A. Fuel Facility Inspection Guidance Regarding Applicable Title 10 of the *Code of Federal Regulations* Part 21

In response to this Technical Assistance Request (TAR), on December 5, 2023, Office of Material Safety and Safeguards, Division of Fuel Management, Inspection Oversight Branch staff provided training to Division of Fuel Facility Inspection staff in the Region II office on the requirements contained in Title 10 *Code of Federal Regulations* (10 CFR) Part 21, "Reporting of Defects and Noncompliance" and how they apply to facilities licensed under Parts 40, "Domestic Licensing of Source Material," 70, "Domestic Licensing of Special Nuclear Material," and other non-power production facilities. In response to the specific questions posed in the TAR, the following information was provided.

1. Does 10 CFR Part 21 only apply to the fuel manufacturing (Appendix B supplier) program at Framatome and if not, where is this requirement and its scope of applicability?

    a) The fuel manufacturing program a Framatome is not the only one subject to the regulatory requirements in 10 CFR 21.

    b) 10 CFR 21.2(a), "Scope", specifically states that it is applicable to facilities or activities licensed under Parts 30, 40, 50, 52, 60, 61, 63, 70, 71, and 72. The applicability of 10 CFR 21 is also included in Parts 31, 33, 34, 35, 36, and 39 which were issued after the last revision to Part 21.

    c) With regards to facilities licensed under 10 CFR 70, 10 CFR 21 applies to Items Relied on For Safety (IROFS) needed to reduce the likelihood or mitigate high or intermediate-consequence events as well as criticality accidents, as defined in the Performance Requirements of 10 CFR 70.61. These requirements directly correlate with the criteria of a substantial safety hazard as set forth in the original Statements of Consideration (SOC) for 10 CFR 21.

    d) 10 CFR 21 does not require a supplier or licensee quality program that complies with 10 CFR 50 Appendix B for basic components.

    e) Differences between the requirements for power production facilities and non-power production facilities were identified and discussed during a training session to Region II (ML24116A265). Specific differences that were covered were:

        a. Definition of "Basic component"
        b. Definition of "Commercial grade item" (CGI)
        c. Definition of "Dedication"
        d. Definition of "Defect"
        e. Applicability of the term "Critical characteristic"
        f. Applicability of the term "Dedicating entity"

    f) The procedural, posting, and reporting requirements of 10 CFR 21 were also communicated during the training.

2. Was the control module – a necessary part of an active engineered control – a basic component as defined in 10 CFR Part 21?

    a) The control module referenced in the TAR was listed in the licensee's Integrated Safety Analysis (ISA) Summary as an IROFS that was needed to mitigate an event of intermediate consequence. As previously mentioned, the criteria for an event of intermediate consequence in 10 CFR 70 align with that of a substantial safety hazard as set forth in the SOC for 10 CFR 21. As such, the failure of the component could create a substantial safety hazard and should be considered a basic component.

3. If the module is a basic component, was the failure of the IROFS a substantial safety hazard as defined in 10 CFR Part 21?

    a) Yes. As previously discussed, the original SOC for 10 CFR 21 set forth the criteria for a substantial safety hazard. These criteria align with those of an intermediate-consequence event and criticality prevention requirements defined in 10 CFR 70.61, "Performance Requirements." The failure of the IROFS creates a substantial increase in risk compared to what is specified in the licensee's approved ISA summary. A more detailed analysis and discussion on this topic can be found in the NRC's response to question "Q4" in "QUESTIONS ASKED AT THE 2011 FUEL CYCLE INFORMATION EXCHANGE RELATED TO TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 21" (ML11259A039).

