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**U.S. Nuclear Regulatory Commission Staff Responses  
to Public Comments on Proposed Rule:  
*“Amendments to Material Control and Accounting  
Regulations”* and Associated Draft Guidance  
78 FR 67224 and 78 FR 67225 (November 8, 2013)**

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**U.S. Nuclear Regulatory Commission**

**Office of Nuclear Material Safety and Safeguards**

**2018**



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## Section I INTRODUCTION

This document presents the U.S. Nuclear Regulatory Commission's (NRC's) responses to written public comments received on the proposed rule, "Amendments to Material Control and Accounting Regulations," published in the *Federal Register* (78 FR 67225, November 8, 2013). The public comments on the proposed rule are addressed in Section III of this document.

This document also provides the NRC's responses to written comments received on associated guidance noticed in the *Federal Register* (78 FR 67224, November 8, 2013) in parallel with the proposed rule:

- NUREG-1280, Revision 2, "Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Strategic Special Nuclear Material" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13253A308);
- NUREG-2159, "Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Special Nuclear Material of Moderate Strategic Significance" (ADAMS Accession No. ML13253A310);
- NUREG-1065, Revision 3, "Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Special Nuclear Material of Low Strategic Significance" (ADAMS Accession No. ML13253A305);
- NUREG-2158, (formerly NUREG/CR-5734), "Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Low Enriched Uranium Enrichment Facilities" (ADAMS Accession No. ML13253A309); and
- NUREG/BR-0096, Revision 2, "Instructions and Guidance for Completing Physical Inventory Summary Reports" (ADAMS Accession No. ML13253A303).

In addition, this document provides the NRC's responses to public comments on a related draft regulatory guide, DG-5057, "Special Nuclear Material Control and Accounting System for Non-Fuel Cycle Facilities" (ADAMS Accession No. ML15015A271). This regulatory guide was developed after the above *Federal Register* notice (FRN) was published, and subsequently published for public comment (80 FR 27709, May 14, 2015). This guide expands the scope of the guidance in Revision 2 of Regulatory Guide (RG) 5.29 to cover additional MC&A requirements that would be added to Title 10 of the *Code of Federal Regulations* (10 CFR), Part 74, "Material Control and Accounting of Special Nuclear Material." The purpose of DG-5057 is to provide non-fuel cycle facilities<sup>1</sup> with an approach to demonstrate compliance with the MC&A requirements applicable to special nuclear material (SNM). The guidance outlined in DG-5057 reflects the MC&A requirements in the new rule and was developed in response to the comments from the public meetings. The public comments on all of these draft guidance documents are addressed in Section IV of this document.

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<sup>1</sup> The term "non-fuel cycle facility licensees" used in this document refers to those licensees authorized to possess SNM under 10 CFR Part 70, but who are not subject to Subpart H of 10 CFR Part 70 or the requirements in Subparts C, D, or E of 10 CFR Part 74, as well as those facilities authorized to possess SNM under other Parts of 10 CFR, such as nuclear reactors or storage installations. While all existing licensees subject to Subparts C, D, or E are involved in fuel cycle activities, other types of future facilities (e.g., those that use SNM for production of isotopes for medical use) may be subject to these subparts.

## Section II OVERVIEW OF COMMENTERS AND COMMENTS

A 100-day comment period was originally provided in the notice of proposed rulemaking. The NRC received a request for an extension of the public comment period, granted that request, and extended the comment period to 120 days, ending on March 10, 2014 (78 FR 79328, December 30, 2013). The submitted comment that only requested an extension is not discussed further here.

The NRC received 27 comment submissions from 23 individual commenters during the comment period. Of these submissions, 2 were from private citizens, 2 were from Agreement State organizations, and the others were from members of the nuclear industry representing 18 organizations. Tables 1 and 2 present information on these comment submissions. The “Identifier” is used in Sections III and IV of this document to reference the submitted comments.

Table 1. Identification of Commenters on Proposed 10 CFR Part 74 Rule

Name	Affiliation	ADAMS Accession No.	Identifier
Gary Kodman	Private Citizen	ML14029A312	GK
Michael Welling	Virginia Department of Health	ML14034A360	VA-1
R. Van Bynum	SHINE Medical Technologies	ML14049A457	SHINE
Charles England	B&W Nuclear Operations	ML14084A308	BW-1
Wayne Sepitko	Westinghouse Nuclear Fuel	ML14069A459	WEC
Robert Borland	First Energy Nuclear	ML14069A484	FE
Brantley Buerger	Haddam Neck	ML14069A549	HN-1
Robert Mitchell	Yankee Nuclear Power	ML14069A553	YA
J. Stanley Brown	Maine Yankee ISFSI	ML14069A556	MY-1
Adrian Heymer	Nuclear Energy Institute	ML14070A329	NEI-1
Robert Link & Donald Parker	AREVA Inc.	ML14069A583	AREVA
Scott Murray	Global Nuclear Fuel – Americas	ML14070A242	GNF
Kelly Trice	Shaw-AREVA MOX Services	ML14070A583	MOX
Michael Welling	Organization of Agreement States	ML14071A259	OAS
Anonymous	Private Citizen	ML14072A223	AN

T. R. Huber	Dominion Resources Services	ML14079A395	DO
Russell Smith	Wolf Creek Nuclear	ML14080A559	WC
Peter Miner	American Centrifuge Plant	ML14080A570	ACP
Daniel Shrum	Energy Solutions	ML14125A344	ES
David Helker	Exelon Generation	ML14085A385	EG-1

Table 2. Identification of Commenters on Draft Guidance Documents.

Name	Affiliation	ADAMS Accession No.	Identifier
Damon Bryson	VC Summer Nuclear Station	ML15163A024	VC
Brantley Buerger	Haddam Neck	ML15163A025	HN-2
J. Stanley Brown	Maine Yankee	ML15167A039	MY-2
Charles England	B&W Nuclear Operations	ML14127A438	BW-2
Brian Smith	Yankee Rowe ISFSI	ML15175A160	YR
James Barstow	Exelon Generation	ML15181A347	EG-2
Janet Schlueter	Nuclear Energy Institute	ML15216A358	NEI-2

### Section III NRC STAFF RESPONSES TO COMMENTS ON THE PROPOSED RULE

In the notice of proposed rulemaking, the NRC posed questions in nine topical areas. Four of these areas covered technical aspects of the proposed rule revisions: (1) general performance objectives (GPOs), (2) item control system, (3) tamper-safing, and (4) material balance areas (MBAs) and material custodians. The remainder concerned programmatic areas: (5) alternatives resulting in equivalent outcome and less burden, (6) plain writing, (7) regulatory analysis, (8) Paperwork Reduction Act statement, and (9) regulatory flexibility certification.

Most of the comments received addressed these nine topical areas. Some comments outside of these topical areas were also received. They are discussed in two additional groups in this section: “Other Comments” and “Out-of-Scope Comments.” Eleven of the comment submissions explicitly endorsed the comments submitted by the Nuclear Energy Institute (NEI) on behalf of its members (identified as “NEI-1”).

The discussion of comments in each of the first nine topical areas begins with the questions posed in the FRN for that area. Comments that raise similar or identical matters are binned into a single comment summary, and the identifier for each comment submission is given following the summary.

This section provides the NRC staff responses to comments received on the proposed rule. Specific responses to comments on the proposed revisions to guidance documents are given in Section IV, "NRC Staff Responses to Comments on Draft Guidance."

## Topical Area 1. General Performances Objectives

**In 10 CFR 74.3, the NRC proposes GPOs that would apply to all licensees authorized to possess greater than 350 grams of SNM. Are there other GPOs that the NRC should consider adding? Do the proposed GPOs impose unnecessary expenses or burdens on licensees? Should the regulatory threshold for GPOs be higher or lower than 350 grams, and if so, why? If this threshold amount is lower than 350 grams, the NRC would add a similar set of GPO requirements to 10 CFR part 150 to apply to Agreement State licensees. If that were done, how could the NRC best ensure compliance with the GPOs in Agreement States?**

Comment 1.1: Multiple commenters stated that the proposed changes related to GPOs would result in a modification or addition to the procedures to operate a facility, and may also result in a modification or addition to the structures, systems, and components (SSCs) of a facility. [AREVA, NEI-1, BW-1, GNF, WEC, SHINE, FE, HN-1, YA, MY-1, DO, WC, ES, and EG-1]

Response 1.1: The NRC staff agrees, in part, with the comments that the proposed changes related to GPOs may result in some modification or addition to the MC&A procedures of a facility. As described in the paragraph below, and in the regulatory analysis, the NRC staff anticipates that such modifications or additions would be minor in nature and would result in a one-time cost to each affected facility.

The NRC staff disagrees, in part, with the comments that the proposed changes for GPOs would impact operating procedures or SSCs, or have more than minor effects on licensees with MC&A programs that have been reviewed by the NRC or inspected by the NRC at existing facilities. The NRC expects that only minor, if any, changes will be needed to existing programs to meet the GPOs in § 74.3. The GPO provisions represent the fundamental principles of an effective MC&A program. The final rule consolidates these existing principles that are reflected in the existing MC&A programs and associated MC&A procedures used by existing licensees. Existing licensees that are subject to MC&A requirements are already achieving the GPOs by implementing the MC&A procedures that are required by 10 CFR Part 74. The NRC staff does not foresee that the time required to implement and conduct annual operations for the MC&A program would increase as a result of the revised GPOs. For example, the NRC staff does not expect that a Category III fuel cycle licensee's existing MC&A program that has been reviewed by the NRC or inspected by the NRC and that includes the capability to resolve indications of missing SNM and aid in the investigation and recovery of missing SNM would need more than minor, if any, changes to conform with the new GPOs in 10 CFR 74.3(b), (c), and (d), because the new GPOs are similar to the existing GPOs for such a facility. No changes were made to the rule as a result of this comment.

Comment 1.2: Two commenters stated that in order to meet the proposed GPOs at Category III fuel cycle facilities, where SNM is present both in items and 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. The commenters also stated that 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 uranium-235. [WEC and NEI-1]

Response 1.2: The NRC staff disagrees with the comment. The NRC staff's intention for the GPOs in 10 CFR 74.3 was to elucidate general principles for an effective MC&A program. The NRC staff anticipates that no major changes would be necessary to a Category III fuel cycle licensee's existing MC&A program to implement these GPOs. The GPOs are statements of principles that exist in all existing MC&A programs that have been reviewed by the NRC or inspected by the NRC at existing facilities and the NRC expects that only minor, if any, changes will be needed to existing programs to meet the GPOs in § 74.3. Existing Category III licensees are achieving the GPOs by implementing the written MC&A procedures that are required by the existing 10 CFR Part 74, and thus the NRC staff does not anticipate a need to necessarily alter their MC&A programs in response to the GPOs in the revised rule, or if changes are needed, they would be minor in nature. The hypothetical situation suggested by the commenters, that the new GPOs would necessitate searches of individuals leaving an SNM area, is not required by the new regulations. No changes were made to the rule as a result of this comment.

However, in response to the comments on implementation costs and benefits, the NRC staff revised the regulatory analysis to provide more detail and support for the changes in the rule to ensure that the cost estimates are realistic and include the appropriate requirements.

Comment 1.3: The proposed GPO in 10 CFR 74.3(a) states "Maintain accurate, current, and reliable information on, and confirm the quantities and locations of SNM in its possession." One commenter stated that the new undefined "absolute" qualifiers/terms need further clarification. The commenter stated that these terms are discussed in the draft guidance but are still not defined in practical, plain language. The commenter stated that the proposed requirement to "confirm" quantities and locations of SNM during processing is unclear and should be clarified. [NEI-1]

Response 1.3: The NRC staff agrees, in part, with the comment. The sections that discuss 10 CFR 74.3(a) in the related guidance documents (NUREG-1280, NUREG-2159, NUREG-1065, NUREG-2158, and RG 5.29) have been revised to add clarity on the terms used in this GPO to enable licensees to implement and maintain an acceptable MC&A program. However, the NRC staff disagrees with the comment suggesting that 10 CFR 74.3(a) should be revised for further clarification. As discussed in Response 1.1, the GPOs in 10 CFR 74.3 are intended to elucidate general principles for an MC&A program that has been reviewed by the NRC or inspected by the NRC at an existing facility and is already in use. No changes were made to 10 CFR 74.3(a) as a result of this comment.

