Background and Context for the Draft NUREG-XXXX, "Acceptability of Corrective Action Programs for Fue Cycle Facilities"

In the staff requirements memorandum (SRM) for SECY-10-0031 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML102170054), the Commission directed the U.S. Nuclear Regulatory Commission (NRC) staff to consider how to best reflect in the NRC enforcement policy that most fuel cycle licensees have voluntarily developed Corrective Action Programs (CAPs). In response to the Commission's direction, the staff proposed to change the NRC's Enforcement Policy to disposition Severity Level IV violations as noncited violations if the NRC determines that the licensee's CAP is effective, the licensee enters the violation in its CAP, and other criteria are met. In the SRM for SECY-11-0140 (ADAMS Accession No. ML120050322), the Commission directed to staff to proceed with the development and implementation of the incentives for licensees to maintain an effective CAP.

The purpose of the draft NUREG-XXXX, "Acceptability of Corrective Action Programs for Fuel Cycle Facilities," is to provide guidance to the NRC staff on how to determine, from a licensee's document submittal, that a CAP is acceptable. After the NRC staff determines that the CAP is acceptable, in accordance with the evaluation findings in Section 6 of the draft NUREG-XXXX, the CAP will be incorporated into the license and then its implementation will be verified by an NRC inspection using a CAP inspection procedure.

The purpose of the CAP inspection procedure is to verify that the acceptable CAP is implemented in accordance with the license. After the NRC inspection verifies that the licensee implements its CAP in accordance with the license, then the NRC will consider the CAP to be effective. Once the licensee's CAP is effective and other criteria in the NRC enforcement policy are met, the NRC staff will start dispositioning Severity Level IV violations as noncited violations. The conclusion that the licensee's CAP is effective will be documented in publicly available documents to the licensee (typically, inspection reports). It should be noted that CAP's implementation will be verified periodically by NRC inspectors in accordance with inspection procedures.

NUREG-XXXX: Acceptability of Corrective Action Programs for Fuel Cycle Facilities

Section 1 **Purpose of Review**

According to Title 10 of the *Code of Federal Regulations* (10 CFR) 70.4, "Definitions," management measures includes other quality assurance (QA) elements. NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," states that other QA elements may include some or all of the following elements:

(1) Organization;
(2) QA Program;
(3) Design Control;
(4) Procurement Document Control;
(5) Instructions, Procedures, and Drawing Control;
(6) Document Control;
(7) Control of Purchased Items;
(8) Identification and Control of Item;
(9) Control of Processes;
(10) Inspection;
(11) Test Control;
(12) Control of Measuring and Test Equipment;
(13) Handling, Storage, and Shipping;
(14) Inspection, Test, and Operating Status;
(15) Control of Nonconforming Items;
(16) Corrective Action;
(17) QA Records; and
(18) Audits

For corrective action, Section 11.4.3.8, "Other Quality Assurance Elements," of NUREG-1520 states (see page 11-19) the applicant [or licensee] should specify provisions for promptly identifying conditions adverse to quality and correcting them as soon as practicable.

This guidance expands NUREG-1520 and NUREG-1962, "Guidance on the Implementation of Integrated Safety Analysis Requirements for 10 CFR Part 40 Facilities Authorized to Possess 2,000 Kilograms or More of Uranium Hexafluoride – Draft Report for Comment," in relation to what the U.S. Nuclear Regulatory Commission (NRC) staff considers an acceptable corrective action program (CAP).

Section 2 **Responsibility for Review**

Primary: Quality Assurance Reviewer

Section 3 **Areas of Review**

The specific areas of review of a licensee's CAP are as follows:

(1) Policies, Programs, and Procedures

(2) Identification, Reporting, and Documentation of Safety and Security Issues
(3) Significance Classification and Causal Evaluation of Safety and Security Issues
(4) Development and Implementation of Corrective Actions
(5) Assessment of Corrective Action and Program Effectiveness

Section 4 **Acceptance Criteria**

The CAP should be determined acceptable if:

(1) Procedures are established and described indicating terminology definitions, the CAP expectations, requirements, and implementation processes. The QA organization reviews and documents concurrence with the procedures and revisions thereto.

(2) It includes prompt identification, documentation, assessment, and correction of the safety and security issues (i.e., conditions adverse to quality). Also, the facility's management fosters a "no-fault" attitude toward the identification of conditions adverse to quality and requires all personnel to identify conditions adverse to quality.

(3) Criteria for classifying the significance of conditions adverse to quality (i.e., significant or non-significant) are established. For significant conditions adverse to quality, the root and contributing causes are determined, the extent of condition and cause are evaluated, and preventive actions are taken to preclude recurrence.

(4) Corrective action is documented and initiated following the determination of a condition adverse to quality to address the issue. The QA organization is involved, where appropriate and required by code or license, in the documented concurrence of the adequacy of the corrective action. Reports of conditions that are adverse to quality are analyzed to identify adverse trends in quality performance. These conditions and trends that are adverse to quality are reported to the appropriate level of management.

