

Proposed Rules

Federal Register

Vol. 77, No. 145

Friday, July 27, 2012

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.

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

10 CFR Part 1708

Procedures for Safety Investigations

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Proposed rule.

SUMMARY: The Defense Nuclear Facilities Safety Board (Board) is responsible for making recommendations to the Secretary of Energy and the President regarding health and safety issues at the Department of Energy's (DOE) defense nuclear facilities. In this notice, the Board proposes a rule establishing procedures for conducting preliminary and formal safety investigations of events or practices at DOE defense nuclear facilities that the Board determines have adversely affected, or may adversely affect, public health and safety. The Board's experience in conducting formal safety investigations necessitates codifying the procedures set forth in the proposed rule. These procedures, among other benefits, will ensure a more efficient investigative process, protect confidential and privileged safety information, and promote uniformity of future safety investigations.

DATES: To be considered, comments must be mailed, emailed, or delivered to the address listed below by 5 p.m. on or before August 27, 2012.

ADDRESSES: Comments should be mailed or delivered to John G. Batherson, Associate General Counsel, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004. Send comments by facsimile to (202) 208-6518. Send comments by email to John G. Batherson at JohnB@dnfsb.gov.

FOR FURTHER INFORMATION CONTACT: John G. Batherson, Associate General Counsel, (202) 694-7018.

SUPPLEMENTARY INFORMATION:

Background

The Board is authorized to promulgate this proposed rule pursuant to its enabling legislation in the Atomic Energy Act of 1954, as amended, at 42 U.S.C. 2286b(c), which states that the Board may prescribe regulations to carry out its responsibilities. The Board is vested with broad authority pursuant to 42 U.S.C. 2286a(a)(2) to investigate events or practices which have adversely affected, or may adversely affect, public health and safety at DOE defense nuclear facilities.

The proposed rule establishes a new Part 1708 to the Board's regulations, setting forth procedures governing the specific conduct of safety investigations. The rule is intended to state clearly the Board's policy and procedures for safety investigations convened pursuant to the Board's enabling legislation. The Board has not previously proposed a rule specifically addressing procedures to be utilized in safety investigations. Rather, the Board has conducted preliminary safety inquiries and formal safety investigations pursuant to its statutory authority, when appropriate, following standard safety investigation policies, practices, and procedures. The proposed rule is intended to formalize those practices and procedures. The experience of Board investigators was utilized in drafting the proposed rule. The proposed rule will ensure a more efficient investigative process, and promote uniformity in the investigation of events or practices that have adversely affected, or may adversely affect, health and safety of the public and workers at DOE defense nuclear facilities. The proposed rule also serves the Board's duty to protect confidential and privileged safety information.

It is imperative that Board investigators be able to obtain information from witnesses as necessary to form an understanding of the underlying causes of events or practices that have adversely affected, or may adversely affect, public health and safety at DOE defense nuclear facilities. Frank, open communications are critical if Board investigators are to be effective. The Board must also be viewed as uncompromising in maintaining non-disclosure of privileged safety information. The Board must be able to assure complete confidentiality in order to encourage future witnesses to come

forward without fear of reprisal from employers.

As such, the Board requires the authority to offer witnesses enforceable assurances of confidentiality in order to encourage their full and frank testimony. Without such authority, witnesses may refrain from providing the Board with vital information affecting public health and safety, which will, in turn, frustrate the efficient operation of the Board's oversight mission. To encourage candor and facilitate the free flow of information, the Board adopts in this proposed rule procedures establishing a safety privilege to protect confidential witness statements from disclosure to the maximum extent permitted under existing law.

Matters of Regulatory Procedure

Administrative Procedure Act

This rulemaking complies with the Administrative Procedure Act and allows for a 30-day comment period. Interested persons are invited to submit written comments to the Board on this proposed rule, to be received on or before August 27, 2012. The Board will review all comments received and consider any modifications to this proposal that appear warranted in issuing its final rule.

