

# Federal Law And Regulations Regarding Defects And Noncompliance

## Procedure Adopted Pursuant to NRC Regulations Title 10, Chapter 1, Code of Federal Regulations – Part 21 (1/18/12 Edition)

### Individuals To Whom Reports May be Made

## Mark Comerford, President & CEO • • • • • Jean C. Neel, VP Corporate Affairs

### Section 206, Energy Reorganization Act, 1974 NONCOMPLIANCE

- Sec. 206(a) Any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954 as amended, or pursuant to this Act, who obtains information reasonably indicating that such a facility or activity or basic components supplied to such facility or activity—
- (1) fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order or license of the Commission relating to substantial safety hazards, or
  - (2) contains a defect which could create a substantial safety hazard, as defined by regulations which the Commission shall promulgate, shall immediately notify the Commission of such failure to comply, or of such defect, unless such person has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.
- (b) Any person who knowingly and consciously fails to provide notice required by subsection (a) of this section shall be subject to a civil penalty in an amount equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.
- (c) The requirements of this section shall be prominently posted on the premises of any facility licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended.
- (d) The Commission is authorized to conduct such reasonable inspections and other enforcement activities as needed to insure compliance with the provisions of this section.

## PART 21—REPORTING OF DEFECTS AND NONCOMPLIANCE

### General Provisions

#### § 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

#### § 21.2 Scope.

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to:

- (1) Each individual, partnership, corporation, or other entity applying for or holding a license or permit under the regulations in this chapter to possess, use, or transfer within the United States source material, byproduct material, special nuclear material, and/or spent fuel and high-level radioactive waste, or to construct, manufacture, possess, own, operate, or transfer within the United States, any production or utilization facility or independent spent fuel storage installation (ISFSI) or monitored retrievable storage installation (MRS); and each director and responsible officer of such a licensee;
- (2) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, that constructs a production or utilization facility licensed for manufacture, construction, or operation under parts 50 or 52 of this chapter, an ISFSI for the storage of spent fuel licensed under part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste under part 72 of this chapter, or a geologic repository for the disposal of high-level radioactive waste under part 60 or 63 of this chapter; or supplies basic components for a facility or activity licensed, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or part 72 of this chapter;
- (3) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for a design certification rule under part 52 of this chapter; or supplying basic components with respect to that design certification, and each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, whose application for design certification has been granted under part 52 of this chapter, or who has supplied or is supplying basic components with respect to that design certification;
- (4) Each individual, corporation, partnership, or other entity doing business within the United States, and each director and responsible officer of such an organization, applying for or holding a standard design approval under part 52 of this chapter; or supplying basic components with respect to a standard design approval under part 52 of this chapter;

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license under part 52 of this chapter (for the period of construction until the date that the Commission makes the finding under § 52.103(g) of this chapter), or to manufacture a facility under part 52 of this chapter, evaluation of potential defects and failures to comply and reporting of defects and failures to comply under § 50.55(e) of this chapter satisfies each person's evaluation, notification, and reporting obligation to report defects and failures to comply under this part and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(c) For persons licensed to operate a nuclear power plant under part 50 or part 52 of this chapter, evaluation of potential defects and appropriate reporting of defects under §§ 50.72, 70, or § 73.71 of this chapter, satisfies each person's evaluation, notification, and reporting obligation to report defects under this part, and the responsibility of individual directors and responsible officers of these licensees to report defects under Section 206 of the Energy Reorganization Act of 1974.

(d) Nothing in these regulations should be deemed to preclude either an individual, a manufacturer, or a supplier of a commercial grade item (as defined in § 21.3) not subject to the regulations in this part from reporting to the Commission, a known or suspected defect or failure to comply and, as authorized by law, the identity of anyone so reporting will be withheld from disclosure. NRC regional offices and headquarters will accept collect telephone calls from individuals who wish to speak to NRC representatives concerning nuclear safety-related problems. The location and telephone numbers of the four regions (answered during regular working hours), are listed in appendix D to part 20 of this chapter. The telephone number of the NRC Operations Center (answered 24 hours a day—including holidays) is (301) 816-5100. (e) The regulations in this part apply in accordance with 10 CFR 76.60 to each individual, partnership, corporation, or other entity required to obtain a certificate of compliance or an approved compliance plan under part 76 of this chapter. [56 FR 36089, July 31, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 59 FR 48959, Sept. 23, 1994; 60 FR 48373, Sept. 19, 1995; 66 FR 55790, Nov. 2, 2001; 72 FR 49486, Aug. 28, 2007]