Comment 1.4: The proposed GPO in 10 CFR 74.3(b) requires that licensees be able, in a timely manner, to "detect, respond to, and resolve any anomaly indicating a possible loss, theft, diversion, or misuse of SNM." Multiple commenters stated that the intent of this performance objective should be clarified. The commenters felt that the absolute term "any anomaly" does not allow for a lower threshold of significance, and this objective could be interpreted to imply that a significant level of detection, response, and resolution could be required for in-process materials that the present regulation does not require. [ES, DO, NEI-1, MY-1, YA, HN-1, FE, WEC, and BW-1]

Response 1.4: The NRC staff agrees with the comment and revised the final rule text to address this concern. The NRC staff revised the final rule text of 10 CFR 74.3(b) by replacing the term "any anomaly" with "an anomaly." This language is appropriate for a GPO, and does

not prescribe a lower threshold of significance that would apply to all affected facilities. Threshold levels for specific facilities are appropriate, and these are addressed in other 10 CFR Part 74 requirements (for example, in the item control requirements for Category I, II, and III facilities). As stated in the previous responses for other GPOs, the intent of this GPO is not to impose more stringent controls than currently exist in an effective MC&A program; the ability to identify and address apparent anomalies in material accounting is a fundamental function of an MC&A program. The NRC staff does not expect that the GPOs will necessarily require changes to an existing licensee's MC&A program. If changes are needed, they would be minor in nature.

Comment 1.5: The proposed GPO in 10 CFR 74.3(c) states "Permit rapid determination of whether an actual loss, theft, diversion, or misuse of SNM has occurred." Two commenters stated that the GPO does not allow for a lower threshold of significance, and one commenter stated that the modifier "rapid" was unnecessary. One of the commenters also stated that the GPO contradicts the five formula kilograms of strategic special nuclear material (SSNM) limit provided in the existing 10 CFR 74.51(a)(3) regulation (proposed 10 CFR 74.51(a)(1)(iii). [BW-1 and NEI-1]

Response 1.5: The NRC staff disagrees with the comments. The NRC staff determined that specifying a lower threshold of significance in 10 CFR 74.3(c) that would apply to all facilities is not appropriate because the overall purpose of this GPO is to ensure that a licensee's MC&A program provides the facility with adequate capability to detect and determine with no undue delay whether a loss, theft, diversion, or misuse of SNM has occurred. Further, as stated in Responses 1.1 and 1.2, the GPOs are to elucidate the MC&A general principles, while SNM threshold limits for different types of facilities are specified in various MC&A program elements in accordance with 10 CFR Part 74. Besides the five formula kilograms of SSNM specifically set for the process monitoring program requirement in 10 CFR 74.51(a)(3), lower threshold limits (i.e., 300 grams of uranium-235 in material balance tests) are also specified in 10 CFR 74.53(c)(1), therefore there is no contradiction between this GPO and SNM threshold limits. The term "rapid determination" is used in the existing GPOs at 10 CFR 74.41(a) and 74.51(a) and would now be included in the consolidated 10 CFR 74.3(c) GPO. In addition, an example of "rapid" determination is given in NUREG-1280, which recommends for Category I facilities the alarm response time of 3 working days for a missing container which is not tamper-safed to ensure that the alarm is investigated and resolved promptly while the event information is still fresh, the material is still available for remeasurement, or there are no further changes in process or inventory. No changes were made to the rule as a result of this comment.

Comment 1.6: Multiple commenters stated that there was an indication that compliance with existing recordkeeping requirements would yield compliance with the proposed GPO in 10 CFR 74.3(e). However, the commenters stated that 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. The commenters stated that the discussion in the FRN explicitly indicated that fuel cycle facilities would not need to alter their MC&A programs in response to the GPOs. The commenters stated that if the intent of proposed 10 CFR 74.3(e) would be met for all categories of licensees merely through existing recordkeeping measures, then there is no need for this GPO. [ES, DO, MOX, NEI-1, MY-1, YA, HN-1, FE, WEC, BW-1, and SHINE]

Response 1.6: The NRC staff agrees, in part, with the comment that the proposed rule text for the GPO in 10 CFR 74.3(e) may be seen as redundant to existing recordkeeping requirements and could be stated more clearly. The proposed rule, in 10 CFR 74.3(e), stated "Control access to MC&A information that might assist adversaries to carry out acts of theft, diversion, misuse,



or radiological sabotage involving SNM.” To clarify the intent of this GPO, the NRC staff revised the GPO in 10 CFR 74.3(e) to read “Control access to MC&A information to preclude loss, theft, diversion, or misuse of SNM.” However, the NRC staff disagrees with the comment to remove this GPO because this objective establishes that controlling access to MC&A information, such as those records, to protect its integrity is a fundamental principle of an effective MC&A program.

Comment 1.7: Multiple commenters stated that the statements in the FRN accompanying the proposed 10 CFR 74.3(e) which would require that MC&A information be stored in a locked file cabinet or office are prescriptive and are not aligned with recordkeeping requirements. [NEI-1, BW-1, WEC, FE, HN-1, YA, MY-1, SHINE, and DO]

Response 1.7: The NRC staff agrees that the notice of proposed rulemaking (78 FR 67225, 67227, November 8, 2013) was overly prescriptive in stating that this GPO “would require that information related to MC&A be stored in a locked file cabinet or office.” The rule itself does not stipulate a particular requirement for how information should be stored. The NRC staff has revised the discussion of this requirement to clarify that the intent of the GPO is to include access control for MC&A information in the MC&A plan and not to specify how that is to be achieved. For example, storing MC&A information in a locked file cabinet or office can be an acceptable means for meeting 10 CFR 74.3(e), but there are other procedural alternatives that may be equally suitable. If an existing licensee has successfully implemented procedures for storing and controlling MC&A information (i.e., effective implementation confirmed through routine NRC oversight inspections) that are sufficiently protective of the information, the NRC staff does not expect that the licensee would require changes to its practices as a result of this final rule.

Comment 1.8: Multiple commenters stated that the proposal to adjust the regulatory threshold in some parts of 10 CFR Part 74 downward to 350 grams is an 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. The commenters felt that if the NRC decides to lower the regulatory threshold it should be based on technical analysis that demonstrates the need for such a change. [NEI-1, SHINE, and EG-1]

Response 1.8: The NRC staff disagrees with the comment. This specific change is to correct an inconsistency in some parts of 10 CFR Part 74, by replacing references to a quantity of SNM “exceeding one effective kilogram” with a quantity of SNM “greater than 350 grams.” The potential for confusion in the existing rule arises from the use of the term “exceeding one effective kilogram” in the regulatory thresholds for the different licensee categories subject to Subparts C, D, and E (Category III, Category II, and Category I, respectively), and the term “greater than 350 grams” in reference to overall inventory and recordkeeping requirements (i.e., in the existing 10 CFR 74.19(c)).

In theory, under the existing regulations, a licensee possessing a quantity of SNM greater than 350 grams of contained uranium-235 but less than one effective kilogram may unintentionally be subject to inconsistent requirements for recordkeeping and inventory (i.e., existing 10 CFR 74.19(b) refers to a quantity of SNM “exceeding one effective kilogram” in specifying the set of licensees that must establish written MC&A procedures and existing 10 CFR 74.19(c) refers to a quantity of SNM “greater than 350 grams” in specifying the set of licensees that must conduct physical inventories). This condition does not exist for any existing licensee currently subject to Subpart C, D, or E, as these licensees possess significantly more than one effective kilogram of SNM. In a similar manner, no Agreement State licensees would be affected by the new GPO

requirements in 10 CFR 74.3, which apply to licensees authorized to possess more than 350 grams of SNM. Agreement State licensees are limited to small quantities of SNM (less than a critical mass, as defined in 10 CFR 150.11), and those quantities do not exceed 350 grams of SNM.

As explained in the regulatory analysis, this change affects existing NRC licensees who possess greater than a critical mass of SNM but who are not required under the current 10 CFR Part 74 to have MC&A procedures that address GPOs. The final rule, in 10 CFR 74.3, requires these licensees to “implement and maintain a material control and accounting program that enables the licensee to achieve” the GPOs, and as such would need to document how the GPOs are achieved in their MC&A program. This would require review and possible revision of existing procedures, or development of some new procedures if necessary to address the GPOs.

No changes were made to the rule as a result of these comments.

Comment 1.9: Two commenters stated that the 350-gram regulatory threshold is appropriate and should not be lowered. [OAS, and ES]

Response 1.9: The NRC staff agrees with the comment. The 350-gram threshold for the applicability of 10 CFR Part 74 other than general reporting and recordkeeping remains unchanged in the final rule. The changes in the rule apply this threshold level consistently throughout the regulations, and do not introduce a lower threshold. No changes were made to the final rule as a result of these comments.

## Topical Area 2. Item Control System

**In 10 CFR 74.19(d), the NRC proposes to make item control requirements applicable to licensed reactors and ISFSIs [independent spent fuel storage installations]. Licensees of fuel cycle facilities authorized to possess Category III amounts of SNM are subject to existing item control requirements in subpart C of 10 CFR part 74, and subpart D of 10 CFR part 74 contains item control requirements that would be applicable to any future fuel cycle facility that may be authorized to possess Category II amounts of SNM. Are such requirements necessary at reactor and ISFSI sites? Are there alternatives that should be considered? Should other types of licensees be required to have an item control system? What is the appropriate regulatory threshold for requiring an item control system under 10 CFR part 74? Should there be a threshold for the amount of material that is required to be tracked under an item control system?**

Comment 2.1: Multiple commenters stated that the proposed item control system requirement would result in a modification or addition to the procedures required to operate a facility. In addition, the commenters stated that this requirement would result in significant impacts to a facility (i.e., the computer inventory control systems) to achieve these capabilities without any commensurate or greater increase in the safety or security of the affected facilities. [NEI-1, WEC, SHINE, FE, YA, MY-1, DO, WC, ES, and EG]

Response 2.1: The NRC staff agrees, in part, with the comments, and revised the final rule to address this concern. The final rule retains requirements for an item control system, but the specific requirements have been revised. For facilities subject to Subparts C, D, or E of 10 CFR

Part 74, the final rule was revised such that the exemptions under the item control system requirements in 10 CFR 74.31(c), 74.33(c), and 74.43(b) include additional items that would not need to be tracked in the item control system (e.g., most laboratory samples and standards and many items existing for less than 3 calendar days). Further specific examples are given in the responses to Comments 2.2 and 2.3. The NRC staff expects that no more than minor, if any, changes to the MC&A programs that have been reviewed by the NRC or inspected by the NRC would be needed to conform with these revisions.

The NRC staff also agrees that changes in the MC&A programs for non-fuel cycle facilities will be needed to address new item control requirements. The final rule would include a requirement that reactor facilities licensed under 10 CFR Part 50 or 52 and ISFSIs (both specific and general licenses) and monitored retrievable storage installations (MRS) licensed under 10 CFR Part 72 (collectively referred to as storage installations) establish an item control system. Requiring item control systems at reactors and storage installations will ensure that SNM is adequately accounted for at these sites. This requirement is consistent with guidance developed for nuclear power reactors in American National Standards Institute (ANSI) N15.8, dated February 18, 2009. In June 2013, the NRC published RG 5.29, Revision 2, which endorses use of the ANSI N15.8 guidance. Item control systems for storage installations are included in the final rule to provide consistency for MC&A programs at licensees with SNM in the form of spent nuclear fuel. An item control system provides an additional means of maintaining current knowledge of SNM and supports the fulfillment of inventory and reporting requirements. As discussed in the regulatory analysis and backfit evaluation, the NRC staff anticipates that some additional resources will be needed at these facilities to implement and conduct annual operations for the item control system.

