



# DRAFT REGULATORY GUIDE

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## DRAFT REGULATORY GUIDE DG-3044

*Proposed New Regulatory Guide*

### CORRECTIVE ACTION PROGRAMS FOR FUEL CYCLE FACILITIES

#### A. INTRODUCTION

This regulatory guide describes programmatic elements that the staff of the U.S. Nuclear Regulatory Commission (NRC) considers acceptable when developing corrective action programs (CAPs) for fuel cycle facilities that are licensed under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 40, “Domestic Licensing of Source Material” (Ref. 1) or 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material” (Ref. 2) ; or holders of certificates of compliance or approvals of a compliance plan for gaseous diffusion plants under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants” (Ref. 3).

NRC regulations or licenses generally require fuel cycle licensees to implement some CAP elements for certain aspects of their licensed activities. These elements include the identification and implementation of corrective actions for failures associated with items relied on for safety (IROFS) or management measures, audit and assessment findings, and incident investigation results. Some fuel cycle licensees voluntarily implement CAPs that go beyond the scope of NRC requirements. In the staff requirements memorandum (SRM) for SECY-10-0031, “Revising the Fuel Cycle Oversight Process” (Ref. 4), the Commission directed the NRC staff to consider how the NRC Enforcement Policy could best reflect that most fuel cycle licensees had voluntarily developed CAPs. The SRM stated that the Enforcement Policy should provide such licensees with incentives to maintain strong CAPs as an important facet of sustaining high safety and security performance. In response to the Commission’s direction, the staff revised Section 2.3.2 of the NRC Enforcement Policy (Ref. 5). Section 2.3.2 of the revised policy permits Severity Level (SL) IV violations to be dispositioned as non-cited violations (NCVs) if the NRC finds that the licensee has implemented an adequate CAP, and that the Section 2.3.2a criteria are met.

In SRM-SECY-11-0140, “Enhancements to the Fuel Cycle Oversight Process” (Ref. 6), the Commission directed the staff to proceed with the development and implementation of incentives for

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This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position. Public comments are being solicited on this draft guide and its associated regulatory analysis. Comments should be accompanied by appropriate supporting data. Written comments may be submitted through the Federal rulemaking Web site at <http://www.regulations.gov>, by searching for Docket ID NRC-2014-0021. Alternatively, comments may be submitted to the Rules, Announcements, and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Comments must be submitted by March 14, 2014.

Electronic copies of this draft regulatory guide, previous versions of this guide, and other recently issued guides are available through the NRC’s public Web site under the Regulatory Guides document collection of the NRC Library at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>. The draft regulatory guide is also available through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML13219B204. The regulatory analysis may be found in ADAMS under Accession No. ML13219B210.

licensees to maintain an effective CAP, as part of the ongoing actions to improve the Fuel Cycle Oversight Process.

The staff initially provided proposed guidance for fuel facility CAPs in draft NUREG-2154, “Acceptability of Corrective Action Programs for Fuel Cycle Facilities” (Ref. 7). That document was issued for public comment in the *Federal Register* (Ref. 8) in February 2013 and was discussed during an April 2013 public meeting (Ref. 9). After the public meeting, the Nuclear Energy Institute (NEI) submitted to the NRC a letter (Ref. 10) providing comments on the draft NUREG. One comment recommended conversion of the draft NUREG to a regulatory guide. The NRC staff agreed with the recommendation and has accordingly prepared this draft regulatory guide. This regulatory guide will be used to support NRC determination of CAP adequacy for fuel facilities using the process described in Section B of this regulatory guide.

## **Applicable Rules and Regulations**

The regulations established by the NRC in 10 CFR Part 40, “Domestic Licensing of Source Material,” establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct materials; provide for the disposal of byproduct material and for the long-term care and custody of byproduct material and residual radioactive material; and establish certain requirements for the physical protection of import, export, and transient shipments of natural uranium.

