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March 10, 2014

Ms. Annette L. Vietti-Cook
Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
ATTN: Rulemakings and Adjudications Staff

11/8/2013
78 FR 67224
8

Subject: Industry Comments on Proposed Rulemaking and Guidance, "Amendments to Material Control and Accounting Regulations," Docket IDs NRC-2009-0096 and NRC-2013-0195

Project Number: 689

Dear Ms. Vietti-Cook:

On behalf of the nuclear energy industry, the Nuclear Energy Institute (NEI)¹ provides the following comments on the proposed rule and guidance for 10 CFR Part 74, "Amendments to Material Control and Accounting Regulations," which were published in the *Federal Register* on November 8, 2013 (78 FR 67224 and 78 FR 67225).² The industry considers material control and accounting (MC&A) to be an integral part of an overall security strategy; as such, program enhancements are made without the need for new regulations. Our commitment to the control and accounting of special nuclear material (SNM) is demonstrated by the fact that there has not been a confirmed theft or diversion of SNM in more than 30 years.

The U.S. Nuclear Regulatory Commission (NRC) and the industry have mutual regulatory goals: effective regulation imposed in a manner that is consistent with the NRC's Principles of Good Regulation and efficient focus of industry and NRC resources on matters of the highest safety significance. Regulations and the

¹ NEI is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel cycle facilities, nuclear materials licensees, and other organizations and entities involved in the nuclear energy industry.

² The NRC subsequently extended the comment period to March 10, 2014 (78 FR 79328).

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accompanying guidance should be coherent, logical and practical and should be readily understood, easily applied and consistent with the degree of risk reduction they achieve. As written, the proposed rule would not adhere to these goals and principles nor provide a commensurate or greater increase in safety or security.

We believe that based on the incomplete and inconclusive regulatory analysis and regulatory basis, the rule language, and the public interactions on this proposed rule, the rulemaking efforts to "strengthen" MC&A requirements in 10 CFR Part 74 should be discontinued. If the NRC decides to proceed with the rulemaking, the proposed rule should be withdrawn and re-noticed for public comment because of the substantive changes that are necessary to make the rule functional and unambiguous. The re-noticed rulemaking must include a clear regulatory analysis and basis for action, including a backfit analysis based on realistic implementation estimates. It is critical that the clarity of these proposed regulations be improved to ensure industry implementation in the most effective and efficient manner, consistent with the associated risk and current industry practices for MC&A, which the Commission finds acceptable today.

The industry's main concerns with the Part 74 proposed rule, which are further discussed in greater detail in the attachments to this letter, can be summarized as follows:

- The rulemaking package fails to provide a clear and well documented regulatory basis for strengthening the requirements for various types of licensees.
- The draft implementing guidance does not provide guidance for the entire suite of affected licensees (i.e., power reactors, independent spent fuel storage installations (ISFSIs), non-power reactors and other non-fuel cycle licensees).
- The proposed rule is inconsistent with the 1985 Commission decision that there should be significant differences in the MC&A requirements for low enriched uranium (LEU) when compared to strategic SNM, given the low safeguards importance of LEU, the 10 CFR Part 73 physical protection requirements, and the high probability of detecting a loss, theft or diversion of a significant amount of LEU.
- The use of encompassing (e.g., all, any) and ambiguous terms create a broad array of potential requirements and interpretations that are impracticable for licensees to implement and for NRC to enforce in a predictable manner.
- The unjustified elimination of exemptions for item control system requirements when less burdensome alternatives would still ensure adequate control and accurate accounting for SNM.

- The absence of a backfit analysis for proposed provisions that would result in a modification or addition to a system, structure or component, procedure or organization required to operate a facility.
- The absence of a realistic regulatory analysis that properly addresses industry implementation (quantitative costs) and security and safeguards considerations (qualitative benefits).

The industry appreciated the early opportunity for input on this rulemaking by publishing preliminary rule language in May 2011 (76 FR 28193). However, several of key industry comments, provided in an industry comment letter dated June 30, 2011, have not been considered and the extent of key provisions remains unclear. Further, we found the NRC public meetings held on January 9, 2014, and February 5, 2014, to be informative. The meetings assisted stakeholders in gaining a better understanding of the intent behind several of the proposed revisions. Yet, the proposed rule language and supplementary information in the *Federal Register* are inconsistent with the intent of the proposed rule, as explained by the NRC staff in these meetings. The proposed rule, if adopted, would introduce significant regulatory uncertainty by making the regulations less clear and open to broad and varying interpretation.

In these comments we offer alternative rule language that would resolve our concerns with the impact of the proposed rule language, while ensuring adequate control and accurate accounting of SNM. While we believe the proposed alternative rule language would be less burdensome and would assist in addressing regulatory analysis problems, formal and separate backfit and regulatory analyses would still need to be developed for the alternative language.

We note that there are several unfortunate similarities between this rulemaking and the rulemaking for 10 CFR Part 37 on physical protection of byproduct material. We believe the recent rulemaking process enhancements highlighted as part of the NRC's efforts to address cumulative effects of regulation, if followed, would have prevented some of the problems noted in these comments. For example, the NRC has not provided stakeholders with a clear regulatory basis or statement of the regulatory problem this rulemaking is intended to solve. As another example, the NRC has not provided stakeholders with draft guidance to support the proposed changes for power reactors, ISFSIs, non-power reactors and other non-fuel cycle licensees. These significant deficiencies are compounded by a regulatory analysis that does not fully consider the costs/benefits of the proposal and by the lack of a backfit analysis for this rulemaking.

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We appreciate the opportunity to comment on the proposed rule and guidance. If you have any questions concerning these comments, please contact Janet Schlueter (202-739-8098; jrs@nei.org) or Andrew Mauer (202-739-8018; anm@nei.org).

Sincerely,

A handwritten signature in black ink, appearing to read "Adrian P. Heymer". The signature is fluid and cursive, with a horizontal line extending from the end.

Adrian P. Heymer

Attachments

c: Ms. Catherine Haney, NMSS, NRC
Mr. Brian Holian, FSME, NRC
Mr. Eric J. Leeds, NRR, NRC
Ms. Marissa G. Bailey, NMSS/FCSS, NRC
Mr. Anthony T. Gody Jr., R-II/DFFI, NRC
Mr. Christopher G. Miller, FSME/DILR, NRC

Consistency With Agency's Rulemaking Process Enhancements

Need for Documented Regulatory Basis

We believe that the lack of a documented regulatory basis for this rulemaking is the root cause of the uncertainty being expressed through our review of the proposed regulations and guidance. The proposed rule does not identify any generic issue that justifies strengthening NRC's existing MC&A requirements. Although certain background documents refer to SECY-05-0143 and the SRM for SECY-05-0143 as containing key information supporting the regulatory basis for this rulemaking, those documents are not available to stakeholders. The inability to review key documents which could justify the need to strengthen existing requirements prevents the industry from understanding and responding to NRC's claim that there is a generic issue requiring that the NRC strengthen its existing MC&A requirements.¹ The rulemaking plan for this effort that is documented in SECY-08-0059 is publically available, but does not provide an adequate basis for this proposed rule. We experienced an analogous situation in our review of the 10 CFR Part 37 rulemaking as it was to be applied to power reactor and fuel cycle licensees.

We believe it is necessary that the NRC identify the technical basis that justified strengthening existing MC&A regulations. MC&A regulatory revisions, if any, should be guided by the low risk of theft and diversion at these facilities, and the findings of the staff's previous vulnerability assessments, which demonstrated that the MC&A posture of these facilities is adequate as well as the risk that is represented by low enriched uranium (LEU) on the one hand and strategic special nuclear material (SSNM) on the other. The extent to which the proposed rule considered these principles is unclear. The rule language suggests that the NRC seeks to align the regulations for lower-risk facilities with higher-risk facilities without providing any quantifiable analysis of the benefits nor recognition of the costs to do so. Given the significant differences in the risk profile and significant resources associated with strengthening the MC&A requirements, consistency for the sake of consistency appears unjustified. Further, the proposed rule appears diametrically opposed to the fundamental underpinnings of the current regulations that emphasize the negligible safeguards risk to public health from low enriched uranium (47 FR 55951). The proposed rule provides no data or analysis suggesting that it is appropriate to revisit this fundamental regulatory structure for the current MC&A regulations.

As an example concerning Category III fuel cycle facilities, the proposed rule would establish new requirements for item control, through the removal of two exemptions related item control. The proposed rule, however, fails to provide any risk assessment that demonstrates that it is necessary for lower risk Category III facilities to implement these MC&A requirements, which are similar to the requirements at higher risk Category I facilities. This is one example, but the context is not limited to fuel cycle facilities. The proposed rule would establish new requirements for item control systems at power reactors and ISFSIs without any risk assessment that demonstrates the necessity. By not providing key documents or otherwise justifying the need to strengthen the existing requirements, it makes it particularly challenging for stakeholders to identify alternatives to what is being proposed.

¹ See *Connecticut Light & Power Co. v. NRC*, 673 F.2d 525, 530-31 (D.C. Cir. 1982) ("An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary.").