The NRC staff disagrees, in part, that the item control system requirements would not benefit the implementation of MC&A at a facility. An explanation and justification of these additional requirements are given in the regulatory analysis that accompanies this rule, which examines the benefits and costs associated with the rule changes. The conclusion of the regulatory analysis is that the benefits of the rule outweigh the costs associated with the rule. In addition, the rule is accompanied by a backfit evaluation of the regulatory provisions being added or amended in this rule. The backfit evaluation shows that the changes are necessary to ensure adequate protection of public health and safety and are in accord with the common defense and security.

Comment 2.2: Several comments from fuel cycle facilities expressed opposition to the proposed removal of the two item control exemptions that are included in the existing regulations. One commenter stated that these exemptions have been in place for many years without any indication that there is a major problem that warranted their rescission, and the impact for eliminating these exemptions is understated because the NRC assumes incorrectly that licensees have in-house systems for tracking items in near real time. The commenters also stated that 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 fuel cycle facilities, and would decrease the efficiency of the labs by approximately 10 to 15 percent, as it would now subject samples and laboratory standards to item control. The commenters suggested that laboratory samples and standards containing less than 100 grams of uranium-235 should be exempted, and also supported a reduction in the amount of time that an item can exist without being placed under item control. The commenters stated that provisions to remove the existing exemptions would cause significant impacts without any commensurate or greater increase in the safety or security of the affected facilities. [WEC, GNF, NEI-1, and AREVA]

Response 2.2: The NRC staff agrees, in part, with the comment and revised the final rule text to address the exemption provisions. The final rule includes exemptions for SNM in low-concentration solutions, for laboratory samples or reference standards, and for items existing less than 3 calendar days and containing less than 100 grams of uranium-235, as well as for waste items. Including the exemption for laboratory samples and standards, which was not in the proposed rule, addresses the commenters' concerns for the impact on analytical activities. The final rule therefore sets a clear threshold level for the item control system and revises the exemption conditions, rather than including the more strict provisions in the proposed rule. The lower thresholds and exemption conditions are consistent with existing facility operating practices. These practices help preclude items with relatively large quantities of SNM from being exempt from a facility's item control system so that a more complete and comprehensive inventory is achieved.

The NRC staff disagrees, in part, with the comment concerning the time period for which an item may be exempt. Based on consideration of public comments on the proposed rule (which would have eliminated the existing 14-day exemption), the final rule instead reduces the time period for the exemption provision for items existing for less than 14 days to those existing for less than 3 days. The existing 14-day exemptions dated from the time when most facilities did not have automated tracking systems and computer-based accounting systems as part of their MC&A programs to help track SNM items. Today, licensees have the capability to track items in a more timely manner instead of relying on the update of a manual ledger. In response to comments received on the proposed rule, the NRC staff is maintaining an exemption for items with limited duration, but reducing the period for which they remain exempt. A time frame of less than 3 calendar days for exempt items provides for an effective item control system for SNM while allowing sufficient time to maintain current item data. This is consistent with general MC&A practices (and guidance for Category III licensees), which indicate that the suggested time frame for resolution of MC&A anomalies is 72 hours, or 3 days. This is also consistent with guidance for Category III licensees that suggest shipping container identification and integrity of tamper-indicating devices be verified within 3 days of receipt (e.g., NUREG-1065, "Acceptable Standard Format and Content for the Fundamental Nuclear Material Control (FNMC) Plan Required for Low-Enriched Uranium Facilities"). As described in the regulatory analysis, the NRC staff anticipates that such changes would result in limited additional cost to each affected licensee. As described in the backfit evaluation, these revisions to the item control provisions for Category III licensees, in §§ 74.31(c)(6) and 74.33(c)(6), are necessary to ensure that these licensees maintain adequate protection of the health and safety of the public and are in accord with the common defense and security.

Comment 2.3: Several commenters stated that in 10 CFR 74.31(c)(6) and 74.33(c)(6) the proposed rule requires the licensee to detect "any" unauthorized removal of any SNM. The commenters stated that this requirement has far reaching implications in the context of implementation of this entire proposed rule and cannot be met without extraordinary impact. The commenters felt that 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. [AREVA, WEC, and NEI-1]

Response 2.3: The NRC staff agrees, in part, with the comment, and revised the final rule text in 10 CFR 74.31(c)(6) and 74.33(c)(6) to establish uniform thresholds for removal of material from one or more items in the item control system for Category III facilities, with analogous revisions to 10 CFR 74.43(b)(5) for Category II facilities. The revised text would maintain the existing threshold levels for material removal from one or more items in 10 CFR 74.33(c)(6) and

74.43(b)(5). The threshold level in the revised text for 10 CFR 74.31(c)(6) would be 500 grams of uranium-235, the same as the existing level for enrichment facilities in 10 CFR 74.33(c)(6). This provides a uniform threshold level for all Category III facilities while preserving the graded approach between Category II and III facilities.

The item control provisions for detection in 10 CFR 74.31(c)(6), 74.33(c)(6), and 74.43(b)(5) have been revised to include unauthorized removals of individual items, as stated in the proposed rule. As discussed in the response to Comment 2.2, however, specific exemptions for items that would not need to be tracked in the item control system would also be retained. In addition, material in process that has not been designated as an item would not need to be tracked.

The NRC staff disagrees, in part, with the comment that the regulation should “include a practical timeframe for licensees to update item information in the item control system and for receiving and entering receipts into accounting records.” The revised language in these sections provides a licensee flexibility in designing and implementing its system without specifying an exact timeframe. The NRC staff expects that existing practices in updating item information would allow licensees to meet the revised provisions for their item control systems.

Comment 2.4: The proposed regulation states that 10 CFR 74.19(d) applies to production or utilization facilities licensed under 10 CFR Part 50 or 10 CFR Part 52 and ISFSIs licensed under 10 CFR Part 72. Multiple commenters stated that this language was not clear as to which 10 CFR Part 50 or 52 licensees are included, and recommended that the NRC clarify applicability of the proposed 10 CFR 74.19(d) for a facility that is not a reactor, but which is licensed under 10 CFR Part 50. [NEI-1, SHINE, FE, YA, MY-1, DO, WC, ES, and EG]

Response 2.4: The NRC staff agrees with the comment and revised the final rule text in 10 CFR 74.19(d) to state that this section would apply only to nuclear reactor facilities that are licensed under 10 CFR Part 50 or 52 and to storage installations licensed under 10 CFR Part 72. Other licensees, including Part 50 or 52 licensees that are not nuclear reactors, as defined in 10 CFR 50.2, are not included in this section. Such licensees would be subject to the requirements of Subparts C, D, or E of 10 CFR Part 74 if they possess the quantities of SNM as specified in those subparts.

### Topical Area 3. Tamper-safing

**In 10 CFR 74.31(c)(9) and 74.33(c)(9), the NRC proposes a new requirement for tamper-safing containers and vaults. The NRC also proposes clarifying the existing requirements for tamper-safing in 10 CFR 74.43(c)(3) and 74.59(f)(2)(i) to provide a consistent approach for all Category I, II, and III licensees. Should tamper-safing be required for Category III licensees? Are there alternative measures that should be considered?**

Comment 3.1: Several commenters stated that the new requirements in 10 CFR 74.31(c)(9) and 74.33(c)(9) for Category III facilities would require new tamper-safing devices and expand the existing use of tamper-safing devices, and would result in a modification or addition to the organization required to operate a facility because they would require that licensees designate responsible personnel to implement tamper-safing requirements. [NEI-1, GNF, and WEC]

Response 3.1: The NRC staff disagrees with the comment. Tamper-safing is a common practice in the industry, and tamper-safing activities consistent with the new requirements are already used at all existing Category III fuel cycle facilities that fall under 10 CFR 74.31 and 74.33. The new requirements in the final rule do not prescribe the extent to which tamper-safing is to be implemented at a facility, only that a licensee maintain and follow its tamper-safing procedures, if tamper-safe devices are to be used for assuring the validity of prior measurements, and appropriately manage unused seals and records. The regulatory changes would not add appreciable additional burden for the affected facilities, as the revisions would not necessarily require a change to a facility's tamper-safing program that has already been successfully implemented; if changes were needed, they would be minor in nature. Additional information regarding costs of this requirement is included in the Regulatory Analysis. Furthermore, as discussed in the backfit evaluation, this change ensures that Category III licensees provide for the protection of public health and safety and are in accord with the common defense and security.. No changes were made to the rule as a result of these comments.

Comment 3.2: Two commenters stated that new requirements for tamper-safing in 10 CFR 74.31(c)(9) could be interpreted in combination with the proposal in 10 CFR 74.31(c)(6) to detect "any" unauthorized removal of SNM to mean that this requirement would significantly increase the use of tamper seals and/or vaults, etc., at their facilities. [WEC and NEI-2]

Response 3.2: The NRC staff agrees with the comment and revised the final rule text to add clarity. The final rule text in 10 CFR 74.31(c)(9) and 10 CFR 74.33(c)(9) was simplified to make the tamper-safing requirement more flexible by removing the proposed references to "containers or vaults." These tamper-safing requirements are a component of the facility's overall MC&A program that helps protect against unauthorized and unrecorded removals of SNM. In addition, as discussed in the response to Comment 2.3, the item control requirements for Category III facilities were revised in the final rule to include threshold levels for unauthorized removal of material from one or more items, rather than "any" unauthorized removal. As stated in the response to Comment 3.1, the NRC staff expects that currently implemented tamper-safing practices at existing Category III fuel cycle facilities are consistent with the new requirements, and the final rule would not necessarily require a change to a facility's tamper-safing program that has already been successfully implemented. If changes were needed, they would be expected to be minor in nature.

Comment 3.3: One commenter stated that the additions of 10 CFR 74.31(c)(9) and 74.33(c)(9) are understood to only add the requirement that, when tamper-safing of items or vaults containing SNM is utilized by the facility, procedures are established and followed for use and controls of tamper-safing seals. The commenter stated that there is no intention of adding the use of tamper-safing seals to items that are not currently tamper-safe sealed at the facility, and if this is correct, they recommended deleting the words "of containers and vaults (as defined in § 74.4) containing SNM," from this section of the proposed rule. [GNF]

Response 3.3: The NRC staff agrees with the comment and has revised the final rule text to address this concern. The text of 10 CFR 74.31(c)(9) and 74.33(c)(9) in the final rule was revised to remove the words "of containers or vaults (as defined in 10 CFR 74.4) containing SNM."

#### Topical Area 4. Material Balance Areas and Material Custodians

**In 10 CFR 74.31(c)(10), 74.33(c)(10), and 74.43(c)(9), the NRC proposes a new requirement to identify specific MBAs and ICAs, and to designate custodians for these areas. The NRC also proposes that the existing requirement for custodians in 10 CFR 74.59(h)(5) be revised to match the new language to provide a consistent approach for all Category I, II, and III licensees. Should use of MBAs and ICAs be required? Should other facilities be required to have MBAs and ICAs? Are there alternatives that should be considered?**

Comment 4.1: Two commenters stated that the proposed rule would require that licensees modify their MC&A programs by designating MBAs and ICAs, and assigning custodial responsibility for each area. The commenters felt that this new requirement would result in a modification or addition to the procedures and the organization to operate a facility. [NEI-1 and MOX]

Response 4.1: The NRC staff disagrees with the comment. Existing licensees subject to Subpart C or E of 10 CFR Part 74 designate MBAs and ICAs and assign custodial responsibilities under their existing MC&A programs. The NRC staff does not expect that a facility that has already designated such areas would need to revise procedures or reconfigure the facility, and thus the requirement is not expected to result in significant operating changes. The rule change provides flexibility for a licensee to designate one or more MBAs, or a combination of one or more MBAs and one or more ICAs, and to assign custodial responsibility for these areas as needed. Such practices enhance the capability of a licensee to deter and detect unauthorized removals of SNM with minimal additional burden. Designation of MBAs, ICAs, and material custodians is necessary to ensure that licensees maintain adequate protection of the public health and safety and is in accord with the common defense and security. No changes were made to the rule as a result of these comments.