Regulatory Flexibility Act

For purposes of the Regulatory Flexibility Act, the rule will not have a significant economic impact on a substantial number of small entities. The rule addresses only the procedures to be followed in safety investigations. Accordingly, the Board has determined that a Regulatory Flexibility Analysis is not required.

Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995, the proposed rule would not significantly or uniquely affect small governments and would not result in increased expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (as adjusted for inflation).

Executive Order 12866

In issuing this regulation, the Board has adhered to the regulatory philosophy and the applicable principles of regulation as set forth in

section 1 of Executive Order 12866, Regulatory Planning and Review. This rule has not been reviewed by the Office of Management and Budget under that Executive Order since it is not a significant regulatory action within the meaning of the Executive Order.

Executive Order 12988

The Board has reviewed this regulation in light of section 3 of Executive Order 12988, Civil Justice Reform, and certifies that it meets the applicable standards provided therein.

Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this regulation does not contain information collection requirements that require approval by the Office of Management and Budget. The Board expects the collection of information that is called for by the regulation would involve fewer than 10 persons each year.

Congressional Review Act

The Board has determined that this rulemaking does not involve a rule within the meaning of the Congressional Review Act.

List of Subjects in 10 CFR Part 1708

Administrative practice, Procedure, and Safety investigations.

For the reasons set forth in the preamble, the Defense Nuclear Facilities Safety Board proposes to add Part 1708 to 10 CFR chapter XVII to read as follows:

PART 1708—PROCEDURES FOR SAFETY INVESTIGATIONS

- Sec.
- 1708.100 Authority to conduct safety investigations.
 - 1708.101 Scope and purpose of safety investigations.
 - 1708.102 Types of safety investigations.
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 - 1708.104 Confidentiality of safety investigations and privileged safety information.
 - 1708.105 Promise of confidentiality.
 - 1708.106 Limitation on participation.
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 - 1708.108 Cooperation: ready access to facilities, personnel, and information.
 - 1708.109 Rights of witnesses in safety investigations.
 - 1708.110 Multiple interests.
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 - 1708.112 Appearance and practice before the Board.
 - 1708.113 Right to submit statements.
 - 1708.114 Official transcripts.
 - 1708.115 Final report of safety investigation.
 - 1708.116 Procedure after safety investigations.

Authority: 42 U.S.C. 2286b(c); 42 U.S.C. 2286a(a)(2); 44 U.S.C. 3101–3107, 3301–3303a, 3308–3314.

§ 1708.100 Authority to conduct safety investigations.

(a) The Defense Nuclear Facilities Safety Board (Board) is an independent federal agency in the executive branch of the United States Government.

(b) The Board's enabling legislation authorizes it to conduct safety investigations pursuant to the Atomic Energy Act of 1954, as amended (42 U.S.C. 2286a(a)(2)).

§ 1708.101 Scope and purpose of safety investigations.

(a) The Board shall investigate any event or practice at a Department of Energy defense nuclear facility which the Board determines has adversely affected, or may adversely affect, public health and safety.

(b) The purpose of any Board investigation shall be:

(1) To determine whether the Secretary of Energy is adequately implementing standards (including all applicable Department of Energy orders, regulations, and requirements) at Department of Energy defense nuclear facilities;

(2) To ascertain information concerning the circumstances of such event or practice and its implications for such standards;

(3) To determine whether such event or practice is related to other events or practices at other Department of Energy defense nuclear facilities; and

(4) To provide to the Secretary of Energy such recommendations for changes in such standards or the implementation of such standards (including Department of Energy orders, regulations, and requirements) and such recommendations relating to data or research needs as may be prudent or necessary.

§ 1708.102 Types of safety investigations.

(a) The Board may initiate a preliminary safety inquiry or order a formal safety investigation.

(b) A preliminary safety inquiry means any inquiry conducted by the Board or its staff, other than a formal investigation. Where it appears from a preliminary safety inquiry that a formal safety investigation is appropriate, the Board's staff will so recommend to the Board.

(c) A formal safety investigation is instituted by an Order of Safety Investigation issued either after a recorded notational vote of Board Members or after convening a meeting in accordance with the Government in

the Sunshine Act and voting in open or closed session, as the case may be.

