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NRC INSPECTION MANUAL

FCSS

MANUAL CHAPTER: XXXX

USING A PART 70 LICENSEE
INTEGRATED SAFETY ANALYSIS
TO ASSESS THE RISK OF A NON-COMPLIANCE

Enclosure 2

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Assessing Risk of Non-Compliances Under 10 CFR 70 Subpart H

IDENTIFY NON-COMPLIANCE

Consequence

Upset Condition

Control/IROFS Failure

LICENSEE ISA

Apply Available Control to Accident Sequence

Determine **CONSEQUENCE**

Assess Available **CONTROLS**

AVAILABLE CONTROLS

Remaining Credited IROFS

Applicable Uncredited IROFS

Other Applicable Controls Meeting Implementation Standard

LIKELIHOOD

Assess Likelihood of the affected Accident Sequence

with the failed IROFS

in the as-found condition

RISK METRICS

Magnitude - increase in level of risk attained

Duration - consider if failure not self-revealing

Defense-in-Depth - consider for multiple, overlapping controls

SEVERITY LEVEL

SL I - high consequence result

SLII - high consequence sequence "not unlikely"
- intermediate consequence result

SLIII - high consequence sequence "unlikely"
- intermediate consequence sequence "not unlikely"

SLIV - other failure to meet 70.61

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XXXX-01 PURPOSE

This manual chapter (MC) provides guidance on determining, for application to the NRC enforcement process, the change to the risk of an accident sequence due to a non-compliance. Specifically, this MC details an approach to analyze an upset condition or control failure using the licensee's Integrated Safety Analysis (ISA) methodology to establish the increased level of risk resulting from the non-compliance, for a specific accident scenario, based on the availability of IROFS.

XXXX-02 OBJECTIVES

NRC has determined that staff will use risk information to evaluate non-compliances at fuel cycle facilities based on the risk to a facility at the time of the non-compliance. At facilities with approved ISAs, the facility risk at the time of the non-compliance(s) will be the primary factor in determining the Severity Level of any violation(s). This risk-informed approach consists of determining whether a violation occurred that was within the responsibility and control of the licensee and then making an enforcement decision based on what the facility risk was at the time of the violation.

XXXX-03 APPLICABILITY

This process is applicable to Part 70 licensees with an approved ISA when a potential non-compliance with 10 CFR 70.61 is observed that was within a licensee's responsibility and control. The process requires adherence to the licensee ISA methodology. This approach is not intended to modify NRC's emphasis on compliance with requirements.

Enforcement decisions will be based on Items Relied on for Safety (IROFS) that were credited at the time of the non-compliance. Some credit may be given for non-IROFS that affect the non-compliance. Prior to the loss of an IROFS, a licensee must have documented that those non-IROFS existed to operate the plant or to meet regulatory requirements, and established appropriate measures on the non-IROFS to prevent or mitigate the accident sequence affected by the lost IROFS. If a licensee develops the documentation after the loss of an IROFS, then NRC will not give licensees credit for the non-IROFS. The failure of an IROFS would not normally constitute a violation, if the failure occurred within the reliability defined for the IROFS even if the consequence occurred.

XXXX-04 DEFINITIONS

04.01 Integrated Safety Analysis (ISA)

An ISA is a systematic analysis to identify potential accident sequences at a facility that could exceed the performance requirements in 10 CFR 70.61(b) or (c) and to identify IROFS that prevent or mitigate the consequence of the accident sequence.

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04.02 Items Relied On For Safety (IROFS)

IROFS are structures, systems, equipment, components, and activities of personnel that are relied on to prevent or mitigate the consequences of potential accidents and are specifically credited in a licensee ISA to demonstrate meeting the performance requirements of 10 CFR 70.61.

04.03 Likelihood

The term "not unlikely" means that the likelihood is more than "unlikely." The terms "highly unlikely" and "unlikely" are defined by individual fuel cycle licensees in their ISA methodologies.

