NRC INSPECTION MANUAL

NMSS

MANUAL CHAPTER 2606

ASSESSMENT OF THE CHANGE IN RISK
RESULTING FROM A VIOLATION
AT A FUEL CYCLE FACILITY

Enclosure 2 contains “Proprietary” information. When separated from Enclosure 2, this document becomes decontrolled.

2606-01 PURPOSE

This inspection manual chapter (IMC) provides guidance for determining the change in the risk of an accident sequence at a fuel cycle facility due to a violation. Specifically, this IMC details an approach to analyze an upset condition or control failure using the licensee's safety basis to identify any increase in the level of risk resulting from the violation, based on the availability of controls.

2606-02 OBJECTIVES

This IMC provides the Nuclear Regulatory Commission (NRC) staff with a method to use likelihood information to evaluate violations at fuel cycle facilities based on the change of risk at the facility during the time of the violation. This IMC provides the NRC staff with risk-informed guidance in the disposition of violations regarding the assignment of severity levels established by the NRC Enforcement Policy. The IMC uses a risk-informed analytical process which is intended to resemble ISA methodologies and is not intended to modify NRC's emphasis on compliance with requirements.

2606-03 APPLICABILITY

This IMC provides NRC staff a means to apply risk information to the enforcement process. This IMC is applicable to fuel cycle licensees, licensed under 10 CFR Parts 40, 70, and 76, with or without an accepted ISA, when a potential violation is observed that was within a licensee's responsibility and control. (Note: As the safety and safeguards inspection program is applied to facilities certified under 10 CFR Part 76, "license" shall read as "certificate," and "licensee" shall read as "certificate holder" for such facilities.) The process requires the use of either the licensee ISA methodology or the methodology in Section 2606-05 of the IMC to assess change in risk. The IMC defines and then uses specialized risk terminology in a structured analytical process which is intended to resemble methodologies in ISAs.

Enforcement decisions will be based on controls, including Items Relied on for Safety (IROFS), which were credited at the time of the violation. Credit may be given for other documented controls that affect the risk but were not credited in the safety basis for the specific accident sequences affected. Prior to the loss of a control, a licensee must have documented controls which existed to operate the plant or to meet regulatory requirements. If a licensee develops the documentation after the violation occurs, NRC will not give credit for the other controls. The failure of a control may not constitute a violation, if the failure occurred consistent with the reliability credited for the control in the safety analysis. To receive credit for a control that was not originally credited in the safety basis to the accident sequence, the licensee must have established appropriate measures assuring the availability and reliability of the control.

2606-04 DEFINITIONS

04.01 Accident Sequences.

An accident sequence is a set of events necessary for the occurrence of a specified consequence. Several different series of events, or accident sequences, may lead to the same consequences. Licensees with ISAs have identified credible accident sequences leading to consequences defined in 10 CFR 70 Subpart H. Licensees without ISAs have an accepted

safety basis which can be used by staff to identify the accident sequence associated with the specific violation.

04.02 Integrated Safety Analysis (ISA).

An ISA is a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety. The ISA takes joint consideration of, and protection from, all relevant hazards including radiological, nuclear criticality, fire, and chemical.

04.03 Items Relied On For Safety (IROFS).

IROFS are structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in 70.61 or to mitigate their potential consequences. This does not limit the licensee from identifying additional structures, systems, equipment, components, or activities of personnel as items relied on for safety beyond the minimal set necessary for compliance. Further, licensees may establish valid safety controls to prevent accidents that are not credited in the ISA, nor identified as IROFS, but are established through the licensee's safety management process. These latter controls are referred to in this IMC as "un-credited" controls.