Enhancements to Rulemaking Process to Address Cumulative Effects of Regulation

We recognize that to some extent this proposed rule precedes many of the recent enhancements to the rulemaking process. However, consideration of these enhancements would likely have resulted in less uncertainty with the proposed rule. For example, SECY-11-0032 "Consideration of the Cumulative Effects of Regulation in the Rulemaking Process," SECY-12-0137 "Implementation of the Cumulative Effects of Regulation Process Changes," and NRC Management Directive 6.3 "The Rulemaking Process"² emphasize the need and value of interacting with stakeholders early when developing a regulatory basis. Further, when the Commission approved revisions to the MC&A regulations in 2005, it recognized the need for a strong regulatory basis for the proposed changes by directing that the rulemaking plan "clearly state ... the scope of the problem or problems the staff is addressing." We have reviewed the rulemaking plan and were not able to identify a clear regulatory basis or statement of the regulatory problem this rulemaking is intended to address.

The Federal Register Notice (FRN) provides no safety basis for changes to licensee MC&A programs, but instead offers general platitudes indicating that the proposed rule is intended to "incorporate common practices and procedures" and "achieve a more complete and comprehensive inventory," and amounts to a minimal regulatory burden because licensees "already have automated tracking systems." The use of these phrases in lieu of an articulated problem statement does not support informed public comments. Further, the January 9, 2014 presentation by NRC staff emphasized that several of the proposed enhancements were codifying industry best practices, which is not a sound regulatory basis and could be a disincentive to continuous improvement efforts at these facilities.

The FRN also appears to be inconsistent with the direction contained in staff requirements memorandum (SRM) for SECY-11-0175, which indicated, "the staff should revise the draft FRN to provide a full and clear justification for the staff's proposed changes and clearly delineate how each new requirement will be applied to each class of facility." Such a justification would have been helpful in clearing up the uncertainties with this rulemaking. For example, page 67227 of the FRN discusses the general performance objectives in 10 CFR 74.3 as they would apply to fuel cycle facilities and is silent on their application to power reactors, ISFSIs, and other Part 70 licensees authorized to possess greater than 350 grams of SNM.

² SECY-11-0032 (March 2011) – "The rulemaking process will require that the NRC staff interact with external stakeholders during development of the rulemaking regulatory basis." The SRM for SECY-11-0175 directed the staff to specifically consider SECY-11-0032.

SECY-12-0137 (October 2012) – "The NRC's current regulatory process encourages stakeholder interaction during the early stages of the rulemaking process, which begins with the development of the regulatory basis and may include an advance notice of proposed rulemaking. The staff believes that *early stakeholder interaction leads to a more informed regulatory basis, identifies issues earlier that could result in implementation problems, and reveals areas where guidance is needed.* This early interaction also improves the quality and completeness of problem statements for the rulemaking. In the past, stakeholder interactions did not always occur at the regulatory basis stage. *Going forward, stakeholder interactions will be conducted routinely at the regulatory basis stage of a rulemaking.*"

NRC Management Directive 6.3 "The Rulemaking Process" – Section M(4)(b) assigns the Director, Office of Federal and State Materials and Environmental Management Programs, as delegated by the EDO, to *release preliminary proposed rule text, statements of consideration, and the regulatory basis for public review and comment.*

Finally, the SRM for SECY-11-0032 and SECY-12-0137, both emphasize the Commission's commitment to providing draft guidance to stakeholders along with the proposed rule. As we have noted, the proposed rule was not accompanied with implementation guidance for all impacted licensees. In fact, the NRC only provided the draft guidance that was applicable to fuel cycle facilities. SECY-11-0032 indicated that the staff "will revise the rulemaking process to coordinate publication of draft implementation guidance in parallel with the proposed rule for public comment. Unless otherwise directed by the Office of the Executive Director for Operations (EDO), the staff will not provide the proposed rule package to the Commission or EDO, as applicable, until draft guidance is complete." The Commission's SRM approved this recommendation and directed that "the EDO should promptly inform the Commission of any instances, and the associated reasons, where a proposed rule package will be provided to the Commission without having completed the draft guidance. Exceptions to this approach should be very limited and approved by the Commission." We are unaware of the staff justifying or the Commission approving an exception to this approach for this proposed rule.

Proposed Rule Should Reflect the Low Strategic Risk of Low Enriched Uranium

The NRC is currently proposing to modify the MC&A requirements of 10 CFR 74 for low enriched uranium (LEU). These changes diverge from significant determinations made by the Commission which date back to the proposed rule for MC&A that was published in the *Federal Register* in 1982 (47 FR 55951).

The NRC studied the regulations applied to LEU in fuel cycle facilities and determined that given the low safeguards importance of LEU, in tandem with 10 CFR Part 73 physical protection requirements, and the high probability of detecting loss, theft, or diversion of a significant amount of LEU, there should be significant differences in the MC&A requirements for LEU when compared to the requirements for strategic special nuclear material (SSNM). As such, these differences reflect the low strategic significance of LEU.

This decision and the resulting regulations in 10 CFR 74 which were published in 1985 (50 FR 7575) were based primarily on the following facts and to a degree on the operating environment at the fuel cycle facilities.

1. The consequences that could result from LEU sabotage are a negligible safeguards risk to public health.
2. It is impossible to construct a clandestine fissile explosive device with uranium enriched less than 6% and the majority of material held at the fuel cycle facilities is less than 6%.
3. Even for material enriched to 6-10%, it appears to be outside the capability of a subnational group to enrich the material to the degree necessary to produce a clandestine fissile explosive.
4. The radiological hazard of LEU is essentially the same as naturally-occurring uranium. In addition, making dispersible compounds of uranium is very difficult and most likely outside the capability of subnational groups.
5. Fuel facilities process their uranium in controlled access areas and the current physical security measures in place at the facilities protect against theft of a significant quantity of material (i.e. 16 metric tons at 3% enriched).
6. Goal quantities were determined on the basis of the amount of uranium enriched to 6% that would be required to produce a fast critical mass with enrichment technology—below 6% the amount is 500 kg. U-235. To attain this goal quantity in a year would require a steady daily removal of around 100 pounds per day. Process requirements would be sensitive to this amount of removal, internal MC&A routines would detect problems before a year was up, physical security measures would detect the diversions, and the diversion would be detected by the annual physical inventories.

The NRC has not articulated how the events of 9/11 and other security-related events relate to the proposed rule's new MC&A requirements or undermine the six key findings underpinning the NRC's 1985 MC&A rule. These current requirements appropriately differentiate between the risk significance of LEU and SSNM and adequately protect the public from the risk of LEU. Therefore, it is inappropriate to require the industry and the government to expend critical and limited resources to implement MC&A activities that provide an unarticulated safety benefit.

Specific Comments on Proposed Rule and Guidance

As further explained below, there are a number of specific concerns regarding the proposed rule and guidance. The most significant concerns with the rulemaking are the following:

- 1) New general performance objectives in 74.3
 - 2) New item control requirements in 74.19
 - 3) Tracking of "all" SNM required by 74.19(a)(1)
 - 4) Removal of two exemptions related to item control and addition of new absolute language in 74.31(c)(6) and 74.33(c)(6)
 - 5) New requirements for tamper-safing in 74.31(c)(9) and 74.33(c)(9)
- 74.3 - General Performance Objectives
 - These general performance objectives place unnecessary expenses and burden on licensees, are being proposed without the necessary clarity to support effective implementation by licensees, and appear to mix concerns amongst impacted stakeholders subject to various parts of the NRC's regulations (i.e. Part 50/52/70/72).
 - The NRC has not provided guidance to all categories of impacted licensees and during the public meeting on January 9, 2014 appeared to direct the power reactors to guidance developed for fuel cycle facilities which appears to mix the MC&A risks for significantly different facilities.
 - The Federal Register notice and accompanying materials do not provide sufficient insight into NRC's intent, do not articulate a statement of the problem, or the expected safety/security benefit of implementing the proposed rule.
 - The Introduction and Summary of Proposed revisions to MC&A Regulations states in regard to the General Performance Objectives, "The NRC does not expect that Category I, II, and III licensees would need to alter their MC&A programs in response to the 10 CFR 74.3 GPOs, because these GPOs are similar to the existing GPOs." This is inconsistent with the plain language of the proposed GPOs which indicate to facilities that they would need to implement new and more stringent material and information access controls. NRC needs to resolve this discrepancy by rewording the GPOs to clearly define performance objectives that are consistent with existing performance capabilities of fuel cycle facilities with approved FNMC Plans.
 - 74.3(a) – "Maintain accurate, current and reliable information on, and confirm the quantities and locations of SNM in its possession." These are new undefined "absolute" qualifiers/terms need further clarification. These underlined terms are discussed in the draft guidance but are still not defined in practical, plain language. The proposed requirement to "confirm" quantities and locations of SNM during processing is unclear and should be clarified.