04.04 Performance Requirements

10 CFR 70.61(b) requires that the likelihood of occurrence of a credible high-consequence event be limited to highly unlikely, 10 CFR 70.61(c) requires that the likelihood of occurrence of a credible intermediate-consequence event be limited to unlikely and 10 CFR 70.61(d) requires that all nuclear processes be subcritical under normal and credible abnormal conditions. High- and intermediate-consequence events are defined in 10 CFR 70.61 which requires that the risk of credible high- and intermediate-consequence events be limited by engineered controls, administrative controls, or both, to reduce the likelihood of occurrence or mitigate the consequences.

04.05 Uncredited Controls

Uncredited controls are considered non-IROFS unless they are specifically credited by the licensee in the ISA as IROFS for the accident sequence in question. An IROFS credited for a different accident sequence may be credited to the given accident sequence, for enforcement consideration only (as opposed to reportability consideration), if that IROFS is sufficiently reliable and is implemented adequately through appropriate management measures for that given accident sequence. Other controls may be credited to the given accident sequence, for enforcement consideration only, using the same criteria.

XXXX-05 BACKGROUND

NRC revised 10 CFR Part 70 to implement a new regulatory approach for fuel cycle facilities, based on facility-specific ISAs. The revised regulation requires fuel cycle licensees to develop an ISA, based on a licensee-devised methodology. A licensee ISA is required to identify accident sequences resulting in specified consequences, and to provide assurance that IROFS are in place to control risk within specified performance requirements. Fuel cycle licensees are then required to submit ISA Summaries for NRC approval. This MC provides a flexible risk-based approach to assess risk of non-compliances at licensees with an approved licensee ISA. This MC also provides specific examples demonstrating use of an approved licensee ISA methodology to

evaluate risk resulting from an upset condition or control failure.

The requirements to conduct and maintain an ISA are in parts of §70.62(c) and (d), which require an ISA to identify: (a) potential accident sequences; (b) the consequence and likelihood of occurrence for each potential accident sequence; (c) each item relied on for safety (IROFS); and (d) the management measures, for each IROFS, necessary to demonstrate that the performance requirements of §70.61 are being met.

The performance requirements include that a high-consequence sequence must be highly unlikely and that an intermediate-consequence sequence must be unlikely. Those consequences are listed in §70.61(b) and (c), while description of the definitions of 'unlikely,' 'highly unlikely,' and 'credible' used in the ISA are in the ISA Summary which is prepared by the licensee in accordance with §70.65(c). The term 'not unlikely' means that the likelihood is more than 'unlikely.'

XXXX-06 RISK METRICS

This manual chapter describes a method for understanding a change in risk resulting from an upset condition or control failure. If the consequence of an accident sequence is fixed, as with criticality, what is evaluated to characterize the effect on risk is the likelihood component of the risk. If a mitigative control is affected by the upset condition or control failure, the consequence will change. An unanalyzed condition, is an additional non-compliance that may be identified by an upset condition or control failure.

Several quantities affect an understanding of the change in risk of a particular situation.

06.01 Risk Magnitude

An increase in the level of risk (likelihood x consequence) that is attained without regard to the duration of the failure is the magnitude of the incurred additional risk. Comparing the magnitude of the risk with and without the upset condition or control failure is the most straightforward method to evaluate the change in risk. Most decisions related to enforcement based on risk will use the magnitude.

06.02 Duration

Combining the magnitude of the incurred additional risk and duration of the upset condition or control failure (risk x duration) may be necessary in a situation where a relatively lengthy duration occurred or was possible because the upset condition or control failure was not self-revealing. If the licensee has analyzed duration, the duration indices from the ISA may be used. Otherwise, the judgment of the staff will be relied on to determine duration.

06.03 Defense-in-Depth

When an upset condition or control failure affects defense in depth but not the IROFS

supporting the determination of meeting performance requirements, a qualitative decision may be made regarding the affect on risk. This approach would only be used when multiple, overlapping controls are in place that the licensee wishes to credit in an enforcement situation.

