QUESTIONS ASKED AT THE 2011 FUEL CYCLE INFORMATION EXCHANGE RELATED TO TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* PART 21

Q1. How are basic component and substantial safety hazard defined?

Title 10 of the *Code of Federal Regulations* (10 CFR) 21.3 provides definitions for basic component and substantial safety hazard.

The definitions of basic component in 10 CFR 21.3 paragraphs (3) and (4) apply to facilities or activities licensed under 10 CFR Parts 30, 40, 60, 63, 70, 71, and 72. This includes licensees and holders of a certificate of compliance, applicants, and suppliers of basic components to any facility or activity subject to the requirements of Part 21.

> *Basic component* (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."
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> *Basic component* (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."

A *substantial safety hazard* is defined in 10 CFR 21.3 as "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."

Pursuant to 10 CFR 21.2(e) and 76.60(e), a specified subset of the 10 CFR Part 21 regulations (§§ 21.6, 21.21 and 21.31) are applicable to any individual, partnership, corporation or other entity required to obtain a certificate of compliance or an approved compliance plan under 10 CFR Part 76. Because the definitions of *basic component* and *substantial safety hazard* set forth above are used in 10 CFR § 21.21, these definitions are applicable to 10 CFR Part 76 certificate holders.

Q2. Under what circumstances would an item(s) relied on for safety (IROFS) nonconformance require a Part 21 notification?

A nonconformance is a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.[1] IROFS, as defined in 10 CFR 70.4, are "structures, systems, equipment, components, and activities

[1] Definition from ASME NQA-1-2008.

of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel (i.e., beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety."

A nonconformance in an IROFS would be reportable under 10 CFR Part 21 in the following circumstances: (1) the IROFS is a basic component, and (2) the nonconformance represents a deficiency that has been evaluated and determined to be a defect or a failure to comply that could create a substantial safety hazard.

Note that an interim report must be submitted to the NRC under 10 CFR 21.21(a)(2) when the evaluation of a deviation or failure to comply that is or may be associated with a *substantial safety hazard* cannot be completed within 60 days of discovery.

Q3. Does Part 21 apply only to IROFS?

IROFS, or items relied on for safety, is a term defined for Part 70 facilities. IROFS include structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in § 70.61 or to mitigate their potential consequences.

Part 21 applies to all basic components. For further discussion of the relationship between IROFS and basic components, see response to Question 4.

Q4. Should hardware IROFS be considered basic components? That is, does a failure of an IROFS meet the substantial safety hazard criteria?

Yes. As discussed below, the Part 70 provisions regarding IROFS are consistent with the Part 21 definitions of *basic component* and *substantial safety hazard,* and there may be situations where both the Part 70 IROFS provisions and the Part 21 substantial safety hazard criteria are applicable.

The performance requirements of § 70.61 require that the risk of each credible high-consequence event be limited (§ 70.61(b)); the risk of each credible intermediate-consequence event be limited (§ 70.61(c)); and the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical—including the use of an approved margin of subcriticality for safety (§ 70.61(d)). Each engineered or administrative control or control system necessary to comply with paragraphs (b), (c), or (d) of § 70.61 must be designated as an IROFS.

The Part 21 definition of *basic component* quoted above in response to Q1 states that its scope includes facilities licensed under 10 CFR Part 70. As more fully stated there, the term means a structure, system, or component that affects the safety function, is directly procured by the licensee, and in which a defect or failure to comply with any applicable requirement could create a substantial safety hazard. The Part 21 definition of *substantial safety hazard* refers, in relevant part, to "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." Note that the phrase "public health and safety" as used here includes both

members of the public and licensee workers/employees. The Statements of Consideration published with issuance of 10 CFR Part 21 on June 6, 1977 (42 FR 28892) stated that criteria appropriate for determination of creation of a substantial safety hazard include: moderate exposure to, or release of, licensed material; major degradation of essential safety-related equipment; major deficiencies involving design, construction, inspection, test or use of licensed facilities or material; and, to the extent that failures to comply or defects in a security system can contribute to a substantial safety hazard, such failures and defects are within the scope of Part 21

