International Isotopes Inc.

February 09, 2011

ATTN: Document-Control Desk
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: Submittal of Responses to Requests for Additional Information (RAI)
TAC L32739

To Whom it May Concern,

The following document is provided as a response to the US Nuclear Regulatory Commission RAIs pertaining to the International Isotopes Fluorine Products Inc. December 30, 2009 application to license a depleted uranium hexafluoride de-conversion and fluorine extraction process facility.

(1) Quality Assurance (Management Measures)

Please contact me by phone at (208) 524-5300 or by email at jjmiller@intisoid.com if you have questions regarding these responses.

Sincerely,

John J. Miller, CHP
Radiation Safety Officer

(1) Enclosure as stated

JJM-2011-11

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Quality Assurance (Management Measures)

QA-1 (QA-2) In the fourth paragraph of the introduction of Section 11, "Management Measures" the application states, "The provisions contained in this QA Program Description are applicable during design and construction of the IIFP Facility for design activities taking place beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls during design and construction phase of the IIFP Facility beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls." Consistent with 10 CFR 70.64, "Safety program and integrated safety analysis" clarify this sentence and its intent, and correct the editorial errors. In addition, clarify if the provisions in Chapter 11 or QAPD are just applicable to design and construction? What documents will be applicable to operations?

RESPONSE: All management measures are considered and addressed accordingly during all phases of the IIFP Project, from the design and construction phase through the operations of the IIFP Facility. Two sentences will be added to the subject paragraph explaining the evaluation of the QA programs of prospective DB contractors.

Management measures also apply throughout the operations and maintenance of the facility. The next paragraph (fifth paragraph) deals with the startup and operation of the facility. It is stated that "The COO/PM (IIFP Chief Operations Officer/Plant Manager) (COO/PM will be changed to "COO" and IIFP Chief Operations Officer) is responsible for implementing and maintaining the management systems ("systems" will be changed to "measures" as shown below) for the operating facility. The FEP/DUP facility line managers are responsible, with commensurate delegated authority, for implementing and maintaining the management measures policies and procedures in accordance with the approved facility safety design basis, licenses and permit requirements and the QAP." QAP will be changed to QA program as shown below. A clarifying statement will be added that the management measures also apply to operations.

A new paragraph will be added as the sixth paragraph on documents applicable to operations.

Figure 11-2 "IIFP Plant Organization during Operations of the FEP/DUP Facility" will be removed and replaced with Figure 11-2 "Plant Operation Organization" depicting the organizational structure of the Facility, in response to RAI OA-7A.

License Documentation Impact: Revisions will be made to the 4th and 5th paragraphs of the IIFP License Application, Revision A, Chapter 11 introduction, and a new 6th paragraph will be inserted (subsequent paragraphs will be shifted down, accordingly) and the revisions will read as follows:
(Note: Former subsection of 11.8.4 "Graded Application" will become Subsection 11.8.2.2 due to revision.)

IIFP is a wholly owned subsidiary of International Isotopes, Inc. (INIS). The President ~~and Chief Executive Officer (CEO)~~ of IIFP is the highest level of management responsible for IIFP's corporate QA policies, goals, and objectives. The IIFP project is currently in its development, initial conceptual design and licensing application phase. ~~Management measures described in this Chapter become effective and applicable The IIFP project is currently in its development, initial conceptual design and licensing application phase.~~ During the selection of the design/build (DB) contractor, the QA programs of the respective bidders will be evaluated to ensure the prospective DB contractors have mature QA programs and to ensure that the organization has all the controls and methodologies in place for design and change control

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processes. The design must be developed and implemented in accordance with IIFP management measures to ensure that the critical components and the items relied on for safety will be available and reliable to perform their function when needed. The provisions contained in ~~this~~ the QA Program Description are applicable during design and construction of the IIFP Facility for design activities taking place beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls during the design and construction phase of the IIFP Facility. ~~beginning on the date the DB contactor assumes the detailed design and engineering role and establishes the design organization and controls~~ Once the design, engineering and construction ~~phase (referred to as design/build (DB))~~ of the FEP/DUP ~~project~~ Facility begins, the IIFP Chief Operations Officer ~~/ Commercial Facility Project Director~~ (COO/~~CFPD~~), to be appointed by ~~the President and CEO~~ and reporting to the ~~INIS~~ IIFP President/~~CEO~~, is responsible for assuring implement~~ing~~ation of the management measures necessary for safe design and construction in accordance with the graded QA Program. (See Figure 11-1, "IIFP Project ~~Organization during~~ Design and Construction Organization" ~~of the FEP/DUP Facility~~).

