

# Rules and Regulations

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## OFFICE OF PERSONNEL MANAGEMENT

### 5 CFR Part 185

RIN 3206-AF43

#### Implementation of the Program Fraud Civil Remedies Act of 1986

**AGENCY:** Office of Personnel Management.

**ACTION:** Final rule.

**SUMMARY:** The Office of Personnel Management (OPM) is publishing regulations to implement the Program Fraud Civil Remedies Act (PFCRA). Publication of these regulations will enable OPM to institute administrative proceedings against persons who have presented false claims or statements to OPM.

**EFFECTIVE DATE:** March 13, 1995.

**FOR FURTHER INFORMATION CONTACT:** Murray M. Meeker, Attorney, Office of the General Counsel, (202) 606-1980.

**SUPPLEMENTARY INFORMATION:** On October 21, 1986, Congress enacted the Program Fraud Civil Remedies Act (PFCRA), Public Law 99-509, 31 U.S.C. 3801-3812. Public Law 99-509 provides a statutory right for the Federal Government to take direct action against fraud, provided that proper notification is provided and that the procedures provided for in this part are followed. On May 12, 1994, OPM published these regulations as a proposed rule. 59 FR 24661. OPM received several oral comments from officials of other Federal agencies who were unclear about the scope of OPM's PFCRA regulations, i.e., they did not know whether the proposed regulations had Government-wide applicability. These commenters were advised that the proposed regulations were limited to programs administered by OPM. One commenter noted that on November 5, 1990, Congress enacted section 101(c)(1)(A)(ii)

of Public Law 101-509 which provides that any reference outside of title 5 of the United States Code to "the minimum rate of pay for grade GS-16 of the General Schedule" shall be considered a reference to the minimum rate payable under section 5376 of title 5 of the United States Code. We have amended the definition of *reviewing official* in section 185.102 of the proposed regulations to reflect this enactment. OPM also received a written comment from an employee organization in which the organization commented that the proposed regulations were inconsistent with judicial decisions which have held that actions may only be taken against bargaining unit members in accordance with negotiated grievance procedures. In response to this comment, OPM requested guidance from the Justice Department and was advised that in implementing the PFCRA, there was no need to make an exception for bargaining unit employees, and that unlike overtime pay disputes, PFCRA proceedings are not processed as grievances. The Department of Justice did confirm the organization's recommendation that proposed section 185.108(a) refer to Rule 4 of the Federal Rules of Civil Procedure rather than Rule 4(d). This change has been made in the final regulations.

#### Executive Order 12866, Regulatory Review

This rule has been reviewed by the Office of Management and Budget in accordance with Executive Order 12866.

#### Regulatory Flexibility Act

I certify that these regulations will not have a significant economic impact on a substantial number of small entities because the effects are limited primarily to federal employees and other entities who do business with OMB.

#### List of Subjects in 5 CFR Part 185

Claims.

Office of Personnel Management.

**Lorraine A. Green,**

*Deputy Director.*

Accordingly, OPM is adding part 185 of title 5, Code of Federal Regulations as follows:

## Federal Register

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## PART 185—PROGRAM FRAUD CIVIL REMEDIES

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**Authority:** 31 U.S.C. 3801-3812.

### § 185.101 Purpose.

This subpart implements the Program Fraud Civil Remedies Act of 1986, Public Law 99-509, 6101-6104, 100 Stat. 1874 (October 21, 1986), codified

at 31 U.S.C. 3801–3812. Section 3809 requires each authority head to promulgate regulations necessary to implement the provisions of the statute. The subpart establishes administrative procedures for imposing civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to authorities or to their agents, and specifies the hearing and appeal rights of persons subject to allegations of liability for such penalties and assessments. The moneys collected as a result of these procedures are deposited as miscellaneous receipts in the Treasury of the United States.

#### **§ 185.102 Definitions.**

For the purposes of this part—

*ALJ* means an Administrative Law Judge in the authority appointed pursuant to 5 U.S.C. 3105 or detailed to the authority pursuant to 5 U.S.C. 3344.

*Authority* means the Office of Personnel Management (OPM).

*Authority head* means the Director of the Office of Personnel Management or the Director's designee.

*Benefit* is very broad, and is intended to cover anything of value, including but not limited to any advantage, preference, privilege, license, permit, favorable decision, ruling, status or loan guarantee.

*Claim* means any request, demand, or submission—

(a) Made to the authority for property, services, or money (including money representing benefits, grants, loans or insurance);

(b) Made to a recipient of property, services, or money from the authority or to a party to a contract with the authority:

(1) For property or services if the United States—

(i) Provided such property or services; (ii) Provided any portion of the funds for the purchase of such property or services; or

(iii) Will reimburse such recipient or party for the purchase of such property or services; or

(2) For the payment of money (including money representing grants, loans, insurance, or benefits) if the United States:

(i) Provided any portion of the money requested or demanded; or

(ii) Will reimburse such recipient or party for any portion of the money paid on such request or demand; or

(c) Made to the authority which has the effect of decreasing an obligation to pay or account for property, services, or money.

*Complaint* means the administrative complaint served by the reviewing

official on the defendant under § 185.107.

*Defendant* means any person alleged in a complaint under § 185.107 to be liable for a civil penalty or assessment under § 185.103.

*Government* means the United States Government.

*Individual* means a natural person.

*Initial decision* means the written decision of the ALJ required by § 185.110 or § 185.137, and includes a revised initial decision issued following a remand or a motion for reconsideration.

*Investigating Official* means the Inspector General or the Inspector General's designee.

*Knows or has reason to know* means that a person, with respect to a claim or statement:

(a) Has actual knowledge that the claim or statement is false, fictitious, or fraudulent;

(b) Acts in deliberate ignorance of the truth or falsity of the claim or statement; or

(c) Acts in reckless disregard of the truth or falsity of the claim or statement.

*Makes* shall include the terms presents, submits, and causes to be made, presented, or submitted. As the context requires, making or made, shall likewise include the corresponding forms of such terms.

*Person* means any individual, partnership, corporation, association, or private organization, and includes the plural of that term.

*Representative* means an attorney who is in good standing of the bar of any State, Territory, or possession of the United States or of the District of Columbia or the Commonwealth of Puerto Rico or other individual designated in writing by the defendant.