The regulations established by the NRC in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material,” establish procedures and criteria for the issuance of licenses to receive title to, own, acquire, deliver, receive, possess, use, and transfer special nuclear material. The provisions of 10 CFR 70.60, “Applicability,” and 10 CFR 70.62, “Safety Program and Integrated Safety Analysis,” require that licensees authorized to possess greater than a critical mass of special nuclear material establish management measures to ensure compliance with the performance requirements of 10 CFR 70.61, “Performance Requirements.” As stated in 10 CFR 70.4, “Definitions,” management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance elements. The requirements for management measures are stated in 10 CFR 70.62(d).

The regulations in 10 CFR 70.22(f) further require that applicants for a license to possess and use special nuclear material in a plutonium-processing and fuel fabrication plant provide a description of the quality assurance (QA) program to be applied to the design, fabrication, construction, testing, and operation of the structures, systems, and components of the plant. This description should include a discussion of how the criteria in Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to 10 CFR Part 50, “Domestic Licensing of Production and Utilization Facilities,” (Ref. 11) will be met for a plutonium processing and fuel fabrication plant. As stated in 10 CFR 70.23(b), the criteria in Appendix B of 10 CFR Part 50 will be used by the NRC to determine the adequacy of the QA program for this type of facility.

The regulations established by the NRC in 10 CFR Part 76, “Certification of Gaseous Diffusion Plants,” establish requirements that govern the operation of those portions of the Paducah Gaseous Diffusion Plant that are leased by the United States Enrichment Corporation (USEC). The provisions of 10 CFR 76.93, “Quality Assurance,” require that USEC establish, maintain, and execute a quality assurance program satisfying each of the applicable requirements of ASME NQA-1-1989, “Quality Assurance Program Requirements for Nuclear Facilities” (Ref. 12), or satisfying acceptable alternatives to the applicable requirements.

## Related Guidance

The following NRC staff documents provide guidance that may address some, but not necessarily all, of the CAP elements defined in this regulatory guide.

- NUREG-1520, “Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility” (Ref. 13), provides guidance for the development of management measures for facilities licensed in accordance with 10 CFR Part 70 and subject to the requirements of Subpart H of 10 CFR Part 70. Management measures may include corrective action provisions as part of Section 11.4.3.8, “Other Quality Assurance Elements,” in NUREG-1520.
- NUREG-1718, “Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility” (Ref. 14), provides guidance for the application review for the Mixed Oxide (MOX) Fuel Fabrication Facility (MFFF) in Aiken, SC. The MFFF is subject to the requirements of Subpart H of 10 CFR Part 70 and Appendix B to 10 CFR Part 50 for quality assurance. Section 15, “Management Measures,” of NUREG-1718 provides guidance for the development of management measures and a quality assurance program that meets the requirements of Appendix B to 10 CFR Part 50. Management measures may include corrective action provisions as part of other quality assurance elements, and Appendix B to 10 CFR Part 50 includes requirements for corrective actions in Criterion XVI, “Corrective Actions.”
- U.S. Nuclear Regulatory Commission, “Enforcement Policy,” sets forth the general principles governing the NRC Enforcement Program, including the process for assessing and dispositioning violations of NRC requirements. If certain criteria are met, Section 2.3.2 of the Enforcement Policy allows the NRC to disposition SL IV violations as NCVs after NRC has determined that an adequate CAP has been implemented.

## Purpose of Regulatory Guides

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency’s regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants and licensees (licensees)<sup>1</sup>. Regulatory guides are not substitutes for regulations and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

## Paperwork Reduction Act

This regulatory guide contains information collection requirements covered by 10 CFR Parts 40 and 70 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0020 and 3150-0009, respectively. The information collection requirements contained in 10 CFR Part 76 are of limited applicability because they apply to a wholly owned instrumentality of the United

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<sup>1</sup>In this regulatory guide, the terms “licensee” or “licensees” is used inclusively to describe holders of and applicants for one of the following: (1) a source material license issued under 10 CFR Part 40, “Domestic Licensing of Source Material;” (2) a special nuclear material license issued under 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material;” or (3) a certificate of compliance or approval of a compliance plan for gaseous diffusion plants under 10 CFR Part 76, “Certification of Gaseous Diffusion Plants.”

States and affect fewer than 10 respondents. Therefore, OMB clearance is not required under the Paperwork Reduction Act (44 U.S.C. 350 et seq.).