Management measures not only apply during the design and construction of the IIFP Facility but throughout the operations and maintenance of the facility. Upon completion of construction, the Plant O~~o~~perations O~~o~~rganization takes responsibility for startup and operation of the facility; led by the IIFP Chief Operations Officer/~~Plant Manager~~ (COO/~~PM~~) who reports to the ~~INIS~~ IIFP President/~~CEO~~. The COO /~~PM~~ is responsible for implementing and maintaining the management ~~systems~~ measures for the operating facility. The FEP/DUP F~~f~~acility line managers are responsible, with commensurate delegated authority, for implementing and maintaining the management measures policies and procedures in accordance with the approved facility safety design basis, licenses and permit requirements and the QA~~P~~ program requirements. The FEP/DUP F~~f~~acility operating organization is shown in Figure 11-2. In the operating organization, the Plant Manager and the Engineering ~~Engineering/Maintenance~~ Manager ~~and the Production/Technical Manager~~ have key roles in ensuring the safe design and operation of the facility is maintained.

Critical documents applicable to operations include procedures. All activities involving IROFS and QA Level 1 and 2 items (see subsection 11.8.2.2) are conducted in accordance with approved procedures. As noted throughout this document, procedures are used to control IROFS activities to ensure the activities are carried out in a safe manner and in accordance with regulatory requirements. Applicable safety limits and IROFS are clearly identified in the procedures. IIFP will incorporate a methodology for identifying, developing, approving, implementing, and controlling operating procedures. Identifying needed procedures will include consideration of ISA results.

License Documentation Impact: Remove Figure 11-2 and title and replace with revised Figure 11-2 "Plant Operations Organization" in the Chapter 11 of IIFP License Application, Revision A, (also in response to RAI OA-7) the revised Figure and will appear as follows:

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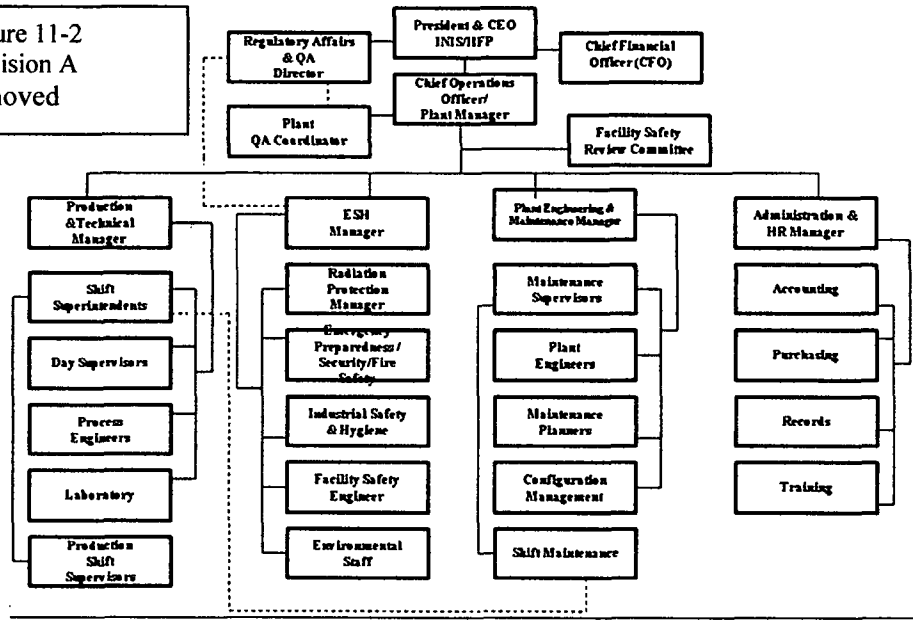
Figure 11-2
Revision A
removed



~~Figure 11-2 IIFP Plant Organization during Operations of the FEP/DUP Facility~~