*Reviewing Official* means the General Counsel of OPM or the General Counsel's designee. For the purposes of § 185.105 of these rules, the General Counsel personally, or members of the General Counsel's immediate staff, shall perform the functions of the reviewing official provided that such person or persons serve in a position for which the rate of basic pay is not less than the minimum rate payable under section 5376 of title 5 of the United States Code. All other functions of the reviewing official, including administrative prosecution under these rules, shall be performed on behalf of the General Counsel by members of the Office of the General Counsel.

*Statement* means any representation, certification, affirmation, document, record, or accounting or bookkeeping entry made:

(a) With respect to a claim or to obtain the approval or payment of a claim (including relating to eligibility to make a claim); or

(b) With respect to (including relating to eligibility for):

(1) A contract with, or a bid or proposal for a contract with; or

(2) A grant, loan, or benefit from, the authority, or any State, political subdivision of a State, or other party, if the United States Government provides any portion of the money or property under such contract or for such grant, loan, or benefit, or if the Government will reimburse such State, political subdivision, or party for any portion of the money or property under such contract or for such grant, loan, or benefit.

#### **§ 185.103 Basis for civil penalties and assessments.**

(a) In addition to any other remedy that may be prescribed by law, any person shall be subject to a civil penalty of not more than \$5,000, where the person makes a claim and knows or has reason to know that the claim:

(1) Is false, fictitious, or fraudulent;

(2) Includes, or is supported by, any written statement which asserts a material fact which is false, fictitious, or fraudulent;

(3) Includes, or is supported by, any written statement that:

(i) Omits a material fact;

(ii) Is false, fictitious, or fraudulent as a result of such omission; and

(iii) Is a statement in which the person making such statement has a duty to include such material fact; or

(4) Is for payment for the provision of property or services which the person has not provided as claimed.

(b) Each voucher, invoice, claim form, or other individual request or demand for property, services, or money constitutes a separate claim.

(c) A claim shall be considered made to the authority, recipient, or party when such claim is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the authority, recipient, or party.

(d) Each claim for property, services, or money is subject to a civil penalty regardless of whether such property, services, or money is actually delivered or paid.

(e) If the Government has made any payment (including transferred property or provided services) on a claim, a person subject to a civil penalty under paragraph (a)(1) of this section may also be subject to an assessment of not more than twice the amount of such claim or

that portion thereof that is determined to be in violation of paragraph (a)(1) of this section. Such assessment shall be in lieu of damages sustained by the Government because of such claim.

(f) Any person who makes a written statement that:

(1) The person knows or has reason to know:

(i) Asserts a material fact which is false, fictitious, or fraudulent; or

(ii) Is false, fictitious, or fraudulent because it omits a material fact that the person making the statement has a duty to include in such statement; and

(2) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement may be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than \$5,000 for each such statement.

(g) Each written representation, certification, or affirmation constitutes a separate statement.

(h) A statement shall be considered made to the authority when such statement is actually made to an agent, fiscal intermediary, or other entity, including any State or political subdivision thereof, acting for or on behalf of the authority.

(i) No proof of specific intent to defraud is required to establish liability under this section.

(j) In any case in which it is determined that more than one person is liable for making a claim or statement under this section, each such person may be held liable for a civil penalty under this section.

(k) In any case in which it is determined that more than one person is liable for making a claim under this section on which the Government has made payment (including transferred property or provided services), an assessment may be imposed against any such person or jointly and severally against any combination of such persons.

#### **§ 185.104 Investigation.**

(a) If an investigating official concludes that a subpoena pursuant to the authority conferred by 31 U.S.C. 3804(a) is warranted, he or she may issue a subpoena.

(1) The subpoena so issued shall notify the person to whom it is addressed of the authority under which the subpoena is issued and shall identify the records or documents sought;

(2) The investigating official may designate a person to act on his or her behalf to receive the documents sought; and

(3) The person receiving such subpoena shall be required to tender to the investigating official, or the person designated to receive the documents, a certification that

(i) The documents sought have been produced;

(ii) Such documents are not available and the reasons therefor; or

(iii) Such documents, suitably identified, have been withheld based upon the assertion of an identified privilege.

(b) If the investigating official concludes that an action under the Program Fraud Civil Remedies Act may be warranted, the investigating official shall submit a report containing the findings and conclusions of such investigation to the reviewing official.

(c) Nothing in this section shall preclude or limit an investigating official's discretion to refer allegations directly to the Department of Justice for suit under the False Claims Act or other civil relief, or to defer or postpone a report or referral to the reviewing official to avoid interference with a criminal investigation or prosecution.

(d) Nothing in this section modifies any responsibility of an investigating official to report violations of criminal law to the Attorney General.

#### **§ 185.105 Review by the reviewing official.**

If, based on the report of the investigating official under § 185.104(b), the reviewing official determines that there is adequate evidence to believe that a person is liable under § 185.103, the reviewing official shall transmit to the Attorney General a written notice of the reviewing official's intention to have a complaint issued under § 185.108. Such notice shall include:

(a) A statement of the reviewing official's reasons for issuing a complaint;

(b) A statement specifying the evidence that supports the allegations of liability;

(c) A description of the claims or statements upon which the allegations of liability are based;

(d) An estimate of the amount of money, or the value of property, services, or other benefits, requested or demanded in violation of § 185.103;

(e) A statement of any exculpatory or mitigating circumstances that may relate to the claims or statements known by the reviewing official or the investigating official; and

(f) A statement that there is a reasonable prospect of collecting an appropriate amount of penalties and assessments.

#### **§ 185.106 Prerequisites for issuing a complaint.**

(a) The reviewing official may issue a complaint under § 185.107 only if:

(1) The Department of Justice approves the issuance of a complaint in a written statement described in section 3803(b)(1) of title 31 of the United States Code, and

(2) In the case of allegations of liability under § 185.103(a) with respect to a claim, the reviewing official determines that, with respect to such claim or a group of related claims submitted at the same time such claim is submitted (as defined in paragraph (b) of this section), the amount of money, or the value of property or services, demanded or requested in violation of § 185.103(a) does not exceed \$150,000.

(b) For the purposes of this section, a related group of claims submitted at the same time shall include only those claims arising from the same transaction (e.g., grant, loan, application, or contract) that are submitted simultaneously as part of a single request, demand, or submission.

(c) Nothing in this section shall be construed to limit the reviewing official's authority to join in a single complaint against a person, claims that are unrelated or were not submitted simultaneously, regardless of the amount of money, or the value of property or services, demanded or requested.

#### **§ 185.107 Complaint.**

(a) On or after the date the Department of Justice approves the issuance of a complaint in accordance with section 3803(b)(1) of title 31 of the United States Code, the reviewing official may serve a complaint on the defendant, as provided in § 185.108.