The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

## **B. DISCUSSION**

### **Reason for Issuance**

This guide is being issued to describe the programmatic elements of an acceptable CAP for a fuel cycle facility licensed or certified in accordance with 10 CFR Part 40, 70, or 76.

### **Background**

This regulatory guide describes programmatic elements that the NRC staff considers acceptable when developing fuel cycle facility CAPs. Licensees may choose to develop and implement CAPs for the purpose of applying Section 2.3.2 of the NRC Enforcement Policy. The NRC Enforcement Policy identifies that once the NRC has determined that an adequate CAP has been implemented by the licensee, the NRC may disposition SL IV violations as NCVs provided that the criteria in Section 2.3.2a of the NRC Enforcement Policy have been met. For the NRC to make the determination that a CAP is adequate, the licensee needs to demonstrate that it has an acceptable CAP and the NRC must determine (through inspection) that the CAP is effective, as described below.

- a. A licensee that wishes to establish an acceptable CAP for ensuring facility safety and security should request a license amendment to incorporate the licensee's commitment to either (1) comply with the provisions in Section C of this regulatory guide (see Appendix A for a sample letter), or (2) comply with an alternative CAP (described in their license amendment request) that effectively implements controls to identify, document, and correct conditions adverse to safety and security.<sup>2</sup> Upon staff review and approval, the license would be amended to add a license condition reflecting the licensee's commitment to comply with the CAP elements outlined in Section C of this regulatory guide or the alternative CAP submitted by the licensee.
- b. After the license has been amended and the licensee has implemented a CAP that complies with the guidance in Section C of this regulatory guide (or approved alternate CAP), the licensee should notify the NRC in writing to request that NRC conduct an inspection of CAP implementation and effectiveness (see Appendix B for a sample letter). Upon successful verification of CAP effectiveness through inspection, the NRC will issue a letter to the licensee documenting that the CAP is adequate and, as such, any future SL IV violations may be dispositioned as NCVs, provided that the applicable criteria in Section 2.3.2a of the NRC Enforcement Policy are met.

### **Harmonization with International Standards**

The NRC staff has not identified any international standards related to this guide.

### **Documents Discussed in Staff Regulatory Guidance**

This regulatory guide does not endorse the use of any codes or standards developed by external organizations or other third-party guidance documents.

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<sup>2</sup> The terms "conditions adverse to safety and security" and "significant conditions adverse to safety and security" will be defined by the licensee using the guidance in paragraph C.2.b and Appendix D of this regulatory guide.

## C. STAFF REGULATORY GUIDANCE

This section describes the programmatic elements that the NRC staff considers acceptable when developing CAPs for fuel cycle facilities. When a licensee commits to comply with the regulatory guidance in this section, the licensee is committing to treat “should” statements within the CAP elements in items 1-6 below as “shall” statements.

1. The licensee should develop a CAP organization that includes an independent reviewing organization that is auditable and independent of the licensee’s production organization.
  - a. The independent reviewing organization may be a separate, independent division of the licensee’s organization, such as a quality assurance or quality control organization. However, it is also acceptable for the licensee to assign independent review duties to an existing part of the licensee’s organization, such as Environmental Health and Safety, provided that the licensee describes this designation in its CAP and commits to ensure that the organization or individuals are sufficiently independent, trained, and able to meet the guidance established in this regulatory guide.
  - b. Facility management should provide the independent reviewing organization sufficient authority, access to work areas, and organizational independence to perform its responsibilities.
  - c. The independent reviewing organization should be responsible for concurring on CAP policies and procedures and revisions thereto, in accordance with the guidance in this regulatory guide.
  - d. If the reviewing organization has other concurrent duties, the CAP implementing documents should describe measures that will be taken to avoid a possible conflict of interest.
2. The licensee should develop, implement, and maintain written policies, programs, and procedures that describe the CAP.
  - a. Policies, programs, and procedures should describe CAP organization, expectations, personnel responsibilities, and implementation processes in sufficient detail to enable effective, consistent implementation of the CAP. Policies, programs, and procedures should describe the licensee’s process for implementing the elements of the CAP. Appendix C illustrates a sample CAP implementation process.
  - b. Policies, programs, and procedures should describe CAP terminology and definitions, including, at a minimum, definitions of the terms “conditions adverse to safety and security” and “significant conditions adverse to safety and security” (or equivalent terminology). The definitions of these two terms should reflect the following:
    - i. “Conditions adverse to safety and security” is an inclusive term that applies to conditions that affect safety, security, or both safety and security. Security issues include those related to information security, physical security, and safeguards associated with licensed material.
    - ii. Conditions adverse to safety and security include failures, malfunctions, deficiencies, defective items, processes that are outside their control parameters, regulatory noncompliances, and nonconformances (a nonconformance is a failure to meet a contract requirement related to NRC activities; e.g., a failure to meet the specifications included in a procurement document).