(d) Orders of Safety Investigations will outline the basis for the investigation, the matters to be investigated, the Investigating Officer(s) designated to conduct the investigation, and their authority.

(e) The Office of the General Counsel shall have primary responsibility for conducting and leading a formal safety investigation. The Investigating Officer(s) shall report to the Board.

(f) The Board, or an individual Board Member authorized by the Board, may hold such closed or open hearings and sit and act at such times and places, and require the attendance and testimony of such witnesses and the production of such evidence as the Board or an authorized member may find advisable, or exercise any other applicable authority as provided in the Board's enabling legislation.

(g) Subpoenas in formal safety investigations may be issued only by signature of the Chairman, or any Member of the Board designated by the Chairman, and shall be served by any person designated by the Chairman, or otherwise as provided by law.

§ 1708.103 Request to conduct safety investigations.

(a) Any person may request that the Board perform a preliminary safety inquiry or conduct a formal safety investigation concerning a matter within the Board's jurisdiction.

(b) Actions the Board may take regarding safety investigation requests are discretionary.

(c) The Board will offer to protect the identity of a person requesting a safety investigation to the maximum extent permitted by law.

(d) Board safety investigations are wholly administrative and investigatory in nature and do not involve a determination of criminal culpability, adjudication of rights and duties, or other quasi-judicial determinations.

§ 1708.104 Confidentiality of safety investigations and privileged safety information.

(a) Information obtained during the course of a preliminary safety inquiry or a formal safety investigation may be treated as confidential, safety privileged, and non-public by the Board and its staff, to the extent permissible under existing law. The information subject to this protection includes but is not limited to: Identity of witnesses; recordings; statements; testimony; transcripts; emails; all documents, whether or not obtained pursuant to Board subpoena; any conclusions based

on privileged safety information; any deliberations or recommendations as to policies to be pursued; and all other related investigative proceedings and activities.

(b) The Board shall have the discretion to assert the safety privilege when safety information, determined by the Board as protected from release, is sought by any private or public governmental entity or by parties to litigation who attempt to compel its release.

(c) Nothing in this section voids or otherwise displaces the Board's legal obligations with respect to compliance with the Freedom of Information Act, the Government in the Sunshine Act, or any procedures or requirements contained in the Board's regulations issued pursuant to those Acts.

§ 1708.105 Promise of confidentiality.

(a) The Investigating Officer(s) may give a promise of confidentiality to any individual who provides evidence for a safety inquiry or investigation, to encourage frank and open communication.

(b) A promise of confidentiality must be explicit.

(c) A promise of confidentiality must be documented in writing.

(d) A promise of confidentiality may be given only as needed to ensure forthright cooperation of a witness and may not be given on a blanket basis to all witnesses.

(e) A promise of confidentiality must inform the witness that it applies only to information given to the Investigating Officer(s) and not to the same information if given to others.

§ 1708.106 Limitation on participation.

(a) A safety investigation under this rule is not a judicial or adjudicatory proceeding.

(b) No person or entity has standing to intervene or participate as a matter of right in any safety investigation under this regulation.

§ 1708.107 Powers of persons conducting formal safety investigations.

The Investigating Officer(s) appointed by the Board may take informal or formal statements, interview witnesses, take testimony, request production of documents, recommend issuance of subpoenas, recommend taking of testimony in a closed forum, recommend administration of oaths, and otherwise perform any lawful act authorized under the Board's enabling legislation in connection with any safety investigation ordered by the Board.

§ 1708.108 Cooperation: ready access to facilities, personnel, and information.

(a) Section 2286c(a) of the Atomic Energy Act of 1954, as amended, requires the Department of Energy to fully cooperate with the Board and provide the Board with ready access to such facilities, personnel, and information as the Board considers necessary, including ready access in connection with a safety investigation.