#### § 21.3 Definitions.

As used in this part:

**Basic component.** (1)(i) When applied to nuclear power plants licensed under 10 CFR part 50 or part 52 of this chapter, basic component means a structure, system, or component, or part thereof that affects its safety function necessary to assure:

- (A) The integrity of the reactor coolant pressure boundary;
- (B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- (C) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(ii) Basic components are items designed and manufactured under a quality assurance program complying with appendix B to part 50 of this chapter, or commercial grade items which have successfully completed the dedication process.

(2) When applied to standard design certifications under subpart C of part 52 of this chapter and standard design approvals under part 52 of this chapter, basic component means the design or procurement information approved or to be approved within the scope of the design certification or approval for a structure, system, or component, or part thereof, that affects its safety function necessary to assure:

- (i) The integrity of the reactor coolant pressure boundary;
- (ii) The capability to shut down the reactor and maintain it in a safe shutdown condition; or
- (iii) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to those referred to in § 50.34(a)(1), § 50.67(b)(2), or § 100.11 of this chapter, as applicable.

(3) When applied to other facilities and other activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72 of this chapter, basic component means a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the licensee of a facility or activity subject to the regulations in this part and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could create a substantial safety hazard.

(4) In all cases, basic component includes safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the component hardware, design certification, design approval, or information in support of an early site permit application under part 52 of this chapter, whether these services are performed by the component supplier or others.

**Commercial grade item.** (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, commercial grade item means a structure, system, or component, or part thereof that affects its safety function, that was not designed and manufactured as a basic component. Commercial grade items do not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, commercial grade item means an item that is:

- (i) Not subject to design or specification requirements that are unique to those facilities or activities;
- (ii) Used in applications other than those facilities or activities; and
- (iii) To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, a catalog).

**Commission** means the Nuclear Regulatory Commission or its duly authorized representatives.

**Constructing or construction** means the analysis, design, manufacture, fabrication, placement, erection, installation, modification, inspection, or testing of a facility or activity which is subject to the regulations in this part and consulting services related to the facility or activity that are safety related.

**Critical characteristics.** When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, critical characteristics are those important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

**Dedicating entity.** When applied to nuclear power plants licensed pursuant to 10 CFR Part 50, dedicating entity means the organization that performs the dedication process. Dedication may be performed by the manufacturer of the item, a third-party dedicating entity, or the licensee itself. The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process.

**Dedication.** (1) When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60, dedication is an acceptance process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, appendix B, quality assurance program. This assurance is achieved

by identifying the critical characteristics of the item and verifying their acceptability by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following: commercial grade surveys; product inspections or witness at holdpoints at the manufacturer's facility, and analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B. The process is considered complete when the item is designated for use as a basic component.

(2) When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication occurs after receipt when that item is designated for use as a basic component.

#### Defect means:

(1) A deviation in a basic component delivered to a purchaser for use in a facility or an activity subject to the regulations in this part if, on the basis of an evaluation, the deviation could create a substantial safety hazard;

(2) The installation, use, or operation of a basic component containing a defect as defined in this section;

(3) A deviation in a portion of a facility subject to the early site permit, standard design certification, standard design approval, construction permit, combined license or manufacturing licensing requirements of part 50 or part 52 of this chapter, provided the deviation could, on the basis of an evaluation, create a substantial safety hazard and the portion of the facility containing the deviation has been offered to the purchaser for acceptance;

(4) A condition or circumstance involving a basic component that could contribute to the exceeding of a safety limit, as defined in the technical specifications of a license for operation issued under part 50 or part 52 of this chapter; or

(5) An error, omission or other circumstance in a design certification, or standard design approval that, on the basis of an evaluation, could create a substantial safety hazard.