- iii. Significant conditions adverse to safety and security are conditions that, if left uncorrected, could have a serious effect on safety or security. See Section D-2 of Appendix D for examples of significant conditions adverse to safety and security.
  - c. Policies, programs, and procedures should describe the use of delegation authority and should require that delegation authority be documented.
    - i. Specific responsibilities within the CAP may be delegated, but the licensee should retain the responsibility for the program's effectiveness and for performing periodic audits and assessments.
  - d. Policies, programs, and procedures should describe the manner in which sensitive information will be managed for CAP functions if the licensee chooses to maintain any sensitive information outside the main CAP database or information management system.
    - i. When conditions adverse to safety and security involve sensitive and/or classified information that requires controlled access, the licensee may take measures to segregate sensitive and/or classified information from the general CAP system or database. This may involve the generation of a non-sensitive (usually numbered) placeholder in the CAP to track the issue and enable trending while the sensitive and/or classified information is housed separately.
    - ii. When the licensee addresses conditions adverse to safety and security involving sensitive and/or classified information in a system that is separate from the main CAP system or database, the licensee should do so in a manner that addresses all the elements of Section C of this regulatory guide.
- 3. The licensee should identify, report, and document safety and security issues.
  - a. The CAP should require all personnel, including contractors, staff, supervisors and managers, to promptly identify, document, and report safety and security issues (i.e., conditions adverse to safety and security) in a manner that supports the timely and effective assessment and correction of the issues. The term "promptly" indicates the actions should be performed or executed without delay, in a turnaround commensurate with an issue's significance, and in as brief a time period as is reasonably achievable.
  - b. Employees should receive training to ensure that they are able to identify adverse conditions and understand their CAP responsibilities.
  - c. The CAP should require the documentation of safety and security issues from identification to closure.
  - d. The CAP should include a process for tracking and trending of issues and for reporting these issues to the NRC when required.
- 4. The licensee should evaluate and classify the significance of safety and security issues and determine the cause of significant issues.
  - a. The CAP should include a process for evaluating the actual and potential significance of conditions adverse to safety and security, and for classifying conditions as significant or non-

significant. The licensee's significance assessment should enable the organization to appropriately apply a graded approach, based on the issue's significance, to the timing and scope of response to the issues, including the depth and detail of causal evaluations (where applicable). Section D-1 of Appendix D provides examples of criteria for assessing the significance of conditions adverse to safety and security.

- b. For significant conditions adverse to safety and security, the CAP should include measures to ensure that:
  - (1) the root and contributing causes are determined, and
  - (2) the extent of condition and cause is evaluated, including assessing the extent to which other items and activities, including work in progress, may be affected so that appropriate action can be taken.
5. The licensee should develop and implement corrective and preventative actions, as appropriate, for conditions adverse to safety and security.
  - a. The CAP should establish measures to ensure that corrective action(s) are promptly developed and initiated following the identification of a condition adverse to safety and security.
  - b. The CAP should include measures to verify the completion and proper implementation of corrective actions. The CAP should ensure timeliness of corrective action implementation, verification of effectiveness, and closure in a manner commensurate with the safety and security significance of the issues identified. The process should include timeliness expectations in order to ensure prompt resolution of safety and security issues.
  - c. For significant conditions adverse to safety and security, the CAP should include:
    - i. Measures to prevent recurrence of the same issue or the occurrence of similar, significant conditions adverse to safety and security; and
    - ii. Review of corrective action development, implementation, and verification, as appropriate, by the independent reviewing organization.
  - d. The CAP should include measures to ensure that conditions and trends that are adverse to safety and/or security are reported to the appropriate level of management.
6. The licensee should develop, implement, and maintain an assessment process to evaluate the CAP's effectiveness in the identification, reporting, assessment, and correction of safety and security issues and the prevention of the recurrence of the same issues or occurrence of similar issues.
  - a. The CAP assessment process should include measures for reviewing conditions adverse to safety and security to determine the existence of adverse trends and repetitive problems.
  - b. The licensee should use the CAP assessment process to evaluate the timeliness of CAP elements and the ability of the CAP to follow up and enable closure of corrective actions that are past their due date.
  - c. The licensee should evaluate CAP effectiveness at regular, specified intervals.