Comment 4.2: One commenter remarked on the designation of ICAs and MBAs and identification of custodians who would be responsible for monitoring these areas, as stated in the proposed requirements in 10 CFR 74.31(c)(10), 74.33(c)(10), 74.43(c)(9), and 74.59(h)(5). They stated that 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 commenter felt that 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, the commenter did not see a need for this new requirement and its expansion to other facilities.

The commenter also stated that the rule language implies that there is a change to custodial responsibilities from the existing version of the regulation, and suggests that MBAs be established so that anomalies can be resolved by performance of a mass balance, and that custodians are responsible for authorizing individual transfers of material between MBAs/ICAs. [NEI-1]

Response 4.2: The NRC staff disagrees with the comment that the proposed text for designation of MBAs, ICAs, and custodians would introduce new uncertainty in how these are used by licensees. The new rule text in 10 CFR 74.31(c)(10), 74.33(c)(10), 74.43(c)(9), and 74.59(h)(5) is intended to provide uniform requirements in this area for Category I, II, and III facilities, and is not intended to introduce uncertainty to existing programs. MBAs, ICAs, and

material custodians are common features of MC&A existing programs and requirements. The NRC staff's intent is to provide clarification of existing requirements in this area. In response to the comments, the NRC staff have slightly revised the final rule text in each of the relevant sections from the proposed rule, to refer to "one or more" MBAs and "one or more" ICAs so as to provide additional clarity. This allows the flexibility for a licensee to designate one or more MBAs or a combination of one or more MBAs and one or more ICAs, and to assign custodial responsibility for the areas as they currently do in their MC&A plans. The revisions do not prescribe specific areas or specific custodial responsibilities. The NRC staff does not expect that a facility that has already designated such areas and had designated custodians assigned to them will need to implement revised procedures, reconfigure the facility, or redesign its anomaly resolution program. The new rule, therefore, would not be expected to result in significant changes in licensee programs.

The NRC staff disagrees with the comment that the proposed rule for MBAs, ICAs, and material custodians introduces uncertainty and does not articulate a problem statement. The proposed rule FRN and the documents referenced therein (such as the rulemaking plan in SECY-08-0059) provide the basis for the proposed changes in the regulations. The MC&A requirements in the regulations are an important component of nuclear material safeguards (as distinct from nuclear safety) and follow a graded approach for safeguards that is tied to the quantity and form of SNM possessed. As previously stated in response to comment 4.1, designation of MBAs, ICAs, and material custodians is necessary to ensure licensees maintain adequate protection of the public health and safety and is accord with the common defense and security.

Comment 4.3: Several commenters stated that the wording of 10 CFR 74.31(c)(10) seems to force licensees to designate more than one MBA and at least one ICA. It implies that there is a change to custodial responsibilities from the existing version of the regulation and uses the term "contiguous" within the definition, which could be in conflict with current industry practices. [GNF, NEI-1, and MOX]

Response 4.3: The NRC staff agrees with the comment and has revised the final rule text to address this concern. Rather than limiting the licensee's program capability, the revised rule provision of 10 CFR 74.31(c)(10) would provide flexibility for a licensee to design one or more MBAs or a combination of one or more MBAs and one or more ICAs, and to assign custodial responsibility for the areas. The phrase "one or more" has been added in modifying MBAs and ICAs in the final rule to provide flexibility on the number of each. The word "contiguous" has been deleted from the definition of MBA in the final rule text in 10 CFR 74.4 to allow for designation of MBAs that are non-contiguous, in keeping with common practices.

## Topical Area 5. Alternatives Resulting in Equivalent Outcome and Less Burden

**Throughout this proposed rule, the NRC is proposing measures that would strengthen MC&A requirements at licensee sites. Are there alternative ways to strengthen existing MC&A requirements that would impose less burden on NRC licensees while still maintaining adequate control and accounting of SNM? What specific alternatives should be considered? For the proposed requirements that go beyond consolidation and clarification, the NRC is seeking input on the need for such requirements in relation to the proportionate levels of risk represented by the processes and material**



**quantities and forms of SNM that are used at different types of licensee facilities.**

Comment 5.1: Multiple commenters stated that the proposed rule would not provide a commensurate or greater increase in safety or security, and would place unnecessary regulatory burden and cost on licensees. One commenter asserted that the proposed rule would provide a disincentive for licensees. Additionally, they stated that the NRC failed to justify provisions to “strengthen” the requirements for various licensees, and the proposed rule should have been withdrawn and re-noticed for public comment. [WES, EG-1, WC, GNF, NEI-1, AREVA, YA, MY-1, HN-1, and FE]

Response 5.1: The NRC staff disagrees with the comments. The goal of the amendments to the regulations is to revise and consolidate the MC&A requirements, and to update, clarify, and strengthen them. As discussed in the rulemaking plan (SECY-08-0059; ADAMS Accession No. ML080580307), and the regulatory analysis that accompanies this rule, the final rule is the culmination of a multi-year effort to address MC&A areas that were identified for consolidation, clarification, and strengthening by several systematic reviews of the NRC’s MC&A framework. The conclusion of the regulatory analysis is that the benefits of the rule outweigh the associated costs. In addition, the rule is accompanied by a backfit evaluation of the regulatory provisions being added or amended in this rule. The backfit evaluation shows that the changes either do not constitute a backfit or are necessary to ensure adequate protection of the public health and safety and are in accord with the common defense and security.

No changes were made to the final rule as a result of these comments. The regulatory analysis was significantly revised in response to public comments and the backfit evaluation was developed as described above.

Given the limited scope of the rule changes, the comments received, and the revisions to the proposed rule in response to comments, the NRC staff has determined that republishing for an additional comment period is not needed.

Comment 5.2: Multiple commenters stated that the technical bases for the proposed rule changes were not sufficiently well established and that if NRC chooses to proceed with revisions to 10 CFR Part 74, the technical and regulatory bases should be better established and the proposed rule be republished for comment. [EG-1, WC, NEI-1, AREVA, MY-1, HN-1, YA, FE, and WEC]

Response 5.2: The NRC staff disagrees with the comment. As described in the proposed rule (78 FR 67225, 67227; November 8, 2013), the NRC staff developed a rulemaking plan that included technical information supporting the regulatory basis for the MC&A rulemaking and included a range of options for changes in the regulations in SECY-08-0059 (dated April 25, 2008; ADAMS Accession No. ML080580307). In SRM-SECY-08-0059 (dated February 5, 2009; ADAMS Accession No. ML090360473), the Commission directed the NRC staff to revise and consolidate the existing MC&A regulations in 10 CFR Part 74. The current rulemaking implements the Commission direction. Further discussion of the basis and impacts of the revisions is provided in the regulatory analysis and backfit evaluation that accompany this rulemaking. No changes were made to the final rule as a result of these comments.

Given the limited scope of the rule changes, the comments received, and the revisions to the proposed rule in response to comments, the NRC staff has determined that republishing for an additional comment period is not needed.

Comment 5.3: Several commenters stated that 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. The commenters stated that the absence of a backfit analysis was inappropriate because proposed provisions to the rule would result in a modification or addition to a system, structure or component, procedure or organization required to operate a facility. [HN-1, YA, and NEI-1]

Response 5.3: The NRC staff prepared a detailed backfitting evaluation for the final rule. The NRC staff evaluated whether any of the final provisions for MC&A programmatic activities are backfits, and if any such backfits are required for adequate protection or common defense and security. The evaluation determined that a limited number of these provisions constitute backfits (for those facilities subject to backfitting provisions), but are necessary to ensure adequate protection to the health and safety of the public and are in accord with the common defense and security, consistent with 10 CFR 70.76(a)(4) and analogous regulations for other affected facilities. The NRC staff's backfit evaluation accompanies this rule.

Comment 5.4: One commenter stated that the lack of an articulated problem statement in the FRN does not support informed public comments. The commenter stated that the FRN provides no safety basis for changes to licensee MC&A programs, but instead offers only general platitudes. [NEI-1]

Response 5.4: The NRC staff agrees with the comment that there was no safety basis for changes to licensee MC&A programs, because the MC&A requirements are principally based on security and safeguards considerations. The NRC staff disagrees with the comment that the proposed rule FRN failed to articulate the problem statement. The proposed rule FRN and the documents referenced therein (such as the rulemaking plan in SECY-08-0059) provide the basis for the proposed changes in the regulations. The MC&A requirements in the regulations are an important component of nuclear material safeguards (as distinct from nuclear safety), and follow a graded approach for safeguards that is tied to the quantity and form of SNM possessed. In developing the final rule documentation, the NRC staff has focused on clearly articulating the basis that was established in these earlier documents.

The NRC staff has engaged with the public on this rulemaking effort. For example, the NRC staff held two public meetings on the proposed rule during the public comment period to explain the goals of the changes, discuss its justification for the proposed changes, and gather input on their impact on industry. In response to the discussions at the public meetings and the comments received, the NRC staff revised 10 CFR 74.3, 74.19, 74.31, 74.33, and 74.43 of the final rule for clarification on the GPOs, item control system, tamper-safing, MBAs, and material custodians.

No changes were made to the final rule as a result of this comment.

Comment 5.5: Several commenters stated that 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, physical protection and high probability of detecting a loss, or theft or diversion of SNM. Commenters suggested that the NRC has made requirements too stringent on LEU facilities (Category III), without specifying how the requirements should be adjusted. [NEI-1, YA, MY-1, HN-1, WEC, and AREVA]

Response 5.5: The NRC staff agrees, in part, with the comment that some aspects of the proposed rule may have appeared too stringent for Category III facilities, and the final rule has been revised to clarify the requirements for such facilities. As discussed in the response to Comment 2.3, for example, the requirements for item control systems at Category III facilities have been revised to establish uniform thresholds for removal of material from one or more items in the item control system. The revised text would provide a uniform threshold level for all Category III facilities while preserving the graded approach among Category I, II, and III facilities.

The NRC staff disagrees, in part, with the comment that the revisions are inconsistent with maintaining the differences in MC&A requirements for licensees that possess different types or quantities of SNM. The final rule to amend the MC&A requirements in 10 CFR Part 74 continues to reflect the safeguards graded approach to MC&A. The proposed changes do not diverge from the well-recognized significant differences in the MC&A requirements for LEU when compared to the requirements for high enriched uranium (HEU) or SSNM, and continue to differentiate between the risk significance of LEU and HEU.

Comment 5.6: One commenter stated that, in Appendix A of the proposed rule, the regulatory easing that reduces accounting/protection by one category level for certain irradiated fuels allows the fuel to be considered, in essence, as “self-protecting” and would not require greater levels of physical protection and accountability. The commenter stated that the “self protecting” level should be between 500 and 650 rad/hr (between 5 and 6.5 Gy/hr) at one meter, rather than 100 rad/hr (1 Gy/hr). [GK]

Response 5.6: The NRC staff disagrees with the comment. The material categorization in the new Appendix A of 10 CFR Part 74 would apply only to the MC&A requirements as referenced in 10 CFR Part 74, and not to definitions of “self-protecting” or other aspects of physical protection. The dose level of 100 rad/hr (1 Gy/hr) at one meter, unshielded, for a change in the material categorization of irradiated fuel in Appendix A, Table 1, is included for consistency with the same categorization considerations given in Appendix M of 10 CFR Part 110, which is derived from international guidance on material categorization (i.e., IAEA Nuclear Security Series No. 13; INFCIRC/225 Rev.5; Table 1). No changes were made to the final rule as a result of this comment.

Comment 5.7: One commenter stated that the new proposed rewording of 10 CFR 74.51(c)(2) seems to change the group of people that must be considered when preventing collusion. [MOX]

Response 5.7: The NRC staff agrees with the comment that the proposed language, by being more general about the program responsibilities of the individuals, could be construed as referring to a broader group for potential collusion. The final rule text has been revised to retain the phrasing in the existing 10 CFR 74.51(b)(2), so that the focus remains on preventing collusion among individuals with MC&A and security responsibilities.