(b) The complaint shall state the following:

(1) The allegations of liability against the defendant, including the statutory basis for liability, an identification of the claims or statements that are the basis for the alleged liability, and the reasons why liability allegedly arises from such claims or statements;

(2) The maximum amount of penalties and assessments for which the defendant may be held liable;

(3) Instructions for filing an answer, including a specific statement of the defendant's right to request a hearing and to be represented by a representative; and

(4) The fact that failure to file an answer within 30 days of service of the complaint will result in the imposition of the maximum amount of penalties and assessments without right to appeal, as provided in § 185.110.

(c) At the same time the reviewing official serves the complaint, he or she shall serve the defendant with a copy of these regulations.

#### **§ 185.108 Service of complaint.**

(a) Service of a complaint must be made by certified or registered mail or by delivery in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure. Service is complete upon receipt.

(b) Proof of service, stating the name and address of the person on whom the complaint was served, and the manner and date of service, may be made by:

(1) Affidavit of the individual serving the complaint by delivery;

(2) A United States Postal Service return receipt card acknowledging receipt; or

(3) Written acknowledgment of receipt by the defendant or his or her representative.

#### **§ 185.109 Answer.**

(a) The defendant may request a hearing in the answer filed with the reviewing official within 30 days of service of the complaint.

(b) In the answer, the defendant:

(1) Shall admit or deny each of the allegations of liability made in the complaint;

(2) Shall state any defense on which the defendant intends to rely;

(3) May state any reasons why the defendant contends that the penalties and assessments should be less than the statutory maximum; and

(4) Shall state the name, address, and telephone number of the person authorized by the defendant to act as defendant's representative, if any.

(c) If the defendant is unable to file an answer meeting the requirements of paragraph (b) of this section within the time provided, the defendant may, before the expiration of 30 days from service of the complaint, file with the reviewing official a general answer denying liability and requesting a hearing, and a request for an extension of time within which to file an answer meeting the requirements of paragraph (b) of this section. The reviewing official shall file promptly with the ALJ the complaint, the general answer denying liability, and the request for an extension of time as provided in § 185.110. For good cause shown, the ALJ may grant the defendant up to 30 additional days within which to file an answer meeting the requirements of paragraph (b) of this section. The ALJ shall decide expeditiously whether the defendant shall be granted an additional period of time to file such answer.

#### **§ 185.110 Default upon failure to file an answer.**

(a) If the defendant does not file an answer within the time prescribed in § 185.109(a), the reviewing official may refer the complaint to the ALJ.

(b) Upon the referral of the complaint, the ALJ shall promptly serve on the defendant in the manner prescribed in § 185.108, a notice that an initial decision will be issued under this section.

(c) The ALJ shall assume the facts alleged in the complaint to be true and, if such facts establish liability under § 185.103, the ALJ shall issue an initial decision imposing the maximum amount of penalties and assessments allowed under the statute.

(d) Except as otherwise provided in this section, by failing to file a timely answer the defendant waives any right to further review of the penalties and assessments imposed under paragraph (c) of this section and the initial decision shall become final and binding upon the parties 30 days after it is issued.

(e) If, before such an initial decision becomes final, the defendant files a motion with the ALJ seeking to reopen on the grounds that extraordinary circumstances prevented the defendant from filing an answer, the initial decision shall be stayed pending the ALJ's decision on the motion.

(f) If, on such motion, the defendant can demonstrate extraordinary circumstances excusing the failure to file a timely answer, the ALJ shall withdraw the initial decision in paragraph (c) of this section, if such a decision has been issued, and shall grant the defendant an opportunity to answer the complaint.

(g) A decision of the ALJ denying a defendant's motion under paragraph (e) of this section is not subject to reconsideration under § 185.138.

(h) The defendant may appeal to the authority head the decision denying a motion to reopen by filing a notice of appeal with the authority head within 15 days after the ALJ denies the motion. The timely filing of a notice of appeal shall stay the initial decision until the authority head decides the issue.

(i) If the defendant files a timely notice of appeal with the authority head, the ALJ shall forward the record of the proceeding to the authority head.

(j) The authority head shall decide expeditiously whether extraordinary circumstances excuse the defendant's failure to file a timely answer based solely on the record before the ALJ.

(k) If the authority head decides that extraordinary circumstances excused the defendant's failure to file a timely

answer, the authority head shall remand the case to the ALJ with instructions to grant the defendant an opportunity to answer.

(l) If the authority head decides that the defendant's failure to file a timely answer is not excused, the authority head shall reinstate the initial decision of the ALJ, which shall become final and binding upon the parties 30 days after the authority head issues such decision.

#### **§ 185.111 Referral of complaint and answer to the ALJ.**

Upon receipt of an answer, the reviewing official shall file the complaint and answer with the ALJ.

#### **§ 185.112 Notice of hearing.**

(a) When the ALJ receives the complaint and answer, the ALJ shall promptly serve a notice of hearing upon the defendant in the manner prescribed by § 185.108. At the same time, the ALJ shall send a copy of such notice to the reviewing official or his or her designee.

(b) Such notice shall include:

(1) The tentative time and place, and the nature of the hearing;

(2) The legal authority and jurisdiction under which the hearing is to be held;

(3) The matters of fact and law to be asserted;

(4) A description of the procedures for the conduct of the hearing;

(5) The name, address, and telephone number of the representative of the Government and of the defendant, if any; and

(6) Such other matters as the ALJ deems appropriate.

#### **§ 185.113 Location of hearing.**

(a) The hearing may be held:

(1) In any judicial district of the United States in which the defendant resides or transacts business;

(2) In any judicial district of the United States in which the claim or statement in issue was made; or

(3) In such other place as may be agreed upon by the parties and the ALJ.

(b) Each party shall have the opportunity to present argument with respect to the location of the hearing.

(c) The hearing shall be held at the place and at the time ordered by the ALJ.

#### **§ 185.114 Parties to the hearing.**

(a) The parties to the hearing shall be the defendant and OPM.

(b) Except where the authority head designates another, OPM shall be represented by the members of the Office of the General Counsel.

(c) Pursuant to section 3730(c)(5) of title 31, United States Code, a private

plaintiff under the False Claims Act may participate in these proceedings to the extent authorized by the provisions of that Act.

