
INSPECTION PROCEDURE 88161

CORRECTIVE ACTION PROGRAM (CAP) IMPLEMENTATION AT FUEL CYCLE FACILITIES

PROGRAM APPLICABILITY: 2600

88161-01 INSPECTION OBJECTIVES

The purpose of this Inspection Procedure (IP) is to (1) verify that the licensee's Corrective Action Program (CAP) is consistent with licensee commitments and regulatory documents and (2) verify that the implementation of the program is effective. The initial program and implementation inspection will be performed after the licensee has committed to implement a CAP per Regulatory Guide (RG) 3.75 or an equivalent license amendment request and has requested an NRC inspection in writing. Each section of this procedure identifies inspection attributes for the verification of CAP effectiveness, including attributes for assessment of (1) CAP implementing documents and processes and (2) effectiveness of implementation of the CAP.

In the event that the inspection determines that the licensee is identifying and correcting problems in accordance with the RG 3.75, as verified through implementation of this IP, the inspector will conclude that the licensee's CAP was 'effective.' As a result of this determination, NRC will provide publically-available notification to the licensee that future Severity Level IV violations will typically be dispositioned as non-cited violations per Section 2.3.2a of the NRC Enforcement Policy.

Once the licensee's CAP has been determined to be effective, this inspection procedure will be performed on a biennial basis.

For licensees that have not committed to the RG 3.75 guidance or an equivalent license amendment, the inspection procedure may be used as a reference for reactive or regional initiative inspections on an as-needed basis.

Since various aspects of the licensee's CAP may have been reviewed during core inspection activities, inspectors should review facility inspection reports for the last two years to determine if credit is appropriate for any of the inspection requirements in this procedure.

88161-02 INSPECTION REQUIREMENTS AND GUIDANCE

General Guidance

When selecting a sample of CAP items (i.e., condition reports) for review, choose reports that address issues involving conditions adverse to nuclear safety and security, such as:

- issues associated with Items Relied on for Safety (IROFS) or management measures documented in the licensee's Integrated Safety Analysis (ISA),
- inadequacies in emergency preparedness and fire protection programs,
- cited or non-cited violations of regulatory requirements,
- repeat system, component, or program failures,
- issues identified through operating experience, and/ or
- weaknesses or problems identified in licensee audits and assessments.

Selection of CAP items for evaluation during this inspection should be based on the safety or security significance of the issue, actual or potential impact on related activities, and past performance. Review of audit, surveillance, and trend reports should encompass a sample of items over the inspection period. If, during the inspection period, the licensee conducted any self-initiated assessments of the Safety Conscious Work Environment (SCWE), or of the safety culture that included an assessment of the environment for raising concerns and CAP, this assessment should be selected for review. Special focus should be given to condition reports, trends, and audit/surveillance findings in which the issue impacts an IROFS.

When reviewing licensee policies and procedures, inspection activities should verify that program documents are adequately detailed to enable effective implementation and are internally consistent.

02.01 Organization.

a. Inspection Requirements

1. Verify that the licensee has a CAP organization that includes an Independent Reviewing Organization (IRO) that is auditable and independent of the licensee's production organization.
2. Verify that the IRO is provided appropriate authority, access to work areas and organizational independence to effectively perform its responsibilities.

b. Inspection Guidance

1. Verify that the licensee has developed and implemented a CAP organization, including the identification of positions, responsibilities, and organizational interfaces. Determine whether an IRO is established with the authority, access to work areas and organizational independence required to effectively perform its responsibilities. 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 the CAP documents and ensures that the organization and/or individuals are appropriately trained and sufficiently independent. If the designated IRO has concurrent duties, verify that the

licensee has described how possible conflicts of interest will be addressed. If the licensee has chosen to have a consultant perform the independent review duties, verify that the licensee retains overall responsibility for the CAP.

2. Determine if the IRO has sufficient authority, access to work areas and organizational independence to conduct its duties. Conduct interviews with members of the IRO to assess their independence and ensure they are able to act independent of production concerns and without pressure or fear of retaliation.

02.02 Policies, Programs, and Procedures.

a. Inspection Requirements.