The performance requirements in § 70.61 are consistent with events that could cause moderate radiological exposure or releases of licensed material, or represent major deficiencies associated with the use of licensed facilities or material. Thus, the failure of a basic component that is required to prevent an accident or mitigate the consequences of an accident in accordance with § 70.61 meets the substantial safety hazard criteria. Consequently, an IROFS (whether in the form of hardware or any other items or activities relied on for safety) is a basic component if the following statements are true:

(1) The IROFS is necessary to ensure compliance with the performance requirements in § 70.61; and

(2) The IROFS is a structure, system, or component, or part thereof, that affects their safety function, that is directly procured by the Part 70 licensee; or

(3) The IROFS is a commercial grade item that has been dedicated in accordance with 10 CFR Part 21 and has been designated for use as a basic component; or

(4) The IROFS is an activity, such as safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with (2) or (3) above, if a defect or failure to comply associated with the activity could create a substantial safety hazard.

Examples of exposure levels and radiological releases that would be considered a substantial safety hazard have previously been identified in NUREG-0302, Revision 1, “Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance,” dated July 12-26, 1977 (ADAMS Accession No. ML062080399) and Information Notice 91-39, “Compliance with 10 CFR Part 21, “Reporting of Defects and Noncompliance,” dated June 17, 1991 (ADAMS Accession No. ML03119504).

Q5. Could you give an example of a “failure to comply” that has been reported to the U.S. Nuclear Regulatory Commission (NRC)?

Title 10 of the *Code Of Federal Regulations* Part 21.21 requires that notification be made to the Commission when a facility, activity, or basic component supplied to such facility or activity that is regulated pursuant to 10 CFR Part 21 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.

Examples of such failures to comply may include the failure to invoke 10 CFR Part 21 in procurement documents for the purchase of basic components, establishment or use of an inadequate 10 CFR Part 21 procedure, and failure to report a defect or failure to

comply under Part 21 or failure to make a report within the proper timelines. Past reports of failures to comply have been submitted to the Commission are available in the NRC Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html. Two such reports may be found at ADAMS Accession Numbers ML080650194 and ML021550411.

These examples do not represent the totality of scenarios in which a reportable failure to comply may exist.

Q6. If a matter is reported to the NRC under Appendix A to Part 70, does Part 21 have to be referenced? [Also, what are the expectations for timeliness of reporting given that the Appendix A and Part 21 reporting] timelines are different?

If the safety event that was reported under Appendix A to 10 CFR Part 70 was caused by a defect in a basic component or a failure 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, then 10 CFR Part 21 would need to be referenced in the Appendix A report to identify that the report is informing the Commission of a defect in a basic component or a failure to comply.

10 CFR 21.21(d)(2) states that "[t]he 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." In order for the report made under Appendix A to 10 CFR Part 70 to satisfy the requirements of 10 CFR 21.21(d)(2), the following criteria should be met:

(1) all information required per § 21.21(d)(4) should be included in the written report,

(2) 10 CFR Part 21 should be referenced in the initial notification and written report, and

(3) the timeliness of notification must meet the two-day initial notification and 30-day written notification requirements identified in § 21.21(d)(3)(i) and § 21.21(d)(3)(ii) for reporting defects and failures to comply.

Should these criteria not be met by the Part 70, Appendix A report, a separate initial notification and/or written report must be made to ensure compliance with 10 CFR Part 21.

For a discussion of the timeliness requirements for reports made under Appendix A of 10 CFR Part 70 that also serve as notification of a defect or failure to comply in accordance with 10 CFR Part 21, please see Q11.(a).

Q7. What is the relationship between Part 21 and the full disclosure provisions of the rule on completeness and accuracy of information?

NRC regulations, including, but not limited to §§ 30.9, 40.9, 60.10, 63.10, 70.9, 71.7, 72.11, and 76.9, specify requirements for the completeness and accuracy of information provided to the Commission. These regulations require, in part, that: (1) information

provided to the Commission be complete and accurate in all material respects; and (2) notification be made to the Commission upon identification of any information having a significant implication for public health and safety or common defense and security.