04.04 Likelihood.

The term "likelihood" refers to the anticipated probability or frequency of occurrence of a consequence. Likelihood is evaluated as part of the Integrated Safety Analysis. These ISA evaluations usually are of relatively long-term operations so that the duration of exposure of persons to such likelihood of consequences is for their lifetime. In the significance evaluation in this IMC the durations of exposure of persons to increased frequency of accidental consequences may be much less than a lifetime, and proportionately of less significance. The terms "highly unlikely," "unlikely," and "not unlikely" are defined by individual fuel cycle licensees in the ISA or safety basis for use in evaluating the long-term adequacy of a set of controls preventing an accident. In this IMC, the terms "highly unlikely," "unlikely," and "not unlikely," reference the levels of probability of the consequence incurred because of a violation that are equivalent to these long-term likelihoods evaluated in the ISA

a. Highly Unlikely. A term that means the likelihood of a consequence is less than unlikely.

b. Unlikely. A term that means the likelihood of a consequence is greater than highly unlikely.

c. Not Unlikely. A term that means the likelihood of a consequence is greater than unlikely.

04.05 Management Measures.

The functions performed by the licensee, generally on a continuing basis, that are applied to safety controls, to ensure the items are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, record management, and other quality assurance elements.

04.06 Non-Compliance.

The Inspection Manual defines a Non-compliance as a violation, a deviation, or a non-conformance. Non-conformances apply to vendor requirements, which are not often encountered with fuel cycle facilities.

A violation is defined as a licensee failure to comply with a legally binding commitment, including regulations, rules, orders, license conditions, or a technical specification.

A deviation is defined as a licensee failure to satisfy a written commitment, or to conform to a standard that, although not legally binding, is expected to be implemented.

04.07 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.

04.08 Safety Basis.

Licensee documents which describe, support, or assure the safe operation of the facility with licensed materials. The documents include ISAs, license applications, safety analyses, technical evaluations, calculations and all other supporting documents used to describe facilities processes, procedures, and safety controls.

04.09 Un-credited Controls.

Controls not specifically designated in the ISA or safety basis for the protection of a defined accident sequence. These controls may be used during enforcement consideration in the instance that the controls are sufficiently reliable, applicable to the accident sequence, and are implemented adequately through appropriate management measures. Un-credited controls may include the following:

a. Safety controls at a facility when the licensee does not have an ISA or does not have controls defined in the safety basis.

b. The licensee maintains an ISA, however the safety control was not identified as an IROFS.

c. The safety control was not specifically credited by the licensee in the ISA or safety basis for the accident sequence in question; however the safety control was credited for another accident sequence.

2606-05 IDENTIFYING THE NON-COMPLIANCE

05.01 Identify the Upset Condition or Control Failure.

Evaluate the upset condition or control failure identified by the NRC staff as the result of an inspection, event, or some other means. The upset condition or control failure may also be self-identified by the licensee.

05.02 Determine the Non-Compliance.

The NRC staff shall determine that the upset condition or control failure observed does not meet the intent of the regulatory requirements, license commitments, or regulatory-significant approved procedures. The staff shall determine that the non-compliance occurred within the scope of the license in that it pertains to licensed material, operations with licensed materials, the potential safety of licensed materials, and/ or chemicals produced from licensed material. The staff should determine whether the upset condition that occurred was within the responsibility and control of the licensee. The determination of whether an upset condition is a violation is independent of risk or safety significance. This IMC only provides guidance on assessment for violations at a fuel cycle facility in accordance with the NRC Enforcement Policy.

05.03 Determine Method of Assessment.

The NRC staff shall determine whether the violation is captured in the scope of the NRC Enforcement Policy Section 6.2. If the NRC staff determines that it is within the scope, then Section 2606-06 should be utilized as guidance in assessing the severity level in accordance with the NRC Enforcement Policy. Other forms of non-compliance are covered in Section 2.3.7 of the NRC Enforcement policy and are outside the scope of this IMC.

2606-06 ASSESSING RISK RESULTING FROM VIOLATIONS

This IMC describes a method for assessing the licensee evaluation of the change in risk resulting from an upset condition or control failure and then recommending a severity level for enforcement consideration. The process for assessing the change in risk due to the violation is shown in Figure 1. The NRC staff should use the following method to evaluate the change in risk, usually due to the change of likelihood, caused by a violation at a fuel cycle facility.