(5) Follow-up action is taken by the QA organization to verify proper implementation of the corrective action and to close out the corrective action in a timeframe consistent with the safety or security significance of the issue. Specific responsibilities within the CAP may be delegated, but the licensee maintains the responsibility of the program's effectiveness.

Section 5 **Review Procedures**

For each area of review specified in Section 3, the review procedure is identified below. These review procedures are based on the identified acceptance criteria in Section 4. For deviations from these specific acceptance criteria, the staff should review the licensee's evaluation of how the proposed alternatives to the acceptance criteria provide an acceptable method to determine that the CAP is acceptable.

Section 5.1 *Policies, Programs, and Procedures*

The reviewer should confirm that the licensee describes the CAP expectations, requirements, and implementation processes in policies, programs, and/or procedures that apply to and are implemented across the licensees' organization and licensed operations.

Section 5.2 *Identification, Reporting, and Documentation of Safety and Security Issues*

The reviewer should verify that in the CAP description requires that the licensee staff, supervisors, and managers promptly report safety and security issues in a manner that supports the timely and effective assessment of the issues. The reviewer should also verify that the licensee provides adequate training to employees on the CAP responsibilities. CAP related information is appropriately documented and retained for reference to support the communication, tracking, and trending of information as well as reporting to the NRC.

Section 5.3 *Significance Assessment and Causal Evaluation of Safety and Security Issues*

The reviewer should evaluate whether the licensees' assessment of the actual and potential significance of issues enables it to appropriately apply its graded risk approach, based on the issue's significance, to the timing and scope of response to the issues, including the depth and detail of the causal evaluation. For significant conditions adverse to quality, the licensees' application of its causal evaluation process routinely enables it to adequately identify the issue's cause and the contributing factors.

Section 5.4 *Development and Implementation of Corrective Actions*

The reviewer should verify that the licensees' identification and implementation of corrective actions is appropriately prioritized and timely and routinely effective in preventing the recurrence of the same issue or the occurrence of similar significant conditions adverse to quality. For significant conditions adverse to quality, the licensee evaluates the extent to which other items and activities, including work in process, may be affected so that appropriate action can be taken.

Section 5.5 *Assessment of Corrective Action and Program Effectiveness*

The reviewer should verify that the licensees' implementation of its CAP results in the identification and implementation of effective corrective actions and the recognition and resolution of ineffective corrective actions. The licensee implements a CAP assessment process that enables it to identify and correct CAP performance issues that reduce CAP 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.

Section 6 **Evaluation Findings**

The staff's evaluation should verify that the license application provides sufficient information to satisfy the acceptance criteria in Section 4. On the basis of this information, the staff should conclude that the licensee's CAP is acceptable. The reviewer should write a suitable safety evaluation report (SER). The SER should include a summary statement of what was evaluated and the basis for the reviewer's conclusions.

Section 7 **Examples**

Conditions adverse to quality include failures, malfunctions, deficiencies, defective items, out-of-control processes, and nonconformances.

Criteria for assessing the significance of conditions adverse to quality include the following:

- impact on health and safety of workers, the public and environment;
- impact on reliability, availability, or maintainability of the equipment of facility;
- importance in meeting regulatory requirements;
- consequence of recurrence; and
- the extent to which the adverse condition may apply to other items or activities beyond the specific occurrence where it may have greater impact.

Significant conditions adverse to quality include the following:

- trend of multiple conditions adverse to quality;
- 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 after it has been released for use;
- loss of essential data; and
- repeated failure to implement a portion of an approved procedure.

Section 8 **References**

American National Standards Institute/American Society of Mechanical Engineers Standard, "Quality Assurance Requirements for Nuclear Facility Application," ANSI/ASME NQA-1-2008.

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 70, "Domestic Licensing of Special Nuclear Material."

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 50, "Domestic Licensing of Production and Utilization Facilities."

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 40, "Domestic Licensing of Source Material."

U.S. Code of Federal Regulations, Chapter I, Title 10, "Energy," Part 21, "Reporting of Defects and Noncompliance."

U.S. Nuclear Regulatory Commission, "Management Measures," Chapter 11 NUREG-1520 Revision 1, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility," May 2010. Agencywide Documents Access and Management System (ADAMS) Accession No. ML101390110.

U.S. Nuclear Regulatory Commission, "Suggested Guidance Relating to Development and Implementation of Corrective Action," Information Notice 96-28, May 1996. ADAMS Accession No. ML003726705.

U.S. Nuclear Regulatory Commission, "Quality Assurance During the Design and Construction Phases," Section 17.1 Revision 2 NUREG-0800, "Standard Review Plan for the Review of

Safety Analysis Reports for Nuclear Power Plants: LWR Edition," July 1981. ADAMS Accession No. ML052350349.

U.S. Nuclear Regulatory Commission, "Quality Assurance During the Operations Phase," Section 17.2 Revision 2 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," July 1981. ADAMS Accession No. ML052350361.

U.S. Nuclear Regulatory Commission, "Quality Assurance Program Description," Section 17.3 Revision 0 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," August 1990. ADAMS Accession No. ML052350376

U.S. Nuclear Regulatory Commission, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," Section 17.5 Initial Issuance NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition," March 2007. ADAMS Accession No. ML063190019.