XXXX-07 DETERMINING RISK FOR ENFORCEMENT

When a specific non-compliance or consequence has been identified at a fuel cycle facility, staff must initially determine if there is a violation of a requirement. If a violation is identified that is related to 10 CFR 70.61, such as the failure of an IROFS, staff must determine the severity level of the violation. Evaluation of potential non-compliance related to IROFS and other controls is based on the licensee ISA. When the licensee does not comply with 10 CFR 70.61, i.e. a non-compliance has been identified relative to an accident sequence because of a failed IROFS or other issue including the absence of an accident sequence, the following method will be used to compare the risk significance:

07.01 Identify the Non-Compliance

The enforcement process is initiated when a non-compliance is identified by the NRC as the result of an inspection, an allegation, an event or by some other means. A non-compliance means that there was a specific, written requirement that was not met. The occurrence of a consequence can usually be linked to a non-compliance but the consequence is not normally the non-compliance. Staff should have a clear idea of the non-compliance before proceeding with this analysis.

07.02 Identify the Accident Sequence or Sequences

Determine from the licensee ISA, the accident sequence or sequences associated with the upset condition or control failure that was identified as a non-compliance.

Determine, from the ISA, the consequence of the accident sequence (high- or intermediate-consequence) and the likelihood of the accident sequence (“highly unlikely” or “unlikely”) before the non-compliance (with all credited controls in place).

07.03 Identify and Score IROFS

Identify all IROFS associated with each accident sequence identified and assign scores to each IROFS based on the licensee ISA methodology. In most cases, the assigned score will be the score shown in the licensee ISA. The score for a degraded or failed IROFS will normally be 0. If a degraded or failed IROFS is not scored 0, staff should assess whether a non-compliance has actually occurred.

If duration of the failure is considered to be an issue in evaluating the effect on risk, the duration will be evaluated in accordance with the licensee ISA methodology.

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07.04 Identify and Score Other Controls

Determine whether IROFS credited for other accident sequences can be credited for protection of the accident sequence in question. Identify any other control affecting the accident sequence, (from those controls not designated IROFS), which can be credited for protection of the accident sequence in question. For controls not designated IROFS, establish that the control is implemented to a level comparable to an IROFS, if not, the control may not be credited to the accident sequence for enforcement.

Score any acceptable controls in this category using the licensee ISA methodology. For controls that are not already scored by the licensee in the approved ISA, staff shall use judgment while being mindful to assure that the analysis corresponds to the licensee methodology.

07.05 Score New Risk Based on the Non-Compliance

If the consequence is fixed by the description of the accident sequence in the ISA, the new level of risk based on the upset condition or control failure can now be determined based on the new likelihood. If mitigative controls are involved, the change in consequence must be determined. Using the IROFS scores developed above, determine the likelihood of the accident sequence occurring during the time of the IROFS failure as either did occur, “not unlikely,” “unlikely,” or “highly unlikely.” Severity level for the non-compliance is based on this likelihood determination.

END

Attachments:

Attachment 1 – Specific Non-compliance Examples
Attachment 2 – Example Non-compliance Evaluation Situations

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Attachment 1: Specific Non-compliance Examples

In most cases, a non-compliance that will be handled as a violation would be cited against a commitment in the license, the license application, or the ISA. Part 70 licensees have different commitments in these documents but all commitments are related to specific regulatory requirements. The following are examples of potential non-compliances with Part 70 requirements that may be analyzed in accordance with this Manual Chapter:

Regulatory Requirement	Possible Non-compliance
§70.61(a)	ISA did not demonstrate compliance with the performance requirements
§70.61(b)	High-consequence result occurred or high-consequence accident sequence was either “not unlikely” or “unlikely” due to degraded or failed IROFS
§70.61(c)	Intermediate-consequence result occurred or intermediate-consequence accident sequence was “not unlikely” due to degraded or failed IROFS
§70.61(d)	Criticality accident occurred, criticality accident sequence used mitigative controls, or criticality safety basis had less than the required margin of subcriticality for safety
§70.61(e)	Engineered or administrative control needed to meet the performance requirements was not designated an IROFS or else the safety program did not ensure that each IROFS will be available and reliable to perform its intended function when needed
§70.62(c)(1) (iv-vi)	ISA did not identify potential accident sequences, consequence and likelihoods of potential accident sequences, and IROFS needed to meet the performance requirements
§70.62(d)	Management measures not established or did not ensure that IROFS were available and reliable to perform their intended function when needed

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Attachment 2: Non-compliance Evaluation Situations

The examples that follow provide guidance on evaluating non-compliance(s) of the requirements in Part 70 and relating the non-compliance(s) to the severity levels described in Supplement IX of the NRC Enforcement Policy. The situations apply to all safety disciplines (e.g., chemical safety, criticality safety, fire safety, radiation protection).