(b) Each contractor operating a Department of Energy defense nuclear facility under a contract awarded by the Secretary is also required, to the extent provided in such contract or otherwise with the contractor's consent, to fully cooperate with the Board and provide the Board with ready access to such facilities, personnel, and information of the contractor as the Board considers necessary in connection with a safety investigation.

(c) The Board may make a written request to persons or entities relevant to the safety investigation to preserve pertinent information, documents, and evidence, including electronically stored information, in order to preclude alteration or destruction of that information.

§ 1708.109 Rights of witnesses in safety investigations.

(a) Any person who is compelled to appear in person to provide testimony or produce documents in connection with a safety investigation is entitled to be accompanied, represented, and advised by an attorney.

(b) If an executive branch agency employee witness is represented by counsel from that same agency, counsel shall identify who counsel represents to determine whether counsel represents multiple interests in the safety investigation.

(c) Counsel for a witness may advise the witness with respect to any question asked where it is claimed that the testimony sought from the witness is outside the scope of the safety investigation, or that the witness is privileged to refuse to answer a question or to produce other evidence. For these permissible objections, the witness or counsel may object on the record to the question and may state briefly and precisely the ground therefore. If the witness refuses to answer a question, then counsel may briefly state on the record that counsel has advised the witness not to answer the question and the legal grounds for such refusal. The witness and his or her counsel shall not otherwise object to or refuse to answer any question, and they shall not otherwise interrupt any oral examination.

(d) When it is claimed that the witness has a privilege to refuse to answer a question on the grounds of self-incrimination, the witness must assert the privilege personally.

(e) Any objections made during the course of examination will be treated as continuing objections and preserved throughout the further course of testimony without the necessity for repeating them as to any similar line of inquiry.

(f) Counsel for a witness may not interrupt the examination by making any unnecessary objections or statements on the record.

(g) Following completion of the examination of a witness, such witness may make a statement on the record, and that person's counsel may, on the record, question the witness to enable the witness to clarify any of the witness's answers or to offer other evidence.

(h) The Investigating Officer(s) shall take all measures necessary to regulate the course of an investigative proceeding to avoid delay and prevent or restrain obstructionist or contumacious conduct or contemptuous language.

(i) The Investigating Officer(s) may report to the Board any instances where counsel for a witness, or other representative, has refused to comply with his or her directions, or has engaged in obstructionism or contumacy. The Board may thereupon take action as the circumstances may warrant.

(j) Witnesses appearing voluntarily do not have a right to have counsel present during questioning, although the Investigating Officer, in consultation with the Office of the General Counsel, may permit a witness appearing on a voluntary basis to be accompanied by an attorney or non-attorney representative.

§ 1708.110 Multiple interests.

(a) If counsel representing a witness appears in connection with a safety investigation, counsel shall state on the record all other persons or entities counsel represents in that investigation.

(b) When counsel does represent more than one person or entity in a safety investigation, counsel shall inform the Investigating Officer and each client of counsel's possible conflict of interest in representing that client.

(c) When an Investigating Officer, or the Board, as the case may be, in consultation with the Board's General Counsel, has concrete evidence that the presence of an attorney representing multiple interests would obstruct or impede the safety investigation, the Investigating Officer(s) or the Board may

prohibit that attorney from being present during testimony.

§ 1708.111 Sequestration of witnesses.

(a) Witnesses shall be sequestered during interviews, or during the taking of testimony, unless otherwise permitted by the Investigating Officer(s), or by the Board, as the case may be.

(b) No witness, or counsel accompanying any such witness, shall be permitted to be present during the examination of any other witness called in such proceeding, unless permitted by the Investigating Officer(s), or the Board, as the case may be.

§ 1708.112 Appearance and practice before the Board.

(a) Counsel appearing before the Board or the Investigating Officer(s) must conform to the standards of ethical conduct required of practitioners before the Courts of the United States.

(b) The Board may suspend and deny, temporarily or permanently, the privilege of appearing or practicing before the Board in any way to a person who is found:

- (1) Not to possess the requisite qualifications to represent others; or
- (2) To have engaged in unethical or improper professional conduct; or
- (3) To have engaged in obstructionism or contumacy; or
- (4) To be otherwise not qualified.