1. Verify that the licensee-established CAP policies and procedures include definitions of key terms, CAP expectations, CAP requirements, personnel responsibilities and implementation processes. Ensure the policies and procedures provide sufficient guidance to ensure the licensee's implementation of the requirements of Sections 02.01-02.06 of this procedure and that they are maintained up to date.
2. Verify that policies and procedures describe the management of sensitive information if that information will be managed outside the CAP database.
3. Verify that the IRO reviews and documents concurrence with new and revised CAP policies and procedures.
4. Verify that the delegation of CAP responsibilities is documented.
5. Verify that periodic audits and assessments are performed to evaluate the effectiveness of the licensee's CAP. Ensure that the licensee retains responsibility for CAP effectiveness.

b. Inspection Guidance.

1. Determine whether the CAP policies, programs and procedures are in accordance with commitments made in the facility's license and delineated in Sections 02.01-02.06 of this procedure. Verify that licensee procedures are updated as necessary to be consistent with licensee processes, structure, and functions. Determine if policies and program documents pertaining to the CAP provide implementation of program responsibilities, requirements and expectations. Verify that the licensee's CAP policies and procedures require all personnel to promptly identify, document and report conditions adverse to safety or security.

Verify that key terms are defined and at a minimum include conditions adverse to safety or security and significant conditions adverse to safety or security (The

licensee may use equivalent terminology.) Verify that criteria are established for classifying the significance of conditions adverse to safety or security.

- (a) “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.
 - (b) Conditions adverse to safety and security include failures, malfunctions, deficiencies, deviations, defective items, regulatory noncompliances, and nonconformances (a nonconformance is a deficiency in characteristic, documentation, or procedure that renders the safety and security attributes of an item or activity unacceptable or indeterminate).
 - (c) Significant conditions adverse to safety and security are conditions that, if left uncorrected, could have a serious effect on safety or security.
2. If the licensee chooses to manage sensitive or classified information (e.g., information associated with employee concerns; proprietary information or trade secrets; confidential, secret, or top secret information, etc.) in a database or system that is separate from the primary CAP database or information management system, determine if the licensee has established sufficient controls to ensure that the issue is tracked, trended, and corrected. This may entail the generation of a non-sensitive (usually numbered) placeholder in the CAP while the sensitive and/or classified information is housed separately.
 3. Review the activities associated with all new and revised CAP policies and procedures implemented since the last performance of this inspection procedure. Verify that the IRO reviewed and documented approval for all new or revised CAP policies and procedures.
 4. Determine if any specific CAP responsibilities have been delegated to non-licensee personnel, organizations, or contractors. If any delegations have been made, then verify that the delegation authority is documented in writing or electronically and that the delegated entity is sufficiently qualified to perform the delegated functions.
 5. Verify that periodic audits and assessments are performed routinely and that such evaluations address all elements of the CAP, including the level of detail of CAP documentation and the adequacy of corrective action effectiveness and follow-up. Verify that the licensee is retaining full responsibility for CAP effectiveness. This entails ensuring that the licensee has not delegated programmatic responsibility and ownership of the CAP to an outside organization or contractor.

02.03 Identification, Reporting, and Documentation of Safety and Security Issues.

a. Inspection Requirements.

1. Verify that employees are trained on how to identify and enter items in the CAP.
2. Verify that licensee employees are comfortable with the avenues available to raise safety concerns. Determine if individuals and organizations establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations.
3. Verify conditions adverse to safety or security are entered into the CAP.

b. Inspection Guidance.

1. Verify that CAP training for all employees has provided the knowledge and ability to enter items into the CAP. Appendix A provides further detail on assessment of employee knowledge and use of the CAP.
2. Determine if a SCWE is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination. Inspectors should review the allegations for the past performance review period to date and determine if there is evidence of a chilled work environment/safety culture concern. Appendix A provides further detail on assessment of SCWE attributes and follow-up actions to take in the event that inspectors become aware of a negative SCWE.¹
3. Verify that conditions adverse to safety and security, as they occur throughout the facility, are promptly identified and documented.
 - (a) Select a sample of condition reports and confirm effective implementation of the program. Verify that the licensee has implemented its process for identifying conditions adverse to safety and that conditions identified include those delineated in 02.02.b.2.(b) above. Verify that the licensee documents, and reports conditions adverse to safety and security to appropriate levels of management responsible for the conditions and to the organization responsible for tracking and that such actions were taken in a timely manner.
 - (b) Select a sample of documented CAP items (i.e. condition reports or equivalent) for conditions adverse to safety and security and verify that the