06.01 Identify the Accident Sequence or Sequences.

Determine from the licensee ISA or safety basis documentation, the accident sequence or sequences associated with the upset condition or control failure that was identified as a

violation. When the licensee ISA or safety basis documentation does not specifically identify all accident sequences, NRC staff should identify the accident sequences affected by the upset condition or control failure.

In the case that accident sequences were not identified or analyzed in the NRC-accepted ISA and the unanalyzed conditions should have been within the scope of the ISA, the NRC staff should assess if the licensee is in compliance with all regulatory requirements, license commitments, or regulatory-significant approved procedures regardless of risk or safety significance.

06.02 Identify the Consequence.

NRC staff should determine the unmitigated consequence of the accident sequence (high, intermediate, or low consequence) before the violation as identified in the licensee ISA or safety basis documentation. The NRC staff should verify that the consequence did not change during or after the violation.

The NRC staff should note that the consequence of an accident sequence, as defined by 10 CFR 70.61, facility-specific ISAs, or Table 1, should be fixed in most instances. In the event that a change in consequence did occur, the staff should use the actual consequence or new potential consequence in the assessment.

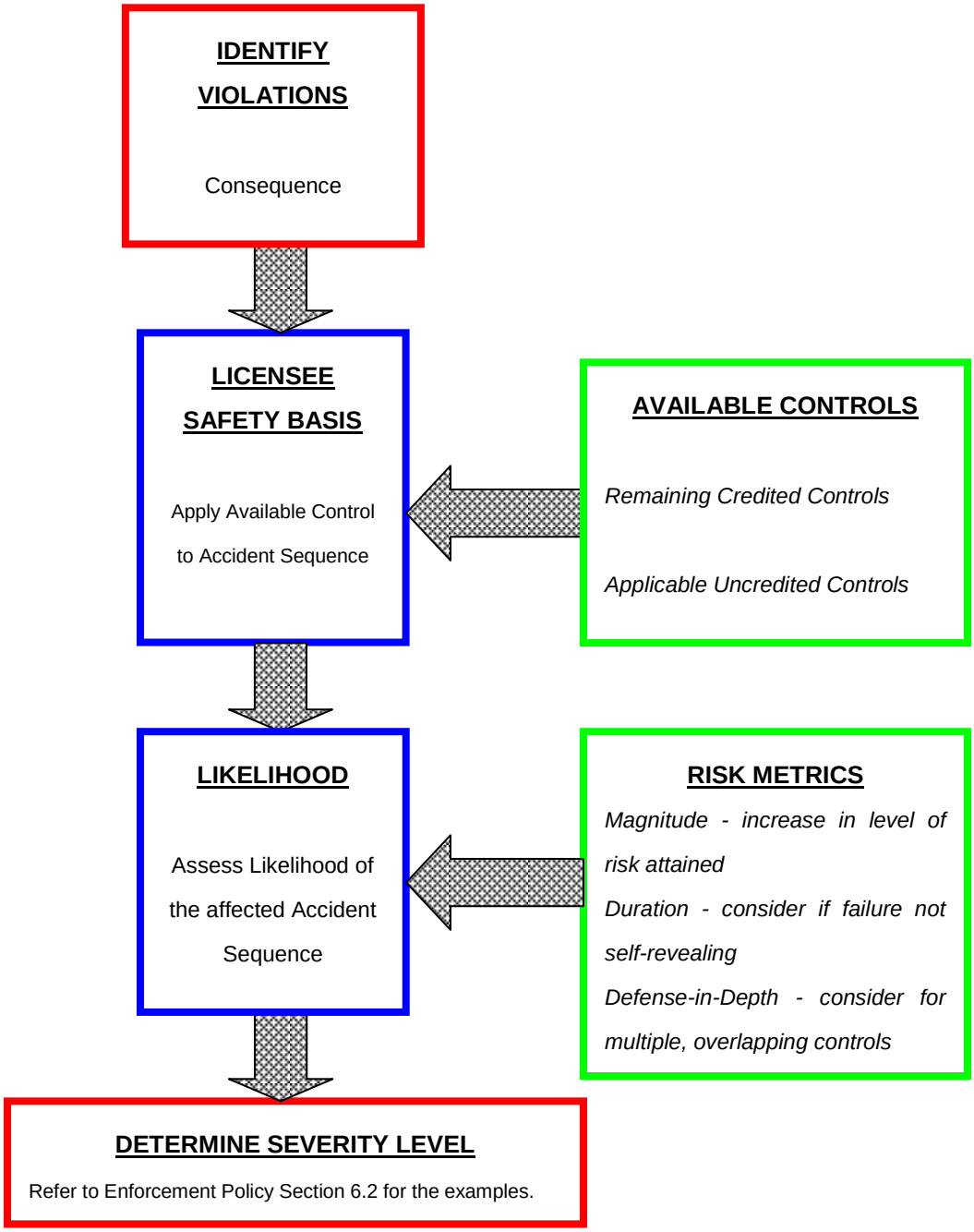
If there was more than one accident sequence impacted, each of the accident sequences should be evaluated. The significance is based upon the set of accident sequences yielding the highest consequence level; and, among these, the accident sequences with the highest evaluated significance should impact the significance of the violation.