The notification requirement (*see, e.g.*, § 70.9(b)) states that it is "not applicable to information which is already required to be provided to the Commission by other reporting or updating requirements." Therefore, information having a significant implication for public health and safety or common defense and security that has been reported in accordance with 10 CFR Part 21 does not need to be reported separately. This provision should not be read as excusing an individual subject to 10 CFR Part 21 from the need to ensure that any notification provided to the Commission in accordance with Part 21 be complete and accurate. Further, any information that has not been reported to the Commission in accordance with 10 CFR Part 21 or another reporting requirement, and is deemed to have a significant implication for public health and safety or common defense and security, must be reported consistent with the applicable completeness and accuracy regulation.

Q8. How big of a deal are counterfeit goods in the industry? How prevalent are they? Have any incidents/accidents occurred due to counterfeit items?

The NRC staff is not aware of any incidents or accidents that have occurred in the domestic nuclear power industry due to counterfeit, fraudulent, or suspect items (CFSI). However, there have been a small number of CFSIs that have been reported to or identified at nuclear facilities or in the supply chain. Examples include capacitors, fuses, valves, and breakers. Presentation slides from an NRC presentation on the topic of "NRC Perspectives on Dedication and Counterfeit Products" (ADAMS Accession No. ML0818301050) provide a detailed list of generic communications that have been issued by the NRC on CFSI issues. Further, three specific issues related to NMSS facilities include: (1) suspect UF_6 cylinder valve stems, as described in Information Notice 2002-31, "Potentially Defective Cylinder Valves (1-inch)," dated October 31, 2002 (ADAMS Accession No. ML023040090); (2) counterfeit fire sprinklers, as described in Information Notice 2007-19, "Fire Protection Equipment Recalls and Counterfeit Notices," dated May 21, 2007 (ADAMS Accession No. ML071090170); and (3) unsubstantiated certified material test reports associated with dry shielded canisters for the storage of spent nuclear fuel assemblies, as described in a report made under 10 CFR Part 21 (ADAMS Accession No. ML093060395).

Q9.(a) Given that Section 206 of the Energy Reorganization Act of 1974 and the implementing regulation, 10 CFR Part 21, are directed solely at radiological health and safety impacts, i.e., a failure to comply or defect must be related to a moderate or severe dose to radiological workers or offsite individuals, do issues associated with IROFS based on an acute chemical exposure from licensed material or hazardous chemicals produced from licensed material (as defined in § 70.61(b)(4)(i) or (ii), or § 70.61(c)(4)(i)) have to be considered for reporting under 10 CFR § 21.21 unless the defect or failure to comply also causes a radiological release meeting the thresholds of § 70.61(b)(1)-(3) or (c)(1)-(3)?

Section 206 of the Energy Reorganization Act of 1974, and the implementing regulation, 10 CFR Part 21, address the protection of public health and safety through the reporting of defects and failures to comply that could create a substantial safety hazard. As discussed in the statements of consideration that were published with the initial issuance

of 10 CFR Part 21 (42 FR 28891), criteria that are appropriate for determination of creation of a substantial safety hazard include: moderate exposure to, or release of, licensed material; major degradation of essential safety-related equipment; and major deficiencies involving design, construction, inspection, test or use of licensed facilities or material.

If an individual receives acute chemical exposure from licensed material or hazardous chemicals produced from licensed material as specified in § 70.61(b)(4)(i) or (ii), or § 70.61(c)(4)(i), that exposure would constitute a major reduction in the degree of protection to public health and safety. Under 10 CFR Part 21, such exposure would represent a substantial safety hazard associated with a major deficiency in the use of licensed facilities or material. 10 CFR Part 21 requires the reporting of any defect or failure to comply that could create a substantial safety hazard. Although a defect or failure to comply might not operate to trigger the performance requirements in § 70.61, the defect or failure to comply could, based on an evaluation, result in a major reduction to the degree of protection provided to public health and safety, which would require reporting under 10 CFR Part 21.

The 10 CFR 70.61 requirements referenced above follow the Memorandum of Understanding (MOU) between NRC and the Occupational Safety and Health Administration (OSHA) (53 FR 43950; October 31, 1988). There, the following three kinds of hazards were identified as falling within the NRC's jurisdiction: (1) radiation risk produced by radioactive materials; (2) chemical risk produced by radioactive materials; and (3) plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk to workers. Thus, a 10 CFR Part 21 substantial safety hazard can exist in association with these three hazards, and would be reportable under 10 CFR Part 21.