Comment 5.8: Multiple commenters expressed disagreement with the proposed change in the frequency of the physical inventory from “intervals not to exceed 12 months,” to “intervals not to exceed 12 months or 370 days.” That interpretation of the regulation is: “If a licensee completes physical inventory in a given month, the next physical inventory must be completed by the last day of the same month in the following year.” The commenters recommended that the reference to “or 370 days” be struck from the requirement. [NEI-1, FE, DO, WC, and EG-1]

Response 5.8: The NRC staff agrees with the commenters that the existing term “every 12 months” for the frequency of the conduct of physical inventories should be retained in the final rule in 10 CFR 74.19(c) and 74.31(c)(5). It was not the NRC staff’s intent to change this term in the proposed rule, however a discussion in the notice of proposed rulemaking (78 FR 67234) created confusion by referencing the existing use of “370 calendar days” in 10 CFR 74.33(c)(4). This reference was intended to act as an example of the use of “calendar days,” which will be applied in the final rule for a period such as three or six months. The final rule would not replace the references to an inventory frequency of 12 months with calendar days. No changes were made to the rule as a result of these comments.

Comment 5.9: One commenter stated that no additional controls are needed beyond existing recordkeeping programs required by 10 CFR Part 74. The commenter felt that the NRC should confirm that the proposed regulation was not meant to control access to physical areas containing SNM beyond existing access control, for the sake of protecting MC&A information (e.g., fuel pool contents). In addition, the commenter felt that the NRC should also state that the proposed GPO on access to MC&A information is not intended to institute a new information protection/handling regime (e.g., treating SNM records as Safeguards Information), and was not meant to control paper copies of MC&A information, such as printed core maps, or 741 forms. [NEI-1]

Response 5.9: The NRC staff disagrees with the comment that no additional provisions are needed, but agrees that the NRC staff’s intent could be made more clear. As stated in the notice of proposed rulemaking, the GPO in 10 CFR 74.3(e) supports the recordkeeping requirements in 10 CFR Part 74 and the notification requirements in 10 CFR 74.11. The addition of this GPO is not intended to require any new MC&A information protection and handling program or introduce any new access controls to physical locations of SNM beyond those already implemented under an existing MC&A program. No changes were made to the rule as a result of this comment.

Comment 5.10: One commenter stated that the rulemaking may require major changes to information and record control protocols. The commenter stated that, for example, the GPO in 10 CFR 74.3(e) implies that MC&A records should be treated as safeguards information or require protection beyond how they are currently handled, which could result in significant and costly regulatory burdens for licensees. [NEI-1]

Response 5.10: The NRC staff disagrees with the comment. None of the revisions to the rule would necessitate MC&A records being treated as safeguards information or necessarily add additional handling requirements. As discussed in the response to Comment 1.7, the intent of this GPO is to allow flexibility in this area. Considerations for the impacts of the rulemaking, including costs and benefits, are included in the regulatory analysis that accompanies this rule. No changes were made to the rule as a result of this comment.

Comment 5.11: One commenter stated that it is unclear if the changes would impact operations at existing low-level radioactive waste (LLW) disposal facilities, which are currently subject to Exemption Orders from 10 CFR Part 70 requirements for possession of SNM with more than 350 grams of uranium enriched in uranium-235. The commenter felt that language in the proposed rule, such as the GPOs in 10 CFR 74.3, created ambiguity in the applicability of the exclusions of disposal facilities stated in 10 CFR 74.31(a), 74.41(a), and 74.51(a). [ES]

Response 5.11: The NRC staff agrees with the comment, and revised the final rule text in 10 CFR 74.2 to clarify which licensees are within the scope of 10 CFR Part 74, and that LLW disposal facilities are not included. LLW disposal facilities are currently licensed under Agreement State programs. Such facilities are not required to have a 10 CFR Part 74 MC&A program and are excluded from the requirements of Subparts C, D, and E in 10 CFR Part 74. The current rulemaking is not intended to expand the scope of 10 CFR Part 74 to include LLW disposal facilities. Accordingly, the NRC staff has determined that there is no impact to operations at these facilities with respect to the applicability of the GPO principles for an MC&A program in 10 CFR 74.3.

Comment 5.12: One commenter stated that the FRN proposes an effective date of 90 days after the final rule is published and asked whether 6 months from the final rule's publication is sufficient to implement the new proposed rule. The commenter also notes an inconsistency in the FRN discussion of the effective date versus the implementation date. [NEI-1]

Response 5.12: The NRC staff agrees with the commentor that there were inconsistencies in the FRN for the proposed rule regarding the effective date versus the implementation date of the rule. In response to the comment, NRC clarified the dates to ensure consistency throughout the rule and accompanying FRN.

Also in response to this commentor, the NRC staff gave further consideration to the sufficiency of the implementation period. Following discussions of the final rule with industry and other members of the public in a public meeting held on August 28, 2018, the NRC staff revised the implementation date to 24 months after the publication date..

## Topical Area 6. Plain Writing

**The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31883). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.**

Comment 6.1: Two commenters stated that without improving clarity of the proposed rule language, and improved consistency with the regulatory guidance, adoption of the proposed rule would introduce a great potential for inconsistent interpretation of the regulations by licensees and NRC MC&A inspectors. [NEI-1 and WEC]

Response 6.1: The NRC staff agrees with the comment, and, as noted in the responses herein, revised the final rule language and associated guidance documents in several places to improve clarity. The NRC staff developed plain language revisions to improve understanding of the requirements, including the definitions for commonly used terms and clarifications of some existing definitions. In addition, the final rule text was revised in multiple locations to avoid ambiguity and reduce the likelihood of inconsistent interpretation.

Comment 6.2: Multiple commenters stated that the existing fuel cycle facilities do not see any need to formally change the titles of their fundamental nuclear material control (FNMC) plans to MC&A plans in response to the proposed terminology change in 10 CFR 74.31(b). The

commenters stated that the industry supports the proposed rule to the extent it indicates that any such change would be voluntary. They see no reason to incur the costs associated with the change for no known benefit, and felt that to make the voluntary nature of this provision clear, the NRC should include an explicit grandfather clause and/or exemption for current licensees. [ES, NEI-2, MY-2, YA, and HN-2]

Response 6.2: The NRC staff agrees with the comment in principle, but disagrees that an explicit grandfather clause or exemption for existing licensees is necessary. As stated several times in the discussion of the rule changes, for both the proposed and final rule, the term “MC&A plan” is not intended to be an exact name that licensees are required to use, and there would be no need for licensees to incur costs in renaming their plans. The change from “FNMC” plan in the existing rule to “MC&A” plan is based in plain language considerations. The term FNMC is in many ways outdated, in that it does not include term “accounting” and thus does not fully encompass the accounting aspect of a MC&A program. No changes were made to the final rule as a result of these comments.

## Topical Area 7. Regulatory Analysis

**The Commission has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the Commission. The Commission requests public comment on the draft regulatory analysis (RA), which can be found at ADAMS Accession No. ML13228A223.**

Comment 7.1: Multiple commenters stated that an appropriate regulatory analysis needs to be developed because the NRC failed to perform an adequate regulatory analysis that properly addresses industry implementation (quantitative costs) and security and safeguards considerations (qualitative benefits). The commenters also stated that the cost estimates for implementation of the rule changes in the regulatory analysis are too low. [NEI-1, WEC, GNF, AREVA, HN-1, YA, MY-1, WC, ACP, and ES]

Response 7.1: The NRC staff agrees with the comment. The NRC published for public comment its draft regulatory analysis along with the proposed rule to amend its MC&A regulations (78 FR 67225, November 8, 2013). The NRC staff held two public meetings during the comment period to discuss its cost estimates and to share preliminary information about the draft final rule text. The NRC staff held an additional public meeting on September 25, 2014, to seek further clarification of the cost estimates associated with the draft regulatory analysis. In response to the comments, the NRC staff has revised and expanded the regulatory analysis to provide more detail and additional support for the proposed changes in the rule, and to ensure that the cost estimates are realistic. The revised regulatory analysis (ADAMS Accession No. ML18061A055) accompanies the final rule.

Comment 7.2: One commenter stated that the review of the regulatory analysis addresses the impacts of the entire proposed rule, whereas the draft regulatory analysis only analyzes two rule provisions. [NEI-1]

Response 7.2: The NRC staff agrees with the comment. The regulatory analysis (ADAMS Accession No. ML18061A055) that accompanies the final rule has been revised to discuss all new regulatory requirements.

#### Topical Area 8. Paperwork Reduction Act Statement

**This proposed rule amends information collection requirements contained in 10 CFR parts 72 and 74 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). These information collection requirements have been submitted to the Office of Management and Budget (OMB) for review and approval. The proposed changes to 10 CFR parts 40, 70, and 150 do not contain new or amended information collection requirements. Existing requirements were approved by the OMB, approval numbers 3150-0132 and 3150-0123. The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule.**

No comments were received on this topic.

#### Topical Area 9. Regulatory Flexibility Certification

**In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if promulgated, have a significant economic impact on a substantial number of small entities. The majority of companies that own these plants do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810). The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comment from licensees who qualify as small businesses, specifically as to how the proposed regulation will affect them and how the regulation may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security.**

No comments were received on this topic.

#### Topical Area 10. Other Topics

Comment 10.1: Several commenters expressed support for "common-sense measures to improve the clarity and effectiveness of the current MC&A rule," but they felt that taken as a whole, the NRC must recognize that the current MC&A program has for many years effectively provided adequate mechanisms to account for the special nuclear material subject to the current rule's requirements. They stated that in light of the fact that there appears no clear problem that the NRC is trying to address, the NRC should reconsider whether the current proposed revisions to the MC&A rule are consistent with the NRC's Principles of Good Regulation and its current policies and procedures with respect to rulemaking. [WEC, NEI-1, AREVA, and ES]

Response 10.1: The NRC staff agrees with the commenters that MC&A programs implemented under the existing 10 CFR Part 74 have in general been effective for control and accounting of SNM at existing facilities, but disagrees that the proposed changes are inconsistent with NRC's Principles of Good Regulation or its rulemaking policies. In accord with the commenters, the NRC staff considers the changes to be "common sense measures to improve the clarity and

effectiveness of the current MC&A rule.” The revisions would follow the Commission direction to revise and consolidate the regulations, which is in accord with NRC’s Principles of Good Regulation (e.g., “Clarity: Regulations should be coherent, logical, and practical.”). The regulatory analysis that accompanies this rule provides the explanation and justification of the rule changes, including a statement of the problem (which was also discussed in earlier rulemaking documents including the 2008 Rulemaking Plan), and examines the associated benefits and costs. The conclusion of the regulatory analysis is that the benefits of the rule outweigh the associated costs.

Comment 10.2: One commenter stated that the FRN 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. [NEI-1]

Response 10.2: The NRC staff agrees with the comment to the extent that it could have provided additional clarity in the proposed rule with respect to the problem statement and expected benefits. While the notice of proposed rulemaking and the documents referenced therein (such as the rulemaking plan in SECY-08-0059) provide the basis for the proposed changes, the NRC staff has expanded the discussion of its intent, consistent with these earlier rulemaking documents, in the regulatory analysis that accompanies this rule as well as provided clarifying language in the final rule FRN. For example, the notice of proposed rulemaking (78 FR 67225, November 8, 2013) stated that the goal of the NRC in this rulemaking is “to revise and consolidate the MC&A requirements in order to update, clarify, and strengthen them.” This high-level description remains valid. The notice of proposed rulemaking outlined the proposed revisions and solicited public comments. The NRC staff held two public meetings during the comment period to improve the understanding of the proposed rule, to encourage written comments, and to obtain clarifying information from industry representatives about the cost estimates for the regulatory analysis. The regulatory analysis that accompanies the final rule examines the benefits and costs associated with the rule changes, and includes further discussion of the NRC staff’s intent. The conclusion of the regulatory analysis is that the benefits of the rule outweigh the associated costs.