    b) Substantial Safety Hazard Criteria, 10 CFR 21 (42 *Federal Register* 28892)

        i. <u>Moderate Exposure:</u>
            1. Exposure in excess of 25 rem whole body and exposure to an individual in an unrestricted are of 0.5 rem.
            2. Moderate exposure to, or release of, licensed material reportable under 10 CFR 20.2202(a)
            3. Exposure of an individual in an unrestricted area to a dose to the whole body in any period of one calendar year in excess of 0.5 rem

        ii. <u>Major Degradation:</u>
            1. Loss of redundancy in essential safety related equipment if, in conjunction with a single failure, a required safety function could not be performed.
            2. Deviation or failure to comply could cause a redundant basic component to fail.
            3. Exceeding a safety limit as defined in the facility technical specification is considered a major degradation.

        iii. <u>Major Deficiency:</u>
            1. A condition or circumstance involving the design, construction, inspection, test, or use of licensed material or safety related equipment, which under normal operating conditions or anticipated transient could contribute to exceeding a safety limit or cause an accident or in the event of an accident due to the other causes could, considering an independent single failure.

2. A deviation or failure to comply which seriously comprised the ability of a confinement system to perform its designated function is considered a major deficiency.

c) Intermediate-Consequence and Criticality Event Criteria, 10 CFR 70.61(c), "Performance Requirements"

(c) The risk of each credible intermediate-consequence event must be limited. Engineered controls, administrative controls, or both shall be applied to the extent needed so that, upon implementation of such controls, the event is unlikely or its consequences are less than those in paragraphs (c)(1)-(4) of this section. Intermediate consequence events are those internally or externally initiated events that are not high consequence events, that result in:

(1) An acute worker dose of 0.25 Sv (25 rem) or greater total effective dose equivalent;

(2) An acute dose of 0.05 Sv (5 rem) or greater total effective dose equivalent to any individual located outside the controlled area identified pursuant to paragraph (f) of this section;

(3) A 24-hour averaged release of radioactive material outside the restricted area in concentrations exceeding 5000 times the values in Table 2 of Appendix B to Part 20; or

(4) An acute chemical exposure to an individual from licensed material or hazardous chemicals produced from licensed material that:

(i) Could lead to irreversible or other serious, long-lasting health effects to a worker, or

(ii) Could cause mild transient health effects to any individual located outside the controlled area as specified in paragraph (f)of this section. If an applicant possesses or plans to possess quantities of material capable of such chemical exposures, then the applicant shall propose appropriate quantitative standards for these health effects, as part of the information submitted pursuant to § 70.65 of this subpart.

(d) In addition to complying with paragraphs (b) and (c) of this section, the risk of nuclear criticality accidents must be limited by assuring that under normal and credible abnormal conditions, all nuclear processes are subcritical, including use of an approved margin of subcriticality for safety. Preventive controls and measures must be the primary means of protection against nuclear criticality accidents.

4. If the module is a basic component, was the new failure mode of the module (i.e., it could fail in a non-safe manner without alerting operators) a deviation and defect, subject to the reporting requirements of 10 CFR Part 21?

a. It was determined that there was not sufficient information gathered by the inspection team to make the determination as to whether the failure constituted a defect as defined by 10 CFR 21.

b. The inspection team was able to provide the following information:
   i. Corrective action report
   ii. Maintenance order
   iii. ISA Summary
   iv. Component manufacturer information

c. It was discussed that to make a determination the following additional information may be needed:
    i. Procurement documents
    ii. Receipt inspection records
    iii. Design basis information (including source)
    iv. Licensee commercial grade dedication procedures/records

B. 10 CFR 21 Backfit Screening for Fuel Cycle Facilities

Backfitting Definition (50.109, 70.76, 72.62, 76.76)
Backfitting is defined as the modification of, or addition to, systems, structures, or components of a facility; or to the procedures or organization required to operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position.