#### **§ 185.115 Separation of functions.**

(a) The investigating official, the reviewing official, and any employee or agent of the authority who takes part in investigating, preparing, or presenting a particular case may not, in such case or a factually related case:

(1) Participate in the hearing as the ALJ;

(2) Participate or advise in the initial decision or the review of the initial decision by the authority head, except as a witness or a representative in public proceedings; or

(3) Make the collection of penalties and assessments under section 3806 of title 31, United States Code.

(b) The ALJ shall not be responsible to or subject to the supervision or direction of the investigating official or the reviewing official.

#### **§ 185.116 Ex parte contacts.**

No party or person (except employees of the ALJ's office) shall communicate in any way with the ALJ on any matter at issue in a case, unless on notice and opportunity for all parties to participate. This provision does not prohibit a person or party from inquiring about the status of a case or asking routine questions concerning administrative functions or procedures.

#### **§ 185.117 Disqualifications of reviewing official or ALJ.**

(a) A reviewing official or ALJ in a particular case may disqualify himself or herself at any time.

(b) A party may file with the ALJ a motion for disqualification of a reviewing official or an ALJ. Such motion shall be accompanied by an affidavit alleging personal bias or other reason for disqualification.

(c) Such motion and affidavit shall be filed promptly upon the party's discovery of reasons requiring disqualification, or such objections shall be deemed waived.

(d) Such affidavit shall state specific facts that support the party's belief that personal bias or other reason for disqualification exists and the time and circumstances of the party's discovery of such facts. It shall be accompanied by a certificate of the representative of record that it is made in good faith.

(e) Upon the filing of such a motion and affidavit, the ALJ shall proceed no further in the case until he or she resolves the matter of disqualification in accordance with this section.

(f) If the ALJ determines that a reviewing official is disqualified, the

ALJ shall dismiss the complaint without prejudice.

(2) If the ALJ disqualifies himself or herself, the case shall be reassigned promptly to another ALJ.

(3) If the ALJ denies a motion to disqualify, the authority head may determine the matter only as part of his or her review of the initial decision upon appeal, if any.

#### **§ 185.118 Rights of parties.**

Except as otherwise limited by this part, all parties may:

(a) Be accompanied, represented, and advised by a representative;

(b) Participate in any conference held by the ALJ;

(c) Conduct discovery as provided under § 185.122;

(d) Agree to stipulations of fact or law, which shall be made a part of the record;

(e) Present evidence relevant to the issues at the hearing;

(f) Present and cross-examine witnesses;

(g) Present oral arguments at the hearing as permitted by the ALJ; and

(h) Submit written briefs and proposed findings of fact and conclusions of law after the hearing.

#### **§ 185.119 Authority of the ALJ.**

(a) The ALJ shall conduct a fair and impartial hearing, avoid delay, maintain order, and assure that a record of the proceeding is made.

(b) The ALJ has the authority to:

(1) Set and change the date, time, and place of the hearing upon reasonable notice to the parties;

(2) Continue or recess the hearing in whole or in part for a reasonable period of time;

(3) Hold conferences to identify or simplify the issues, or to consider other matters that may aid in the expeditious disposition of the proceeding;

(4) Administer oaths and affirmations;

(5) Issue subpoenas requiring the attendance of witnesses and the production of documents at depositions or at hearings;

(6) Rule on motions and other procedural matters;

(7) Regulate the scope and timing of discovery;

(8) Regulate the course of the hearing and the conduct of representatives and parties;

(9) Examine witnesses;

(10) Receive, rule on, exclude, or limit evidence;

(11) Upon motion of a party, take official notice of facts;

(12) Upon motion of a party, decide cases, in whole or in part, by summary judgment where there is no disputed issue of material fact;

(13) Conduct any conference, argument, or hearing on motions in person or by telephone; and

(14) Exercise such other authority as is necessary to carry out the responsibilities of the ALJ under this part.

(c) The ALJ does not have the authority to find Federal statutes or regulations invalid.

#### **§ 185.120 Prehearing conferences.**

(a) The ALJ may schedule prehearing conferences as appropriate.

(b) Upon the motion of any party, the ALJ shall schedule at least one prehearing conference at a reasonable time in advance of the hearing.

(c) The ALJ may use prehearing conferences to discuss the following:

(1) Simplification of the issues;

(2) The necessity or desirability of amendments to the pleadings, including the need for a more definite statement;

(3) Stipulations and admissions of fact or as to the contents and authenticity of documents;

(4) Whether the parties can agree to submission of the case on a stipulated record;

(5) Whether a party chooses to waive appearance at an oral hearing and to submit only documentary evidence (subject to the objection of other parties) and written argument;

(6) Limitation of the number of witnesses;

(7) Scheduling dates for the exchange of witness lists and of proposed exhibits;

(8) Discovery;

(9) The time and place for the hearing; and

(10) Such other matters as may tend to expedite the fair and just disposition of the proceedings.

(d) The ALJ may issue an order containing all matters agreed upon by the parties or ordered by the ALJ at a prehearing conference.

#### **§ 185.121 Disclosure of documents.**

(a) Upon written request to the reviewing official, generally prior to the filing of an answer, the defendant may review any relevant and material documents, transcripts, records, and other materials that relate to the allegations set out in the complaint and upon which the findings and conclusions of the investigating official under § 185.104(b) are based, unless such documents are subject to a privilege under Federal law. Upon payment of fees for duplication, the defendant may obtain copies of such documents.

(b) Upon written request to the reviewing official, the defendant, may

also obtain a copy of all exculpatory information in the possession of the reviewing official or investigating official relating to the allegations in the complaint, even if it is contained in a document that would otherwise be privileged. If the document would otherwise be privileged, only that portion containing exculpatory information must be disclosed.

(c) The notice sent to the Attorney General from the reviewing official as described in § 185.105 is not discoverable under any circumstances.

(d) The defendant may file a motion to compel disclosure of the documents subject to the provisions of this section. Such a motion may only be filed with the ALJ following the filing of an answer pursuant to § 185.109.

#### § 185.122 Discovery.

(a) The following types of discovery are authorized:

(1) Requests for production of documents for inspection and copying;

(2) Requests for admissions of the authenticity of any relevant document or of the truth of any relevant fact;

(3) Written interrogatories; and

(4) Depositions.

(b) For the purpose of this section and § 185.123, the term *documents* includes information, documents, reports, answers, records, accounts, papers, and other data and documentary evidence. Nothing contained herein shall be interpreted to require the creation of a document.

(c) Unless mutually agreed to by the parties, discovery is available only as ordered by the ALJ. The ALJ shall regulate the timing of discovery.