- d. The CAP assessment process should define actions for the resolution of ineffective corrective actions, trends, and performance issues.

## D. IMPLEMENTATION

### Use by Applicants and Licensees

Applicants and licensees may voluntarily<sup>3</sup> use the guidance in this document to develop and implement a CAP. Licensees may choose to develop and implement CAPs that meet the guidance in this regulatory guide for the purpose of applying Section 2.3.2 of the NRC Enforcement Policy. The NRC staff may find methods or solutions that differ from those described in this regulatory guide acceptable for the purpose of applying Section 2.3.2 of the NRC Enforcement Policy if those methods or solutions effectively implement controls to identify, document, and correct conditions adverse to safety and security.

The guidance in this regulatory guide does not establish methods for compliance with 10 CFR Parts 40, 70, or 76; rather, it describes corrective action elements that should be used to establish a CAP that is adequate to identify and correct conditions adverse to safety and security to support the safe operation of the facility.

### Use by NRC Staff

The NRC staff does not intend or approve any imposition or backfitting of the guidance in this regulatory guide. The NRC staff does not expect any existing licensee to use or commit to using the guidance in this regulatory guide, unless the licensee makes a change to its licensing basis. The NRC staff does not expect or plan to request licensees to voluntarily adopt this regulatory guide to resolve a generic regulatory issue. The NRC staff does not expect or plan to initiate NRC regulatory action which would require the use of this regulatory guide. Examples of such unplanned NRC regulatory actions include issuance of an order requiring the use of the regulatory guide, generic communication, or promulgation of a rule requiring the use of this regulatory guide without further backfit consideration.

During regulatory discussions on plant-specific operational issues, the staff may discuss with licensees various actions consistent with staff positions in this regulatory guide and may suggest them to be acceptable means of developing and implementing a CAP that is adequate for the purpose of applying Section 2.3.2 of the Enforcement Policy. Such discussions would not ordinarily be considered backfitting. However, unless this regulatory guide is part of the licensing basis for a facility, the staff may not represent to the licensee that the licensee's failure to comply with the positions in this regulatory guide constitutes a violation.

If an existing licensee voluntarily seeks a license amendment or change and (1) the NRC staff's consideration of the request involves a regulatory issue directly relevant to this new or revised regulatory guide and (2) the specific subject matter of this regulatory guide is an essential consideration in the staff's determination of the acceptability of the licensee's request, the staff may request that the licensee either follow the guidance in this regulatory guide or provide an equivalent alternative process that demonstrates compliance with the underlying NRC regulatory requirements. This is not considered backfitting as defined in 10 CFR 70.76(a)(1) or 10 CFR 76.76(a)(1).

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<sup>3</sup> In this section, "voluntary" and "voluntarily" mean that the applicant, licensee, or certificate holder is seeking the action of its own accord, without the force of a legally binding requirement or an NRC representation of further licensing or enforcement action.

Additionally, an existing applicant may be required to comply with new rules, orders, or guidance if 10 CFR 70.76(a)(3) or 10 CFR 76.76(a)(3) applies.

If a licensee believes that the NRC is either using this regulatory guide or requesting or requiring the licensee to implement the methods or processes in this regulatory guide in a manner inconsistent with the discussion in this Implementation section, the licensee may file a backfit appeal with the NRC in accordance with the guidance in NUREG-1409, "Backfitting Guidelines" (Ref. 15), and NRC Management Directive 8.4, "Management of Facility-Specific Backfitting and Information Collection" (Ref. 16).