In the instance where the consequence has occurred at the licensed facility, the NRC staff should refer directly to the NRC Enforcement Policy for the evaluation of the severity level for an identified violation.

Table 1
Consequence

High	Intermediate	Low
Accidental criticality. An acute radiological dose of 100 rem or greater, or a chemical exposure that could endanger the life of a worker. An acute radiological dose of 25 rem or greater, or a chemical exposure that could lead to irreversible or other serious long-lasting health effects to a person outside the controlled area (public).	An acute radiological dose of 25 rem or greater, or a chemical exposure that could lead to irreversible or other serious long-lasting health effects to a worker. An acute radiological dose of 5 rem or greater, or a chemical exposure that could lead to mild or transient health effects to a member of the public.	A chronic radiological or chemical exposure due to licensed material, or an acute exposure less than intermediate.

Figure 1
Assessing Risk of Violations



06.03 Identify Initial Likelihood.

Determine the likelihood of the accident sequence before the violation (with all credited safety controls in place) as identified and defined in the licensee ISA or safety basis documentation. If there is more than one accident sequence, each of the accident sequences should be evaluated.

In the case that the licensee does not have an ISA or have likelihood defined in the safety basis, then the initial likelihood should be described as highly unlikely, unlikely, or not unlikely using Table 2.

Table 2
Likelihood Matrix

	Highly Unlikely	**Unlikely**	**Not Unlikely**
Based on event likelihood	Less than 10^{-5} per event per year	Between 10^{-4} and 10^{-5} per event per year	More than 10^{-4} per event per year
Based on in-place controls	Two controls, including at least one engineered (2 PECs[1], 2 AECs[2], one ADM[3] plus a PEC)	Two ADM controls, or a single PEC, or an AEC plus an ADM	No controls or lesser controls than for unlikely.

Notes for Table 2:

[1]PEC - passive engineered control
[2]AEC - active engineered control
[3]ADM - administrative control

06.04 Identify and Assess Controls.

Identify all controls associated with each accident sequence identified and assign scores to each control based on the licensee ISA methodology. In most cases, the assigned score will be the score shown in the licensee ISA. The reason for a violation is usually loss of control so 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 violation has actually occurred. If partial credit will be applied to a degraded IROFS, that control should not be the basis for the violation.

In some cases a violation places an instantaneous demand on a control that then prevents the accident. There is then no continuing demand on the control. In such cases, the “duration” of the non-compliant demand is not meaningful. The risk incurred is the probability of failure on demand of the remaining control. If staff determines, that duration impacts the probability of an accident, the effect of that duration on that probability should be addressed. Duration of the failure may be quantified in accordance with the licensee ISA methodology or by simply increasing the likelihood using Table 2 as a reference. Modify likelihood (shift likelihood to the right or left in Table 2), if one of following conditions is met:

a. When the increased likelihood due to a deficiency applies to a very large number of accident sequences (> about 30), shift to right.

b. If the duration of a violation is a factor in the change in probability of an accident, it should be considered proportionately together with the magnitude of the change in frequency. The product is the change in probability of an accident. For example, a high consequence accident for a worker should be highly unlikely for a working lifetime of 50 years. If a violation causes it to have a frequency that would be only "unlikely" if the situation were to have persisted for 50 years, but it actually was only for a few days, then the severity level should be lowered.

c. Duration is clearly a factor and the facility does not have an ISA or duration is not discussed in the ISA, in which case shift one cell to the right in Table 2 if the duration is longer than one year.