(d) Motions for discovery are to be handled according to the following procedures:

(1) A party seeking discovery may file a motion with the ALJ. Such a motion shall be accompanied by a copy of the requested discovery, or in the case of depositions, a summary of the scope of the proposed deposition.

(2) Within 10 days of service, a party may file an opposition to the motion and/or a motion for protective order as provided in § 185.125.

(3) The ALJ may grant a motion for discovery only if he or she finds that the discovery sought:

(i) Is necessary for the expeditious, fair, and reasonable consideration of the issues;

(ii) Is not unduly costly or burdensome;

(iii) Will not unduly delay the proceeding; and

(iv) Does not seek privileged information.

(4) the burden of showing that discovery should be allowed is on the party seeking discovery.

(5) The ALJ may grant discovery subject to a protective order under § 185.125.

(e) Depositions are to be handled in the following manner:

(1) If a motion for deposition is granted, the ALJ shall issue a subpoena for the deponent, which may require the deponent to produce documents. The subpoena shall specify the time and place at which the deposition will be held.

(2) The party seeking to depose shall serve the subpoena in the manner prescribed in § 185.108.

(3) The deponent may file with the ALJ within 10 days of service a motion to quash the subpoena or a motion for a protective order.

(4) The party seeking to depose shall provide for the taking of a verbatim transcript of the deposition, which it shall make available to all other parties for inspection and copying.

(f) Each party shall bear its own costs of discovery.

#### § 185.123 Exchange of witness lists, statements and exhibits.

(a) At least 15 days before the hearing or at such other time as may be ordered by the ALJ, the parties shall exchange witness lists, copies of prior statements of proposed witnesses, and copies of proposed hearing exhibits, including copies of any written statements that the party intends to offer in lieu of live testimony in accordance with § 185.133(b). At the time the above documents are exchanged, any party that intends to rely on the transcript or deposition testimony in lieu of live testimony at the hearing, if permitted by the ALJ, shall provide each party with a copy of the specific pages of the transcript it intends to introduce into evidence.

(b) If a party objects, the ALJ may not admit into evidence the testimony of any witness whose name does not appear on the witness list or any exhibit not provided to the opposing party as provided above unless the ALJ finds good cause for the failure or that there is no prejudice to the objecting party.

(c) Unless another party objects within the time set by the ALJ, documents exchanged in accordance with paragraph (a) of this section shall be deemed to be authentic for the purpose of admissibility at the hearing.

#### § 185.124 Subpoenas for attendance at hearing.

(a) A party wishing to procure the appearance and testimony of any

individual at the hearing may request that the ALJ issue a subpoena.

(b) A subpoena requiring the attendance and testimony of an individual may also require the individual to produce documents at the hearing.

(c) A party seeking a subpoena shall file a written request therefor not less than 15 days before the date fixed for the hearing unless otherwise allowed by the ALJ upon a showing of good cause. Such request shall specify any documents to be produced and shall designate the witnesses and describe the address and location thereof with sufficient particularity to permit such witnesses to be found.

(d) The subpoena shall specify the time and place at which the witness is to appear and any documents the witness is to produce.

(e) The party seeking the subpoena shall serve it in the manner prescribed in § 185.108. A subpoena on a party or upon an individual under the control of a party may be served by first class mail.

(f) A party or the individual to whom the subpoena is directed may file with the ALJ a motion to quash the subpoena within 10 days after service or on or before the time specified in the subpoena for compliance if it is less than 10 days after service.

#### § 185.125 Protective order.

(a) A party or a prospective witness or deponent may file a motion for a protective order with respect to discovery sought by an opposing party or with respect to the hearing, seeking to limit the availability or disclosure of evidence.

(b) In issuing a protective order, the ALJ may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense, including one or more of the following:

(1) That the discovery not be had;

(2) That the discovery may be had only on specified terms and conditions, including a designation of the time or place;

(3) That the discovery may be had only through a method of discovery other than that requested;

(4) That certain matters not be the subject of inquiry, or that the scope of discovery be limited to certain matters;

(5) That discovery be conducted with no one present except persons designated by the ALJ;

(6) That the contents of discovery or evidence be sealed;

(7) That a sealed deposition be opened only by order of the ALJ;

(8) That a trade secret or other confidential research, development,

commercial information, or facts pertaining to any criminal investigation, proceeding, or other administrative investigation not be disclosed or be disclosed only in a designated way; or

(9) That the parties simultaneously file specified documents or information enclosed in sealed envelopes to be opened as directed by the ALJ.

#### **§ 185.126 Evidence.**

(a) The ALJ shall determine the admissibility of evidence.

(b) Except as provided in this part, the ALJ shall not be bound by the Federal Rules of Evidence. However, the ALJ may apply the Federal Rules of Evidence where appropriate, e.g. to exclude unreliable evidence.

(c) The ALJ shall exclude irrelevant and immaterial evidence.

(d) Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or by considerations of undue delay or needless presentation of cumulative evidence.

(e) Although relevant, evidence may be excluded if it is privileged under Federal law.

(f) Evidence concerning offers of compromise or settlement shall be inadmissible to the extent provided in Rule 408 of the Federal Rules of Evidence.

(g) The ALJ shall permit the parties to introduce rebuttal witnesses and evidence.

(h) All documents and other evidence offered or taken for the record shall be open to examination by all parties, unless otherwise ordered by the ALJ pursuant to § 185.125.

#### **§ 185.127 Fees.**

The party requesting a subpoena shall pay the cost of the fees and mileage of any witness subpoenaed in the amounts that would be payable to a witness in a proceeding in United States District Court. A check for witness fees and mileage shall accompany the subpoena when served, except that when a subpoena is issued on behalf of the authority, a check for witness fees and mileage need not accompany the subpoena.

#### **§ 185.128 Form, filing and service of papers.**

(a) *Form.* Documents filed with the ALJ shall include an original and two copies. Every pleading and paper filed in the proceeding shall contain a caption setting forth the title of the action, the case number assigned by the ALJ, and a designation of the paper (e.g., motion to quash subpoena). Every

pleading and paper shall be signed by, and shall contain the address and telephone number of the party or the person on whose behalf the paper was filed, or his or her representative.

(b) *Filing.* Papers are considered filed when they are mailed. Date of mailing may be established by a certificate from the party or its representative or by proof that the document was sent by certified or registered mail.

(c) *Service.* A party filing a document with the ALJ shall, at the time of filing, serve a copy of such document on every other party. Service upon any party of any document other than those required to be served as prescribed in § 185.108 shall be made by delivering a copy or by placing a copy of the document in the United States mail, postage prepaid and addressed, to the party's last known address. When a party is represented by a representative, service shall be made upon such representative in lieu of the actual party.