Comment 10.3: One commenter stated that the proposed revision to 10 CFR 74.41(a)(2) states that production and utilization facilities licensed under 10 CFR Part 50 are not subject to the requirements of 10 CFR Part 74, Subpart D, “Special Nuclear Material of Moderate Strategic Significance,” and therefore a medical isotope production facility licensed as a production facility under 10 CFR Part 50 that possesses SNM of moderate strategic significance would not be subject to Subpart D in the new regulation. The existing 10 CFR 74.41(a) excludes nuclear reactors licensed pursuant to 10 CFR Part 50, so that a medical isotope production facility which is not a nuclear reactor would be subject to 10 CFR Part 74, Subpart D. The commenter stated that other than 10 CFR Part 74, Subpart A, “General Provisions,” and Subpart B, “General Reporting and Recordkeeping Requirements,” there do not appear to be applicable regulations to address a medical isotope production facility in the proposed revision to 10 CFR Part 74. [SHINE]

Response 10.3: The NRC staff agrees with the comment, and revised the final rule text to address this concern. To clarify the requirements applicable to a production facility licensed under 10 CFR Part 50 that possesses SNM of moderate strategic significance, 10 CFR 74.41(a)(2) has been revised to read “Nuclear reactor facilities licensed under 10 CFR Part 50 or 52 of this chapter...are not subject to the requirements of Subpart D of this part.” The MC&A requirements contained in Subpart D of 10 CFR Part 74 would be applicable to non-



reactor production or utilization facilities that possess SNM of moderate strategic significance, including a medical isotope production facility.

Comment 10.4: One commenter stated that Subparts A and B in 10 CFR Part 74 contain proposed requirements applicable to a 10 CFR Part 70 license authorizing possession of more than 350 grams. The commenter recommends the NRC clarify the requirements that would be applicable to a facility licensed under 10 CFR Part 50 and authorized to possess more than 350 grams of SNM. [SHINE]

Response 10.4: The NRC staff agrees with the comment. The final rule text has been revised to more clearly state that Subparts A and B of 10 CFR Part 74 apply to any licensee who is authorized under 10 CFR Parts 50, 52, 60, 63, 70, or 72 to possess or use SNM in a quantity greater than 350 grams. Therefore, Subparts A and B would both apply to any facility that meets these criteria.

Comment 10.5: One commenter stated that the NRC should consider revising the final rule to include both ISFSIs and MRS. [AN]

Response 10.5: The NRC staff agrees with the comment that both ISFSIs and MRS should be included. The final rule text for 10 CFR 74.2 has been revised to include "...each person licensed under Parts 50, 52, 60, 63, 70, or 72..." as within the scope of the rule. In addition, the final rule text in 10 CFR 72.72(b) has been revised to state that "Each licensee shall follow the requirements of 10 CFR part 74, subparts A and B, for special nuclear material." This statement applies to all storage installation licensees under 10 CFR Part 72, including both ISFSIs and MRS—collectively referred to as storage installations in the rule.

Comment 10.6: Several commenters stated that the draft implementing guidance does not provide guidance for the entire suite of affected licensees (i.e., power reactors, ISFSIs, non-power reactors, and other non-fuel cycle licensees). The commenters felt that 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. [NEI-1, MY-1, YA, and HN-2]

Response 10.6: The NRC staff agrees with the comment, and has prepared additional guidance. In November 2013, the NRC published for public comment the proposed rule to amend its MC&A regulations (78 FR 67225, November 8, 2013), and in parallel a proposed suite of guidance documents for fuel cycle facilities associated with the proposed rule (78 FR 67224; November 8, 2013). In February 2015, the NRC staff prepared and published for public comment additional draft guidance for non-fuel cycle facilities (DG-5057; 80 FR 27709; May 14, 2015), including nuclear reactors and storage installations. All of these guidance documents have been revised based on the comments received, and the revised guidance is included as a part of the final rule package.

Comment 10.7: One commenter stated that in Appendix A, the NRC should consider revising the use of sievert, an SI unit of dose equivalent, to indicate radiation level of irradiated fuel, to use the SI unit gray for absorbed dose. The commenter also stated a need to add a non-SI unit where meter was used in the related footnote. [AN]

Response 10.7: The NRC staff agrees, in part, with the comment as to the use of gray rather than sievert in this context. Footnote 2 of the table in the final Appendix A has been revised to use gray (Gy) as the SI unit for radiation level.

The NRC staff disagrees, in part, with the comment on adding a non-SI unit where “meter” is used. Although this is a standard practice in general, the NRC staff does not consider it necessary to provide a non-SI equivalent for distance in this footnote. As discussed in the response to Comment 5.7, the language in this footnote is consistent with that in the table on material categorization in existing Appendix M of 10 CFR Part 110.

Comment 10.8: One commenter stated that for some facilities both high-enriched uranium and plutonium are present in “significant” quantities. The commenter asked NRC to clarify whether the new Appendix A will address this situation. [NEI-1]

Response 10.8: The NRC staff considered this comment and determined that further clarification is not needed in Appendix A. The material categorization and quantity thresholds are given in the table in Appendix A, along with formulas for calculating quantities of SSNM as defined in 10 CFR 74.3. This information is sufficient for categorizing a facility based on the quantities of SNM or SSNM present in any combination.

Comment 10.9: Multiple commenters stated that given the low risks associated with spent nuclear fuel stored in dry canisters at stand-alone ISFSI sites, the industry believes that the NRC should utilize a risk-informed approach to determine if modifying the MC&A rules associated with the regulation of stand-alone ISFSIs is appropriate or necessary to achieve a safety benefit. [DO, AN, NEI-1, MY-1, YA, and HN-1]

Response 10.9: The NRC staff disagrees with the comment. The changes for the MC&A requirements for storage installations, including “stand-alone” ISFSIs, that would occur under this revision are (1) the relocation of the requirements from 10 CFR Part 72 to 10 CFR Part 74, including requirements for reporting to the Nuclear Materials Management and Safeguards System (NMMSS); (2) the application of the GPOs to the MC&A program; and (3) establishment of an item control system. The first is an administrative change, and should have minimal impact, if any, on licensees. The impact of the second change should also be minimal, since as discussed in the responses to the comments in Topical Area 1, these GPOs represent fundamental principles of effective MC&A programs. The NRC staff expects that the third change would impose some limited new burden on storage installations, but this burden is justified by the benefits of an item control system, as described further in the regulatory analysis. As stated in the response to Comment 2.1, an item control system provides a means of maintaining current knowledge of SNM, and supports the fulfillment of inventory and reporting requirements. The NRC staff expects that given the nature of their operations and inventories, a storage installation would be able to meet the item control requirements using a relatively simple and straightforward system. The final rule would allow the licensee the flexibility to design and implement an appropriate system, subject to NRC oversight. As discussed in the regulatory analysis and the backfit evaluation, the NRC staff anticipates that some additional resources will be needed at these facilities to design and implement a system and conduct annual activities for the new requirements. As noted, the requirement for storage installations is not intended to be prescriptive. Including specific separate criteria for “stand-alone” ISFSIs apart from the requirements for all 10 CFR Part 72 storage installations would be inconsistent with this performance-based approach. No changes were made to the rule as a result of these comments.

Comment 10.10: One commenter stated that the NRC should consider revising the final rule to expand the scope of the rulemaking to include conforming changes to 10 CFR Parts 60 and 63. [AN]

Response 10.10: The NRC staff agrees with the comment regarding the inclusion of 10 CFR Parts 60 and 63 in the rulemaking. The rule text is revised to include the conforming changes to 10 CFR Parts 60 and 63 that reflect the relocation of MC&A requirements from 10 CFR Part 72 to Part 74.

#### Topical Area 11. Out-of-Scope Topics

Comment 11.1: One commenter stated that the NRC should consider revising the final rule to also include potential Geological Repository Operations Area (GROA) licensees in 10 CFR Part 74. [AN]

Response 11.1: The NRC staff disagrees that further changes should be made for potential licensees under those Parts. The revisions for this area are limited to those needed to conform to the changes to 10 CFR Part 72, and further revisions for potential GROA facilities are outside the scope of this rulemaking. A separate MC&A rulemaking for a GROA was initiated in 2007 (72 FR 72522; December 20, 2007). Action on this rulemaking is currently deferred pending future appropriations for geologic disposal activities (SRM-SECY-16-0021; ADAMS Accession No. ML16141A044).

Comment 11.2: One commenter stated that the NRC should consider revising the final rule to (1) clarify that spent nuclear fuel storage casks can be welded or mechanically sealed, and (2) indicate whether the operation of a dry transfer system at an ISFSI falls within the general MC&A performance objectives of proposed 10 CFR 74.3, or if more rigorous MC&A requirements are necessary during dry transfer system operations. [AN]

Response 11.2: The NRC staff agrees, in part, with this comment and has revised the discussion of the final rule in the FRN to clarify that not all dry storage canisters are welded.

The NRC staff disagrees, in part, with this comment to include further changes in the MC&A requirements for dry storage at ISFSIs. As discussed in the response to Comment 9.2, the revision of the MC&A regulations for storage installations would include consolidation and limited changes for uniform application of the GPOs and item control systems. Further revision of these MC&A provisions to consider operations not currently implemented or planned for the near term is outside the scope of this rulemaking.

Comment 11.3: One commenter stated that the NRC should consider revising the final rule to clarify whether the MC&A provisions applicable to ISFSIs apply to both light water reactor (LWR) and non-LWR SNF, stored in an ISFSI or MRS. [AN]

Response 11.3: The NRC staff disagrees with the comment to add additional clarifying information on different types of SNF stored at an ISFSI or MRS. The existing MC&A regulations for storage installations in 10 CFR Part 72 do not distinguish between LWR and non-LWR SNF. Within the current rulemaking, as stated in the response to Comment 10.10, changes to the MC&A regulations for 10 CFR Part 72 facilities would be limited. Further revision of these MC&A provisions to address differences not currently considered in 10 CFR Part 72 is outside the scope of this rulemaking.

Comment 11.4: One commenter stated that the NRC should consider revising a final rule to apply the proposed Appendix A direction to the post-irradiation, total SNM content, rather than just considering the pre-irradiation SNM inventory of the fuel assemblies. [AN]

Response 11.4: The NRC staff disagrees with the comment. Appendix A to 10 CFR Part 74 is a tabularized description of the SNM categorization, following a similar table on material categorization in existing Appendix M of 10 CFR Part 110. Appendix A is not intended to consider in any detail the post-irradiation aspect or total SNM content for irradiated fuel beyond that given in footnote 2. Revision of these MC&A provisions is outside the scope of this rulemaking.

Comment 11.5: Multiple commenters stated that the word “all” in 10 CFR 74.19(a)(1) should be replaced with “reportable quantity”. [NEI-1, FE, HN, YA, MY-1, DO, WC, and EG-1]

Response 11.5: The NRC staff disagrees with this comment, because it would represent a significant change that is out of the scope of this rulemaking. The revision proposed by the commenters represents a significant departure from the current approach for MC&A, and would be a change in longstanding NRC policy. Such a revision, therefore, is inconsistent with the Commission direction for this rulemaking to revise and consolidate the MC&A regulations.

#### Section IV      NRC STAFF RESPONSES TO COMMENTS ON DRAFT GUIDANCE

This section provides the NRC staff’s responses to comments on the six draft guidance documents: NUREG-1065, NUREG-1280, NUREG-2158, NUREG-2159, NUREG/BR-0096, and DG-5057.