Reduce likelihood one order of magnitude (shift likelihood one cell to the left in Table 2), if there was substantial margin such that an extreme or multiple failures would be needed beyond what is reasonable to assume before an accident can occur.

06.05 Identify and Assess Un-credited Controls.

Determine whether un-credited controls should be credited for the accident sequence in question. Determine if a control credited for another accident sequence should also be credited for protection of the accident sequence in question. Credit may be given for other safety controls that affect the risk impact of the violation but were not credited in the ISA or safety basis for the specific accident sequence.

The NRC staff shall evaluate the un-credited controls to determine if the safety control is sufficiently reliable and is implemented adequately through appropriate management measures for the accident sequence in question. The NRC staff shall establish that the control in question is implemented to a level consistent with designated controls. The NRC staff shall verify that the licensee completed the evaluation using the guidance in the facility-specific ISA for the management and assurance measure criteria for passive engineering controls, active engineering controls, or administrative controls. The NRC staff may also compare the safety control to an IROFS or designated control of a similar type. The safety controls (or other facts or features) should be able to prevent or limit consequences of accidents. The safety control should be a formally maintained control and should be reliable. The results of the management and assurance measure affecting the safety control should be documented, if applicable to the type of measure.

If the evaluation of the un-credited controls determines that the controls are acceptable, then the controls may be used in enforcement consideration only. The controls should be credited to the accident sequence in question only. If the un-credited safety control is not implemented to an acceptable level, as determined by the licensee ISA methodology, the control may not be credited to the accident sequence for enforcement.

In the instance that the licensee does not have an ISA or accident sequences in the safety basis, the staff should utilize Table 2 as guidance. Table 2 suggests a relationship between the number and type of controls and respective likelihood. If the number of IROFS and credited controls in the accident sequence falls outside of those presented in Table 2, the NRC staff should collaborate with the risk analyst staff in NMSS and/ or Region II to determine if a full risk assessment should be conducted.

06.06 Determine Effect on Risk Based on the Violation.

The violation has typically caused a change (increase) in risk, that is a change in either the likelihood or consequences of accident sequences. Either way, one of the states of increased risk has happened, as described in Section 6 of the Enforcement Policy. For example, the violation might disable an IROFS for some period of time, making a high consequence sequence now "not unlikely". Using the licensee's ISA methods, or that in Section 06.04 above, determine the new likelihood of the accident sequence as either did occur, "not unlikely," "unlikely," or "highly unlikely." Severity level for a violation is based on the examples in Section 6.2 of the Enforcement Policy.

06.07 Risk Effects at Non-ISA Facilities.

Facilities without ISAs also have enforcement severity levels characterized as a change in risk. The change in risk at a non-ISA facility is based on assessment of the accident sequence associated with the violation in accordance with Table 3:

Table 3
Risk Significance for Disposition of a Violation
for a Licensee Not Regulated under 10 CFR 70 Subpart H

Consequence	Increase in Likelihood	Risk Significance For Enforcement
High	Highly unlikely to not unlikely	A very substantial increase in the likelihood of a consequence
	Highly unlikely to unlikely	A substantial increase in the likelihood of a consequence
Intermediate	Unlikely to not unlikely	A significant increase in the likelihood of a consequence

06.08 Examples of Evaluating Violations.

Examples are provided in Enclosure 1, Evaluating Violation Situations, to help the NRC staff work through the process for assessing the change in risk resulting from a violation at a fuel cycle facility.