**Deviation** means a departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

**Director** means an individual, appointed or elected according to law, who is authorized to manage and direct the affairs of a corporation, partnership or other entity. In the case of an individual proprietorship, director means the individual.

**Discovery** means the completion of the documentation first identifying the existence of a deviation or failure to comply potentially associated with a substantial safety hazard within the evaluation procedures discussed in § 21.21. (a).

**Evaluation** means the process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

**Notification** means the telephonic communication to the NRC Operations Center or written transmittal of information to the NRC Document Control Desk.

**Operating or operation** means the operation of a facility or the conduct of a licensed activity which is subject to the regulations in this part and consulting services related to operations that are safety related.

**Procurement document** means a contract that defines the requirements which facilities or basic components must meet in order to be considered acceptable by the purchaser.

**Responsible officer** means the president, vice-president or other individual in the organization of a corporation, partnership, or other entity who is vested with executive authority over activities subject to this part.

**Substantial safety hazard** means a loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export, under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

**Supplying or supplies** means contractually responsible for a basic component used or to be used in a facility or activity which is subject to the regulations in this part.

[42 FR 28893, June 6, 1977; 42 FR 36803, July 18, 1977, as amended at 43 FR 48622, Oct. 19, 1978; 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 56 FR 36089, July 31, 1991; 59 FR 5519, Feb. 7, 1994; 60 FR 48373, Sept. 19, 1995; 61 FR 65171, Dec. 11, 1996; 64 FR 72000, Dec. 23, 1999; 66 FR 55790, Nov. 2, 2001; 72 FR 49486, Aug. 28, 2007]

#### § 21.4 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding upon the Commission.

#### § 21.5 Communications.

Except where otherwise specified in this part, written communications and reports concerning the regulations in this part must be addressed to the NRC's Document Control Desk, and sent by mail to the U.S. Nuclear Regulatory

Commission, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at <http://www.nrc.gov/site-help/e-submittals.html>; by e-mail to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov); or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. In the case of a licensee or permit holder, a copy of the communication must also be sent to the appropriate Regional Administrator at the address specified in appendix D to part 20 of this chapter.

[56 FR 36089, July 31, 1991 as amended at 68 FR 58802, Oct. 10, 2003; 70 FR 69421, Nov. 16, 2005; 72 FR 33386, Jun. 18, 2007; 72 FR 49487, Aug. 28, 2007; 74 FR 62680, Dec. 1, 2009]

#### § 21.6 Posting requirements.

(a)(1) Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of —

- (i) The regulations in this part;
- (ii) Section 206 of the Energy Reorganization Act of 1974; and
- (iii) Procedures adopted pursuant to the regulations in this part.

(2) These documents must be posted in a conspicuous position on any premises within the United States where the activities subject to this part are conducted.

(b) If posting of the regulations in this part or the procedures adopted pursuant to the regulations in this part is not practicable, the licensee or firm subject to the regulations in this part may, in addition to posting section 206, post a notice which describes the regulations/procedures, including the name of the individual to whom reports may be made, and states where they may be examined.

(c) The effective date of this section has been deferred until January 6, 1978. [42 FR 28893, June 6, 1977, as amended at 60 FR 48374, Sept. 19, 1995]

#### § 21.7 Exemptions.

The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items. [42 FR 28893, June 6, 1977, as amended at 43 FR 48622, Oct. 19, 1978]

#### § 21.8 Information collection requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0035.

(b) The approved information collection requirements contained in this part appear in §§ 21.7, 21.21, and 21.51. [62 FR 52185, Oct. 6, 1997]

### Notification

#### § 21.21 Notification of failure to comply or existence of a defect and its evaluation.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall adopt appropriate procedures to —

(1) Evaluate deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards as soon as practicable, and, except as provided in paragraph (a)(2) of this section, in all cases within 60 days of discovery, in order to identify a reportable defect or failure to comply that could create a substantial safety hazard, were it to remain uncorrected, and

(2) Ensure that if an evaluation of an identified deviation or failure to comply potentially associated with a substantial safety hazard cannot be completed within 60 days from discovery of the deviation or failure to comply, an interim report is prepared and submitted to the Commission through a director or responsible officer or designated person as discussed in § 21.21(d)(5). The interim report should describe the deviation or failure to comply that is being evaluated and should also state when the evaluation will be completed. This interim report must be submitted in writing within 60 days of discovery of the deviation or failure to comply.

(3) Ensure that a director or responsible officer subject to the regulations of this part is informed as soon as practicable, and, in all cases, within the 5 working days after completion of the evaluation described in paragraphs (a)(1) or (a)(2) of this section if the manufacture, construction, or operation of a facility or activity, a basic component supplied for such facility or activity, or the design certification or design approval under part 52 of this chapter—

(i) Fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission or standard design approval under part 52 of this chapter, relating to a substantial safety hazard, or

(ii) Contains a defect.

(b) If the deviation or failure to comply is discovered by a supplier of basic components, or services associated with basic components, and the supplier determines that it does not have

the capability to perform the evaluation to determine if a defect exists, then the supplier must inform the purchasers or affected licensees within five working days of this determination so that the purchasers or affected licensees may evaluate the deviation or failure to comply, pursuant to § 21.21(a).

(c) A dedicating entity is responsible for —

(1) Identifying and evaluating deviations and reporting defects and failures to comply associated with substantial safety hazards for dedicated items; and

(2) Maintaining auditable records for the dedication process.

(d)(1) A director or responsible officer subject to the regulations of this part or a person designated under § 21.21(d)(5) must notify the Commission when he or she obtains information reasonably indicating a failure to comply or a defect affecting —

(i) The manufacture, construction or operation of a facility or an activity within the United States that is subject to the licensing requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter and that is within his or her organization's responsibility; or

(ii) A basic component that is within his or her organization's responsibility and is supplied for a facility or an activity within the United States that is subject to the licensing, design certification, or approval requirements under parts 30, 40, 50, 52, 60, 61, 63, 70, 71, or 72 of this chapter.

(2) The notification to NRC of a failure to comply or of a defect under paragraph (d)(1) of this section and the evaluation of a failure to comply or a defect under paragraphs (a)(1) and (a)(2) of this section, are not required if the director or responsible officer has actual knowledge that the Commission has been notified in writing of the defect or the failure to comply.

(3) Notification required by paragraph (d)(1) of this section must be made as follows —

(i) Initial notification by facsimile, which is the preferred method of notification, to the NRC Operations Center at (301) 816 - 5151 or by telephone at (301) 816 - 5100 within two days following receipt of information by the director or responsible corporate officer under paragraph (a)(1) of this section, on the identification of a defect or a failure to comply.

Verification that the facsimile has been received should be made by calling the NRC Operations Center. This paragraph does not apply to interim reports described in § 21.21(a)(2).

(ii) Written notification to the NRC at the address specified in § 21.5 within 30 days following receipt of information by the director or responsible corporate officer under paragraph (a)(3) of this section, on the identification of a defect or a failure to comply.

(4) The written report required by this paragraph shall include, but need not be limited to, the following information, to the extent known:

(i) Name and address of the individual or individuals informing the Commission.

(ii) Identification of the facility, the activity, or the basic component supplied for such facility or such activity within the United States which fails to comply or contains a defect.

(iii) Identification of the firm constructing the facility or supplying the basic component which fails to comply or contains a defect.

(iv) Nature of the defect or failure to comply and the safety hazard which is created or could be created by such defect or failure to comply.

(v) The date on which the information of such defect or failure to comply was obtained.

(vi) In the case of a basic component which contains a defect or fails to comply, the number and location of these components in use at, supplied for, being supplied for, or may be supplied for, manufactured, or being manufactured for one or more facilities or activities subject to the regulations in this part.

(vii) The corrective action which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

(viii) Any advice related to the defect or failure to comply about the facility, activity, or basic component that has been, is being, or will be given to purchasers or licensees.

(ix) In the case of an early site permit, the entities to whom an early site permit was transferred.