(b) Confirm that this interpretation is consistent with that contained in NUREG-0302 at pp. 21.2-3 – 21.2-4.

The referenced question and response from NUREG-0302, "Remarks Presented (Questions/Answers Discussed) at Public Regional Meetings to Discuss regulations (10 CFR Part 21) for Reporting of Defects and Noncompliance," dated July 12-26, 1977 (ADAMS Accession No. ML062080399), are as follows:

> Question:
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> "Are non-radiological hazards covered by Part 21? Example, chemicals released to streams or rivers."
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> Response:
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> "No. Part 21 applies only to radiological health and safety."

As indicated in the response to Question 9(a), a 1988 MOU issued a decade after NUREG-0302, and the 10 CFR 70.61 requirements established in 2000, have clarified the scope of NRC regulations. Chemical releases to streams or rivers would not be reportable under 10 CFR Part 21 unless: (1) the releases could have resulted in a substantial safety hazard (*i.e.*, a major reduction in the degree of protection provided to public health and safety for certain facilities or activities licensed, approved or regulated

by the NRC); and (2) the releases were the result of chemical exposure from licensed material or hazardous chemicals produced from licensed material that are covered by 10 CFR § 70.61.

Q10. Are non-radiation worker employees considered members of the public in determining whether the reporting criteria of Part 21 have been met?

Yes. In implementing Part 21, the NRC has viewed "public" as a broad term, as indicated in the following 1977 question and response in NUREG-0302:

> Question:
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> "Does the "substantial safety hazard" definition include "employee safety" or does it apply to "public safety" only?"
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> Response:
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> "The term "public" in Section 21.3(k) [the "substantial safety hazard" definition] includes all individuals -- that is both employees at a facility or activity-licensed or otherwise regulated by the Commission and members of the general public. Of course, the degree of protection afforded and the criteria for determining whether a substantial safety hazard could be created will vary for different types of individuals (e.g., radiation workers as opposed to members of the general public) depending on whether the event is a low probability major accident or a more probable occurrence, and whether the potential release is to a restricted or an unrestricted area."

The reference to "radiation workers" in this 1977 response (Q10 appears to use "non-radiation worker employees" as an antonym) is outdated due to revisions made to 10 CFR Part 20 in 1991. A licensee employee is subject to either the 10 CFR Part 20, subpart C, occupational dose limits, or to the general public dose limits in 10 CFR Part 20, subpart D. The set of dose limits that applies depends on whether the employee receives an *occupational dose*, as defined in 10 CFR § 20.1003 (*i.e.*, do the employee's "assigned duties involve exposure to radiation or to radioactive material …"). The term "radiation workers" is not used in 10 CFR Parts 20 or 21.

Q11.(a) Would not the 1-hour and 24-hour reporting requirements contained in Appendix A to Part 70 subsume the reporting requirements in 10 CFR Part 21, i.e., the reporting requirements of Appendix A are in all cases more stringent and more timely than those of Part 21?

The reporting requirements in Appendix A to Part 70 include the 1-hour and 24-hour initial notification provisions referenced in Q11(a), and follow-up written reports to be submitted within 30 days. If these reporting requirements are met, the timeliness aspects of the 10 CFR § 21.21 reporting requirements would also be met. Thus, for example, if there is a defect in a basic component making the 10 CFR § 21.21(d) initial notification and follow-up reporting requirements applicable, and this information is provided to the NRC in accordance with Appendix A to Part 70 (*i.e.*, initial notification within 24 hours of discovery and a follow up written report within 30 days), the notification and report would be timely. In order for follow up written reports made under

Appendix A to Part 70 to satisfy Part 21 reporting requirements, such reports should include all information required under § 21.21(d)(4), as described in the response to Q6.

(b) If not, which specific requirements of Part 21 could require reporting or reporting on a more timely basis than Appendix A to Part 70?

See response to Question 11(a).