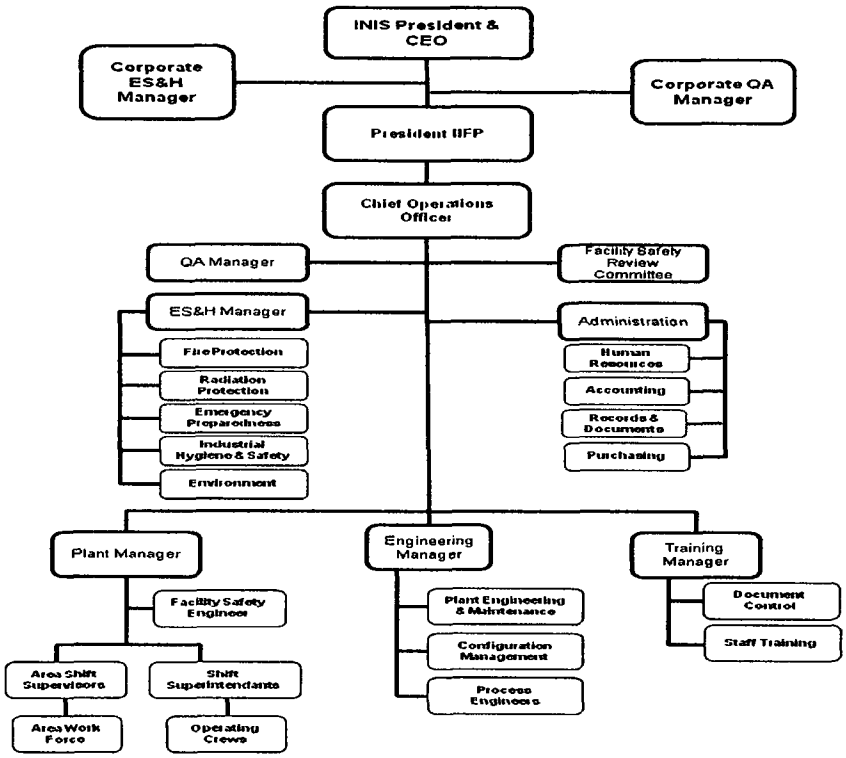


Figure 11-2 Plant Operation Organization

Quality Assurance (Management Measures)

QA-2 *(QA-4) In the fifth paragraph of the introduction of Section 11, "Management Measures" the application states, "The COO/PM is responsible for implementing and maintaining the management systems for the operating facility." Consistent with the acceptance criteria in NUREG 1520 Revision 1, Section 11.4.3.1, in the first three bullets, clarify the wording management systems.*

RESPONSE: As stated above in the response to RAI QA-1, "management systems" was changed to "management measures". Also in response to RAI QA-1, the COO/PM was changed to Chief Operations Officer (COO).

The first bullet of NUREG 1520 Revision 1, Section 11.4.3.1 states that "The application describes the CM program, design requirements, document control, change control, assessments, and design reconstitution (for existing facilities only)." The text will be revised to show where the management measures are described in Chapter 11.

The second bullet of NUREG 1520 Revision 1, Section 11.4.3.1 states that "The application describes the CM program and defines the specific attributes of the levels of CM that will be applied to select IROFS." The text will be revised to show where these attributes are described in Chapter 11.

The third bullet of NUREG 1520 Revision 1, Section 11.4.3.1 states that "The ISA Summary clearly defines the IROFS to be listed under CM along with the assignment of any grades or quality levels." The applicant should indicate in the ISA Summary the level of CM attributes that is applied to a particular IROFS. However, in the ISA Summary, this indication may consist of only an index or category designation." The text will be revised to show where these attributes are described in Chapter 11.

License Documentation Impact: To define the location of management measures identified in the first bullet of NUREG 1520, Revision 1, the following text will be added to the License Application, Rev A, introduction section of Chapter 11 below former paragraph 7:

<u>Management measures include the Configuration Management program which is fully described in License Application Section 11.1 through 11.1.6. The Configuration Management Policy is described in Section 11.1.1, Design Requirements in Section 11.1.2, Configuration Management Controls on the Design Requirements in Section 11.1.3, Document Control in Section 11.1.4, Change Control in Section 11.1.5, and Assessments in Section 11.1.6.</u>

License Documentation Impact: To define the location of the specific attributes of the levels of CM that will be applied to select IROFS identified in the second bullet of NUREG 1520, Revision 1, the following text will be added to LA Rev A, Chapter 11, below the new paragraph above:
(Note: Former subsection of 11.8.4 "Graded Application" will become Subsection 11.8.2.2 due to revision.)