¹ Safety Conscious Work Environment (SCWE) is linked to 10 CFR 70.7, "Employee Protection," and overall CAP effectiveness. As such, it is included as an inspection element in this procedure. Because SCWE is not a direct regulatory requirement or part of the license commitment to follow RG 3.75, observations and conclusions associated with SCWE will be documented as appropriate in inspection reports but will not be cited as violations.

conditions are adequately described in the condition reports and issues are categorized based on significance. Verify that the condition reports provide enough detail regarding the condition, its assessment, and corrective actions/closure to facilitate trending and appropriate follow up.

Review licensee documentation of adverse conditions (including condition reports, failed IROFS reports, criticality incident logs, radiation protection logs, safeguards/security logs, and other tracking databases) and determine if measures were implemented to ensure that conditions adverse to safety and security were promptly identified and reported. Determine if the issues are categorized, as a minimum, by significance. Determine if a review to determine compliance with reportability requirements was conducted. Verify that the documentation for closure of the adverse condition was generated and was completed, signed off, and properly filed and logged into a system to allow for retrieval.

- (c) Inspectors should also utilize alternate means to determine if issues or events occurred that were not entered into the CAP, as required by the licensee's procedures. This can be done by performing interviews, reviewing plant logs, attending work planning or plan of the day meetings. If an inspector identifies examples, the inspector should determine if there is any significance for not documenting the issue in CAP, if corrective actions were taken, and if there are any additional consequences to the issue, such as reportability, not meeting performance requirements, etc.

02.04 Significance Assessment and Causal Evaluation of Safety and Security Issues.

a. Inspection Requirements.

1. Verify that the licensee has applied its classification criteria and appropriately classified the significance of conditions that have been entered in the CAP.
2. Verify that for significant conditions adverse to nuclear safety or security, the licensee determines the root cause, evaluates the extent of condition, and takes actions to prevent recurrence.

b. Inspection Guidance.

1. Verify that criteria for determining the significance of conditions adverse to safety or security were implemented.
 - (a) Select a sample of condition reports and verify that the issue significance is categorized using a graded risk approach. This sample should include conditions of higher risk. For example, select conditions that, if left uncorrected, would have the potential for serious negative impact on NRC-regulated activities or protection of public health and safety.

- (b) Select a small sample of condition reports identified by the licensee to be in the low risk or safety significance category to determine if any of the condition reports may have been incorrectly categorized. If examples are identified, determine the significance for not categorizing the issue correctly. Determine if corrective actions taken were commensurate to the actual safety significance and if there were any additional consequences to the issue, such as reportability or not meeting performance requirements.
2. Verify that the licensee determined the root cause for significant conditions adverse to nuclear safety and security. Determine if the licensee implemented procedural requirements for determining root causes for these issues, which may include approved methodology, analysis structure, qualifications, team structure, approval process, and/or completion timeliness requirements.
- (a) Verify that the causes identified for significant conditions adverse to safety and security are reasonable and appropriate for the event. Gain a level of understanding of the issue, including the sequence of events that led up to the issue, immediate and possible long-term effects, and overall consequences of the event through interviews, documentation review, and/or plant walk-down of the area where the event occurred. Discuss the issue with the NRC resident, Project Inspector or Branch Chief, if necessary.
 - (b) Determine if the licensee performed a generic implications review for the root causes. This review should include extent of condition and extent of cause. Consider if the licensee's reviews adequately evaluated the possibilities that this same condition or same cause currently exists in other IROFS, components, systems, program, people, etc. and if so, has the licensee taken or created corrective actions to address this.
 - (c) Verify that the corrective actions to prevent recurrence address the licensee's identified root cause.
 - (d) Determine if the corrective actions to prevent recurrence were timely and achievable by the licensee in the timeframe needed.
 - (e) Verify for significant conditions adverse to safety and security, that the licensee has also performed an effectiveness review to validate that the actions they created and implemented address the root cause and have been successful in preventing recurrence.

02.05 Development and Implementation of Corrective Actions.

- a. Inspection Requirements.