(d) *Proof of service.* A certificate of the individual serving the document by personal delivery or by mail, setting forth the manner of service, shall be proof of service.

#### **§ 185.129 Computation of time.**

(a) In computing any period of time under this part or in an order issued thereunder, the time begins with the day following the act, event, or default, and includes the last day of the period, unless it is a Saturday, Sunday, or legal holiday observed by the Federal Government, in which event it includes the next business day.

(b) When the period of time allowed is less than 7 days, intermediate Saturdays, Sundays, and legal holidays observed by the Federal Government shall be excluded from the computation.

(c) Where a document has been served or issued by placing it in the mail, an additional 5 days will be added to the time permitted for any response.

#### **§ 185.130 Motions.**

(a) Any application to the ALJ for an order or ruling shall be by motion. Motions shall state the relief sought, the authority relied upon, and the facts alleged, and shall be filed with the ALJ and served on all other parties.

(b) Except for motions made during a prehearing conference or at the hearing, all motions shall be in writing. The ALJ may require that oral motions be reduced to writing.

(c) Within 15 days after a written motion is served, or such other time as may be fixed by the ALJ, any party may file a response to such motion.

(d) The ALJ may not grant a written motion before the time for filing

responses thereto has expired, except upon consent of the parties or following a hearing on the motion, but may overrule or deny such motion without awaiting a response.

(e) The ALJ shall make a reasonable effort to dispose of all outstanding motions prior to the beginning of the hearing.

#### **§ 185.131 Sanctions.**

(a) The ALJ may sanction a person including any party or representative for the following reasons:

(1) Failure to comply with an order, rule, or procedure governing the proceeding;

(2) Failure to prosecute or defend an action; or

(3) Engaging in other misconduct that interferes with the speedy, orderly, or fair conduct of the proceeding.

(b) Any such sanction, including but not limited to those listed in paragraphs (c), (d), and (e) of this section, shall reasonably relate to the severity and nature of the failure or misconduct.

(c) When a party fails to comply with an order, including an order for taking a deposition, the production of evidence within the party's control, or a request for admission, the ALJ may

(1) Draw an inference in favor of the requesting party with regard to the information sought;

(2) In the case of requests for admission, deem each matter of which an admission is requested to be admitted;

(3) Prohibit the party failing to comply with such order from introducing evidence concerning, or otherwise relying upon, testimony relating to the information sought; and

(4) Strike any part of the pleadings or other submissions of the party failing to comply with such request.

(d) If a party fails to prosecute or defend an action under this part commenced by service of a notice of hearing, the ALJ may dismiss the action or may issue an initial decision imposing penalties and assessments.

(e) The ALJ may refuse to consider any motion, request, response, brief or other document which is not filed in a timely fashion.

#### **§ 185.132 The hearing and burden of proof.**

(a) Where requested in accordance with § 185.109 the ALJ shall conduct a hearing on the record in order to determine whether the defendant is liable for a civil penalty or assessment under § 185.103 and, if so, the appropriate amount of any such civil penalty or assessment considering any aggravating or mitigating factors.

(b) The authority shall prove defendant's liability and any aggravating factors by a preponderance of the evidence.

(c) The defendant shall prove any affirmative defenses and any mitigating factors by a preponderance of the evidence.

(d) The hearing shall be open to the public unless otherwise closed by the ALJ for good cause shown.

**§ 185.133 Determining the amount of penalties and assessments.**

(a) In determining an appropriate amount of civil penalties and assessments, the ALJ and the authority head, upon appeal, should evaluate any circumstances that mitigate or aggravate the violation and should articulate in their opinions the reasons that support the penalties and assessments they impose. Because of the intangible costs of fraud, the expense of investigating such conduct, and the need to deter others who might be similarly tempted, double damages and a significant civil penalty ordinarily should be imposed.

(b) Although not exhaustive, the following factors are among those that may influence the ALJ and the authority head in determining the amount of penalties and assessments to impose with respect to the misconduct (i.e., the false, fictitious, or fraudulent claims or statements) charged in the complaint:

(1) The number of false, fictitious or fraudulent claims or statements;

(2) The time period over which such claims or statements were made;

(3) The degree of the defendant's culpability with respect to the misconduct;

(4) The amount of money or the value of the property, services, or benefit falsely claimed;

(5) The value of the Government's actual loss as a result of the misconduct, including foreseeable consequential damages and the costs of investigation;

(6) The relationship of the amount imposed as civil penalties to the amount of the Government's loss;

(7) The potential or actual impact of the misconduct upon public confidence in the management of Government programs and operations;

(8) Whether the defendant has engaged in a pattern of the same or similar misconduct;

(9) Whether the defendant attempted to conceal the misconduct;

(10) The degree to which the defendant has involved others in the misconduct or in concealing it;

(11) Where the misconduct of employees or agents is imputed to the defendant, the extent to which the defendant's practices fostered or attempted to preclude such misconduct;

(12) Whether the defendant cooperated in or obstructed an investigation of the misconduct;

(13) Whether the defendant assisted in identifying and prosecuting other wrongdoers;

(14) The complexity of the program or transaction, and the degree of the defendant's sophistication with respect to it, including the extent of the defendant's prior participation in the program or in similar transactions;

(15) Whether the defendant has been found, in any criminal, civil, or administrative proceeding to have engaged in similar misconduct or to have dealt dishonestly with the Government of the United States or of a State, directly or indirectly;

(16) The need to deter the defendant and others from engaging in the same or similar misconduct; and

(17) The potential impact of the misconduct on the rights of others.

(c) Nothing in this section shall be construed to limit the ALJ or the authority head from considering any other factors that in any given case may mitigate or aggravate the offense for which penalties and assessments are imposed.

**§ 185.134 Witnesses.**

(a) Except as provided in paragraph (b) of this section, testimony at the hearing shall be given orally by witnesses under oath or affirmation.

(b) At the discretion of the ALJ, testimony may be admitted in the form of a written statement or deposition. Any such written statement must be provided to all other parties along with the last known address of such witness, in a manner which allows sufficient time for other parties to subpoena such witness for cross-examination at the hearing. Prior written statements of witnesses proposed to testify at the hearing and deposition transcripts shall be exchanged as provided in § 185.123(a).

