10 CFR Part 21
Reporting of Defects and Noncompliance

Meeting with the Industry and Stakeholders
March 16, 2016

Excerpts from the Draft Regulatory Guide DG-3049, "Reporting of Defects and Noncompliance for Fuel Cycle, Materials, Waste Disposal, Packaging and Transportation, Independent Storage, and Non-Power Reactor Licensees" are being provided for information and discussion. The content provided is draft and is subject to change as a result of potential Commission direction on the Part 21 rulemaking or as the guide undergoes further review. The Draft Regulatory Guide will be posted in the *Federal Register* at a later date for public comment. Any comments or feedback provided to the staff at or after the meeting will be considered during the continued development of the guide.

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Basic Components

Note: This section of the Draft Regulatory Guide is based off of the staff's proposal for rulemaking in the Final Regulatory Basis[1].

Identifying Basic Components

One of two definitions of Basic Components are applicable to non-reactor and non-power reactor facilities. In the instance that the licensee has a license condition requiring compliance with 10 CFR Part 70 Subpart H; the second definition should be used.

1) When applied to facilities and activities licensed under 10 CFR parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70 (other than facilities subject to the requirements of Subpart H of Part 70), 71, 72, or 76 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.

2) Basic component when applied to facilities licensed under 10 CFR Part 70 means a structure, system, or component (SSC), or any part thereof that affects the SSC's safety function, that is designated as an item relied on for safety in accordance with Section 70.61, is directly procured by the licensee, and in which a defect or failure to comply with any applicable regulation in this chapter, order, or license issued by the Commission could cause the performance requirements of Section 70.61 to be exceeded. The SSC is not a basic component if diverse SSCs (but not redundant SSCs) exist whose independent action could prevent the performance requirements of Section 70.61 from being exceeded.

Basic components include all activities affecting the safety-related functions of those structures, systems, and components including the design, analysis, inspection, testing, fabrication, replacement of parts, services, or software. To the extent that failures or defects in a security system could contribute to a substantial safety hazard, such equipment is within the scope of Part 21.

The use of administrative controls, as addressed in the Integrated Safety Analysis for facilities licensed under 10 CFR Part 70 and subject to the requirements of Subpart H, are not considered a basic component or regulated activity by Part 21. However, as noted above, safety-related services (e.g., analysis, welding, etc.) may be basic components if they affect the ability of a SSC to perform its safety function. Engineered IROFS whose potential failure, in the absence of administrative IROFS and redundant IROFS, could result in a failure to meet the performance requirements of Section 70.61 would meet the threshold for designation as a basic component.

Licensees are responsible for identifying basic components at their site or facility, maintaining control of them, and notifying the NRC of defects in basic components.

[1] The Final Regulatory Basis to Clarify 10 CFR Part 21, "Reporting of Defects and Noncompliance," can be found on www.regulations.gov. The docket identification number is NRC-2012-0012-0025.

Guidelines for Moderate Exposure and Release of Radioactivity

Objective: The guidance for determining a Substantial Safety Hazard in NUREG 0302 will be updated by the Regulatory Guide. Specifically, this guidance is meant to supersede the old content which contained references to 10 CFR Part 20 prior to the latest revision.

Substantial Safety Hazard

A substantial safety hazard means the loss of a safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety. A loss of safety function includes (1) a failure or degradation of equipment such that it might not perform the intended safety function when called upon or (2) a major deficiency involving the design, construction, inspection, calibration, or testing which could seriously compromise the ability of a system to perform its designated function. A moderate exposure to or a moderate release of licensed material to members of the public and licensee employees, as defined below, would constitute a major reduction in the degree of protection provided to public health and safety.

Moderate Exposure

1) Acceptable guidelines for determining moderate exposure to licensed material in an occupational worker include the following:

    a) Total effective dose equivalent of 25 rem/year (250 mSv/yr);

    b) Total effective dose equivalent of 5 rem/year (50 mSv/year) to a minor;

    c) Shallow dose equivalent of 250 rem/year (2.5 Sv/yr) to the skin or extremities;

    d) Total organ dose equivalent to any individual organ of 250 rem (2.5 Sv); excluding the lens of the eye, bone marrow, and gonads;

    e) Lens dose equivalent of 100 rem/year (1 Sv/yr);

    f) Total organ dose equivalent of 100 rem (1 Sv) to bone marrow;

    g) Committed dose equivalent to the gonads of 250 rem (2.5 Sv);

    h) Dose to a fetus or embryo of 5 rem (50 mSv) or more; and

    i) An acute chemical exposure from licensed material or hazardous chemicals produced from licensed material that could lead to irreversible or other serious, long-lasting health effects to a worker. Acute chemical exposure includes, but is not limited to, chemical toxicity effects from soluble uranium.

2) Acceptable guidelines for determining moderate exposure to licensed material for an individual in an unrestricted area include the following:

    a) A total effective dose equivalent exceeding 0.5 rem in a period of a year or less;

    b) Underexposure for a medical patient that results in serious health effects;

    c) A misadministration dose of 50 percent higher than the dose prescribed to a medical patient;

    d) A medical event that results in a dose that is equal to or greater than:

        i) 100 rad (1 gray) to a major portion of the bone marrow or lens of the eye

ii) 250 rad (2.5 gray) to the gonads; or
iii) 1,000 rad (10 gray) to any other organ or tissue; and

e) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that could cause mild transient health effects.