The analysis is based on answers to questions such as the following: (1) did a high- or intermediate-consequence result occur?; (2) were any of the chemical or radiation effects in the performance requirements exceeded?; (3) was a sole IROFS needed to meet the performance requirements lost?; (4) were all or some IROFS needed to meet the performance requirements lost?; (5) were those lost IROFS preventive or mitigative for that accident sequence?; (6) were the expected likelihoods of the IROFS failure exceeded?; (7) were the safety function of all or some of the lost IROFS replaced by appropriate non-IROFS?; and (8) did failure to meet the regulatory requirement impact NRC's confidence in the licensee's ability to operate the facility safely?

Situation #1: **High-Consequence Event Occurs**

1a. NRC determined that a violation of the performance requirements occurred and, under control of the licensee: (i) all IROFS failed; and (ii) a high-consequence result occurred, such that a worker received an acute dose of 1 Sievert (100 rem) or greater total effective dose equivalent.

1b. NRC determined that a violation of the performance requirements occurred and, under control of the licensee: (i) all NCS controls failed; and (ii) an inadvertent criticality occurred.

The occurrence of the high-consequence result leads to the non-compliance being characterized as Severity Level I.

Situation #2: **Change in Likelihood of High-Consequence Accident Sequence**

NRC determined that a violation of the performance requirements occurred and, under control of the licensee: (i) some or all of the IROFS failed; and (ii) a high-consequence sequence is now "not unlikely" rather than "highly unlikely."

The high-consequence sequence being changed to now "not unlikely" is characterized as Severity Level II.

If one or more IROFS does not fail or the licensee is able to demonstrate that some appropriate non-IROFS were in place that replaced some of the lost IROFS at the time of the violations such that the high-consequence accident sequence is now "unlikely," the upset is characterized as Severity Level III.

If one or more IROFS does not fail and the licensee is able to demonstrate that appropriate non-IROFS are in place that replaces all of the lost IROFS at the time of the violations, the upset is characterized as Severity Level IV based on the failure of a designated IROFS.

Practical Application: **Increase in Risk of High-Consequence Accident Sequence**

A licensee has a procedure to address a special nuclear material (SNM) spill using two administrative IROFS. Operators are trained to maintain the two IROFS, such that it is unlikely that operators will not follow the procedure. The following upsets would have to occur: (a) a spill involving more than a favorable volume of SNM; (b) unfavorable geometry/volume containers readily available within the processing area; and (c) operators using the unfavorable geometry/volume containers to collect the spill.

IROFS: (1) Unfavorable geometry open containers are administratively restricted from SNM processing areas.

(2) SNM spills are administratively collected in favorable geometry/volume containers.

Other Controls 1: None.

When all IROFS are lost, the high-consequence sequence is now "not unlikely." Since the licensee was not able to demonstrate that any appropriate non-IROFS were in place that replaced any of the lost IROFS at the time of the violations, the event is characterized as Severity Level II.

Other Controls 2: An administrative/preventive operations control for the lost first IROFS.

When all IROFS are lost, the high-consequence sequence is now "not unlikely." Since the licensee was able to demonstrate that some appropriate non-IROFS were in place that replaced some of the lost IROFS at the time of the violations, the event is characterized as Severity Level III.

Other Controls 3: Two administrative/preventive operations controls, one for each lost IROFS.

When all IROFS are lost, the high-consequence sequence is now "not unlikely." Since the licensee was able to demonstrate that appropriate non-IROFS were in place that replaced all of the lost IROFS at the time of the violations, the event is characterized as Severity Level IV.