Comments on the draft guidance documents are grouped as follows:

- A. NUREG-1280, Revision 2, “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Strategic Special Nuclear Material”
- B. NUREG-2159, “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Special Nuclear Material of Moderate Strategic Significance”
- C. NUREG-1065, Revision 3, “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Special Nuclear Material of Low Strategic Significance”
- D. NUREG-2158 (formerly NUREG/CR-5734), “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Low Enriched Uranium Enrichment Facilities”
- E. NUREG/BR-0096, Revision 2, “Instructions and Guidance for Completing Physical Inventory Summary Reports”
- F. DG-5057, “Special Nuclear Material Control and Accounting System for Non-Fuel Cycle Facilities”

**A. NUREG-1280, Revision 2, “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Strategic Special Nuclear Material”**

Comment A.1: One commenter stated that the revision of NUREG-1280 has elevated all SNM to the same level of significance as SSNM. [BW-2]

Response A.1: The NRC staff disagrees with the comment. Revision 2 of NUREG-1280 continues to provide the same guidance for SSNM and does not elevate all SNM to the level of strategic significance as SSNM. This guidance document is consistent with the requirements stated in 10 CFR Part 74 for SSNM compared to other categories of SNM. For example, this guidance continues to address the specific process monitoring program associated only with SSNM. Revision 2 reflects a new document format which aligns with the format of similar guidance for other category facilities. No revision was made to the guidance document as a result of this comment.

Comment A.2: Two commenters stated that many formulas in Revision 2 of NUREG-1280 are incomplete. [BW-2, and NEI-1]

Response A.2: The NRC staff agrees with the comment. During production of the document for publication, some of the formulas were altered and appeared incomplete. NUREG-1280 has been revised so that all formulas will appear correctly in the final published version.

Comment A.3: One commenter stated that the NRC should clarify the intent of the proposed 10 CFR 74.3(b) performance objective with respect to the absolute term “any anomaly.” [BW-2]

Response A.3: The NRC staff agrees with the comment. The rule text for 10 CFR 74.3(b) has been revised to clarify the intent of this GPO and conforming changes were revised in Section 2.0 of this guidance document.

Comment A.4: One commenter stated that if the GPO on rapid determination of whether an actual loss, theft, diversion, or misuse of SNM has occurred in 10 CFR 74.3(c) is removed [as requested in Comment 1.5 above] then the related guidance in NUREG-1280 should be removed as well. [BW-2]

Response A.4: The NRC staff disagrees with the comment, since the NRC staff does not agree with the request to remove the GPO in 10 CFR 74.3(c), as discussed in response to Comment 1.5. As noted in that response, NUREG-1280 provides guidance on timeframes that are relevant to this GPO. No change was made to the guidance in NUREG-1280 as a result of this comment.

Comment A.5: One commenter stated that the statistical equations in Section 4.7, Sample Items, appear to be based on the binominal approximation to the hypergeometric distribution instead of the exact equation. The commenter also stated that it is not clear why it would be necessary to calculate the fraction of the population to be checked each time a test is run, or why the sample size should be doubled for an additional sample if a defective or missing item is encountered in an item test. [BW-2]

Response A.5: The NRC staff disagrees, in part, with the comment. The equations in Section 4.7 are based on the binominal approximation to the hypergeometric distribution instead of the exact equation. However, the guidance states that the formulas are one acceptable way of calculating the sample size. Concerning the doubling of the sample size for an additional sample if a defective or missing item is encountered, these guidelines have been in place in the guidance since 1995, and there has been no observed adverse implication in practices. There is no change in the rule language that warrants changes to this statistical approach. The guidance provides one acceptable way to meet the requirements, and licensees can choose other methods that may be appropriate and supportable. No change was made to this guidance section as a result of this comment.

The NRC staff agrees, in part, with the comment. It is not necessary to recalculate the fraction of the population to be checked each time a test is run. The text on calculating the fraction of the population referenced in Section 4.7 has been revised to state that "...it is not necessary to recalculate the sample size to be checked each time."

Comment A.6: One commenter stated that the guidance in Section 8.2 states that recalibration would be necessary when certain conditions exist. Two of the conditions that are listed in this section do not necessarily warrant recalibration, including a trend, shift, or out-of-control condition at the 0.001 level, and a bias estimate that is statistically significant at the 95-percent confidence level. [BW-2]

Response A.6: The NRC staff agrees with the comment. The guidance has been changed so as not to indicate that recalibration is always needed. The revised text reads "Recalibrations may be necessary if any of the following circumstances exist," rather than "Recalibrations would be deemed necessary when the following circumstances exist."

Comment A.7: One commenter stated that the guidance in Section 8.3, Control Standards, describes the minimum sample size recommendations for key and non-key measurement systems and the representativeness of process material for the control standards. The commenter stated that these practices are simply not practical and should be removed. [BW-2]

Response A.7: The NRC staff disagrees with the comment. These guidelines have been in place in the guidance since 1995, and there has been no observed adverse implication in practices. There is no change in the rule language that warrants changes to this statistical approach. The guidance provides one acceptable way to meet the requirements, and licensees can choose other methods that may be appropriate and supportable. No change was made to this guidance section as a result of this comment.

Comment A.8: Section 8.4 discusses replicate sampling. One commenter recommended to revise the data that can be used to estimate the random measurement variance component for non-sampling measurement systems, and that the scatter in the repeat measurements can be used to estimate the random error variance. In addition, the commenter stated that the criteria for determining the number of replicate samples are not needed because sampling 100 percent of the accountability batches until a minimum of 15 batches is reached is sufficient. [BW-2]

Response A.8: The NRC staff agrees with the first two statements in this comment. The first paragraph of Section 8.4 has been revised to list additional items (calibration data

and engineering evaluations) from which the random measurement variance component can be derived, and the sentence on the scatter in the repeat measurements has been revised to read “can be used...” rather than “is used....”

The NRC staff disagrees with the last statement because there is no change in the rule language that warrants considering changes to this historical statistical approach. These guidelines have been in place in the guidance since 1995, and there has been no observed adverse implication in practices. The guidance provides one acceptable way to meet the requirements, and licensees can choose other methods that may be appropriate and supportable. No change was made to this guidance section as a result of this comment.

Comment A.9: One commenter stated that in Section 8.5.1, Measurement Control Data Analysis, a review every 2 weeks would not be necessary for an established system if the system has historically shown to be stable. [BW-2]

Response A.9: The NRC staff agrees with the comment. A sentence was added to the end of Section 8.5.1 to read as follows: “For an established measurement system, a less frequent review period may be warranted.”

Comment A.10: One commenter stated that Section 8.6 does not provide consistent guidelines for a measurement control program with respect to the methods used to estimate the standard error of the inventory difference (SEID), need for recalibration, collection of measurement program data, requirements for bias correction and reduction of measurement biases, calibration data generated in previous inventory periods, and uncertainties associated with process variabilities. [BW-2]

Response A.10: The NRC staff agrees with the comments. Revisions have been made to Section 8.6 of NUREG-1280 to clarify recommendations and best practices for a measurement control program to be commensurate with the regulatory requirements.

Comment A.11: One commenter stated that Section 9.1 limits its recommendations in statistical methods for determining measurement uncertainties, and suggests a level of detail for the MC&A plan that is typically reserved for a licensee’s procedure. [BW-2]

Response A.11: The NRC staff disagrees with the comment. This guidance document neither limits the use of statistical methods nor suggests a certain level of detail for the MC&A plan in Section 9.1, “Determination of Measurement Uncertainties.” A facility should prepare the MC&A plan through the normal licensing process, and recommendations in this NUREG provide performance-based guidelines to applicants and licensees. No change was made to this guidance section as a result of this comment.

Comment A.12: One commenter stated that there are instances where other defensible methods are necessary for determining the SEID which are not necessarily documented in the Bowen & Bennett or Jaech textbooks. [BW-2]

Response A.12: The NRC staff agrees with the comment. The guidance has been revised to state that other defensible methods based on sound engineering and statistical principles may be used to determine the SEID.

Comment A.13: One commenter stated that Section 9.3 states that biases must be tested for significance at the 95-percent confidence level, and that the two methods for the evaluation of biases in the draft NUREG-1280 and in the regulation of 10 CFR 74.59(e)(6)(i) are not equivalent. [BW-2]

Response A.13: The NRC staff agrees with the comment. This section has been revised to provide a statement of confidence associated with this evaluation of bias corrections that is consistent with 10 CFR 74.59(e)(6)(i).

Comment A.14: One commenter stated that Section 10.7 is supposed to provide guidance for evaluating historical inventory differences, but the leading paragraph concludes with other consideration requirements while 10 CFR 74.59(f)(1)(ii) does not necessarily require consideration of the suggested points. [BW-2]

Response A.14: The NRC staff agrees with the comment. This section has been revised to state that other sound statistical approaches may also be acceptable.

Comment A.15: One commenter stated that Section 16 should be removed or revised significantly depending upon the NRC's resolution to comments regarding proposed performance objectives in 10 CFR 74.3(b) and 74.3(c). The commenter also felt that the absolute term "all potential indicators" in Section 16.1 should also be changed. [BW-2]

Response A.15: The NRC staff agrees with the comments regarding the performance objectives. The rule text for 10 CFR 74.3(b) and guidance document in Section 2.0 have been revised to clarify the intent of this GPO. Section 16.1, "Methods and Procedures for Identifying Indicators," has been revised to clarify the guidance on resolving indications of loss, theft, diversion, or misuse of SNM and SSNM.

## **B. NUREG-2159, "Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Special Nuclear Material of Moderate Strategic Significance"**

Comment B.1: One commenter stated that the code section 10 CFR 74.43(c)(7) is related to the timing of the inventories and does not contain any other requirements. Complete requirements for inventory control and physical inventories are contained in 10 CFR 74.43(c). [SHINE]

Response B.1: The NRC staff agrees with the comment. In response to the comment on the requirements of 10 CFR 74.43(c), the first paragraph of NUREG-2159, Section 7.5, has been revised to read as follows: "Licensees should present a description of the methodology, including cutoff and inventory minimization procedures, and they should identify all measurements (including sampling) sufficient to meet the requirements of 10 CFR 74.43(c)."

Comment B.2: Section 7.7 of NUREG-2159 discusses actions to take if the inventory difference exceeds three times the standard error of the inventory difference and certain other minimal quantities. These actions and quantities are stated in 10 CFR 74.43(c)(8)(iii). One commenter stated that the quantities listed in Section 7.7 of NUREG-2159 are incomplete. [SHINE]

Response B.2: The NRC staff agrees with the comment. Section 7.7 of NUREG-2159 has been revised to include a complete listing of the minimum quantities from



10 CFR 74.43(c)(8)(iii), including 9,000 grams of uranium-235 contained in low enriched uranium.

Comment B.3: Section 8.2 of NUREG-2159 states that containers of solutions in which the plutonium, uranium-233, or uranium-235 concentration is less than five grams per liter can be exempted from item control system coverage. One commenter recommends that the proposed revision of 10 CFR 74.43(b)(6) be changed to be consistent with Section 8.2 of NUREG-2159. [SHINE]

Response B.3: The NRC staff agrees with the comment. The rule text in 10 CFR 74.43(b)(6) has been revised to be consistent with Section 8.2 of NUREG-2159 and to include solutions containing low concentrations of plutonium and uranium-233, as well as uranium-235.

**C. NUREG-1065, Revision 3, “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Special Nuclear Material of Low Strategic Significance”**

Comment C.1: Section 8.0 refers to the definition of “items” as defined in 10 CFR 74.4. One commenter stated that clarification is needed on when licensees must create an item and what is considered processing. [NEI-1]

Response C.1: The NRC staff disagrees with the comment that additional clarification is needed. The terms “item” and “material in process” are clearly defined in 10 CFR 74.4. Section 8.0 of the existing NUREG-1065 also provides additional guidelines and examples on identifying items and distinguishing items and material in process. No change was made to this guidance section as a result of this comment.

Comment C.2: Section 11.3 refers to the description of tamper-safing records. One commenter stated that the language in the third and fourth bullets appear to be related to the former two-person rule and should be deleted. [NEI-1]

Response C.2: The NRC staff disagrees with the comment. This section discusses the practices on records and states that “such records should include, but are not limited to, the following practices.” These recommended practices do not imply the use of the two-person rule but instead provide guidelines to ensure adequate overchecks or sufficient checks and balances of record controls. No change was made to this guidance section as a result of this comment.