## REFERENCES<sup>4</sup>

1. *U.S. Code of Federal Regulations*, “Domestic Licensing of Source Material,” Part 40, Chapter I, Title 10, “Energy” (10 CFR 40).
2. *U.S. Code of Federal Regulations*, “Domestic Licensing of Special Nuclear Material,” Part 70, Chapter I, Title 10, “Energy” (10 CFR 70).
3. *U.S. Code of Federal Regulations*, “Certification of Gaseous Diffusion Plants,” Part 76, Chapter I, Title 10, “Energy” (10 CFR 76).
4. U.S. Nuclear Regulatory Commission, “Revising the Fuel Cycle Oversight Process,” Staff Requirements Memorandum (SRM) for SECY-10-0031, dated August 4, 2010 (ADAMS Accession No. ML102170054).
5. U.S. Nuclear Regulatory Commission, “Enforcement Policy,” dated July 2013 (ADAMS Accession No. ML13228A199).
6. U.S. Nuclear Regulatory Commission, “Enhancements to the Fuel Cycle Oversight Process,” SRM-SECY-11-0140, dated January 5, 2012 (ADAMS Accession No. ML120050322).
7. U.S. Nuclear Regulatory Commission, NUREG-2154, “Acceptability of Corrective Action Programs for Fuel Cycle Facilities—Draft Report for Comment,” dated January 2013 (ADAMS Accession No. ML13036A029).
8. U.S. Nuclear Regulatory Commission, “Acceptability of Corrective Action Programs for Fuel Cycle Facilities,” *Federal Register* Vol. 78, No. 34, February 20, 2013, pp. 11903-4.
9. U.S. Nuclear Regulatory Commission, “Summary of Public Meeting to Discuss Initiatives Related to the Fuel Cycle Industry,” dated May 6, 2013 (ADAMS Accession No. ML13113A251).
10. Schlueter, Janet R., Nuclear Energy Institute, letter to John D. Kinneman, U.S. Nuclear Regulatory Commission, “Industry Comments on DRAFT NUREG-2154, ‘Acceptability of Corrective Action Programs at Fuel Cycle Facilities’ (78 FR 11903; Docket: NRC-2013-0033),” dated April 22, 2013 (ADAMS Accession No. ML13133A219).
11. *U.S. Code of Federal Regulations*, “Quality Assurance,” Appendix B to “Domestic Licensing of Production and Utilization Facilities,” Part 50, Chapter I, Title 10, “Energy” (Appendix B to 10 CFR 50).

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<sup>4</sup> Publicly available NRC published documents are available electronically through the NRC Library on the NRC’s public Web site at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC’s Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>. The documents can also be viewed online or printed for a fee in the NRC’s Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. For problems with ADAMS, contact the PDR staff at 301-415-4737 or (800) 397-4209; fax (301) 415-3548; or e-mail [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov).

12. American Society of Mechanical Engineers, "Quality Assurance Program Requirements for Nuclear Facilities," 1989 Edition (ASME NQA-1-1989).<sup>5</sup>
13. U.S. Nuclear Regulatory Commission, "Management Measures," Chapter 11 of "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," NUREG-1520, Final Report and Rev. 1, dated March 2002 and May 2010 respectively (ADAMS Accession Nos. ML020930033 and ML101390110).
14. U.S. Nuclear Regulatory Commission, "Management Measures," Chapter 15 of "Standard Review Plan for the Review of an Application for a Mixed Oxide (MOX) Fuel Fabrication Facility," NUREG-1718, dated August 2000 (ADAMS Accession No. ML003741461).
15. U.S. Nuclear Regulatory Commission, "Backfitting Guidelines," NUREG-1409, dated July 1990 (ADAMS Accession No. ML032230247).
16. U.S. Nuclear Regulatory Commission, "Management of Facility-Specific Backfitting and Information Collection," NRC Management Directive 8.4, dated October 28, 2004 (ADAMS Accession No. ML050110156).

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<sup>5</sup> Copies of American Society of Mechanical Engineers (ASME) standards may be purchased from ASME, Two Park Avenue, New York, New York 10016-5990; Telephone (800) 843-2763. Purchase information is available through the ASME Web site store at <http://www.asme.org/Codes/Publications/>.