(c) The ALJ shall exercise reasonable control over the mode and order of interrogating witnesses and presenting evidence so as to—

(1) Make the interrogation and presentation effective for the ascertainment of the truth,

(2) Avoid needless consumption of time, and

(3) Protect witnesses from harassment or undue embarrassment.

(d) The ALJ shall permit the parties to conduct such cross-examination as may be required for a full and true disclosure of the facts.

(e) At the discretion of the ALJ, a witness may be cross-examined on matters relevant to the proceedings

without regard to the scope of his or her direct examination. To the extent permitted by the ALJ, cross-examination on matters outside the scope of direct examination shall be conducted in the manner of direct examination and may proceed by leading questions only if the witness is a hostile witness, an adverse party, or a witness identified with an adverse party.

(f) Upon motion of any party, the ALJ shall order witnesses excluded so that they cannot hear the testimony of other witnesses. This rule does not authorize exclusion of the following:

(1) A party who is an individual;

(2) In the case of a party that is not an individual, an officer or employee of the party designated by the party's representative; or

(3) An individual whose presence is shown by a party to be essential to the presentation of its case, including an individual employed by the Government engaged in assisting the representative for the Government.

**§ 185.135 The record.**

(a) The hearing shall be recorded and transcribed. Transcripts may be obtained following the hearing from the ALJ at a cost not to exceed the actual cost of duplication.

(b) The transcript of testimony, exhibits and other evidence admitted at the hearing, and all papers and requests filed in the proceeding constitute the record for the decision by the ALJ and the authority head.

(c) The record may be inspected and copied (upon payment of a reasonable fee) by anyone, unless otherwise ordered by the ALJ pursuant to § 185.125.

**§ 185.136 Post-hearing briefs.**

The ALJ may require the parties to file post-hearing briefs. In any event, any party may file a post-hearing brief. The ALJ shall fix the time for filing such briefs, not to exceed 60 days from the date the parties receive the transcript of the hearing or, if applicable, the stipulated record. Such briefs may be accompanied by proposed findings of fact and conclusions of law. The ALJ may permit the parties to file reply briefs.

**§ 185.137 Initial decision.**

(a) The ALJ shall issue an initial decision based only on the record, which shall contain findings of fact, conclusions of law, and the amount of any penalties and assessments imposed.

(b) The findings of fact shall include a finding on each of the following issues:

(1) Whether the claims or statements identified in the complaint, or any portions thereof, violate § 185.103.

(2) If the person is liable for penalties or assessments, the appropriate amount of any such penalties or assessments considering any mitigating or aggravating factors that he or she finds in the case, such as those described in § 185.133.

(c) The ALJ shall promptly serve the initial decision on all parties within 90 days after the time for submission of post-hearing briefs and reply briefs (if permitted) has expired. The ALJ shall at the same time serve all parties with a statement describing the right of any defendant determined to be liable for a civil penalty or assessment to file a motion for reconsideration with the ALJ or a notice of appeal with the authority head. If the ALJ fails to meet the deadline contained in this paragraph, he or she shall notify the parties of the reason for the delay and shall set a new deadline.

(d) Unless the initial decision of the ALJ is timely appealed to the authority head, or a motion for reconsideration of the initial decision is timely filed, the initial decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued by the ALJ.

#### **§ 185.138 Reconsideration of initial decision.**

(a) Except as provided in paragraph (d) of this section, any party may file a motion for reconsideration of the initial decision within 20 days of receipt of the initial decision. If service was made by mail, receipt will be presumed to be 5 days from the date of mailing in the absence of contrary proof.

(b) Every such motion must set forth the matters claimed to have been erroneously decided and the nature of the alleged errors. Such motion shall be accompanied by a supporting brief.

(c) Responses to such motions shall be allowed only upon request of the ALJ.

(d) No party may file a motion for reconsideration of an initial decision that has been revised in response to a previous motion for reconsideration.

(e) The ALJ may dispose of a motion for reconsideration by denying it or by issuing a revised initial decision.

(f) If the ALJ denies a motion for reconsideration, the initial decision shall constitute the final decision of the authority head and shall be final and binding on all parties 30 days after the ALJ denies the motion, unless the initial decision is timely appealed to the authority head in accordance with § 185.139.

(g) If the ALJ issues a revised initial decision, that decision shall constitute the final decision of the authority head and shall be final and binding on the parties 30 days after it is issued, unless it is timely appealed to the authority head in accordance with § 185.139.

#### **§ 185.139 Appeal to authority head.**

(a) Any defendant who has filed a timely answer and who is determined in an initial decision to be liable for a civil penalty or assessment may appeal such decision to the authority head by filing a notice of appeal with the authority head in accordance with this section.

(1) A notice of appeal may be filed at any time within 30 days after the ALJ issues an initial decision. However, if another party files a motion for reconsideration under § 185.138, consideration of the appeal shall be stayed automatically pending resolution of the motion for reconsideration.

(2) If a motion for reconsideration is timely filed, a notice of appeal shall be filed within 30 days after the ALJ denies the motion or issues a revised initial decision, whichever applies.

(3) If no motion for reconsideration is timely filed, a notice of appeal must be filed within 30 days after the ALJ issues the initial decision.

(4) The authority head may extend the initial 30-day period for an additional 30 days if the defendant files with the authority head a request for an extension within the initial 30-day period and shows good cause.

(b) If the defendant files a timely notice of appeal with the authority head and the time for filing motions for reconsideration under § 185.138 has expired, the ALJ shall forward the record of the proceeding to the authority head.

(c) A notice of appeal shall be accompanied by a written brief specifying exceptions to the initial decision and reasons supporting the exceptions.

(d) The representative for OPM may file a brief in opposition to exceptions within 30 days of receiving the notice of appeal and accompanying brief.

(e) There is no right to appear personally before the authority head.

(f) There is no right to appeal an interlocutory ruling by the ALJ.

(g) In reviewing the initial decision the authority head shall not consider any objection that was not raised before the ALJ unless the objecting party can demonstrate extraordinary

(h) If any party demonstrates to the satisfaction of the authority head that additional evidence not presented at such hearing is material and that there were reasonable grounds for the failure

to present such evidence at such hearing, the authority head shall remand the matter to the ALJ for consideration of such additional evidence.

(i) The authority head may affirm, reduce, reverse, compromise, remand or settle any penalty or assessment determined by the ALJ in any initial decision.

(j) The authority head shall promptly serve each party to the appeal with a copy of the decision of the authority head and a statement describing the right of any person determined to be liable for a penalty or assessment to seek judicial review.