Situation #3: **Intermediate-Consequence Event Occurs**

4. NRC determined that a violation of the performance requirements occurred and, under control of the licensee: (i) an IROFS failed; and (ii) an intermediate-consequence result occurred, such that a 24-hour averaged release of radioactive material outside the restricted area was in a concentration exceeding 5000 times the values in Table 2 of Appendix B to 10 CFR Part 20.

The occurrence of the intermediate-consequence result causes the noncompliance to be characterized as Severity Level II.

Situation #4: **Change in Likelihood of Intermediate-Consequence Accident Sequence**

NRC determined that a violation of the performance requirements occurred and, under the control of the licensee: (i) some or all of the IROFS failed; and (ii) an intermediate-consequence accident sequence was now "not unlikely" rather than "highly unlikely."

The intermediate-consequence sequence being now "not unlikely" is characterized as a Severity Level III.

If the licensee is able to demonstrate that some or all appropriate non-IROFS were in place that replaced some of the lost IROFS at the time of the violations, the upset is characterized as Severity Level IV.

Practical Application: **Increase in Risk of Intermediate-Consequence Accident Sequence**

A licensee operation uses a feed purification trap process UF_6 at a uranium enrichment facility. The operation relies on one active-engineered IROFS and one passive-engineered IROFS. The following upsets would have to occur to cause a release: (a) the feed purification carbon trap becomes saturated with UF_6 and forms a plug on feed purification vacuum pump discharge; (b) high pressure causes the flange seal to fail; and (c) UF_6 is released into the Handling Area.

IROFS: (1) Active-engineered automatic trip of vacuum pump with hard-wired, fail-safe on carbon trap high weight to ensure that the carbon trap does not become saturated with UF_6 (i.e., system is functionally tested periodically).
(2) Passive-engineered flow restriction on the suction of the vacuum pump with valve of maximum flow rate (i.e., configuration management).

Controls 1: None.

When all IROFS are lost, the intermediate-consequence sequence is now "not unlikely." Since the licensee was not able to demonstrate that any appropriate non-IROFS were in place that replaced any of the lost IROFS at the time of the violations, the event is

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characterized as Severity Level III.

Controls 2: One of the IROFS does not fail.

When only one IROFS is lost and the intermediate-consequence sequence is "not unlikely," the event is characterized as Severity Level III. When only one IROFS is lost and the intermediate-consequence sequence is "unlikely," the event is characterized as Severity Level IV.

Situation #5: **Inadequate Subcritical Margin**

NRC determined that a violation of the nuclear criticality safety (NCS) requirements occurred and, under control of the licensee, the licensee had less than the margin of subcriticality described in the license application for an accident scenario described in the ISA.

An accident sequence leading to criticality is a high-consequence accident sequence. The Severity Level of a reduced margin of subcriticality is dependent on the magnitude of risk for the affected accident sequence. If a high-consequence sequence is now "not unlikely" rather than "highly unlikely" the upset is characterized as Severity Level II. If a high-consequence sequence is now "unlikely" rather than "highly unlikely" the upset is characterized as Severity Level III. If the accident sequence leading to criticality remains "highly unlikely" but the subcritical margin is not met, the upset is characterized as Severity Level IV.

Situation #6: **Unanalyzed Accident Sequence**

NRC determined that a violation of the performance requirements occurred and the licensee or NRC discovered an unanalyzed a credible high- or intermediate-consequence accident sequence.

The Severity Level of an unanalyzed accident sequence is dependent on the magnitude of risk for the accident sequence. If the accident sequence was high-consequence, then it would be characterized as Severity Level II. If the accident sequence was intermediate-consequence, then it would be characterized as Severity Level III.

ATTACHMENT 3

Revision History for IMC XXXX

Commitment Tracking Number	Issue Date	Description of Change	Training Required	Training Completion Date	Comment Resolution Accession Number
N/A	10/03/08 CN 08-000	Initial issuance to provide direction assessing non-compliance at fuel cycle facilities.	8 hours	N/A	N/A

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