- 74.3(b) - "Detect, respond to, and resolve any anomaly indicating a possible loss, theft, diversion or misuse of SNM." The absolute qualifier/term "any" implies no lower threshold of significance. It also implies that all items must be measured and must have verification measurements performed at some frequency or be tamper sealed when created and measured. This proposed requirement imposes significant impacts as it would include loss of material in-process and potentially shift focus toward apparent losses of insignificant quantities of material. (As discussed in Attachments 4 and 5, respectively, the proposed rule failed to address the backfit and regulatory analysis implications associated with these significant impacts.)
 - To minimize these significant impacts (and associated backfit and regulatory analysis problems), we offer the following alternative language for 74.3(b): "Detect, investigate, and resolve an apparent loss, theft, diversion, or misuse of an item, or of material contained in an item that exceeds uncertainties associated with the item quantities of element and isotope (e.g. U and U235)."
- 74.3(c) - "Permit rapid determination of whether an actual loss, theft, diversion, or misuse of SNM has occurred." The term "rapid" is an unnecessary adjective and this GPO implies no lower threshold of significance.
 - We offer the following alternative language for 74.3(c): "Permit determination of whether an actual loss, theft, diversion, or misuse of an item, or of material contained in an item that exceeds uncertainties associated with the item quantities of element and isotope (e.g. U and U235)."
- 74.3(e) - "Control access to MC&A information that might assist adversaries to carry out acts of theft, diversion, misuse, or radiological sabotage involving SNM." This provision requires information protection for MC&A information that might assist adversaries to carry out acts of theft, diversion, misuse, or radiological sabotage. The terms "might" and "adversaries" need further discussion/clarification. Determining what type of information "might assist adversaries" is highly subjective and ambiguous without additional, explicit guidance regarding what specific type of information is contemplated. During the public meeting on January 9, 2014, the NRC staff indicated that the intent was to include all MC&A information and require 10 CFR 2.390 or greater controls, though this remains undefined. We understand that 10 CFR 2.390 could not be directly applied to MC&A information maintained and handled at licensee facilities. Based upon the discussion, it would appear that this proposed revision could subject vast amounts of information that is currently handled under record control protocols for each facility to be significantly changed to incorporate undefined increased controls. It remains unclear how this proposed requirement relates to current industry practices across all of the categories of licensees that would be subject to this GPO. It is also not clear in the rule how this information is expected to differ from Safeguards Information. These subjective and ambiguous standards demonstrate that proposed 74.3(e) is inconsistent with NRC's guidelines for performance-based regulations, which indicate that performance-based objectives are inappropriate when they lack measurable parameters to

determine whether an objective performance standard is met.¹ For this reason, the NRC should not include proposed 74.3(e) in any final rule.

- During the February 5, 2014, public meeting the NRC made reference to current practices at all categories of licensees to comply with the respective requirements for recordkeeping that exist today in 10 CFR Part 74. There was an indication that compliance with existing recordkeeping requirements would yield compliance with this proposed GPO. However, such an interpretation is not consistent with the plain language of proposed 10 CFR 74.3(e), which would require licensees to “control access” to MC&A information, not simply implement recordkeeping requirements. To add further confusion, the discussion in the FRN (e.g. page 67227) explicitly indicates that fuel cycle facilities would not need to alter their MC&A programs in response to the GPOs. If the intent of proposed 74.3(e) would be met for all categories of licensees merely through existing recordkeeping measures (and not through new access control measures), there is no need for this GPO. Further, even if this GPO were included in the final rule, the NRC should explicitly state that the rule is linked to and aligned with the recordkeeping requirements. The FRN further notes that 74.3(e) would require that MC&A information be stored in a locked file cabinet or office which is prescriptive and not aligned with recordkeeping requirements, and should be deleted.
- The industry does not believe that any additional controls are needed beyond existing recordkeeping programs required by 10 CFR Part 74. However, if the NRC finalizes this provision, it should confirm that the proposed regulation was not meant to control access to physical areas containing SNM (beyond current access control) for the sake of protecting MC&A information (e.g. fuel pool contents) and that the NRC does not intend there to be a new information protection/handling regime (e.g. Safeguards Information) created as a result of this GPO, and was not meant to control paper copies of MC&A information, e.g., printed core maps, 741 forms, etc.
- As discussed in Attachments 4 and 5, respectively, the proposed rule failed to address the backfit and regulatory analysis implications associated with this requirement. If the NRC believes that additional action by licensees to implement protection of information beyond existing recordkeeping requirements and any additional measures documented in existing FNMCPs, the following alternative language could be considered for 74.3(e) to minimize the rules significant impacts (and the associated backfit and regulatory analysis problems). The following proposed alternative language attempts to address what we perceive to be NRC’s concerns but would have an impact on existing licensee programs that would need to be analyzed and regulatory guidance would need to be developed.
 - “Store, handle, and manage MC&A record information so as to reduce the likelihood that MC&A record information can be compromised by an unauthorized person.”
- 74.4 - Definitions
 - The definition of custodian and the supporting discussion in the draft guidance appear to suggest that custodians are designated people within the material balance area that

¹ NUREG/BR-0303, Guidance for Performance-Based Regulation at 5-6 (Dec. 2002).

authorize the movement between areas. However, the regulation defines them as “responsible for controlling” the movement into, out of, and within an MBA. Further, the discussion section of the proposed rule adds requirements for a licensee to identify custodians who would be responsible for monitoring. NRC needs to resolve this discrepancy by rewording the GPO to clearly define performance objectives that are consistent with existing performance capabilities of fuel cycle facilities with approved FPMC Plans.

- The definition of material balance area as proposed is “a contiguous area in which the control of SNM is such that the quantity of material being moved into, out of, and within the MBA is an assigned value based on measurements of both the element content and isotopic content.” We do not believe it is necessary to include the term “contiguous” within the definition as it could be in conflict with some current industry practices whereby processing areas are spread out over multiple buildings and under control of a single custodian. In such cases, these areas have been defined as a single MBA even though they are not contiguous.
- We recommend deleting “equipment” from within the definition of MC&A as it is not SNM. This revised definition appears unnecessary - MC&A should only apply to SNM and any SNM contained within uranium enrichment equipment is already subject to MC&A.
- As discussed below in the comment on 74.31(c)(6) and 74.33(c)(6), a new definition for “in-process material” is necessary. We offer the following proposed definition:
 - “In process material can include materials that are not containerized, materials that contain less than a reportable quantity of SNM, materials that exist in containers only during their transport within the facility and materials that exist for less than 7 days in their current material form and type. In process material is exempt from item control requirements of 10CFR74.31(c)(6).”
- 74.19 – Item Control System & Tracking of “all” SNM
 - 74.19(a)(1) - A discrepancy exists between the word “all” in 10 CFR 74.19(a)(1) and the NUREG BR-0006/0007 required reportable quantities for special nuclear material at power reactors and resolution of this issue is necessary and important to the industry.

10 CFR 74.19(a)(1) states that “each licensee shall keep records showing the receipt, inventory, acquisition, transfer and disposal of all SNM in its possession regardless of its origin or method of acquisition”. However, NUREG BR-0006 and NUREG BR-0007 both state in their respective Regulatory Authority sections that DOE/NRC Forms (741/742/742C) are required for quantities of SNM of 1 gram or more contained Uranium-235, U-233, or Plutonium. Reporting of PU-238 is to be to the nearest tenth of one gram of the PU-238 isotope.

The discrepancy between the terms “all” and a “reportable quantity” as defined in the NUREGs is not risk-informed, is cumbersome, below the threshold for regulatory concern, and establishes conditions for interpretation and inconsistencies during inspections. Specifically, at power reactors, several of the items required to be tracked under the cumbersome “all” standard are well below the threshold for reporting. Furthermore, these minute, sometimes microscopic quantities, which,

over the life of the facility, would never accumulate to a reportable quantity, result in significant dose exposures and financial burden to track and pose little to no risk to the public or either risk of diversion or theft. However, the word "all" requires that the licensee treat these less than reportable quantities as if they were large curie content items. The discrepancy that exists between the word "all" in the CFR and the NUREG required reportable quantities needs clarification.

The Scope of 10 CFR 74.2 states that: "general reporting and recordkeeping requirements of subpart B of this part apply to each person licensed under this chapter who possesses special nuclear material in a quantity of one gram or more of contained uranium-235, uranium-233, or plutonium; or who transfers or receives a quantity of special nuclear material of one gram or more of contained uranium-235, uranium-233, or plutonium." This would mean that Licensees who possess less than one gram would be exempt from the requirement to report and maintain records of material in any quantity onsite.

The NRC should replace the word "all" in 74.19(a)(1) with "reportable quantity." Reportable quantities are discrete, discernible and tangible. This is also consistent with the definition of an Item from 10 CFR 74 which defines an Item as: "*Item* means any discrete quantity or container of special nuclear material or source material, not undergoing processing, having a unique identity and also having an assigned element and isotope quantity."