<u>License Application Section 11.1.2, provides details on "Design Requirements," IROFS and any items that affect the function of the IROFS are designated as QA Level 1 or QA Level 2 (see subsection 11.8.2.2).</u>

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License Documentation Impact: To define the location of the ISA Summary which defines the IROFS to be listed under CM along with the assignment of any grades or quality levels as identified in the third bullet of NUREG 1520, Revision 1, the following text will be added to the LA Rev A, Section 11 below the new paragraph above:

In Section 6 of the ISA Summary, Table 6-1 provides a list of IROFS in the identified high and intermediate accident sequences. Table 6-1 identifies the control type, the management measures, the initiating event failure frequency index, the IROFS failure probability index, and the failure frequency/probability index basis. A small number of sole IROFS are identified in Table 8-1 of Section 8 of the ISA Summary. Table 8-1 identifies the type of IROFS and the safety function of each sole IROFS.

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QA-3 (QA-5) In the second paragraph of Section 11.1.1, "Configuration Management Policy," the application states, "In addition, the applicant will identify design documents that provide design input, analysis and results specifically for IROFS with the appropriate QA level." Consistent with the acceptance criteria in NUREG 1520 Revision 1, Section 11.4.3.8 in the third bullet, describe the intent of this sentence and provide a description of the QA Levels.

RESPONSE: The above quote comes from the NUREG 1520, Revision 1 document. The acceptance criteria in NUREG 1520 Section 11.4.3.8, in the third bullet, deals with Design Control and states: "The applicant should define, control, and verify its design controls. The applicant should specify and correctly translate design inputs to design documents. Controlled measures, commensurate with those applied to the original design, should govern the adequacy of design and design changes."

Configuration Management Policy will be revised to provide a reference to the description of the QA Levels. In addition, LA Rev A, Sections 11.8.2, 11.8.3, and 11.8.4 are revised to show that each IROFS receives a QA Level 1 or 2 classification and to better define those levels. Sections and subsection will be renumbered in sequence, accordingly

NRC Follow-up Question (1): In Response to Question QA-3, the licensee revised the second paragraph of the LA to read as follows:

"Configuration management provides the means to establish and maintain a technical baseline for the facility based on clearly defined requirements. During the design phase of the project, CM is based on the design control provisions and associated procedural control of the design documents to establish and maintain the technical baseline. Design documents are identified that provide design input, design analysis, or design results specifically for IROFS. ~~are identified with the appropriate QA level.~~ Each IROFS receives a classification of QA Level 1 or Level 2 that applies throughout the life of the facility. Those Quality Assurance (QA) levels are defined in subsection 11.8.2.2. These design documents undergo interdisciplinary review during the initial issue and during each subsequent revision. See Figure 11-1, "IIFP Project Design and Construction Organization." ~~during Design and Construction of the FEP/DUP Facility".~~

Please clarify the intent of the following sentence: "Design documents are identified that provide design input, design analysis, or design results specifically for IROFS.

NRC FOLLOW-UP QUESTION RESPONSE (1): The subject sentence could be better stated that "Design documents are ~~identified~~ those that provide design input, design analysis, or design results specifically for IROFS." The subject sentence has been revised in the license documentation impact.

NRC Follow-up Question (2): In Response to Question QA-1, the applicant stated that QAP was going to be changed to QA Program. In Response to Question, QA-3, QAP appears in two different instances, however, it was changed to QA Program in the first instance and QA Procedures in the second. Please clarify if the intent is to change QAP to QA Program throughout the document and this was a misunderstanding.

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NRC FOLLOW-UP QUESTION RESPONSE (2): For those cases where "QA procedures" were used for the QAP acronym in the RAI response, the license application has been changed to "QA program" for the acronym.

NRC Follow-up Question (3): Also in Response to Question QA-3, the applicant added some paragraphs explaining the different QA levels and the requirements. The new second paragraph for the QA Level 2 requirements states: "The following QA elements are applied equally to QL-1 and QL-2 IROFS: design control; procurement control; document control; control of purchased items and services; identification and control of materials, parts, and components; control of measuring and test equipment; control of nonconforming items; corrective actions; and quality assurance records." Please clarify if procurement control means procurement document control. In addition, please clarify why audits and assessments will not be applied equally to QL1 and QL-2 IROFS.