1. Verify that the licensee is promptly initiating corrective actions following the identification of conditions adverse to safety or security.
 2. Verify that the IRO performs appropriate verifications of corrective actions to ensure CAP effectiveness.
 3. Verify that the licensee uses a graded approach to verify implementation and close out of corrective actions in a time frame consistent with the safety or security significance of the identified issue.
 4. Verify that the licensee reports trends and adverse conditions to the appropriate level of management.
- b. Inspection Guidance.
1. Determine if corrective actions were developed, reviewed, and approved for conditions adverse to safety and security.
 - (a) Verify that corrective actions are implemented commensurate with the significance of conditions. Select several conditions that were resolved and verify that proper implementation of corrective actions and closures were completed in a timely manner.
 - (b) Verify that the licensee had determined the extent of the adverse condition and completed remedial action as soon as practical.
 - (c) Verify that significant conditions adverse to safety and security were evaluated for the impact of the condition on other work in progress and that appropriate actions were taken, including stopping work if needed.
 2. Verify by review of condition reports that the IRO is appropriately involved in review of corrective action determination and implementation.
 - (a) IRO reviews the corrective actions for significant conditions adverse to safety or security.
 - (b) IRO takes follow-up actions as appropriate to verify the proper implementation of corrective actions.
 3. Verify that corrective action implementation and follow-up is effective.
 - (a) Verify that the corrective actions taken for conditions adverse to safety and security adequately address the causes and were performed by qualified personnel using approved methods. For significant conditions adverse to safety and security, verify that corrective actions for root causes have been taken and are effective at addressing the root cause(s) and precluding recurrence of the condition.

- (b) Verify that corrective actions are implemented and closed out in a timely manner consistent with the significance of the conditions.
 - (c) Determine if corrective actions have been effective at preventing recurrence of significant conditions adverse to safety and security.
4. Verify that conditions adverse to safety and security are reported to the appropriate levels of management responsible for the reported conditions and to the responsible organization for tracking.

02.06 Assessment of Corrective Action and Program Effectiveness.

a. Inspection Requirements.

- 1. Verify that the licensee is evaluating the effectiveness of the CAP at specified intervals.
- 2. Verify that the licensee is analyzing condition reports for conditions adverse to safety or security to identify adverse trends in performance.

b. Inspection Guidance.

- 1. Review audits or self-assessments conducted on the corrective action program.
 - (a) Verify that the licensee evaluated if the corrective action program was effective in identification, reporting, assessment of condition significance, and correction of conditions. Verify that the licensee evaluated the effectiveness of corrective actions in preventing the recurrence of the same or similar issues.
 - (b) Determine if the organization's ability to identify and correct program performance issues which reduce program effectiveness was evaluated.
 - (c) Verify that the licensee reports to management the results of reviews conducted on audit reports, internal surveillance reports, or management assessments and initiates corrective actions as necessary.
 - (d) Determine if the licensee verifies completion of the corrective action and ensures timeliness of corrective action verification is commensurate with the safety or security significance of the identified issue.
 - (e) Compare and contrast the problems identified and corrective actions being taken as a result of these audits and self-assessments with the results of this inspection.
- 2. Verify that criteria for identifying and tracking adverse trends are implemented. Verify that CAP data is periodically analyzed by the independent reviewing

organization to identify trends. Verify that trend evaluations are performed in a manner and at a frequency that provides for prompt identification of adverse trends. Verify that trend evaluations are distributed to affected organization management. Verify that identified adverse trends are reported to the management of the organization responsible for corrective action.

88161-03 RESOURCE ESTIMATE

The resource estimate to perform this inspection procedure is estimated to be 90 hours for the initial and subsequent biennial inspections.

88161-04 REFERENCES

- 04.01 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."
- 04.02 DRAFT REGULATORY GUIDE DG-3.044, Corrective Action Programs for Fuel Cycle Facilities.
- 04.03 NUREG-1520, "Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility."
- 04.04 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."
- 04.05 61 Federal Register 24336. Freedom of Employees in the Nuclear Industry To Raise Safety Concerns Without Fear of Retaliation; Policy Statement. May 14, 1996.
- 04.06 NRC Regulatory Issue Summary 2005-18. Guidance for Establishing and Maintaining a Safety Conscious Work Environment. August 25, 2006.
- 04.07 76 Federal Register 34773. Final Safety Culture Policy Statement. June 14, 2011.
- 04.08 NUREG/BR-0500. Safety Culture Policy Statement. Revision 1. December 2012.