Another method to describe discernible, discrete and tangible is to relate those terms to the quantity of material in one fuel pellet. By example, the amount of special nuclear material contained within one PWR fuel pellet is on the average of 8.25 grams. That would mean that a reportable quantity of material would be represented by 1/16th of a fuel pellet. Though small in volume, a 1/16th of a fuel pellet would still be discrete, tangible and discernible. That reportable quantity is also many orders of magnitude larger than the quantity of material found in incore instrumentation and sealed radioactive calibration sources at both PWRs and BWRs. Those instruments and sources routinely hold quantities in the 1×10^{-3} to 1×10^{-8} gram range which is so small compared to a 1/16th of a fuel pellet that the material in an incore instrument is NOT tangible, discernible or discrete and therefore would not be required to be reported. Waste stream, laundry shipments, and irradiated surveillance capsules calculated to hold SNM at the levels sometimes encountered (1×10^{-6} grams, etc.) would not be required to be reported since they are not discrete.

- 74.19(d) - The FR seeks input on whether item control system requirements should be made applicable to licensed reactors and ISFSIs. Control of items at licensed reactors and ISFSIs is accomplished in a manner different than fuel cycle facilities due to the inherently different operational nature. As discussed below, the NRC's objectives in expanding item control system requirements to other categories of licensees are unclear and need further definition.

Given that the NRC has not provided a problem statement and we are unaware of any concerns from the regulator with respect to item control at these facilities, we do not support expanding the application of these requirements absent a regulatory basis and a commensurate or greater increase in the safety or security.

- The proposed rule would require an item control system for all Part 50/52/72 licensees. The FR indicates that this is consistent with ANSI N15.8. However, ANSI N15.8 does not explicitly mention an item control system. As such, it is unclear exactly what is intended by the requirement for an item control system at power reactors. From the relatively low implementation and operational costs in the Regulatory Analysis, it does not appear that "system" means electronic/computer based "system" managing all purchase orders, receipts, storage locations, moves, and shipments, i.e., a cradle to grave material management system. However, there have been instances in the past (e.g. 10 CFR Part 37) where the Regulatory Analysis estimated a much smaller impact to reactors than actual implementation. The NRC should explicitly state that following ANSI N15.8-2009 would satisfy the proposed requirement for an item control system. This is implied on Federal Register pages 67228, 67240, and 67246, but should be explicitly stated to minimize the rules significant backfit and regulatory analysis problems (see Attachments 4 and 5, respectively).
- Aside for power reactor licensees, however, the proposed rule is completely unclear about NRC's expectations. Not all licensees that would be subject to this rule (e.g. non-power reactors) follow the ANSI N15.8-2009 standard, which applies to power plants. Thus, the NRC needs to clearly articulate the expectation for them and allow for an opportunity to provide input prior finalizing any regulation and guidance that would apply non-power reactor licensees.
- Based on both public meetings, it is our understanding that NRC expects licensees to ensure that their Item Control System (ICS) is capable of keeping current and accurate information of SNM items. This would allow determination of theft, loss, etc. and the ability to provide all necessary information for investigation and recovery. We support the proposal to not define a frequency and request that NRC confirm that Section 12 of ANSI N15.8-2009, "System Review and Assessment" could be the framework for any processes a power reactor licensee would want to implement.
- 74.19(c) provides a 12-month inventory interval which the industry strongly supports. Therefore, we suggest that in Section XII of the FRN where it discusses "12 months or 370 day..." that the NRC strike the reference to "370 day" for clarity and consistency.
- As discussed in the January 9, 2014 public meeting, annual physical inventories would satisfy the requirement to "periodically collect and verify the MC&A information recorded on site" (78 FR 67242). Therefore, NRC should replace "periodically" with "every twelve months."
- 74.31(b) – Nuclear Material Control and Accounting Plan
 - Fuel Cycle Facilities do not see any need to formally change the titles of their FNMC plans to MC&A plans. As such, the industry supports the proposed rule to the extent it indicates that

any such change would be voluntary. We see no reason to incur the costs associated with the change for no known benefit. To make the voluntary nature of this provision clear, the NRC should include an explicit grandfather clause and/or exemption for current licensees.

- 74.31(c)(6) & 74.33(c)(6) – Removal of Item Control Exemptions

- These provisions are being modified to remove the exemptions for items existing less than 14 days and individual items containing less than 500g of U235. This proposal would cause significant impacts without any commensurate or greater increase in the safety or security of the affected facilities.
- Fuel Cycle Facilities are opposed to the proposed removal of the two item control exemptions that are included in the current regulations. These exemptions have been in place for decades and are there for a reason. The elimination of the 14-day exemption and the 500 gram exemption would put the site analytical facilities under item control resulting in doubling the number of items at the FCFs and would decrease the efficiency of the labs by approximately 10 - 15%, as it would now subject samples and laboratory standards to item control.
- Many material forms are currently exempted from the item control process because the projected existence time is not expected to exceed 14 days. The impact to industry to apply item control to these materials is greatly understated because the NRC assumes incorrectly that "licensees have in-house systems that track such items in near real time." Though some licensees may have implemented electronic systems to improve their accountability systems, they are by no means required by NRC regulations to do so. The NRC's proposed change to the 14-day exemption assumes that all current and future licensees will employ such a system. Further, the proposed rule incorrectly assumes that existing licensee systems and procedures are already designed and sufficient to accommodate material forms that are currently exempted from the item control process. The NRC should maintain the 14-day exemption to minimize the significant impact (and the associated backfit and regulatory analysis problems) associated with this incorrect assumption (see Attachments 4 and 5, respectively).
- If the NRC were to eliminate either of these exemptions, it should explicitly state that samples and laboratory standards are considered to be undergoing processing and therefore are not items and not subject to item control. While not without significant impact, this clarification would help mitigate impacts from the removal of item control system exemptions.
- The NRC needs to confirm that the elimination of the 14 day exemption for items from the item control system will not impact the facility's approved practice of receiving and entering receipts into accounting records in a timely manner as currently authorized.
- In 10 CFR 74.31(c)(6), the proposed rule requires the licensee to detect "any" unauthorized removal of any SNM. This has far reaching implications in the context of implementation of this entire proposed rule and cannot be met without extraordinary impact. The NRC should reword this provision to include a practical timeframe for licensees to update item

information in the item control system and for receiving and entering receipts into accounting records that is consistent with currently authorized licensee practices.

- The NRC needs to confirm (e.g. in the final rule statements of consideration or final guidance) that items entered into the item control system are not re-measured or handled differently if the measurement and control and surveillance practices permit detection of removal of SNM from an item, and that no additional measures are required to detect removal of an entire item when the facility has an approved practice for item controls and tests.
- Therefore, we suggest rewording this provision to clarify that the requirement only applies to SNM containers that have been put under item control. Also, we suggest clarifying that it is permissible to control SNM in containers under other control provisions of this regulation. In addition, NRC has expressed that the intent of the word changes in this section is that the capability must be maintained to detect diversion of material from an item if such an event is indicated. The following is alternative language that should be considered to minimize the rules significant impacts (and the associated backfit and regulatory analysis problems discussed in Attachments 4 and 5, respectively):
 - "Establish, document, implement, and maintain an item control system as defined in 74.4. Store, handle, and subsequently measure items in a manner so as to detect the unauthorized removal of individual items or to detect the unauthorized removal of a measurable quantity of SNM from an item if such a removal is indicated by material control features or any other method. Exempted from this requirement are in process materials as defined in 10 CFR 74.4 (see above), SNM in solution with a concentration of less than 6 grams of uranium-235 per liter, and items of waste destined for burial, incineration, or other NRC approved means of disposal. Also exempted are quantities of containerized SNM for which the licensee has implemented alternative methods (mass balance, physical controls, surveillance, etc.) to maintain material control and accountability of SNM."
- The lessons learned through implementation of the term "all" (see comment related to 74.19(a)(1) above) should be applied in the context of the term "any" in the proposed 74.31(c)(6) so as to avoid similar problems during implementation for both the NRC and licensees.
- Current item control system capabilities and MC&A processes are designed to only track those material forms currently required to be tracked and not these additional material forms. Under a potential interpretation of the proposed rule, these material forms will need to be containerized in some instances, measured for SNM quantity in certain instances, and entered into the item control tracking system. Containers will have to be modified to include unique identification and item control system software will have to be modified to include transactions to track new material forms/containers. Measurement methods will need to be developed, measurement equipment will need to be procured and integrated with the item control system software. Personnel would potentially have to perform new routine measurements and item control transactions. Material forms likely affected include:

- Items containing trivial quantities of SNM (0-25 grams U-235) such as laboratory process samples, UF₆ P10 samples, liquid residue in shipping packages, fixed contamination on containerized protective clothing
 - Unopened tamper sealed items in shipping packages and conveyances received awaiting unloading and entry into the plant and/or production processes
 - Material in normal process intermediates contained/loaded into process apparatus/conveyances awaiting introduction into process (fuel pellet coater fixtures, pellet sintering furnace boats, pellet pans, uninspected pellet trays, material in oxidation pans)
 - Tamper sealed non-waste items in shipping packages staged for subsequent shipment
 - Packages, containers and process tanks containing solutions with concentrations greater than 5 gU-235 per liter but less than 6 grams U-235 per liter (UN liquid in Shipping packages, bulk storage tanks, liquid process waste and clean out sludge cream cans)
 - Allowances should be made to account for the time it takes for employees to perform transactions or to account for delays in performance of transactions/corresponding physical activity in the event of system difficulties or the need to respond to process or administrative demands. Suggest that the timeframe to update the item control system should be concurrent with change in item attributes, not to exceed end of shift and in any case not to exceed 72 hours. (72 hours is the suggested time frame for resolution of anomalies)
- 74.31(c)(9) and 74.33(c)(9) – Tamper-Safing
 - These provisions are being modified to make tamper-safing requirements applicable to Category III fuel fabrication facilities and uranium enrichment facilities.
 - The FR specifically seeks comment on whether tamper-safing should be required for Category III licensees. Licensees currently tamper safe items in accordance with their procedures. To require additional tamper-safing would be inconsistent with Part 74's performance-based approach, which allows licensees to select the most efficient approach for obtaining results. Given that this provision lacks an articulated problem statement and would not provide any commensurate or greater increase in the safety or security of the affected facilities, it is unclear why a new regulation is necessary. Absent a problem statement and commensurate or greater increase in the safety or security, we do not see a need for this new requirement.
 - If the NRC intends to increase or expand licensees' existing use of tamper-safing, the impact to industry for tamper-safing is greatly understated because the NRC assumes incorrectly that, "all Category III facilities routinely tamper-safe containers of SNM, so this is not expected to be a burden for the affected licensees." Most intermediate process material forms/items are not routinely tamper sealed while in interim storage during the material balance period (MBP) but rather are sealed in preparation for annual inventory at the end of the MBP. The new GPO requirements imply that these items be measured and stored under

tamper seal in order to prevent and or detect unauthorized removal, etc. Mandating increased or expanded tamper-safing would also present backfit and regulatory analysis problems (see Attachments 4 and 5, respectively).

- The intent of the wording in 10 CFR 74.31(c)(9) is unclear. We cannot discern whether the intent was to expand or increase the existing use of tamper seals in our facilities.
 - NRC needs to confirm in the final rule or supporting documentation that the addition of the provision for the tamper safe seal program is only intended for licensees to follow existing procedures and maintain adequate controls of tamper safe seals and not to add additional tamper safe seal usage in facilities.
 - When interpreted in combination with the proposal in 10 CFR 74.31(c)(6) to detect “any” unauthorized removal of any SNM, this requirement would be incredibly onerous and significantly increase the use of tamper seals and/or vaults, etc. at our facilities.
 - The NRC needs to clarify whether a tamper indicating device (TID) would satisfy the detection requirement in 74.4(b)(5) and 74.31(c)(6) to “detect” unauthorized removals of any quantities of material from items.
 - The rule is ambiguous on which items would require TIDs.
 - Dry cask canisters that are welded shut provide sufficient protection and do not need tamper-safing devices. The NRC should clarify that this also applies to bolted dry storage canisters and overpacks that conceal a welded dry storage canister (78 FR 67228).
 - The definition of tamper-safing should also allow tamper-safing other enclosures/containers such as sealable rooms, sealable drum racks etc. such that tampering or removal would be detected.
- 74.31(c)(10), 74.33(c)(10), 74.43(c)(9), and 74.59(h)(5) – ICAs and MBAs
 - These provisions require designation of ICAs and MBAs and identification of custodians who would be responsible for monitoring these areas. The FR specifically seeks comment on whether MBAs and ICAs should be required. Fuel Cycle Facilities currently manage all SNM in inventory through the use of one or more MBA(s) and/or ICA(s). Each individual MBA and ICA has a custodian assigned in a manner that ensures custodial responsibilities can be effectively executed for all SNM possessed under the license. The proposed requirement introduces uncertainty with respect to existing programs and lacks an articulated problem statement and would not provide a commensurate or greater increase in the safety or security of the affected facilities. Absent a problem statement and a commensurate or greater increase in the safety or security, we do not see a need for this new requirement and its expansion to other facilities.
 - It is unclear whether the intent is to require multiple ICAs and MBAs. Any proposal to change the MBA or ICA designations within our sites needs a clearly articulated problem statement.

- NRC needs to clarify that the intent of adding paragraph 10 is only to identify the current practices of using MBAs and ICAs and not to imply that additional MBAs and ICAs must be created at licensed facilities.
 - The impact to industry for Establishing MBAs, ICAs and SNM Custodians is greatly understated because even though "licensees are voluntarily using MBAs and ICAs and have designated custodians assigned to them," the NRC assumes incorrectly that, existing MBAs, ICAs, key measurement points and Custodian delegations/responsibilities are established such that anomalies can be resolved by performance of a mass balance around the MBA/ICA and that custodians currently exercise control over individual transfers of items between MBAs and ICAs.
 - The specific duties and roles of SNM Custodians are not clearly defined. The requirement seems to imply that MBAs be established so that anomalies can be resolved by performance of a mass balance and custodians are responsible for authorizing individual transfers of material between MBAs/ICAs. For example, a facility may have only one MBA and ICAs are chosen based on practical divisions between process steps and geographic process locations. Custodians are assigned by virtue of their assigned management responsibility over particular processes and manufacturing areas. Control and authorization for SNM transfers is delegated to individual employees by their assigned job function and associated training.
 - The proposed rule is unclear on whether ICAs are required to be used for all item storage (i.e., item monitoring) locations. Transfers in and out presumably would be crossing an accounting boundary and require the rigor of an MBA transfer. This is a significant impact to facilities with multiple item storage locations.
 - The final rule and supporting documentation should be clear as to whether ICAs are required, under what circumstances, the acceptability of having no ICAs in a facility that has item storage locations, and whether ICAs can be a part (i.e., contained within) of an MBA.
 - The wording of this section seems to force licensees to designate more than one MBA and, in addition, at least one ICA. Further, it implies that there is a change to custodial responsibilities from the current version of the regulation. Alternative language that should be considered is as follows:
 - "Licensees shall manage all SNM in inventory through the use of one or more MBA(s) and one or more ICA(s). Each individual MBA and ICA shall have a custodian assigned in a manner that ensures custodial responsibilities can be effectively executed for all SNM possessed under the license."
- 74.51 – Please clarify that the intent of the change in wording of 74.51 (c)(2) is not meant to change the population of potential "colluders" [e.g., from MC&A and physical security to 2 people with SNM access].
 - Appendix A - For some facilities both high enriched uranium (HEU) and Pu are present in "significant" quantities. Please clarify whether the new Appendix A will address this situation. For example, for facilities with a Category I quantity of Pu and a Category III quantity of HEU, it is

unclear what level of accountability is implemented for the HEU material – when combined with Pu and when separate.

- Implementation Guidance – Prior to being finalized, stakeholders should be provided an opportunity to review and comment on any changes to the draft guidance as a result of changes made to the proposed rule.
- NUREG-1065
 - Page 41, Section 8.0 - "Items, as defined in 10CFR 74.4, "Definitions," mean any discrete quantity or container of special nuclear material (SNM) or source material , not undergoing processing." Clarification is needed on when licensees must create an item and what is considered processing.
 - Page 56, Section 11.3, 3rd and 4th bullets – The following language appears to be related to the former proposed two person rule and should be deleted: "identification of the person applying the TID's" and "identification of the person who verified the application of the TID."
 - Page 57, Section 11.4, 3rd bullet – This language indicates for TID control officers that there be "Preferably a single individual, but no more than three individuals." We do not believe that there should be an implied limit of three individuals absent a regulatory basis.
 - Page 57, Section 11.4, 4th bullet – It is unclear what is intended by the language that indicates: "Only individuals authorized for that purpose will apply and remove TIDs."
 - Page 57, Section 11.4, 6th bullet – Clarification is needed with respect to the following statements: "When TIDs are not in storage they are in the possession of authorized individuals (i.e., the TID control officer or person responsible for applying the TID). As a rule, the number of available TIDs issued to these individuals should be limited to a single day's use."
- NUREG-1280
- We have identified several examples of formulas in the guidance that are incomplete. The NRC should review each guidance document for such examples, make the necessary corrections and allow stakeholders an opportunity to review and comment before the guidance is finalized. Below are examples from NUREG-1280:
 - Page 12 – material control tests
 - Page 29 – sampling for item monitoring tests
 - Page 38 – expected number of alarms
 - Page 81 – standard error of inventory difference (SEID)
 - Page 88 – selecting items for re-measurement
 - Page 94 – criteria for Inventory Difference evaluations
 - Page 131 – combined standard error