06.09 Evaluations Based on Specific Licensee ISAs.

Examples are provided in Enclosure 2, Evaluations Based on Specific Licensee ISAs, to allow NRC staff to understand how assessing the change in risk resulting from a violation at a fuel cycle facility could have been used in the past.

2606-07 REFERENCES

07.01 NRC Enforcement Policy, Section 6.2, “Fuel Cycle Operations”
07.02 Code of Federal Regulations, Title 10, Part 70, “Domestic Licensing of Special Nuclear Material”
07.03 Code of Federal Regulations, Title 10, Part 76, “Certification of Gaseous Diffusion Plants”

END

Enclosure 1: Evaluating Violation Situations
Enclosure 2: Evaluations Based on Specific Licensee ISAs (Non-Public)
Attachment 1: Revision History for IMC 2606

Enclosure 1
Evaluating Violation Situations

The situations discussed below demonstrate application of the methodology to a specific non-compliance (i.e. violation) in order to relate the violation to the severity levels described in Section 6.2 of the NRC Enforcement Policy. The examples apply to all safety disciplines (e.g., chemical safety, criticality safety, fire safety, radiation protection) and are intended to be illustrative only, and are neither exhaustive nor controlling for making severity level determinations.

From Figure 1, the risk evaluation process is:

1. Identify a violation
2. Identify an applicable accident sequence
   a. From ISA, or
   b. From available safety basis information
3. Assess likelihood of the accident sequence with available controls
   a. Using ISA methodology, or
   b. Using methodology in Section 06 and Table 1 and Table 2
4. Assign severity level
   a. Enforcement Policy, and
   b. Table 3

Each example steps through the assessment process beginning with the identification of a violation.

Severity Level I

At facilities with ISAs, severity level I violations are assigned to non-compliances associated with high-consequence occurrences. At facilities without ISAs, severity level I violations are assigned to occurrences commensurate with high-consequence accident sequences.

<u>Example #1</u>: A nuclear criticality accident occurs at a fuel cycle facility.

Identify Violation: Credited controls failed outside of planned reliability.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies inadvertent criticality as a high-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: Because the consequence occurred, likelihood has changed to “occurred” and no further evaluation is necessary.

Assign Severity Level: A high-consequence event occurring as the result of a non-compliance is a severity level I violation.

<u>Example #2</u>: An exposure involving licensed material occurs at a fuel cycle facility resulting in death to a worker or permanent injury to a member of the public.

Identify Violation: The violation must have contributed to the fact that the exposure involving

licensed material occurred. It may be that it has disabled one or all of the controls preventing the exposure.

Identify Applicable Accident Sequence and Consequence: The actual exposure meets the definition of a high-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: Because the consequence occurred, likelihood has changed to "occurred" and no further evaluation is necessary.

Assign Severity Level: A high-consequence event occurring as the result of a violation is a severity level I violation.

Severity Level II

At facilities with ISAs, severity level II violations are assigned to non-compliances associated with intermediate-consequence occurrences or a change in the likelihood of a high-consequence accident sequence to "not unlikely." At facilities without ISAs, severity level II violations are assigned to non-compliances associated with occurrences commensurate with intermediate-consequence accident sequences, or a substantial increase in the likelihood of an accident sequence commensurate with an intermediate-consequence accident sequence.

Example #3: A licensee fails to establish or maintain some or all of the IROFS for an accident sequence leading to criticality, such that a nuclear criticality accident was not unlikely.

Identify Violation: Controls failed or were unavailable outside of planned maintenance periodicity.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies inadvertent criticality as a high-consequence event and identifies the specific accident sequence(s) leading to criticality affected by the violation.

Assess Likelihood of Accident Sequence with Available Controls: No IROFS or non-IROFS are identified to replace the lost controls. Staff determines that duration of the failure is not a factor. The high-consequence sequence is now "not unlikely" rather than "highly unlikely."

Assign Severity Level: A high-consequence accident sequence being "not unlikely" as the result of a non-compliance is a severity level II violation.

Example #4: A radiological or chemical exposure occurs at a fuel cycle facility without an ISA resulting in debilitating or permanent injuries to a worker, 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.

