

§ 21.3

10 CFR Ch. I (1–1–23 Edition)

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, 50.73, 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 numbers of the NRC Headquarters Operations Center (answered 24 hours a day—including holidays) are listed in appendix A to part 73 of this chapter.

(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; 85 FR 65661, Oct. 16, 2020]

§ 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 B 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 50, 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 50, 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.

Nuclear Regulatory Commission

§21.6

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; 84 FR 63567, Nov. 18, 2019]

§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; or by writing the Office of the Chief Information Officer, 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.

[72 FR 49487, Aug. 28, 2007, as amended at 74 FR 62680, Dec. 1, 2009; 80 FR 74979, Dec. 1, 2015]

§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]