- Page 135 – standard deviation
- Implementation
 - The Federal Register notice proposes an effective date of 90 day after the final rule is published and asks whether 6 months from the final rule's publication in the Federal Register is sufficient to implement the new proposed requirements (78 FR 67231). During the February 5, 2014 public meeting, the NRC staff suggested that the 6-month implementation period was intended to include approximately 5 months for NRC review and approval of MC&A program changes (e.g. FNMCP). Consequently, additional time beyond the 6 months is necessary to allow for development of proposed changes, NRC approval and subsequent licensee implementation. Based on the language in the proposed rule and the significant associated impacts, the NRC should make the final rule effective 90 days after publication in the Federal Register and require that licensees submit any necessary changes to licensing basis documents within 180 days of the effective date of the final rule. Each submittal would include a proposed implementation schedule, which the NRC would need to review and approve as part of the MC&A program change process. This implementation process is similar to the one used for NRC review and approval of cyber security plans for power reactors (74 FR 13927, 13958). Given the NRC's plans to hold a future meeting to discuss the implementation date, we recognize that expectations regarding specific implementation timeframes may further evolve based upon the final rule language and based upon the NMSS/FCSS integrated schedule of regulatory initiatives.
 - There is also inconsistency in the FRN discussion of the effective date vs. the implementation date. On page 67231, the FRN says that "the revisions to the regulations would become effective 90 days after the publication of the final rule." Then on page 67235, it asks whether an "effective date" of 6 months from the final would be sufficient to implement. This needs to be clarified.
- Regulatory Threshold of 350 Grams
 - This proposal to adjust the regulatory threshold downward to 350 grams is another example of a proposed change that would impact licensees and Agreement States without a problem statement and a commensurate or greater increase in the safety or security. If the NRC decides to lower the regulatory threshold it should be based on technical analysis that demonstrates the need for such a change.
 - The FRN contained specific questions for which the NRC was seeking stakeholder input. The responses to those questions have been incorporated into the contents of this letter

The Proposed Rule Does Not Adequately Address Backfit Implications

Contrary to the direction provided in the SRM addressing SECY-11-0175 and COMSECY-12-0026, the proposed rule contains no backfit analysis. Instead, the proposed rule obscures the backfitting issue by claiming that this lack of analysis is justified because MC&A requirements constitute "information collection and reporting requirements" and the "NRC has long taken the position that information collection and reporting requirements are not subject to the NRC's backfitting and issue finality regulations, as reflected in past MC&A rulemakings published in the Federal Register (e.g., 56 FR 55991; October 31, 1991, 67 FR 78130; December 23, 2002, and 73 FR 32453; June 9, 2008)."¹ In support of this conclusion, the proposed rule provides a table that claims to identify key substantive provisions that include information collection and reporting requirements. As discussed below, the proposed rule does not properly address the proposed rule's backfit implications for at least three primary reasons. We believe that if a backfit analysis was performed, the proposed enhancements would not be justified as substantial safety enhancements.

First, the proposed rule contains a flawed analytical approach to backfitting and does not recognize that it would impose new regulatory requirements that go beyond simple information collections. Questions about whether the proposed rule constitutes a backfit should start with the regulatory definition for backfitting. Rather than addressing whether the proposed rule would require the "modification of, or addition to, systems, structures, or components [SSCs] of a facility; or to the procedures or organization required to operate a facility,"² the NRC only considered whether these new requirements involve information collection. Nothing in NRC regulations exempts the NRC from applying the backfit rule to information collection requirements. Although a mere information collection requirement would not typically meet the backfit definition, that is only because it would not require modification of the SSCs, procedures, or organization required to operate a facility. By not addressing this standard, the proposed rule obfuscates this fundamental analytic question and does not consider the very definition of backfitting, which requires that the NRC consider whether its new or amended rules "result" in modifications to a facility's required SSCs, procedures, or organization.³

If the NRC had taken the appropriate analytical approach and applied the regulatory definition for backfitting, it would have found that the proposed rule results in the "modification of, or addition to, systems, structures, or components [SSCs] of a facility; or to the procedures or organization required to operate a facility."⁴ This failure to recognize the proposed rule's backfit implications is puzzling because the

¹ 78 FR 67240.

² 10 CFR 70.76(a)(1).

³ In other words, a backfitting determination must focus on "cause" (e.g., new or amended rules) and "effect" (e.g., modifications or additions to a facility's SSCs, procedures, or organization). See Final Rule, Revisions of Backfitting Process for Power Reactors, 50 FR 38097, 38102 (Sept. 20, 1985) ("The definition focuses on modifications to systems, structures, components, designs, procedures or organization which may be caused by new or modified Commission rules or orders or staff interpretations of Commission rules or order. Thus, this definition includes both cause and effect of backfitting."). Nothing in the backfit rule excuses this analysis simply because a new requirement involves the NRC collecting information from licensees. Such an interpretation would greatly curtail the backfit rule's usefulness because numerous regulations require that licensees provide the NRC with information.

⁴ 10 CFR 70.76(a)(1).

Commission already rejected a similar "information collection" claim made in the context of the "two-person" rule. Earlier in this rulemaking, the staff took the position that the two-person rule was merely an information collection in order to avoid application of the backfit rule. The Commission unanimously rejected the staff's argument and disapproved the proposed rule's publication without an adequate backfit analysis. Although the proposed rule removed the two-person rule, it recycles this previously-rejected "information collection" argument to avoid application of the backfit rule.

As an example, the proposed rule would require that several fuel cycle facilities make significant plant modifications. These changes would include replacing chain link fencing or administrative boundaries with solid walls to comply with NRC requirements for vaults, the addition of doors and the creation of smaller rooms for improved material control, and the elimination of item carriers (powder/pellet carts, rod trays/channels). These changes would all require significant capital investment but are not addressed by the proposed rule's backfit discussion.

The following table demonstrates that a number of the proposed rule's substantive provisions impose backfits:

Proposed Rule Citation	Description of Proposed Requirement	Explanation of Why the Proposed Requirement Would Result in Modification or Addition to SSC, Procedures, or Organization
10 CFR 74.3(b)	The proposed rule would require that licensees implement and maintain an MC&A program that achieves the following GPO: "Detect, respond to, and resolve any anomaly indicating a possible loss, theft, diversion, or misuse of SNM."	The proposed rule requires that licensees detect, respond to, and resolve "any" anomaly. This suggests no lower threshold of significance. It also suggests that all items must be measured and have verification measures performed at some frequency, or must be tamper sealed when created and measured. These new requirements would result in a modification or addition to the procedures to operate a facility. In addition, these requirements may also result in a modification or addition to the SSCs of a facility.
10 CFR 74.3(e)	The proposed rule would require that licensees implement and maintain an MC&A program that achieves the following GPO: "Control access to MC&A information that might assist adversaries to carry out acts of theft, diversion, misuse, or radiological sabotage involving SNM."	The proposed rule indicates that 10 CFR 74.3(e) would impose greater controls on information related to MC&A and require that such information be stored in a locked file cabinet or office. ⁵ This new requirement would result in a modification or addition to the procedures to operate a facility (e.g., modified or additional access control procedures). In addition, this requirement would also result in a modification or addition to the SSCs of a facility (e.g., modified or additional file cabinets and office locks).
10 CFR 74.19(d)	The proposed rule would require that reactors and ISFSIs establish, document, implement, and maintain an item control system.	The proposed rule would require that licensees create a system to track the creation, identity, element and isotopic content, location, and disposition of all items. Although the NRC has not provided any item control system guidance for reactors and ISFSIs, this requirement would necessarily result in a modification or addition to the procedures required to operate a facility (e.g., modified or additional procedures for managing all SNM

⁵ 78 FR 67227.

Proposed Rule Citation	Description of Proposed Requirement	Explanation of Why the Proposed Requirement Would Result in Modification or Addition to SSC, Procedures, or Organization
		purchase orders, receipts, storage locations, moves, and shipments). It also may result in modification or addition to the SSCs of a facility (e.g., addition of an electronic-based system for managing all purchase orders, receipts, storage locations, moves, and shipments). In addition, licensees would need to identify an individual responsible for overseeing the item control system, which would result in a modification or addition to the organization required to operate a facility.
10 CFR 74.31(c)(6), and 74.33(c)(6)	The proposed rule would require that Category III facilities establish, document, implement, and maintain an item control system for items existing less than 14 days and for individual items each containing less than 500 grams of uranium-235 up to a total of 50 kilograms of uranium-235.	The proposed rule would require that licensees modify their FNMC plans and associated item control procedures. Thus, this new requirement would result in a modification or addition to the procedures required to operate a facility. In addition, this requirement would also result in a modification or addition to the computer inventory control systems of a facility.
10 CFR 74.31(c)(9), and 74.33(c)(9)	The proposed rule would require that licensees maintain and follow procedures for tamper-safing of containers or vaults containing SNM, which include control of access to, and distribution of unused seals and records.	The proposed rule would require that licensees modify their FNMC plans and establish procedures to document the distribution, application, and destruction of tamper-safing devices, as well as routine inventory of unused tamper-safing devices. Thus, this new requirement would result in a modification or addition to the procedures required to operate a facility (e.g., FNMC plan modifications). ⁶ In addition, because the proposed rule would require new tamper-safing devices (e.g., tamper-indicating devices) and expand the existing use of tamper-safing

⁶ See, e.g., NUREG-1065 at 57 ("Written procedures will be maintained to ensure that individuals authorized to handle TIDs are properly trained.").