Historical Summary
The NRC published the final rule for Part 21 in the Federal Register, on June 6, 1977. Although Part 21 was amended in 1991 and 1995, these amendments were only applicable to power production facilities licensed under Part 50. The requirements that were applicable to non-power production facilities, including fuel cycle facilities licensed under Parts 40 and 70, remained unchanged. Part 21 does not contain a statement of applicability to Part 76 facilities. The applicability of Part 21 requirements to Part 76 facilities is found in 76.60(e).
All NRC guidance related to the requirements and applicability of Part 21 to fuel cycle facilities has been consistent beginning with NUREG-0302 that was published in 1977. Additional NRC guidance documents and a comprehensive discussion of how the requirements of Part 21 should be applied to fuel cycle facilities can be found in ML11259A039, “QUESTIONS ASKED AT THE 2011 FUEL CYCLE INFORMATION EXCHANGE RELATED TO TITLE 10 OF THE CODE OF FEDERAL REGULATIONS PART 21.”

Evaluation
The current approved and published NRC guidance on backfitting is found in NUREG-1409, “Backfitting Guidelines,” (ML032230247) that was published in 1990 and only addresses backfitting for Part 50 licensees. In April 2021, Revision 1 of NUREG-1409 (ML21006A433) was provided to the Commission as Enclosure 1 to SECY-21-0037. In the absence of other approved guidance that is specifically applicable fuel cycle facilities, this draft document will be used in the remainder of this backfit analysis. The guidance in the document provides a series of six screening questions that should be answered when performing a backfit analysis. The first three questions are used to determine whether proposed staff actions would constitute backfitting or affect issue finality. These questions with responses are provided below.

1. *Is the proposed action excluded from backfitting and issue finality provisions?*

    Not specifically. NUREG-1409, Revision1 states that information collection and reporting requirements typically do not meet the definition of “backfitting” or constitute a change affecting issue finality because they would not be a procedure or organization required to design, construct, or operate a facility; the NRC nonetheless must ensure that any such requirements do not meet the definition of “backfitting” or constitute a change affecting issue finality. As such, Part 21, “REPORTING OF DEFECTS AND NONCOMPLIANCE,” the staff must ensure the proposed action does not meet the definition of backfitting.

2. *Would the proposed action affect any entity that is within the scope of a backfitting or issue finality provision?*

   Yes. Fuel cycle facilities licensed under Parts 70 and 76 would be affected. It should be noted that licensees under Parts 30 and 40 are not specifically afforded a backfitting provision by regulation.

3. *Would the proposed action constitute backfitting or affect issue finality?*

   In answering Question 3, the guidance directs responses to a series of questions specific to the proposed action. Per the guidance, an answer of "No" to any of the below questions would exclude the action from being considered a backfit.

   Is there either—

   a new or changed (e.g., amended, revised, or modified) NRC requirement (e.g., a regulation or order), or

   No.

   a new or changed staff interpretation of an NRC requirement?

   No. The fact that we have not pursued enforcement of a requirement does not nullify the requirement or set an affirmative staff position that compliance with that requirement is not required. Unless the staff has previously taken a position concerning the staff's enforcement of the requirement (e.g., EGM), the NRC does not create a new position for backfitting purposes just by enforcing the requirement.

   Is the NRC imposing the new or changed requirement or interpretation on an applicable entity?

   N/A, there is not a new or changed requirement.

   Will there be a modification or addition to—

   SSCs of the entity's facility;

   No.

   design (including but not limited to a DC, SDA, or ML) of the entity's facility; or

   No.

   procedures or organization for designing, constructing, or operating the entity's facility?

No. As there has been no new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position, it should be assumed that licensees are complying with the regulations until inspection results show otherwise. It should also be noted that NRC personnel inspecting for compliance with Part 50 and Part 71 requirements have verified that fuel cycle facilities have procedures for complying with Part 21.

Is the modification or addition (third question above) the result of the new or changed requirement or interpretation (first question) that is being imposed (second question)?

No.

Conclusion

As there has not been a change in the requirements or a staff position interpreting the Commission rules, enforcement of existing Part 21 requirements on fuel cycle facilities does not meet the definition of backfitting. This determination was supported by following the guidance provided in NUREG-1409, Revision 1 (Draft) and responding to the screening questions contained therein.