Identify Violation: Controls failed outside of planned reliability.

Identify Applicable Accident Sequence and Consequence: The licensee does not have an ISA but discusses this specific accident sequence in other safety basis documentation. Staff characterizes the sequence using the licensee safety basis documentation, engineering

judgment and Table 1 as an intermediate-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: Because the consequence occurred, likelihood has changed to "occurred" and no further evaluation is necessary.

Assign Severity Level: An intermediate-consequence event occurring as the result of a non-compliance is a severity level II violation.

Example #5: A licensee discovers that a fissile operation has an accident sequence leading to criticality that is not identified, analyzed or controlled.

Identify Violation: A credible high-consequence accident sequence is not controlled due to licensee failure to follow procedures requiring identification and analysis of credible accident sequences.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies inadvertent criticality as a high-consequence event. Since the accident sequence is not in the ISA, staff characterizes the sequence using engineering judgment and Table 1 as a credible high-consequence accident sequence.

Assess Likelihood of Accident Sequence with Available Controls: No controls can be identified affecting the risk of the accident sequence. Staff considers duration of the unanalyzed condition to be a factor and uses Table 2 to adjust the assessment. The risk for the accident sequence is assessed below "not unlikely."

Assign Severity Level: The severity level of an unanalyzed accident sequence is dependent on the magnitude of risk for the accident sequence and the requirement for implementation of controls. A high-consequence accident sequence being "not unlikely" as the result of a non-compliance is a severity level II violation.

Severity Level III

At facilities with ISAs, severity level III violations are assigned to violations associated with a change in the likelihood of a high-consequence accident sequence to "unlikely" or a change in the likelihood of an intermediate-consequence accident sequence to "not unlikely." At facilities without ISAs, severity level III violations are assigned to non-compliances associated with a significant increase in the likelihood of an accident sequence commensurate with a high-consequence accident sequence, or a very substantial increase in the likelihood of an accident sequence commensurate with an intermediate-consequence accident sequence.

Example #6: At a fuel cycle facility without an ISA, some controls credited to a high-consequence accident sequence fail, resulting in the likelihood of the accident sequence being "not unlikely" rather than "highly unlikely."

Identify Violation: Controls failed outside of planned reliability.

Identify Applicable Accident Sequence and Consequence: The licensee does not have an ISA

but discusses this specific accident sequence in other safety basis documentation. Staff characterizes the sequence using the licensee safety basis documentation, engineering judgment and Table 1 as an intermediate-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: Available controls affecting the accident sequence are assessed and the licensee is able to demonstrate that an appropriate control was available to replace the lost controls such that the high-consequence accident sequence was "unlikely" at the time of the violation. Staff determines that duration of the failure is not a factor.

Assign Severity Level: Using Table 3, staff determines that a high-consequence accident sequence being "unlikely" as the result of a non-compliance is a substantial increase in risk and is a severity level III violation.

Example #7: Some or all IROFS for an intermediate-consequence accident sequence fail.

Identify Violation: Controls failed outside of planned reliability.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies the specific accident sequence as an intermediate-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: No controls can be identified to replace the function of the missing or compromised controls. Staff considers duration of the unanalyzed condition to be a factor and uses Table 2 to adjust the assessment. The risk for the accident sequence is assessed below "not unlikely."

Assign Severity Level: An intermediate-consequence accident sequence being "not unlikely" as the result of a non-compliance is a severity level III violation.

Example #8: A fuel cycle licensee without an ISA discovers that a chemical operation has an accident sequence leading to a credible intermediate-consequence that is not identified, analyzed or controlled.

Identify Violation: A credible intermediate-consequence accident sequence is not controlled due to licensee failure to follow procedures requiring identification and analysis of credible accident sequences.

Identify Applicable Accident Sequence and Consequence: The licensee does not have an ISA but has other adequate safety basis documentation. Staff characterizes the sequence using the licensee safety basis documentation, engineering judgment and Table 1 as an intermediate-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: No controls can be identified affecting the risk of the accident sequence. Staff considers duration of the unanalyzed condition to be a factor and uses Table 2 to adjust the assessment. The risk for the accident sequence is assessed below "not unlikely."