## APPENDIX A

### SAMPLE LETTER REQUESTING LICENSE AMENDMENT TO COMMIT TO REGULATORY GUIDE

This appendix provides a sample letter that may be used as a guide for fuel cycle licensees submitting a license-amendment request to commit to comply with the provisions of this regulatory guide. Applicants and certificate holders using this letter should make appropriate changes to the text to appropriately represent their facility's licensing basis.

[DATE]

[Name]  
Director, Fuel Cycle Safety and Safeguards  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Subject: Submittal of License-Amendment Request to Commit to Regulatory Guide 3.XX

Dear [Name, Director, Fuel Cycle Safety and Safeguards],

In accordance with Title 10, [Part 70.34, or insert applicable CFR citation], of the *Code of Federal Regulations*, [Name of Licensee] hereby requests an amendment to [Materials License Number] to add a commitment to comply with the provisions of Section C of Regulatory Guide 3.XX as part of the facility's licensing basis.

[Name of Licensee] recognizes that this action is the first step in establishing an adequate corrective action program (CAP). If the amendment request is granted, [Name of Licensee] will document its CAP implementation in a letter to the NRC, and request inspection of [Name of Licensee]'s CAP implementation.

Sincerely,  
[Name of Licensee Designee]

cc:  
Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

## APPENDIX B

### SAMPLE LETTER REQUESTING NRC INSPECTION OF CAP IMPLEMENTATION

This appendix provides a sample letter that may be used as a guide for fuel cycle licensees requesting U.S. Nuclear Regulatory Commission (NRC) inspection of their corrective action program implementation. Applicants and certificate holders using this letter should make appropriate changes to the text to appropriately represent their facility's licensing basis.

[DATE]

[Name]  
Director, Fuel Cycle Safety and Safeguards  
Office of Nuclear Material Safety and Safeguards  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Subject: Request for NRC Inspection of Corrective Action Program Implementation

Dear [Name, Director, Fuel Cycle Safety and Safeguards],

By letter dated [date of letter committing to the provisions of Regulatory Guide 3.XX], [Name of facility] requested an amendment to [Materials License Number] to add a commitment to comply with the provisions of Section C of Regulatory Guide 3.XX as part of the facility's licensing basis. This commitment was incorporated into [Materials License Number] as License Condition [License Condition Number] on [date].

[Name of Licensee] has implemented the CAP elements outlined in Regulatory Guide 3.XX and hereby requests inspection of [Name of Licensee]'s CAP implementation.