Comment C.3: Section 11.4 discusses commitments and acceptance criteria for a tamper-safing program. One commenter stated that (1) the language in the third bullet of this section indicates there should be an implied limit of three tamper-safing device control officers absent a regulatory basis, (2) the language in the fourth bullet is unclear regarding the authorization of individuals to apply and remove tamper-indicating devices (TIDs), and (3) clarification is needed in the sixth bullet with respect to the possession of TIDs associated with authorized individuals when TIDs are not in storage. [NEI-1]

Response C.3: The NRC staff disagrees with the comment. Section 11.4 provides guidelines and best practices for an acceptable tamper-safing program. The regulatory requirement on tamper-safing is performance-oriented, and acceptance criteria are not to be regarded as requirements. Similar to the discussion in Response C.2, the

recommended guidelines do not imply a required number of operators for the program, and applicants and licensees have many alternatives on how their tamper-safing program is designed, managed, and operated. This permits a risk-informed performance-based approach that focuses on and concentrates facility resources on MC&A activities most important to safeguards. No change was made to this section of the guidance as a result of this comment.

**D. NUREG-2158** (formerly NUREG/CR-5734), “Acceptable Standard Format and Content for the Material Control and Accounting (MC&A) Plan Required for Low Enriched Uranium Enrichment Facilities”

No comments were received on this draft guidance document.

**E. NUREG/BR-0096**, Revision 2, “Instructions and Guidance for Completing Physical Inventory Summary Reports”

No comments were received on this draft guidance document.

**F. DG-5057**, “Special Nuclear Material Control and Accounting System for Non-Fuel Cycle Facilities” (draft Revision 3 to RG 5.29)

Comment F.1: One commenter requested clarification of the applicability of 10 CFR Part 74 and DG-5057 to licensees with less than 1 gram of SNM at adjacent licensee facilities (lab or calibration facility). [NEI-2]

Response F.1: The NRC staff disagrees with the comment that additional clarification is necessary as to whether “adjacent licensee facilities” may not be subject to the requirements. The applicability of the regulations in 10 CFR Part 74 depends, in part, on the amount of SNM possessed by the licensee at the entire facility. If the “lab or calibration facility” is included within the licensed entity at a site, then it is subject to the overall requirements for that license. One aspect of the MC&A program for a given facility is the designation of specific areas within the facility where SNM is present, through, for example, MBAs and ICAs. The MC&A program for the site should then address those areas of the site where SNM is present. No change was made to this guidance section as a result of this comment.

Comment F.2: Several commenters recommended that the guidance be split among power reactors, labs, research and test reactors, ISFSIs, etc., to reflect the differences that exist between licensees that are not addressed in DG-5057. [NEI-2, HN-2, MY-2, and YR]

Response F.2: The NRC staff disagrees with the comment, that this guidance be split into separate documents for different facility types. The text of DG-5057 has been revised to extend its scope from only nuclear power plants to include all non-fuel cycle facilities. This guidance describes the standard format and content suggested for use for all these types of licensees authorized to possess or use SNM in a quantity greater than 350 grams of contained uranium-235, uranium-233, or plutonium or any combination thereof. Licensees may use this guidance when implementing their specific facility’s MC&A program that considers the unique

features of their particular operations. No change was made to this guidance as a result of this comment.

Comment F.3: Two commenters requested clarification as to whether the continued and sole use of ANSI N15.8 is sufficient to meet the MC&A regulatory requirements of 10 CFR Part 74. [NEI-2 and EG-2]

Response F.3: The NRC staff agrees with the comment. The previous revision of this guidance document (Regulatory Guide 5.29, Revision 2) endorsed the guidance in ANSI N.15.8. As stated in Section C, Staff Regulatory Guidance, conformance with ANSI N.15.8 is considered an acceptable approach to meet only certain MC&A requirements in the revised Subpart B of 10 CFR Part 74. However, as described in Section B, Discussion, DG-5057 expands the scope of the guidance to cover additional MC&A requirements (i.e., item control system) in the draft final revisions to 10 CFR Part 74, which go beyond the areas covered by ANSI N.15.8. Therefore, because the limited scope of ANSI N.15.8 does not address all MC&A regulatory requirements in 10 CFR Part 74, the continued and sole use of ANSI N15.8 is not sufficient. No change was made to this guidance section as a result of this comment.

Comment F.4: One commenter stated that DG-5057 should be revised to take into account 10 CFR Part 73 requirements that licensees are already implementing and reflect the fact that sites have extensive physical and personnel security programs. The commenter requested clarification or additional information on the storage and protection of SNM inside and outside protected areas. [NEI-2]

Response F.4: The NRC staff disagrees with the comments with respect to 10 CFR Part 73 physical protection requirements. Although certain physical protection requirements are complementary to the MC&A program elements, the requirements are separate in the regulations. The scope of this rulemaking does not include physical protection, and the NRC does not intend to revise this guidance to take into account 10 CFR Part 73 requirements. Licensees should follow 10 CFR Part 73 requirements in their physical protection plans and programs. No change was made to the guidance as a result of this comment.

Comment F.5: One commenter stated that Section B, Discussion, of this guidance should reflect the proposed final rule. [NEI-2]

Response F.5: The NRC staff agrees with the comment. The final guidance document (Revision 3 of RG 5.29) has been revised to reflect the final rule throughout the guidance document.

Comment F.6: One commenter stated that the discussion in Section B, Harmonization with International Standards, might give the impression that additional requirements are required beyond 10 CFR Parts 73 and 74. [NEI-2]

Response F.6: The NRC staff agrees with the comment. As discussed in Section B of this regulatory guide, this guidance is consistent with the security principles provided in the IAEA Nuclear Services Series No.15. This section has been revised to clarify that this NRC guidance does not outline additional safeguards or security requirements.

Comment F.7: Sections C.1.A through C.1.E discuss the GPOs. Two commenters requested additional guidance and clarification on these objectives. [NEI-2 and VC]

Response F.7: The NRC staff agrees with the comments. The rule change will formalize in 10 CFR Part 74 the GPOs that would apply to all licensees authorized to possess more than 350 grams of SNM. The final rule text and the GPO sections in DG-5057 have been revised to clarify the intent of these GPOs and provide additional guidance.

Comment F.8: Sections C.2.A through C.2.L discuss the Item Control System. Several commenters stated that under the proposed final rule that power reactors and ISFSIs will need an item control system which is proposed in the rulemaking to be added to the definition in 10 CFR 74.4 as “a system for tracking the creation, identity, element and isotopic content, location, and disposition of all items, which would enable the licensee to maintain knowledge of each item in its possession.” The commenters stated that most power reactors and ISFSIs already have some form of this, but it does not need the complexity of the requirements of an Item Control System and the proposed Regulatory Guide. The commenters asked that NRC revise DG-5057 to be less complex and prescriptive. [NEI-2, VC, and EG-2]

Response F.8: The NRC staff agrees, in part, with the comments. A discussion of non-fuel SNM items has been added to Section C.2 of the guidance as a result of the comment.

The NRC staff disagrees with the comment that the item control regulations and guidance are unduly complex and prescriptive. The guidance on the item control system in DG-5057 is more comprehensive than the simple guidelines in ANSI N.15.8. Section C.2 of DG-5057 provides guidelines and best practices for an acceptable item control system. The guidance on an item control system is performance-oriented, and guidelines or recommendations in the guidance are not to be regarded as requirements. With this flexibility, licensees have many alternatives on how their Item Control System is designed, managed, and operated. This permits a risk-informed performance-based approach that focuses on and concentrates facility resources on MC&A activities most important to safeguards. Licensees may use this guidance when implementing their specific facility’s MC&A program that considers the unique features of their particular operations.

Comment F.9: Sections C.3.A through C.3.I discuss the Physical Inventories program. One commenter stated that the following sections should not be included in DG-5057: Sections C.3.D and C.3.E regarding the regulatory language on inventory procedures and practices, Section C.3.F(3) regarding the use of previous measurements, Section C.3.F(5) regarding inventory frequencies, Section C.3.G.(1) regarding the independence of inventory personnel, and Sections C.3.I(1) and C.3.I(2) regarding on the inventory preparation and performance. [NEI-2]

Response F.9: The NRC staff interprets the comments to imply that the commenter differentiates between regulatory requirements and guidelines, and between rigid standards and best practices for the physical inventory program described in Section C.3 of DG-5057. If this is the case, the NRC staff disagrees with the comments that these sections be removed from the guidance. The guidance on the Physical Inventories program in DG-5057 is more comprehensive than the simple guidelines in ANSI N.15.8. Sections C.3 of DG-5057 provides guidelines and best practices for an acceptable Physical Inventories program. The practices, if followed, serve the purpose of a physical inventory program in confirming the presence of all SNM expected to be present based on the accounting records, and further detecting potential unauthorized removal of SNM that could go undetected in the absence of a physical inventory. The guidance on the Physical Inventories program is performance-oriented, and guidelines or recommendations in the guidance are not to be regarded as requirements. With this flexibility, licensees have many alternatives on how their Physical Inventories program is designed,

managed, and operated. This permits a risk-informed performance-based approach that focuses on and concentrates facility resources on MC&A activities most important to safeguards. Licensees may use this guidance when implementing their specific facility's MC&A program that considers the unique features of their particular operations. No change was made to these guidance sections as a result of this comment.

Comment F.10: One commenter asked for clarification on the use of measurements and calculations in Section C.3.H and throughout DG-5057 and if they are interchangeable. [NEI-2]

Response F.10: The NRC staff agrees with the comment that the use of measurements could be limited for certain facilities (e.g., nuclear reactors or storage installations), and methods of calculations may be used for determining SNM quantities. In fact, Sections C.2.I and C.3.H of this guide discuss different methods of computation or calculations used to estimate SNM quantities. For clarification purposes, Sections C.2.A(4) and C.3.F.(4) have been revised to state that measurements or methods of calculations should be applicable depending on particular operations of the facility.

Comment F.11: Section C.4.B contains a reference to 10 CFR 74.19(e). One commenter stated that this is not part of the existing or proposed rulemaking. [NEI-2]

Response F.11: The NRC staff agrees with the comment. The recordkeeping requirements are now specified in 10 CFR 74.19(a) and 74.19(e). The revised 10 CFR 74.19(e) is the former 10 CFR 74.19(d), which has been redesignated to allow for the new 10 CFR 74.19(d). Section C of the guidance has been revised to reflect the recordkeeping requirement in both 10 CFR 74.19(a) and 74.19(e).

Comment F.12: One commenter stated that Sections C.4.E through C.4.J contain similar requirements to those required for fuel cycle facilities, and retention of records requirements are already specified in other regulations and do not need to be restated in DG-5057. [NEI-2]

Response F.12: The NRC staff disagrees with the comment that these sections are not needed in this document. DG-5057 states specifically that the guidance in Section C.4 applies to all non-fuel cycle facilities for the recordkeeping requirements specified in 10 CFR 74.19(a) and 74.19(e). Licensees may use this guidance when implementing their specific facility's MC&A program that considers the unique features of their particular operations. No change was made to these guidance sections as a result of this comment.

Comment F.13: Section C.4.I discusses MC&A records receiving the appropriate level of protection needed for security purposes and that access to such records should be restricted to authorized individuals. One commenter stated that it would be useful to provide practical guidance as to whether file cabinets that contain copies of the original documents need to be locked, or if controlled access to the building via keycard is sufficient. The commenter felt that this section appears to bring MC&A records under the security umbrella, and requested clarification. [NEI-2]

Response F.13: The NRC staff disagrees with the comments regarding the concern that the guidance brings MC&A records under the security umbrella. Section C.4.I provides guidance on records stored at locations to be protected from unauthorized access, theft, sabotage, or damage. Similar to the discussion in the response to Comment 1.7, the use of a locked file cabinet or office is an example of one means of meeting the information protection requirements for recordkeeping. The guidance in this document on recordkeeping and associated MC&A

records is performance-oriented, and guidelines or recommendations are not to be regarded as requirements. Licensees may use this guidance when implementing their specific facility's MC&A program that considers the unique features of their particular operations. No change was made to these guidance sections as a result of this comment.