Assign Severity Level: The severity level of an unanalyzed accident sequence is dependent on the magnitude of risk for the accident sequence and the requirement for implementation of controls. Using Table 4, staff determines that an intermediate-consequence accident sequence being "not unlikely" as the result of a non-compliance is a significant increase in risk and is a severity level III violation.

Severity Level IV

At facilities with ISAs, severity level IV violations are assigned to non-compliances associated with the failure to meet the performance requirements of 10 CFR 70.61 that does not result in a severity level I, II, or III violation. At facilities without ISAs, severity level IV violations are assigned to non-compliances associated with failure of safety systems or controls such that an acceptable safety margin has not been maintained that does not result in a severity level I, II, or III violation.

Example #9: A licensee fails to establish or maintain a criticality control.

Identify Violation: A control required by approved criticality analysis to maintain subcritical margin is not established or maintained due to failure to follow procedural requirements to implement controls.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies inadvertent criticality as a high-consequence event and identifies the specific accident sequence leading to criticality.

Assess Likelihood of Accident Sequence with Available Controls: Adequate controls are in place to ensure that criticality is highly unlikely.

Assign Severity Level: A failure to meet the performance requirements of 10 CFR 70.61 that does not result in a severity level I, II, or III violation is a severity level IV violation.

Example #10: Some or all of the IROFS for an accident sequence leading to criticality fail. Based on credited controls, the accident sequence is now "not unlikely" rather than "highly unlikely."

Identify Violation: Controls failed outside of planned reliability.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies inadvertent criticality as a high-consequence event and identifies the specific accident sequence leading to criticality.

Assess Likelihood of Accident Sequence with Available Controls: The licensee is able to demonstrate that appropriate non-IROFS are present that replace all of the lost IROFS at the time of the violations.

Assign Severity Level: Failure to meet the performance requirements of 10 CFR 70.61 that does not result in a severity level I, II, or III violation is a severity level IV violation.

Example #11: Some or all of the IROFS for an accident sequence leading to an intermediate-consequence event fail. Based on credited controls, the intermediate-consequence sequence is now "not unlikely" rather than "highly unlikely."

Identify Violation: Controls failed outside of planned reliability.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies the specific accident sequence as an intermediate-consequence event.

Assess Likelihood of Accident Sequence with Available Controls: The licensee is able to demonstrate that some or all appropriate non-IROFS were in place that replaced the lost IROFS at the time of the violation.

Assign Severity Level: Failure to meet the performance requirements of 10 CFR 70.61 that does not result in a severity level I, II, or III violation is a severity level IV violation.

Example #12: A licensee discovers that a fissile operation has an accident sequence leading to criticality that is not identified, analyzed or controlled.

Identify Violation: A credible high-consequence accident sequence is not controlled due to licensee failure to follow procedures requiring identification and analysis of credible accident sequences.

Identify Applicable Accident Sequence and Consequence: The licensee ISA identifies inadvertent criticality as a high-consequence event. Since the accident sequence is not in the ISA, staff characterizes the sequence using engineering judgment and Table 1 as a credible high-consequence accident sequence.

Assess Likelihood of Accident Sequence with Available Controls: Staff uses Table 2 to establish initial likelihood for the accident sequence. Adequate controls can be identified affecting the risk of the accident sequence and the risk for the accident sequence can be characterized as "highly unlikely."

Assign Severity Level: The severity level of an unanalyzed accident sequence is dependent on the magnitude of risk for the accident sequence and the requirement for implementation of controls. Identification of a credible unanalyzed accident sequence for which existing IROFS or controls provide adequate protection is a severity level IV violation.

Enclosure 2
Evaluations Based on Specific Licensee ISAs (Non-Public)

This Enclosure contains “Proprietary” information and is not for public access.

Attachment 1 - Revision History for IMC 2606

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	ML12254A075 09/26/12 CN 12-022	Initial issuance to provide direction assessing change in risk due to a violation at a fuel cycle facility.	N/A	ML12254A078