NRC FOLLOW-UP QUESTION RESPONSE (3): Procurement control does indeed refer to procurement document control since control of purchased items and services is already included in that listing. The subject listing above has been revised to state "procurement document control" instead of "procurement control."

IIFP intends to apply a basic level of audits and assessments to all IROFS (QL-1 and QL-2). However, as identified in Section 11.5.5, the frequencies are commensurate with the status and importance of the activity, and the twelve bulleted areas of consideration presented in Section 11.8.2.2 would be used in developing these frequencies.

License Documentation Impact: The second paragraph of the License Application, Revision A, Section 11.1.1 will be revised to read as follows:
(Note: Subsection 11.8.2.2 was formerly subsection of 11.8.4 "Graded Application".)

Configuration management provides the means to establish and maintain a technical baseline for the facility based on clearly defined requirements. During the design phase of the project, CM is based on the design control provisions and associated procedural control of the design documents to establish and maintain the technical baseline. Design documents are those that provide design input, design analysis, or design results specifically for IROFS.~~, are identified with the appropriate QA level.~~ Each IROFS receives a classification of QA Level 1 or Level 2 that applies throughout the life of the facility. Those Quality Assurance (QA) levels are defined in subsection 11.8.2.2. These design documents undergo interdisciplinary review during the initial issue and during each subsequent revision. See Figure 11-1~~,~~ "IIFP Project Design and Construction Organization."~~, during Design and Construction of the FEP/DUP Facility".~~

License Documentation Impact: The IIFP License Application, Revision A, Sections 11.8.2, 11.8.3, and 11.8.4 will be revised in their entirety with additional paragraphs added and existing paragraphs revised as follows. Sections and subsections will be renumbered in sequence, accordingly.

Quality Assurance (Management Measures)

11.8.2 Quality Assurance Program Basis

IIFP is committed to ensuring a safe facility operation and to providing the best quality products possible. It is IIFP policy that its activities will comply fully with all applicable regulations, codes and standards to which the work is subject.

~~INIS~~ IIFP has developed a ~~QAP~~ QA program that applies to the design, construction, operation, and decommissioning of the IIFP F~~f~~acility. The QA program is applied to the design, fabrication, testing, operation, procurement, inspection, maintenance, and modification of IROFS and activities affecting those IROFS. The QA program is applied in a graded approach based on an item's importance to safety.

~~Application of the QAP is mandatory for IROFS in accordance with 10 CFR 70.4, "Definitions" (CFR, 2009a), 10 CFR 70.61, "Performance Requirements" (CFR, 2009b), and 10 CFR 70.64 (CFR, 2009d). The QAP, in conjunction with the other management measures, ensures IROFS are available and reliable to perform the required safety functions when needed.~~

The ~~QAP~~ QA program specifies mandatory requirements for performing activities affecting quality and is set forth in procedures which are distributed on a controlled basis to organizations and individuals responsible for quality. When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an unsafe condition, work is stopped until proper corrective action is taken. If procedures cannot be used as written, then work is stopped until the procedures are modified. Revisions to these procedures are also distributed on a controlled basis. Applicable portions of the ~~QAP~~ QA program are documented, approved and implemented prior to undertaking an activity.

~~**11.8.3 Applicability**~~

11.8.2.1 Applicability

The IIFP QA program applies to IIFP workers at all levels of the organization, including contractor personnel, who perform quality-affecting activities associated with safety-related aspects of the IIFP Facility. The QA program is risk-based and utilizes only those elements and principles appropriate for assuring the quality-related aspects (management measures) of the facility.

IIFP contractors may work under the IIFP QA program or their respective QA programs per approved written procurement procedures. Contractor QA programs shall be consistent with the requirements of the IIFP QA program for quality-affecting activities. The interfaces between contractors and IIFP shall be documented. IIFP and contracted personnel have the responsibility to identify quality problems.

The ~~QAP~~ QA program is a management system established to ensure that IIFP products are safe and reliable and that those products and IIFP services meet or exceed customers' requirements, needs, and expectations. The ~~QAP~~ QA program applies to all products and services using a graded approach as described in the QA Program Description of the IIFP LA Appendix A (and in the summary Section 11.8.~~4~~ 2.2 below). The establishment of the program shall include

consideration of the technical aspects of the activities affecting quality. The ~~QAP~~ QA program sets forth the minimum requirements for those items, activities, and services and is established, maintained, and executed as described in Appendix A of the LA.

