

Problem Statement: The 2016 Draft RIS on Embedded Digital Devices (EDD) introduces a new definition for “safety related” as it applies to Part 70 and Part 40 licensed facilities. This new definition is a significant departure from the standard “safety related” definition used in industry for decades. In this draft RIS, the criteria for a Part 70 or Part 40 “safety related” EDD is basically any EDD needed for compliance with our license commitments and ISA. (See page 11 RIS excerpt below.)

In the RIS, the “safety related” definition used for power reactors is consistent with the standard definition. See Part 50 and Part 21 text below in **green** font. In the RIS, the “safety related” definition used for Part 70 and Part 40 licensees is **NOT** consistent with the standard definition. See Part 70 and Part 21 text below in **red** font.

10CFR50.2

Safety-related structures, systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:

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

Substantial safety hazard means, for the purposes of § 50.55(e) of this chapter, 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 authorized by the construction permit issued under this part.

Basic component means, for the purposes of § 50.55(e) of this chapter:

- (1) When applied to nuclear power reactors, any plant structure, system, component, or part thereof 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.
- (2) When applied to other types of facilities or portions of such facilities for which construction permits are issued under § 50.23, a component, structure, system or part thereof that is directly

procured by the construction permit holder for the facility subject to the regulations of 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 parts, or consulting services that are associated with the component hardware, whether these services are performed by the component supplier or other supplier.

10CFR70.4

No definition for safety related. *The standard definition for Part 70 and Part 40 facilities comes from Part 21.*

10CFR21.3

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.

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.

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Page 6: For non-power reactors, the term “**safety-related structures, systems and components**,” as used in this RIS, refers to **those structures, systems and components (SSCs) required to ensure the safety of the public, and to protect the environment, as described in each facility’s safety analysis report.**

Page 11: For the purpose of this RIS, the term “**safety-related**” as applicable to FCFs applies to systems, structures, components, procedures and controls (of a facility or a process) **that are relied upon to protect the health and safety of workers, the public, and the environment. Their functionality ensures key regulatory requirements (and license commitments), such as exposures to or levels of radiation, radioactivity, or hazardous chemicals released, are met.**

Page 12: The regulation in 10 CFR Part 21, “Reporting of Defects and Noncompliance” applies to FCFs, but is not included in the above list because it applies to licensees or applicants, not equipment. Nevertheless, licensees should comply with this regulation because it supports quality, reliability, procurement planning, and material control of equipment with EDDs.