Proposed Rule Citation	Description of Proposed Requirement	Explanation of Why the Proposed Requirement Would Result in Modification or Addition to SSC, Procedures, or Organization
		<p>devices, it would result in a modification or addition to the SSCs of a facility.⁷</p> <p>Furthermore, this new requirement would result in a modification or addition to the organization required to operate a facility because it would require that licensees designate responsible personnel to implement tamper-safing requirements (e.g., designation of a control officer to be responsible for seal application and destruction).⁸</p>
10 CFR 74.31(c)(10), and 74.33(c)(10)	The proposed rule would require that licensees designate material balance areas and item control areas and assign custodial responsibility for each of these areas.	The proposed rule would require that licensees modify their FNMC plans by designating material balance areas and item control areas. Thus, this new requirement would result in a modification or addition to the procedures to operate a facility. In addition, the proposed rule would require that licensees assign custodial responsibility for each material balance area and item control area. This new requirement would result in a modification or addition to the organization required to operate a facility.
10 CFR 74.3, 74.19, 74.31, 74.33, 74.41, 74.43, 74.51, 74.55, and 74.59	This proposed rule may necessitate changes to approved Final Safety Analysis Reports (FSARs) and FNMC plans.	This proposed rule may necessitate that licensees modify their FSARs, FNMC plans, and/or associated operating procedures.

Second, the reference to NRC's "long taken position" that MC&A rulemakings are not subject to the backfit requirements does not establish that the backfit rule is inapplicable to the changes contained in the proposed rule. The Commission has already definitively rejected this argument in the context of the two-person rule. Moreover, the past rulemakings referenced in the proposed rule say nothing about whether the changes currently proposed are subject to the backfit rule. One of the referenced rulemakings used to

⁷ See, e.g., NUREG-1065 at 57 ("Only [tamper-indicating devices] that are controlled and accounted for will be used to maintain the validity of previously established SNM quantities associated with items.").

⁸ See, e.g., NUREG-1065 at 57.

support this position predated the backfit regulation applicable to 10 CFR Part 70 facilities.⁹ The other two referenced rulemakings were narrowly tailored to address MC&A reporting requirements and reduce regulatory burden,¹⁰ which means that the need for an appropriate backfit analysis was not at issue during those rulemakings. In contrast, the current proposed rule involves far more than amendments to MC&A information collection and reporting requirements, and therefore requires a full backfit analysis.

Third, the proposed rule conflates NRC's information collection regulations (10 CFR 50.54(f), 52.98(g), 70.22(d), and 72.62(d)) with its backfit regulations (10 CFR 50.109, 52.98(a)-(c), 70.76, and 72.62(a)-(c)), but never addresses the relevant regulatory requirements for information collections. For example, the proposed rule does not address the requirement in 10 CFR 50.54(f) that the NRC "prepare the reason or reasons for each information request prior to issuance to ensure that the burden to be imposed on respondents is justified in view of the potential safety significance of the issue to be addressed in the requested information."

It is our understanding that the underlying intent of the NRC's historical exclusion of "information collections" from backfitting is related to the difficulty of determining the safety benefits of collecting information for the purpose of the NRC determining whether further regulatory action is needed such as orders, rulemaking, or enforcement.¹¹ Here, the information that is recorded and reported is directly for the purpose of ensuring the protection and control of the material, not for purposes of aiding the NRC in determining whether future action is needed.

In summary, the proposed rule erroneously concludes that the backfit rule is inapplicable because it only involves information collections and reporting requirements. To the contrary, the backfit rule applies to the proposed rule because it plainly imposes new regulatory requirements that would result in modifications to the SSCs, procedures, or organization of a facility. Moreover, the Commission has already determined that the backfit rule should apply to MC&A rulemakings and the past MC&A rulemakings referenced in the proposed rule say nothing about whether the changes currently proposed are subject to the backfit rule. Even assuming for argument's sake that NRC's information collection regulations had some relevance to the proposed rule, the proposed rule still fails to address the regulatory requirements applicable to information collections.

For these reasons, we believe that a backfit analysis is necessary and once performed, the proposed enhancements would not be justified as substantial safety enhancements.

⁹ See Final Rule, Material Control and Accounting Requirements for Uranium Enrichment Facilities Producing Special Nuclear Material of Low Strategic Significance, 56 FR 55991 (Oct. 31, 1991); Final Rule, Domestic Licensing of Special Nuclear Material; Possession of a Critical Mass of Special Nuclear Material, 65 FR 56211, 56218, 56230 (Sept. 18, 2000).

¹⁰ Final Rule, Regulatory Improvements to the Nuclear Materials Management and Safeguards System, 73 FR 32453 (June 9, 2008); Final Rule, Material Control and Accounting Amendments, 67 FR 78130 (Dec. 23, 2002).

¹¹ See 64 FR 33178, 33181 (June 22, 1999) (NRC's comment response in the 1999 rulemaking imposing ISFSI licensing changes, which states that "the existence or non-existence of a record or report usually has no independent safety significance as compared to actions taken by the licensee as a result of the information contained in the record.").

Proposed Regulatory Analysis Comments

The NRC published a draft regulatory analysis along with the preliminary rule language in May 2011. At that time, the NRC received specific cost impact information from fuel cycle facilities, which demonstrated the significant impact associated with these changes. The NRC does not appear to have considered this earlier industry cost input in the most recent regulatory analysis even though industry is often in the best position to estimate cost impacts. In this case, based upon the information contained within the FRN for the proposed rule, the NRC has significantly underestimated those costs (e.g., tens of thousands of dollars versus millions of dollars).

Current dialogue between the industry and the NRC on regulatory analyses, have resulted in the three following initial conclusions, which we strongly encourage that the NRC adopt (to the extent possible) for this rulemaking.

- 1) Clearly define the scope, closure criteria and characteristics so that realistic resources can be estimated for compliance with the new action/position.
 - 2) The scope, regulatory analysis and guidance of the regulation should receive early public input in order to help accurately estimate the costs and benefits of the regulation before issuing the proposed rule for public comment.
 - 3) Regulatory analyses should include information on the basic assumptions and sources that drive the high level estimates and provide a range of estimates based on various sensitivities instead of single point estimates.
- Our review of the regulatory analysis addresses the impacts of the entire proposed rule, whereas the draft regulatory analysis only analyzes two rule provisions. NRC's final regulatory analysis should follow Office of Management and Budget (OMB) Circular A-4, "Regulatory Analysis," which states: "Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternate actions." (OMB Circular A-4 at 26)
 - Regarding the specific cost impact information from fuel cycle facilities provided to NRC in June 2011, which indicated the significant impact associated with these changes, the NRC suggested that it was unable to consider the information given its proprietary nature. For many licensees, the nature of specific cost estimates is often considered proprietary information. The NRC staff has suggested that it may be limited in its ability to consider such information in a rulemaking. Such a position is inconsistent with the NRC's already established process in 10 CFR 2.390, which contemplates that proprietary information may be submitted and considered by the NRC as part of a rulemaking. For example, 10 CFR 2.390(b) addresses how to submit proprietary information to the NRC and request withholding from public disclosure, but contains nothing that precludes the submission of such information in a rulemaking proceeding. To the contrary, 10 CFR 2.390(b) explicitly indicates that the Commission may withhold proprietary information from public disclosure based on its policy of achieving "effective balance between legitimate concerns for protection of

competitive positions and the right of the public to be fully apprised as to the basis for and effects of licensing or rulemaking actions.” Any limitation on the NRC’s ability to consider proprietary information in a rulemaking proceeding would also be inconsistent with prior NRC practice¹ and the practice of other federal agencies.² Courts are aware of and have upheld rules that have followed this practice of considering proprietary comments in rulemaking proceedings.³ For example, the U.S. Court of Appeals for the Third Circuit has upheld NRC’s regulations addressing the withholding of proprietary information in rulemaking proceedings even upon fully recognizing that the “NRC has conducted rulemaking proceedings” where “it has received technical, commercial and financial information from private parties such as equipment manufacturers, architects, engineers, and owners of facilities” and that “[m]uch of this information is proprietary.”⁴ Similarly, the U.S. Court of Appeals for the D.C. Circuit has upheld Environmental Protection Agency rules that considered and addressed comments containing proprietary information.⁵ This is a generic policy issue, which if not resolved, has the potential of discouraging the detailed information NRC is interested in receiving to better inform its regulatory analyses. “By refusing to accept any comments containing [proprietary information], . . . the [agency] limits the extent of public participation and the type of information allowed in its rulemaking proceedings. Such limitation infringes on § 533 of the [Administrative Procedure Act], which allows for any person to comment during an informal rulemaking.”⁶

- The industry appreciates our responsibility to inform this document and recognizes that we are in the best position to estimate impacts, which in this case appear to have been significantly underestimated by the NRC (e.g. tens of thousands of dollars versus millions of dollars). The regulatory analysis should address the impacts of the entire proposed rule.
- There are inherent challenges for the industry to perform a cost analysis absent a documented regulatory basis. Therefore, these comments are based on the industry’s interpretation of the proposed rule language and demonstrate the need for significant change to align the written words with the intent as expressed through the public meetings. Adopting industry’s clarifying comments and other alternative rule language would go a long way to minimize the NRC’s need to completely overhaul and expand its draft regulatory analysis.