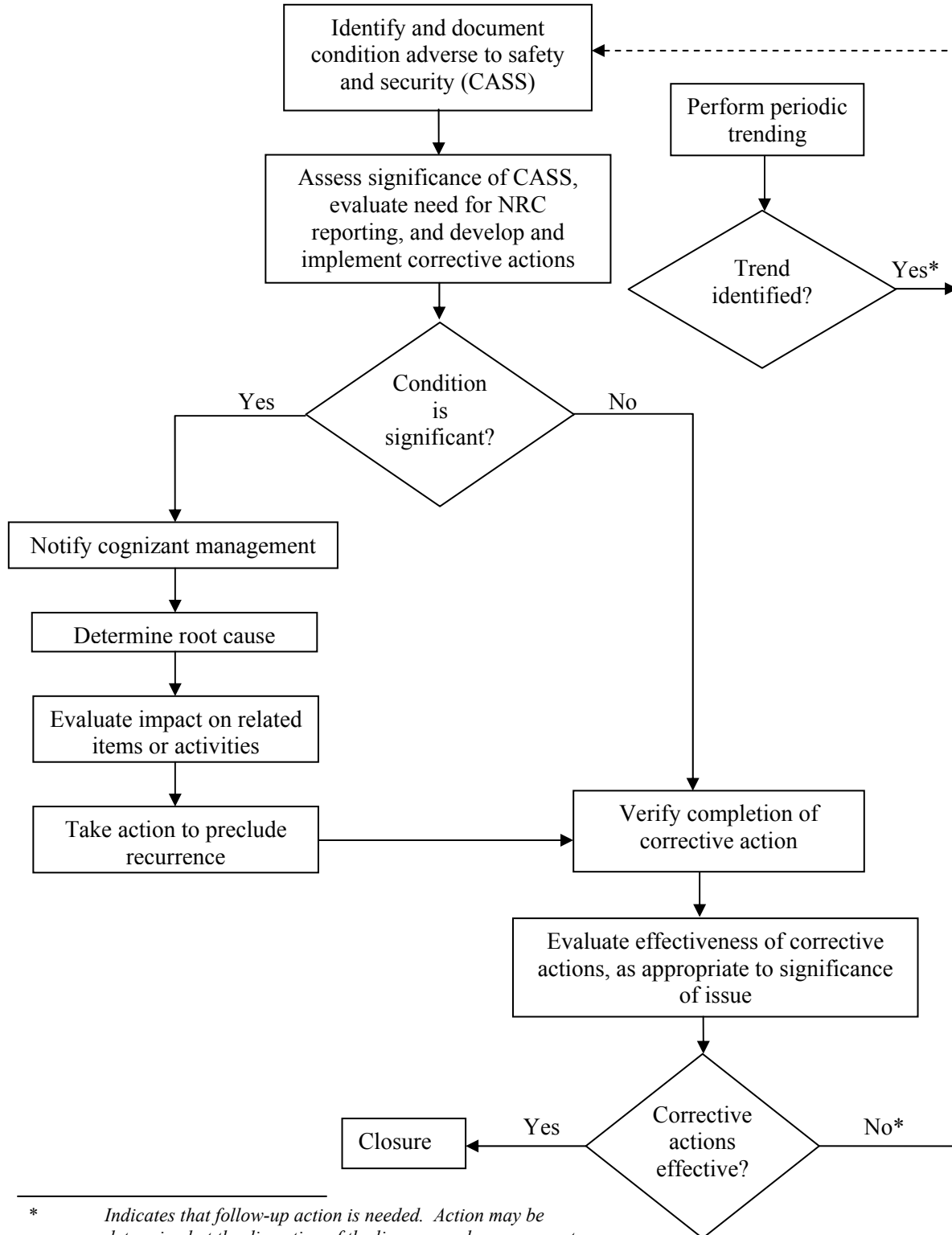
Sincerely,  
[Name of Licensee Designee]

cc:  
Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001



## APPENDIX C

### DIAGRAM OF SAMPLE CORRECTIVE ACTION PROGRAM PROCESS



\* Indicates that follow-up action is needed. Action may be determined at the discretion of the licensee and may warrant notification of facility management and initiation of a new CASS.



## APPENDIX D

### ASSESSMENT AND CLASSIFICATION OF *CONDITIONS ADVERSE TO SAFETY AND SECURITY*

This appendix provides examples of criteria for assessing the significance of *conditions adverse to safety and security*, and examples of situations that could be classified as conditions adverse to safety and security.

#### **D-1. Significance Assessment Criteria**

Criteria for assessing the significance of conditions adverse to safety and security may include:

- impact on the health and safety of workers, the public, and the environment;
- importance in meeting regulatory requirements;
- impact on the reliability, availability, or maintenance of equipment important to nuclear safety or security at the facility;
- consequence and likelihood of recurrence if the condition is not corrected; and
- potential to impact other items or activities beyond the specific occurrence in which the condition may have greater impact.

#### **D-2. Classification of Conditions Adverse to Safety and Security: Significant Conditions**

Significant conditions adverse to safety and security may include:

- a trend of multiple conditions adverse to safety and security
- deficiencies in design, manufacturing, construction, testing, or process requiring substantial rework, repair, or replacement
- damage to a structure, system, component, or facility requiring substantial repairs
- a non-conservative error detected in a computer program or design input after it has been implemented or released for use
- repeated failure to implement a portion of an approved procedure
- operator errors that result in the release of licensed material or significant unplanned exposure of workers to radiation
- theft, diversion, or loss of a reportable quantity of special nuclear material, or discovery of a significant inventory difference

- failure of equipment designated as an item relied on for safety, or failure of administrative controls that result in a substantial increase in the likelihood of an accident
- The neutron multiplication factor (K-effective) license limit is exceeded.