(c) Please give several examples of reports required by Part 21 not required by Appendix A or required on a timelier basis.

Examples of defects and failures to comply that have been reported to the NRC under 10 CFR Part 21 may be reviewed at the following site: http://www.nrc.gov/reading-rm/doc-collections/event-status/part21/. Many of these reports address defects or failures to comply that required reporting under 10 CFR Part 21, but did not lead to actual safety consequences that would prompt reporting under event reporting requirements such as Appendix A to Part 70.

Other general examples of situations that would require reporting under 10 CFR Part 21, but not necessarily Appendix A to Part 70, include the following:

- Appendix A to Part 70 requires one-hour reporting of an event or condition such that no IROFS, as documented in the Integrated Safety Analysis summary, remain available and reliable, in an accident sequence evaluated in the Integrated Safety Analysis, to perform their function in the context of the performance requirements in § 70.61(b) and § 70.61(c) or to prevent a nuclear criticality accident. However, under 10 CFR Part 21, a defect in any IROFS must be reported, even if other IROFS are available to perform the same safety function.

- Appendix A to Part 70 requires reporting of the loss or degradation of IROFS that results in failure to meet the performance requirement of § 70.61. Under 10 CFR Part 21, a defect in an IROFS is reportable even if the IROFS has not lost the ability to perform its safety function and has not resulted in the failure to meet the performance requirement of § 70.61.

(d) Does the possibility of Part 21 being applicable have to be noted in the oral or written reports provided to the NRC under Appendix A?

If a potential defect or failure to comply that could create a substantial safety hazard has been identified but not confirmed, and the reporting entity would like to credit a report made under Appendix A to Part 70 to satisfy any 10 CFR § 21.21 reporting requirements, then the potential applicability of Part 21 must be noted in the Appendix A reports. For example, if an evaluation has not yet been completed in accordance with 10 CFR § 21.21(a), the Appendix A report should state that a separate report may later be made in accordance with 10 CFR § 21.21(a).

(e) Does a definitive analysis have to be provided as to whether the matter is reportable under Part 21?

No, as discussed further below. 10 CFR § 21.21 requires the licensee to evaluate whether a deviation or failure to comply associated with the event (*e.g.*, an event

reported under Appendix A to Part 70) constitutes a defect or failure to comply that could create a substantial safety hazard. If the § 21.21 evaluation results need to be reported, the report to the NRC must contain the information specified in 10 CFR § 21.21(d)(4). The full evaluation (*i.e*. the "definitive analysis") on which this report is based need not be submitted to the NRC, but all related records (*e.g*. documentation of all analyses performed) must be retained for a minimum of five years after the date of the evaluation, in accordance with 10 CFR § 21.51(a)(1).

Q12.(a) Does a deficiency or failure of an IROFS based upon an administrative control need to be considered for reportability under Part 21 because it would not be a "basic component" supplied for such facility or activity?

The failure of an IROFS based upon an administrative control would not be reportable under 10 CFR Part 21 because such an IROFS does not meet the definition of a basic component (*see answer to Question 4*). Note that administrative IROFS do not include safety-related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with IROFS.

(b) If a failure or administrative control has to be considered for reportability, could you give an analogy to failures to implement or deficiencies in procedures that would have to be reported by Part 50 licensees?

See response to Q12.(a).

(c) Could you give examples of such Part 50 reports in the past few years?

See response to Q12.(a).

Q13. If double contingency protection is in place to prevent criticality at a Part 70 facility, do both elements need to be degraded or failed for reportability to be required under Part 21?

No. A deviation in any basic component, whether covered by double contingency practices or not, must be evaluated for reportability under 10 CFR Part 21. The loss of the safety function of a basic component is considered a major reduction in the degree of protection provided to the public health and safety. Given that 10 CFR Part 21 requires the reporting of a defect in a basic component that could create a substantial safety hazard, the existence of redundant or diverse components does not eliminate obligations under

10 CFR Part 21 because it is possible that redundant or diverse basic components could also possess a defect or be unavailable due to reasons such as routine preventive maintenance or inspection. As such, the failure of a redundant basic component is a reportable defect under 10 CFR Part 21.

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