Release of Licensed Materials

Acceptable thresholds for reporting a moderate release of licensed materials include:

a) The release of radioactive material, inside or outside of a restricted area, so that, had an individual been present for 24 hours, the individual could have received an intake five times the annual limit on intake. Releases within locations where personnel are not normally stationed during routine operations, such as hot-cells or process enclosures, are not applicable.

b) An acute chemical exposure from licensed material to an individual located outside the controlled area that could lead to irreversible or other serious, long-lasting health effects to a worker or could cause mild transient health effects. Acute chemical exposure includes, but is not limited to, chemical toxicity effects from soluble uranium.

Basic Component Examples

Objective: In order to aid applicants, licensees, and vendors in better understanding the implementation of Part 21 for their facilities and activities, examples of basic components in different technical areas will be provided in the DG. The examples drafted for fuel cycle facilities and fuel facilities under construction are being provided for the target audience of the meeting. Additional examples for other technical areas are under development as well.

Basic Components – Examples

The guidance in this regulatory guide applies to fuel cycle facilities, in-situ recovery and milling, irradiators, radiography, medical licensees, broad scope and specific licensees, well logging, non-power production and utilization facilities, packaging and transportation of radioactive material, independent storage of spent nuclear waste, land disposal of radioactive waste, and geologic repositories for high-level radioactive waste. In order to aid licensees and vendors in better understanding the implementation of Part 21 for their facilities and activities, examples of basic components in different technical areas are provided below. These examples are not all-inclusive and may not be applicable to all facilities or activities within a designated category. Rather, they are intended to be illustrative as an aid to better understand the regulations.

The requirements of Part 21 are applicable to facilities under construction. Examples have been provided for Fuel Cycle Facilities under construction to illustrate the relevance for licensees or applicants that are constructing facilities. These examples acknowledge that a facility under construction would not yet possess the licensed material required for the given accident scenarios. Regardless, a material defect of a safety-related piece of equipment or system would be reportable under Part 21 due to the potential of a future loss of safety function to the extent that there would be a major reduction in the degree of protection to the worker. The licensee or applicant should acknowledge the maximum amount of licensed material anticipated in a given system, building, or equipment when evaluating if the potential for a substantial safety hazard could be created by the identified defect. In addition, the Part 21 evaluation should be conducted with the assumption that the deviation remains uncorrected.

Fuel Cycle Facility

1) *Autoclave and associated connections.* An equipment failure in an autoclave or associated connection during the heating of uranium hexafluoride at a fuel cycle facility could result in a release of gaseous uranium hexafluoride. The release could create a substantial safety hazard as the uranium hexafluoride interacts with water in the air to create hydrogen fluoride. The hydrogen fluoride could cause an acute chemical exposure that could lead to lung or respiratory damage in a worker; a serious, long-lasting health effect. A defect that could create a potential failure might be insufficient welding, design error, corrosion due to inadequate materials used during construction, etc.

2) *High Efficiency Particulate Air (HEPA) filters and/or dust collection systems on airborne effluent stacks.* The equipment failure of a HEPA or a dust collection system on a high-flow airborne effluent stack could result in a release of licensed material. If the equipment failure is unidentified due to an unrelated failure in monitoring, a release of radiological material contributing to a total effective dose equivalent exceeding 0.5 rem is possible. A defect that could create a potential failure might be improperly constructed air filters as supplied by the vendor, an air filter being too small for the encasing, equipment errors with the associated radiation detection equipment, etc.

3) *Respirators; half mask, Self-Contained Breathing Apparatus (SCBA), etc.* An equipment failure of a respirator used in an Airborne Radioactivity Area could result in a substantial safety hazard to a worker. The respirator is used during planned work in order to decrease exposure to radionuclides or chemical hazards associated with licensed material. The failure of a respirator in an area containing uranium hexafluoride or hydrogen fluoride (from a licensed material) could result in an acute chemical exposure that could impact the respiratory system; an irreversible or other serious,

long-lasting health effect to a worker. The failure of a respirator in an airborne area of soluble uranium could result in an intake at a concentration which could result in kidney damage; another serious, long-lasting health effect. The unidentified failure of a respirator during repeated exposures to an environment containing insoluble uranium could result in a total effective dose equivalent of 25 rem/ year from chronic exposures.

A defect that could create a potential failure with a half mask respirator might be improperly constructed combination air filters as supplied by the vendor, a design error in the construction of the respirators' straps or buckles, a non-conservative practice used during routine respirator fit testing, etc. A defect that could create a potential failure with self-contained breathing apparatus respirators might be suits provided by a vendor made with material prone to ripping, a design flaw, faulty connection to the tank, error with tank pressure gauges, etc.