88161-05 PROCEDURE COMPLETION

Implementation of each applicable inspection requirement will constitute completion of this procedure. Individual inspection samples and breadth of review will be determined by the inspector based on requirement compliance, risk- significance of activity, and extent of the activity or records available.

END

APPENDIX A

GUIDANCE FOR GATHERING INFORMATION ON EMPLOYEE USE OF THE CAP AND OTHER AVENUES TO RAISE SAFETY AND SECURITY CONCERNS

The following are questions that may be used when discussing issues with licensee individuals or during plant tours. It is not intended that these questions be asked verbatim, but rather, that they form the basis for gathering insights regarding whether the work environment is such that employees are comfortable with raising safety and security concerns. When performing interviews, inspectors should select a sample of employees that represents a cross-section of the licensee staff (i.e., skilled tradespersons, engineers, managers, etc.).

Interview Questions

Employee Knowledge and Use of the CAP:

1. Tell me about the CAP at [facility].
2. Can you describe the training you have had on the CAP?
3. How would you enter an item in the CAP? Are there other ways to enter an issue into the CAP (i.e., electronic, paper, anonymous, etc.)?
4. Have you ever entered an item into the CAP?
 - a. If so, how was the issue resolved? Were you made aware of the status, reason for issue disposition, etc.?
5. Are there alternative means you could use to address issues found, other than the official CAP?
6. Can anyone at the site (contractor, security officer, etc.) enter an issue into the CAP? When someone enters an issue into the CAP, does the entry have to be approved by a supervisor? (If yes, does this affect what gets put in the CAP?)

Safety Conscious Work Environment:

Verify that the licensee meets the Statement of Policy regarding Safety Conscious Work Environment as described in 61 Federal Register 24336. If inspectors become aware of a negative SCWE, the inspectors should consult with management and Enforcement and Incident Coordination Staff (EICS) to determine whether an adjustment to the approved inspection plan or other actions are warranted. Follow-up actions may consider additional guidance in IP 93100, "Safety Conscious Work Environment Issue Follow-up."

1. Are you willing to raise a safety concern? Are there any conditions under which you would be hesitant to raise a safety concern?

- a. Have there been any issues recently (2 years) that would affect your willingness to raise safety issues? Your confidence in the corrective action program?
 - b. Are you aware of any situations where any employee or contractor may have been hesitant to raise concerns? If so, could you tell me about them?
2. Where would you go to raise a safety issue? [The NRC inspector should be aware of the following avenues for raising concerns, but should not prompt the interviewee by listing them as potential answers to the question: supervisor, corrective action program, alternative program (Employee Concerns Program (ECP)/Ombudsman), NRC, or other avenue.]
 - a. Why would you pick this avenue? Have you or others had any experiences, or know of any situations, that have influenced your decision to pick this avenue? If so, please describe.
 - b. Are there other avenues available to you for raising safety issues (i.e., supervisor, corrective action program, ECP/ombudsman, NRC, or other avenues)? Ask each of the questions listed below for each avenue available.
 - i. Do you think it's worth taking time to place problems found into the CAP process?
 - ii. Have you ever submitted a safety issue to {insert method}? If not, why not?
 - iii. If yes, was the issue adequately addressed? Why or why not?
 - iv. If not adequately addressed, did you further pursue the issue? If not, why not?
 - v. Given the nuclear safety importance of the issue, did you receive timely feedback?
3. In your opinion, if employees don't receive a response that they are happy with, are they able to escalate their concern to a higher level of management? Is this encouraged by management?
4. What happens when a safety concern is raised that affects the schedule and thus the production goal is not met?
5. Are you aware of any actions taken by your management to prevent and detect retaliation and/or a chilling effect?
6. Are you aware of any instance in which someone on site has experienced a negative reaction from a supervisor or manager for raising a safety issue?

Revision History for IP 88161

CORRECTIVE ACTION PROGRAM (CAP)
IMPLEMENTATION AT FUEL CYCLE FACILITIES

| Commitment Tracking Number | Accession Number Issue Date Change Notice | Description of Change | Description of Training Required and Completion Date | Comment and Feedback Resolution Accession Number |
|----------------------------|---|---|--|---|
| N/A | ML14178A494 07/28/14 CN14-017 | Initial issue of new Inspection Procedure | N/A | ML14178A491 |