(c) Obstructionist or contumacious conduct in an investigation before the Board or the Investigating Officer(s) will be grounds for exclusion of any person from such safety investigation proceedings and for summary suspension for the duration of the course of the investigation.

(d) A witness may retain replacement counsel if original counsel is suspended or excluded.

§ 1708.113 Right to submit statements.

At any time during the course of an investigation, any person may submit documents, statements of facts, or memoranda of law for the purpose of explanation or further development of the facts and circumstances relevant to the safety matter under investigation.

§ 1708.114 Official transcripts.

(a) Official transcripts of testimony of witnesses, whether or not compelled by subpoena to appear before a Board safety investigation, shall be recorded either by an official reporter, or by any other person or means designated by the Investigating Officer or the Board's General Counsel.

(b) Such witness, after completing the compelled testimony may file a request with the Board's General Counsel to procure a copy of the official transcript

of that witness's testimony. The General Counsel shall rule on the request, and may deny for good cause.

(c) Good cause for denying a witness's request to procure a transcript may include, but shall not be limited to, the protection of a trade secret, non-disclosure of confidential or proprietary business information, security sensitive operational or vulnerability information, safety privileged information, or the integrity of Board investigations.

(d) Whether or not a request is made, the witness and his or her attorney shall have the right to inspect the official transcript of the witness's own testimony, in the presence of the Investigating Officer or his designee, for purposes of conducting errata review.

(e) Transcripts of testimony are otherwise considered confidential and privileged safety information and in no case shall a copy or any reproduction of such transcript be released to any other person or entity, except as provided in paragraph (2) above or as required under the Freedom of Information Act or the Government in the Sunshine Act, or any procedures or requirements contained in Board regulations issued pursuant to those Acts.

§ 1708.115 Final report of safety investigation.

(a) The Board will complete a final report of the safety investigation fully setting forth the Board's findings and conclusions.

(b) The final report of the safety investigation is confidential and protected by the safety privilege, and is therefore not releasable.

(c) The Board in its discretion may sanitize the final report of the safety investigation by redacting confidential and safety privileged information so that the report is put in a publically releasable format.

(d) Nothing in this section voids or otherwise displaces the Board's legal obligations with respect to compliance with the Freedom of Information Act, the Government in the Sunshine Act, or any procedures or requirements contained in the Board's regulations issued pursuant to those Acts.

§ 1708.116 Procedure after safety investigations.

(a) If a formal safety investigation results in a finding that an event or practice has adversely affected, or may adversely affect, public health and safety, the Board may take any appropriate action authorized to it under its enabling statute, including, but not limited to, making a formal recommendation to the Secretary of Energy, convening a hearing, or establishing a reporting requirement.

(b) If a safety investigation yields information relating to violations of Federal criminal law involving Government officers and employees, the Board shall expeditiously refer the matter to the Department of Justice for disposition.

(c) If in the course of a safety investigation a safety issue or concern is found to be outside the Board's jurisdiction, that safety issue or concern shall be referred to the appropriate entity with jurisdiction for disposition.

(d) Statements made in connection with testimony provided to the Board in an investigation are subject to the provisions of 18 U.S.C. 1001.

Dated: July 20, 2012.

Jessie H. Roberson,
Vice Chairman.

[FR Doc. 2012-18180 Filed 7-26-12; 8:45 am]

BILLING CODE 3670-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA-2012-N-0447]

Antimicrobial Animal Drug Sales and Distribution Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or Agency) is soliciting comments regarding potential changes to its regulations relating to records and reports for approved new animal drugs. FDA is considering revisions to this regulation to incorporate the requirements of section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105). As part of that process, FDA is reviewing other reporting requirements applicable to antimicrobial new animal drug sponsors to determine whether additional information should be reported. Collecting data on antimicrobial drugs used in food-producing animals will assist FDA in tracking antimicrobial use trends and examining how such trends may relate to antimicrobial resistance.

DATES: Submit electronic or written comments by September 25, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0447, by any of the following methods: