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§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—

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(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.

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(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