE ASSESSMENT OF CIVIL PENALTIES FOR CLASSIFIED INFORMATION SECURITY VIOLATIONS**

#### **§ 824.1 Purpose and scope.**

This part implements subsections a., c., and d. of section 234B of the Atomic Energy Act of 1954, 42 U.S.C. 2282b, which provides that any person who has entered into a contract or agreement with the Department of Energy (DOE), or a subcontract or subagreement thereto, and violates (or whose employee violates) any applicable rule, regulation or order under the Atomic Energy Act relating to the security or safeguarding of Restricted Data or other classified information, shall be subject to a civil penalty not to exceed \$100,000 for each violation. Specifically, these regulations establish procedures for assessing civil penalties against any entity that violates DOE regulations which impose requirements for the protection of classified information or that violates a compliance order issued under this part.

#### **§ 824.2 Applicability.**

(a) *General.* These regulations apply to any entity that is subject to DOE security requirements for the protection of classified information.

(b) *Limitations.* In the case of the following entities, DOE may not assess any civil penalty against the entity until it enters into a new contract with DOE or an extension of a current contract with DOE, and the total amount of civil penalties may not exceed the total amount of fees paid by the DOE to that entity in that fiscal year:

(1) Entities (including subcontractors and suppliers thereto) specified at subsection d. of section 234A of the Atomic Energy Act of 1954; and

(2) Any nonprofit educational institution under the United States Internal Revenue Code.

(c) *Individual employees.* No civil penalty may be assessed against an individual employee of a contractor or any other entity which enters into an agreement with DOE.

#### **§ 824.3 Definitions.**

(a) As used in this part:

(1) *Act* means the Atomic Energy Act of 1954 (42 U.S.C. 2011 *et seq.*)

(2) *Classified information* means Restricted Data and Formerly Restricted Data protected against unauthorized disclosure pursuant to the Act and National Security Information protected against unauthorized disclosure under Executive Order 12958 (April 17, 1995) or any predecessor or successor executive order.

(3) *Contractor* means any person under contract or other agreement (including suppliers and access permittees) with the Department of Energy, including the National Nuclear Security Administration (NNSA), or a subcontract or subagreement thereto, to perform activities or to supply services or products that are subject to DOE security requirements.

(4) *Deputy Secretary* means the Deputy Secretary of Energy.

(5) *Director* means the Director, Office of Security, or any person to whom the Director's authority under this part is re-delegated.

(6) *Person* means any person as defined in section 11.s. of the Atomic Energy Act, 42 U.S.C. 2014, or any affiliate or parent corporation thereof, who enters into a contract or agreement with the Department of Energy, including a subcontract or subagreement thereto.

(7) *Secretary* means the Secretary of Energy.

(b) Words in the singular also include the plural and words in the masculine gender also include the feminine and vice versa, as the case may require.

#### **§ 824.4 Civil penalties.**

(a) Any person who violates a requirement of any of the following is subject to a civil penalty under this part:

(1) 10 CFR Part 1016—Safeguarding of Restricted Data;

(2) 10 CFR Part 1045—Nuclear Classification and Declassification;

(3) 10 CFR Part 1046—Physical Protection of Security Interests; and

(4) Any other DOE rule, regulation or order related to the safeguarding or

security of classified information that specifically indicates that violation of its provisions may result in a civil penalty pursuant to subsection a. of section 234B of the Act.

(b) If, without violating any regulation listed in paragraph (a) of this section, a person by an act or omission jeopardizes the security of classified information, the Secretary may issue a compliance order to that person requiring the person to take corrective action and notifying the person that violation of the compliance order is subject to a notice of violation and assessment of a civil penalty. If a person wishes to contest the compliance order, the person must file a notice of appeal with the Secretary within 15 days of receipt of the compliance order.

(c) The Deputy Secretary, based on a recommendation from the Director, may propose imposition of a civil penalty for violation of a requirement of a rule, regulation or order listed in paragraph (a) of this section or a compliance order issued under paragraph (b) of this section, not to exceed \$100,000 for each violation.

(d) If any violation is a continuing one, each day of such violation shall constitute a separate violation for the purpose of computing the applicable civil penalty.