¹ See, e.g., Final Rule, AP1000 Design Certification, 76 FR 82079 (Dec. 30, 2011) (discussing proprietary documents NRC relied upon to form basis for rule).

² See, e.g., EPA, Final Rule, Regulation of Fuels and Fuel Additives, 78 FR 14190 (Mar. 5, 2013) (addressing industry comments containing confidential business information).

³ See, e.g., *National Wildlife Federation v. EPA*, 286 F.3d 554, 563-65 (D.C. Cir. 2003).

⁴ *Westinghouse v. NRC*, 555 F.2d 82, 85 (3d Cir. 1977).

⁵ *National Wildlife Federation*, 286 F.3d at 565 (rejecting a challenge to EPA, Final Rule, National Emission Standards for Hazardous Air Pollutants for Source Category: Pulp and Paper Production, 63 FR 18504, 18550 (Apr. 15, 1998), and upholding EPA’s consideration of proprietary comments).

⁶ H. Kilgore, Signed, Sealed, Protected: Solutions to Agency Handling of Confidential Business Information in Informal Rulemaking, 56 Admin. L. Rev. 519, 528 (2004).

- **Fuel Cycle Facilities**

- Fuel Cycle Facilities take strong exception to the NRC cost estimates to implement the new requirements (one-time cumulative industry costs of <\$200K and annual costs of <\$100K). FCFs believe that the annual costs are significantly underestimated. One-time costs would vary widely from facility to facility but for example at Category III fuel cycle facilities the one-time costs would exceed millions of dollars with similar numbers for annual costs.
- In order to meet the proposed GPOs at Category III fuel cycle facilities, which include both SNM in items and SNM that is in-process, it may be necessary to search every person and their belongings each time they leave an area within the plant where SNM is stored and/or processed. This would be extremely expensive and time consuming and, because LEU is a relatively weak alpha emitter that is easily shielded from detection equipment it is uncertain if equipment even exists that could handle the throughput at the sensitivity level required to detect the removal of 1 gram of U²³⁵.
- In addition, with respect to 74.3(e), the NRC indicated that their expectations for this GPO included storing all MC&A information in locked cabinets, files, offices, etc. and printing MC&A information only in secure locations. This level of access control is not currently in place and if staff expectations are clarified to include this level of control then physical changes to facilities and administrative changes to routine operations will be required. An estimate of the cost to complete both the physical and administrative changes including potential software changes are on the order of \$200K.
- Elimination of the two exemptions to item control requirements for items containing less than 500 grams U-235 and items that exist for less than 14 days would have serious cost impacts at Category III fuel cycle facilities. Currently lab samples and standards contained in the various lab facilities are exempted from item control and can therefore be transported to the lab for analysis without being weighed, tracked, etc. as items. We note that some laboratories are under mass control rather than item control. We estimate that elimination of these exemptions would reduce lab efficiency by up to 20%. It would also require facility modification, equipment procurement and installation to procure containers and ID them with permanent IDs and to add stations for the weighing, scanning, and updating the item control system for items not currently tracked under item control because they are not expected to exist for more than 14 days. This estimate does not include information technology costs to modify our item control system for these new materials required to be tracked.
- Current item control system capabilities and MC&A processes are designed to only track those material forms currently required to be tracked and not these additional material forms. These material forms will need to be containerized in some instances, measured for SNM quantity in certain instances, and entered into the item control tracking system. Containers will have to be modified to include unique identification and item control system software will have to be modified to include transactions to track new material forms/containers. Measurement methods will need to be developed, measurement

equipment will need to be procured and integrated with the item control system software. Personnel will have to perform new routine measurements and item control transactions.

- This proposed requirement, in conjunction with new requirements for detecting the loss, theft, diversion, or misuse of any SNM would necessitate tamper safing of all items throughout the year rather than only at the time of annual physical inventories. Although the staff has stated in the public meetings that the intent of the requirement is to require a robust tamper-safing program subject to control, audits, and inspection, the wording of the new requirements lacks the clarity necessary to make this determination. Therefore, our cost analysis is based on the regulation as written. For example, in order to implement a fulltime tamper-safing program at one Category III fuel cycle facility that included all items from creation to destruction and would include all items currently exempt from item control requirements 8 additional FTEs would be required at an annual cost of \$600K (\$75K/FTE) and that the cost of additional seals would be \$500K annually. Additionally, one-time costs to "harden" certain existing storage facilities are estimated to be \$250K. If the new requirements are reworded to make it clear that the new requirements do not impose requirements above what industry is doing now then there would be no additional costs, since our current programs are well defined with controls that have been acceptable to NRC for years.

Industry Analysis for Fuel Cycle Facilities

CFR Citation	Description	Annual Cost Per License	One-Time Implementation Cost per License
74.3	General Performance Objectives	\$6M	\$1.7M - \$10M
74.31(c)(6) & 74.33 (c)(6)(ii)	Item Control Exemptions	\$0.5M	\$5-10M
74.31(c)(9) & 74.33 (c)(9)	Tamper Safing	\$1.1M	\$0.25M

- **Power Reactors**

- *Note:* For the purpose of the following cost estimates, we use a rate of \$87/hour.

- **10 CFR 74.3 – General Performance Objectives (GPOs)**

- The general performance objectives were unanalyzed by the NRC in the draft regulatory analysis.
- In particular, 10 CFR 74.3(e) has the potential for significant impacts. During the public meeting on January 9, 2014, the NRC staff indicated that the intent was to include all MC&A

information and require 10 CFR 2.390 or greater controls, though this remains undefined. We understand that 10 CFR 2.390 could not be directly applied to MC&A information maintained and handled at licensee facilities. Based upon that meeting, it would appear that this proposed revision could subject vast amounts of information that is currently handled under record control protocols for each facility to be significantly changed to incorporate undefined increased controls and potentially Safeguards Information.

- During the February 5, 2014, public meeting the NRC made reference to current practices at all categories of licensees, including power reactors to comply with existing requirements for recordkeeping (i.e. 10 CFR 74.19). The indication was that compliance with existing recordkeeping requirements would yield compliance with this proposed GPO. However, page 67227 of the FRN, explicitly indicates that fuel cycle facilities would not need to alter their MC&A programs in response to the GPOs. If this is the intent for all categories of licensees, it should be explicitly stated. The FRN further notes that 74.3(e) would require that MC&A information be stored in a locked file cabinet or office which is prescriptive and not aligned with recordkeeping requirements.
- The very nature of MC&A information generally precludes its designation as Safeguards Information. Therefore, this estimate is based on creating a new program for control of MC&A information that would be considered Sensitive Unclassified Non-Safeguards Information. We estimate one-time costs per site to be \$39,300.
- We estimate the one-time cost to revise procedures and conduct training to be 160 hours (\$13,920).
- Additionally, conversion of records to a new information handling/protection program would appear necessary. We estimate 80 hours (\$6,960) to retrieve and identify records.
- Once records are identified that need new protection, we estimate 160 hours (\$13,920) to research historical records, understand the scope, and reclassify the records. This does not consider reviews of remote storage of duplicate records.
- New storage cabinets (3 at \$1,500 per cabinet) would be needed - \$4,500 per site.
- If the current practices are considered sufficient to satisfy each of the proposed GPOs, the cost impacts for power reactors will require one-time costs of 120 hours (\$10,440) per site (including adoption of a fleetwide approach where appropriate) to update procedures and conduct reviews by Licensing, Qualified Reviewer, Management, and the Plant Safety Review Committee.

- **10 CFR 74.19 – Item Control System**

- The Regulatory Analysis estimate for the implementation of an item control system at power reactors if current industry practices for item control (e.g. consistent with ANSI N15.8) are adequate to satisfy the proposed requirement, would exceed the NRC's cost estimates. The cost impacts for power reactors will require more than 5 hours of effort. Bringing an existing program that is not a requirement under direct regulatory control takes effort. Therefore, the cost impacts for power reactors will require one-time costs of 120 hours (\$10,440) per

site (including adoption of a fleetwide approach where appropriate) to update procedures and conduct reviews by Licensing, Qualified Reviewer, Management, and Plant Safety Review Committee.

- We believe that current annual physical inventories are sufficient. If the NRC's intent is that the periodic SNM audits between annual inventories be conducted we estimate a one-time impact of 160 hours (\$13,920) per site (e.g. determine what is acceptable and procedure revisions) and an ongoing cost of 50 hours (\$4,350) per inspection. The inspection cost assumes that 10 fuel assemblies in the spent fuel pool would be identified, which is the standard NRC inspection criteria and a full day (10 hours) for camera setup/removal, SFP Bridge Crane surveillance, and inspection for 5 people (Reactor Engineering, Operations, and Health Physics).
- If current industry practices for item control are inconsistent with the intent of item control systems at power reactors, and the intent is to develop a full scale material management system, the cost structure in the Regulatory Analysis is underestimated and the resulting system may be contradictory to the intent of the other General Performance Objective to control MC&A information. We are unable to estimate the costs based upon the information provided but expect that they would be significant.