

facility licensed for the manufacture, construction, or operation pursuant to part 50 or part 52 of this chapter, an ISFSI for the storage of spent fuel licensed pursuant to part 72 of this chapter, an MRS for the storage of spent fuel or high-level radioactive waste pursuant to 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.

(b) For persons licensed to construct a facility under either a construction permit issued under § 50.23 of this chapter or a combined license issued under § 52.227 of this chapter, or approved to hold a permit for a site or sites for one or more nuclear power facilities under § 52.24 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 such 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 such licensees to report defects under section 206 of the Energy Reorganization Act of 1974.

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16. Section 21.3 is revised to read as follows:

### **§ 21.3 Definitions.**

As used in this part:

*Basic component.* (1)(i) When applied to nuclear power plants licensed pursuant to 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 10 CFR part 50, appendix B, or commercial grade items which have successfully completed the dedication process.

(2) When applied to other facilities and when applied to other activities licensed pursuant to 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.

(3) 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 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 or part 52, 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 or part 52, 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 or part 52, 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. 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 or part 52, 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