#### **§ 824.5 Notice of violation.**

(a) In order to begin a proceeding to impose a civil penalty under this part, the Deputy Secretary, based upon a recommendation of the Director, shall notify the person by a written notice of violation sent by certified mail, return receipt requested, of—

(1) The date, facts, and nature of each act or omission with which the person is charged;

(2) The particular provision of the regulation involved in the violation;

(3) Each penalty which the Deputy Secretary proposes to impose and the amount;

(4) The right of the person to submit a written reply to each of the allegations in the notification letter to the Director within 30 calendar days of receipt of such a notice of violation; and,

(5) The right of the person to submit to the Director a written request for a hearing under § 824.7 or, in the alternative, to elect the procedures specified in 42 U.S.C. 2282a.(c)(3).

(b) Within ten days of receiving a reply or a hearing request letter, the Director shall acknowledge its receipt in writing. In the case of a hearing request letter, the acknowledgment from the Director shall provide information regarding scheduling of the hearing.

(c) The Director, at the request of a person accused of a violation, may extend for a reasonable period the time for submitting a reply or a hearing request letter.

(d) After notifying a person of a violation under paragraph (a) of this section, the Deputy Secretary, based upon the recommendation of the Director, may enter into a settlement regarding the violation with or without conditions.

(e) If a person fails to submit a written request for a hearing within the specified time period, the person relinquishes the right to a hearing. If the person does not request a hearing, the notice of violation including proposed civil penalties shall constitute the final order of DOE.

#### **§ 824.6 Investigations**

The Director, at the request of the Deputy Secretary, may conduct investigations and inspections relating to the scope, nature and extent of compliance by a person with DOE security requirements specified in § 824.4 (a) and (b) and take such action as he deems necessary and appropriate to the conduct of the investigation or inspection, including issuing and serving subpoenas signed by the Deputy Secretary.

#### **§ 824.7 Hearing.**

Any person who receives a notification letter under § 824.5 may request a hearing to answer under oath or affirmation the allegations contained in the letter. The person shall mail or deliver any letter requesting a hearing to the Director within 30 calendar days of receipt of the notification letter. Upon receipt from a person of a written request for a hearing, the Deputy Secretary shall appoint a Hearing Counsel and select an administrative law judge appointed under section 3105 of Title 5, U.S.C., to serve as Hearing Officer.

#### **§ 824.8 Hearing Counsel.**

The Hearing Counsel—

(a) Represents DOE;

(b) Consults with the person or the person's counsel prior to the hearing;

(c) Examines and cross-examines witnesses during the hearing; and

(d) Enters into a settlement of the enforcement proceeding at any time if settlement is consistent with the objectives of the Atomic Energy Act and DOE security requirements.

#### **§ 824.9 Hearing Officer.**

The Hearing Officer—

(a) Administers oaths and affirmations;

(b) Issues subpoenas;

(c) Rules on offers of proof and receives relevant evidence;

(d) Takes depositions or has depositions taken when the ends of justice would serve;

(e) Conducts the hearing in a manner which is fair and impartial;

(f) Holds conferences for the settlement or simplification of the issues by consent of the parties;

(g) Disposes of procedural requests or similar matters;

(h) Makes an initial decision under § 824.12; and

(i) Requires production of documents.

#### **§ 824.10 Rights of the person at the hearing.**

The person may—

(a) Testify or present evidence through witnesses or by documents;

(b) Cross-examine witnesses and rebut records or other physical evidence, except as provided in § 824.11(d);

(c) Be present during the entire hearing, except as provided in § 824.11(d); and

(d) Be accompanied, represented and advised by counsel of the person's choosing.

#### **§ 824.11 Conduct of the hearing.**

(a) DOE shall make a transcript of the hearing;

(b) Except as provided in paragraph (d) of this section, the Hearing Officer may receive any oral or documentary evidence, but shall exclude irrelevant, immaterial or unduly repetitious evidence;

(c) Witnesses shall testify under oath and are subject to cross-examination, except as provided in paragraph (d) of this section;

(d) The Hearing Officer must use procedures appropriate to safeguard and prevent disclosure of classified information or Unclassified Controlled Nuclear Information to unauthorized persons, with minimum impairment of rights and obligations under this part; and

(e) DOE bears the burden of proving, by a preponderance of the evidence, that a violation has occurred.

#### **§ 824.12 Initial decision.**

(a) The Hearing Officer shall issue an initial decision as soon as practicable after the hearing. The initial decision shall contain findings of fact, conclusions regarding all material issues of law or discretion, as well as reasons therefor. If the Hearing Officer determines that a violation has occurred and that a civil penalty is appropriate, the initial decision shall set forth the amount of the civil penalty based on:

(1) The nature, circumstances, extent, and gravity of the violation or violations;

(2) The violator's ability to pay;

(3) Its effect on the person's ability to do business;

(4) Any history of prior violations;

(5) The degree of culpability; and

(6) Such other matters as justice may require.

(b) The Hearing Officer shall serve all parties with the initial decision by certified mail, return receipt requested. The initial decision shall include notice that it constitutes a final order of DOE, unless within 15 days of receipt of notification a request for review by the Secretary is filed with the Director.

#### **§ 824.13 Final order.**

(a) Upon receipt of a request for review of the initial decision, the Director shall forward the request, along with the entire record, to the Secretary.

(b) The Secretary shall issue a final order as soon as practicable after completing his review. The Secretary may, at his discretion, order additional proceedings, remand the matter or modify the amount of the civil fines assessed in the initial determination. The person shall be notified of the Secretary's final order in writing by certified mail, return receipt requested.

#### **§ 824.14 Special procedures.**

A person receiving a notice of violation under § 824.5 may elect in writing within 30 days of receipt of such notice, the application of special procedures regarding payment of the penalty that are set forth in section 234A.c.(3) of the Atomic Energy Act, 42 U.S.C. 2282a.c.(3). The Deputy Secretary, based upon a recommendation of the Director, shall promptly assess a civil penalty, by order, after the date of such election. If the civil penalty has not been paid within sixty calendar days after the assessment has been issued, the Deputy Secretary shall institute an action in the appropriate district court of the United States for an order affirming the assessment of the civil penalty.

#### **§ 824.15 Collection of civil fines.**

If any person fails to pay an assessment of a civil penalty after it has become a final order or after the appropriate district court has entered final judgment for DOE under § 824.14, the Deputy Secretary shall institute an action to recover the amount of such penalty in an appropriate district court of the United States. In such action, the validity and appropriateness of such

final order or judgment shall not be subject to review.

[FR Doc. 02-7764 Filed 3-29-02; 8:45 am]

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **21 CFR Part 212**

[Docket No. 99N-4063]

#### **Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Preliminary Draft Proposed Rule; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability of preliminary draft proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a preliminary draft proposed rule on current good manufacturing practice (CGMP) for positron emission tomography (PET) drug products. We are developing CGMP regulations for PET drug products in accordance with the Food and Drug Administration Modernization Act of 1997 (Modernization Act). We are making a preliminary draft of a proposed rule available to allow full discussion of its contents at an upcoming public meeting on CGMP requirements for PET drug products. We are announcing the availability of a companion draft guidance on CGMP for PET drug products elsewhere in this issue of the **Federal Register**.

**DATES:** A public meeting on the preliminary draft proposed rule will be held on May 21, 2002. Submit written or electronic comments on the preliminary draft proposed rule by June 5, 2002.

**ADDRESSES:** A copy of the preliminary draft proposed rule will be on display at the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the preliminary draft proposed rule to the Division of Drug Information (HFD-240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the preliminary draft proposed rule. Submit written comments to the Dockets Management

Branch (address above). Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

#### **FOR FURTHER INFORMATION CONTACT:**

Brenda Uratani, Center for Drug Evaluation and Research (HFD-325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301-594-0098.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On November 21, 1997, the President signed the Modernization Act (Public Law 105-115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of such drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999. In the **Federal Register** of September 22, 1999 (64 FR 51274), we published a notice of availability of preliminary draft regulations on PET drug CGMP. Those preliminary draft regulations were discussed at a public meeting on September 28, 1999.

After considering the comments on the preliminary draft regulations, FDA has decided to make several revisions to its approach to CGMP for PET drug products. In accordance with 21 CFR 10.40(f)(4) and 10.80(b)(2), we are making revised preliminary draft regulations available for comment. The preliminary draft proposed rule does not include sections on the economic impact of the proposed rule, federalism concerns, and Paperwork Reduction Act issues. We will include these sections when we publish a proposed rule, but we invite comments on these matters at this time.

Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a companion draft guidance entitled "PET Drug Products—Current Good Manufacturing Practice (CGMP)." Both the preliminary draft proposed rule and the draft guidance