Fuel Cycle Facility under Construction

1) *Plutonium processing tanks.* An equipment failure of a processing tank used for plutonium purification could result in a substantial safety hazard to a worker. Specifically, the premature failure of the tank's confinement boundary could result in a localized release of plutonium to the process room which could expose a worker to a radiological hazard. There would also be a potential for a nuclear criticality if the tank was credited as a passive engineered control for the prevention of criticality in the nuclear criticality safety evaluation. Both accident scenarios could result in an acute radiological exposure that could result in a total effective dose equivalent of 25 rem/year to the worker. A defect that could cause the potential failure might be a material defect that results in premature corrosion of the tank wall or a significant reduction in mechanical properties of the tank material which adversely impacted the ability of the tank to withstand a seismic event. A fuel cycle facility under construction would not yet possess the licensed material required for the accident scenario, however the material defect would be reportable under Part 21 due to the potential of a future loss of safety function to the extent that there is a major reduction in the degree of protection to the worker.

2) *Safety programmable logic controller.* An equipment failure of a safety programmable logic controller (SPLC) could result in a substantial safety hazard to a worker. The failure could result in equipment not performing its intended safety function to close safety-related building ventilation system dampers following a seismic event to prevent the potential release of radioactive material that could exceed 25 rem/year to the worker or 0.5 rem/year to the public. A defect associated with the SPLC firmware could potentially prevent the SPLC from performing its required safety function and could also be a common mode failure impacting both trains of SPLCs.

3) *Building rebar or structural materials.* A structural failure of a nuclear facility as the result of a natural phenomenon hazard event could result in a substantial safety hazard to a worker or the public. The failure could result in a large chemical or radiological source term release that could exceed 25 rem/year to the worker, 0.5 rem/year to the public, or an acute chemical exposure that could lead to lung or respiratory damage in a worker; a serious, long-lasting health effect. A defect that could create a potential structural failure might be a significant material defect in building rebar or structural materials as supplied by a vendor. A material defect could significantly reduce the mechanical strength of the material to below the level that was assumed in the structural analysis.

Commercial Grade Dedication

Note: The staff proposal in the Final Regulatory Basis is to include specific expectations of Commercial Grade Dedication for licensees that are not nuclear power plants in Regulatory Guidance. The guidance is under development and will seek to clarify the differing processes amongst the wide range of applicable licensees addressed by the Regulatory Guide.

Commercial Grade Dedication

Commercial-grade dedication is a process by which a commercial-grade item is designated for use as a basic component. This acceptance process is undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function. Licensees subject to Part 21 are required to ensure the suitability of commercially procured and dedicated equipment intended for use in safety-related applications.

There are currently two ways to create a basic component: (1) to design and manufacture it under an appropriate Quality Assurance program, or (2) to dedicate a commercial grade item in accordance with the dedication process. For the latter, the item would be dedicated by the dedicating entity; an 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 Section 21.21(c), 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. Commercial grade dedication is a regulatory process allowing the use of commercial parts and services as basic components.

Commercial grade dedication occurs after receipt when that item is designated for use as a basic component. The term, delivery, means the acceptance of a basic component through a formal process (i.e. receipt inspection). Once the equipment, part, or service has been accepted as a basic component by the purchaser, the purchaser then bears the responsibility for the Part 21 evaluation and reporting. These responsibilities include the identification and evaluation of deviations in basic components.

Non-reactor and non-power reactor entities licensed to comply with 10 CFR 50 Appendix B, should reference draft regulatory guide DG-1292, “Dedication of Commercial Grade Items” for guidance in the implementation of Commercial Grade Dedication. For non-reactor and non-power reactor entities subject to the requirements of Appendix B to 10 CFR Part 50, including fuel cycle facilities that process plutonium, dedication is performed in accordance with the requirements of Appendix B to 10 CFR Part 50 and Section 21.71(a).

Fuel cycle facilities regulated under 10 CFR 70 Subpart H (except those subject to the requirements of Appendix B to 10 CFR Part 50) perform measures to ensure the availability and reliability of IROFS as part of their management measures programs. Licensees are not expected to implement any measures to ensure the availability and reliability of commercially-procured IROFS beyond those already required by 10 CFR Part 70. The management measures programs satisfy the requirements of commercial grade dedication as specified by Part 21. These licensees should ensure the availability and reliability of IROFS. To verify item quality and functionality in service, licensees may apply a graded approach to elements of procurement, such as supplier evaluation and selection, and inspections and tests. Grading of these practices is permitted in accordance with 10 CFR Part 70.62(d), which states that:

> “The measures applied to a particular engineered or administrative control or control system may be graded commensurate with the reduction of the risk attributable to that control or control system. The management measures shall ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to Section 70.61(e) of this subpart are designed, implemented, and maintained, as necessary, to ensure they are available and reliable to perform their function when needed, to comply with the performance requirements of Section 70.61 of this subpart.”

For facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 71, 72, or 76, commercial grade dedication occurs after receipt when that item is designated for use as a basic component. Specifically, this means… [guidance still in development]

All licensees may receive equipment or services directly from vendors who implement 10 CFR 50 Appendix B Quality Assurance programs with no additional actions necessary.