(5) The director or responsible officer may authorize an individual to provide the notification required by this paragraph, provided that, this shall not relieve the director or responsible officer of his or her responsibility under this paragraph.

(e) Individuals subject to this part may be required by the Commission to supply additional information related to a defect or failure to comply. Commission action to obtain additional information may be based on reports of defects from other reporting entities.

[42 FR 28893, June 6, 1977, as amended at 46 FR 58283, Dec. 1, 1981; 47 FR 57480, Dec. 27, 1982; 52 FR 31611, Aug. 21, 1987; 56 FR 36089, July 31, 1991; 59 FR 14086, Mar. 25, 1994; 60 FR 48374, Sept. 19, 1995; 66 FR 55790, Nov. 2, 2001; 67 FR 77652, Dec. 19, 2002; 72 FR 49487, Aug. 28, 2007]

### Procurement Documents

#### § 21.31 Procurement documents.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall ensure that each procurement document for a facility, or a basic component issued by him, her or it on or after January 6, 1978, specifies, when applicable, that the provisions of 10 CFR Part 21 apply.

[60 FR 48374, Sept. 19, 1995]

### Inspections, Records

#### § 21.41 Inspections.

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission to inspect records, premises, activities, and basic components as necessary to accomplish the purposes of this part.

[60 FR 48374, Sept. 19, 1995]

#### § 21.51 Maintenance and inspection of records.

(a) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall prepare and maintain records necessary to accomplish the purposes of this part, specifically —

(1) Retain evaluations of all deviations and failures to comply for a minimum of five years after the date of the evaluation;

(2) Suppliers of basic components must retain any notifications sent to purchasers and affected licensees for a minimum of five years after the date of the notification.

(3) Suppliers of basic components must retain a record of the purchasers of basic components for 10 years after delivery of the basic component or service associated with a basic component.

(4) Applicants for standard design certification under subpart B of part 52 of this chapter and others providing a design which is the subject of a design certification, during and following Commission adoption of a final design certification rule for that design, shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of design which is the subject of the design certification rule or service associated with the design.

(5) Applicants for or holders of a standard design approval under subpart E of part 52 of this chapter and others providing a design which is the subject of a design approval shall retain any notifications sent to purchasers and affected licensees for a minimum of 5 years after the date of the notification, and retain a record of the purchasers for 15 years after delivery of the design which is the subject of the design approval or service associated with the design.

(b) Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part shall permit the Commission the opportunity to inspect records pertaining to basic components that relate to the identification and evaluation of deviations, and the reporting of defects and failures to comply, including (but not limited to) any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

[56 FR 36090, July 31, 1991, as amended at 60 FR 48374, Sept. 19, 1995; 72 FR 49488, Aug. 28, 2007]

### Enforcement

#### § 21.61 Failure to notify.

(a) Any director or responsible officer of an entity (including dedicating entity) that is not otherwise subject to the deliberate misconduct provisions of this chapter but is subject to the regulations in this part who knowingly and consciously fails to provide the notice required as by § 21.21 shall be subject to a civil penalty equal to the amount provided by section 234 of the Atomic Energy Act of 1954, as amended.

(b) Any NRC licensee or applicant for a license (including an applicant for, or holder of, a permit), applicant for a design certification under part 52 of this chapter during the pendency of its application, applicant for a design certification after Commission adoption of a final design certification rule for that design, or applicant for or holder of a standard design approval under part 52 of this chapter subject to the regulations in this part who fails to provide the notice required by § 21.21, or otherwise fails to comply with the applicable requirements of this part shall be subject to a civil penalty as provided by Section 234 of the Atomic Energy Act of 1954, as amended.

(c) The dedicating entity, pursuant to § 21.21(c) of this part, is responsible for identifying and evaluating deviations, reporting defects and failures to comply for the dedicated item, and maintaining auditable records of the dedication process. NRC enforcement action can be taken for failure to identify and evaluate deviations, failure to report defects and failures to comply, or failure to maintain auditable records.

[60 FR 48374, Sept. 19, 1995; 72 FR 49488, Aug. 28, 2007]

#### § 21.62 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of