(k) Unless a petition for review is filed as provided in section 3805 of title 31, United States Code, after a defendant has exhausted all administrative remedies under this part and within 60 days after the date on which the authority head serves the defendant with a copy of the authority head's decision, a determination that a defendant is liable under § 185.103 is final and not subject to judicial review.

#### **§ 185.140 Stays ordered by the Department of Justice.**

If, at any time, the Attorney General or an Assistant Attorney General designated by the Attorney General transmits to the authority head a written finding that continuation of the administrative process described in this part with respect to a claim or statement may adversely affect any pending or potential criminal or civil action related to such claim or statement, the authority head shall stay the process immediately. The authority head may order the process resumed only upon receipt of the written authorization of the Attorney General or of the Assistant Attorney General who ordered the stay.

#### **§ 185.141 Stay pending appeal.**

(a) An initial decision is stayed automatically pending disposition of a motion for reconsideration or of an appeal to the authority head.

(b) No administrative stay is available following a final decision of the authority head.

#### **§ 185.142 Judicial review.**

Section 3805 of title 31, United States Code, authorizes judicial review by an appropriate United States District Court of a final decision of the authority head imposing penalties and/or assessments under this part and specifies the procedures for such review.

#### **§ 185.143 Collection of civil penalties and assessments.**

Sections 3806 and 3808(b) of title 31, United States Code, authorize actions

for collection of civil penalties and assessments imposed under this part and specify the procedures for such actions.

**§ 185.144 Right to administrative offset.**

The amount of any penalty or assessment which has become final, or for which a judgment has been entered under § 185.142 or § 185.143, or any amount agreed upon in a compromise or settlement under § 185.146, may be collected by administrative offset under section 3716 of title 31, United States Code, except that an administrative offset may not be made under section 3716 against a refund of an overpayment of Federal taxes, then or later owing by the United States to the defendant.

**§ 185.145 Deposit in Treasury of the United States.**

All amounts collected pursuant to this part shall be deposited as miscellaneous receipts in the Treasury of the United States, except as provided in section 3806(g) of title 31, United States Code.

**§ 185.146 Compromise or settlement.**

(a) Parties may make offers of compromise or settlement at any time.

(b) The reviewing official has the exclusive authority to compromise or settle a case under this part at any time after the date on which the reviewing official is permitted to issue a complaint and before the date on which the ALJ issues an initial decision.

(c) The authority head has exclusive authority to compromise or settle a case under this part at any time after the date on which the ALJ issues an initial decision, except during the pendency of any review under § 185.142 or during the pendency of any action to collect penalties and assessments under § 185.143.

(d) The Attorney General has exclusive authority to compromise or settle a case under this part during the pendency of any review under § 185.142 or of any action to recover penalties and assessments under section 3806 to title 31, United States Code.

(e) The investigating official may recommend settlement terms to the reviewing official, the authority head, or the Attorney General, as appropriate. The reviewing official may recommend settlement terms to the authority head, or the Attorney General, as appropriate.

(f) Any compromise or settlement must be in writing.

**§ 185.147 Limitations.**

(a) The notice of hearing with respect to a claim or statement must be served in the manner specified in § 185.108 within 6 years after the date on which such a claim or statement is made.

(b) If the defendant fails to file a timely answer, service of a notice under § 185.110(b) shall be deemed a notice of hearing for purposes of this section.

(c) the statute of limitations may be executed by written agreement of the parties.

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**NUCLEAR REGULATORY COMMISSION**

**10 CFR Part 20**

RIN 3150-AF08

**Frequency of Medical Examinations for Use of Respiratory Protection Equipment**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Final rule.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is amending its regulations concerning the frequency at which medical fitness determinations are required to ensure the safe use of respiratory protection equipment. Section 10 CFR 20.1703(a)(3)(v) currently requires the determination by a physician prior to initial fitting of respirators, and at least every 12 months thereafter, that the individual user is physically able to use the respiratory protection equipment. The amended rule requires determination by a physician prior to initial fitting of respirators and either every 12 months thereafter or periodically at a frequency determined by a physician, that the individual user is medically fit to use the respiratory protection equipment. The final rule reduces the burden on licensees without adversely impacting public health and safety.

**EFFECTIVE DATE:** March 13, 1995.

**FOR FURTHER INFORMATION CONTACT:** Alan K. Roecklein, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 415-6223.

**SUPPLEMENTARY INFORMATION:**

**Background**

The requirement for an annual medical examination to ensure safe use of respiratory equipment has been in the regulations for some time. The need for these examinations was reconfirmed by the American National Standards Institute (ANSI) in ANSI Z88.2-1992. However, considerable experience with implementation of the requirement has indicated that the annual frequency of medical examinations is costly and

could be reduced significantly with no adverse impact on health and safety. The NRC Regulatory Review Group reviewed the existing requirement and concluded that the frequency of medical examinations could be reduced without adverse impact on worker safety. This change was recommended to the Commission as a candidate for licensee burden reduction in SECY-94-003 and supported by the Commission by memorandum from Samuel J. Chilk to James M. Taylor dated February 14, 1994.

The ANSI reviewed this issue and, in ANSI Z88.6 1984, published a recommendation that the frequency of medical examination should be determined by a physician and should be reduced based on age of the worker. ANSI recommended an examination every 5 years up to age 35, every 2 years up to age 45, and annually thereafter. ANSI also recommended special additional evaluations after prolonged absence from work for medical reasons or whenever a functional disability has been identified. These ANSI recommendations were reconfirmed in ANSI Z88.2-1992.

A proposed rule was published in the **Federal Register** on September 16, 1994 (59 FR 47565), for public comment. Ten letters of comment were received, all supporting the proposed rule. Consequently the NRC is codifying the rule as it was proposed.

The final rule provides for periodic medical examinations at either the 12-month interval as currently required or optionally at a frequency determined by a physician. Under this rule, licensees can elect to have the physician include in the initial medical examination or at the next 12-month reexamination, a determination of when each individual would need to be reexamined. Part 20 requires written procedures for use of respiratory protection equipment. Consequently, current procedures and license conditions likely include the annual frequency and a change in procedures or license conditions will be needed to implement a change in frequency of reexamination. The recommended frequencies contained in the ANSI standard may provide guidance on determining an appropriate frequency of reexamination which may be useful to physicians in determining frequency of reexamination. However, the Commission is not endorsing this standard. Rather the Commission believes that the frequency of reexamination should be determined by the examining physician.

The final rule uses the terminology "medically fit" rather than "physically able" to use a respirator. As indicated in