The ~~QAP~~ QA program for design, construction, and pre-operational testing continues simultaneously with the ~~QAP~~ QA program for the operational phase when construction activities are in progress during plant operation.

~~**11.8.4 Graded Application**~~

11.8.2.2 Graded Application

This section is a summary of the graded application of the IIFP ~~QAP~~QA program. ~~Detailed description is provided in the IIFP LA as Appendix A, Quality Assurance Program Description.~~ Risk is the fundamental consideration in determining to what extent the requirements of the ~~QAP~~ QA program apply. Certain activities, items, or processes may require extensive control measures while others may require only a limited degree of control. The control measures that are to be considered include procedural coverage, qualification and training, peer reviews, surveillances, audits, and assessments. The application and degree to which these control measures are employed for an activity, item, or process is established through the risk assessment decision process.

~~The risk assessment decision process shall take into account such factors as~~

- ~~Risk significance;~~
- ~~Relative importance to safety, safeguards, and security;~~
- ~~Consequences of failure;~~
- ~~Probability of failure;~~
- ~~Applicable regulations, industry codes, and standards;~~
- ~~Complexity or uniqueness of an item/activity and the environment in which it has to function;~~
- ~~Quality history of the item in service or activity;~~
- ~~Degree to which functional compliance can be demonstrated or assessed by test, inspection, or maintenance methods;~~
- ~~Anticipated life span;~~
- ~~Degree of standardization;~~
- ~~Importance of data generated; and~~
- ~~Reproducibility of results.~~

Facility components and processes are assigned a QA level if they are determined to be IROFS based on their safety significance. Each IROFS component will receive a classification of QA Level 1 or Level 2 that applies throughout the life of the facility and is based on the following definitions:

QA Level 1 Requirements The QA Level 1 Program shall conform to the criteria established in 10 CFR 70, Subpart H. The QA Level 1 QA program shall be applied to a single item relied on

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for safety (sole IROFS) preventing or mitigating a high consequence event. All ~~QAP~~ QA program requirements are applied to QA Level-1 (QL-1) IROFS.

QA Level 2 Requirements The QA Level 2 program is applied where two or more IROFS are credited to prevent or mitigate a high consequence event, or any single IROFS (sole IROFS) preventing or mitigating an intermediate consequence event. ~~QAP requirements are applied to QA Level-2 IROFS using a graded approach. The graded approach is implemented through approved written procedures taking into consideration the factors delineated above.~~

~~By appropriately balancing considerations of importance and process capability, an appropriate level of quality is achieved commensurate with the item's importance to safety. The results of the application of the graded approach to quality are incorporated into design requirement documents, specifications, procedures, instructions, drawings, inspection plans, test plans, procurement documents, and other documents that establish the requirements for items or activities.~~ Management measures are applied to QA Level 2 (QL-2) IROFS consistent with the type of IROFS to assure that the IROFS remains reliable at its credited failure frequency when called upon to be available. All applicable QA program requirements are also applied to QL-2 IROFS in a manner necessary to achieve this goal.

The extent that attributes of management measures and QA program elements are applied to QL-1 and QL-2 IROFS will be determined by evaluating the factors that contribute to reliability of each IROFS. The following QA elements are applied equally to QL-1 and QL-2 IROFS: design control; procurement document control; document control; control of purchased items and services; identification and control of materials, parts, and components; control of measuring and test equipment; control of nonconforming items; corrective actions; and quality assurance records. For the QA elements listed above, the management measures that flow from these elements will be the same, regardless of whether the IROFS is QL-1 or QL-2.

For the remaining QA elements, the management measure(s) applied to those aspects of the activity that influence reliability of the IROFS will be determined by evaluating the design, function, and task analyses associated with operating and maintaining the IROFS and by assigning the characteristic to the attribute taking into consideration the following:

- Risk significance;
- Relative importance to safety, safeguards, and security;
- Consequences of failure;
- Probability of failure;
- Applicable regulations, industry codes, and standards;
- Complexity or uniqueness of an item/activity and the environment in which it has to function;
- Quality history of the item in service or activity;
- Degree to which functional compliance can be demonstrated or assessed by test, inspection, or maintenance methods;
- Anticipated life span;
- Degree of standardization;
- Importance of data generated; and
- Reproducibility of results.

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QA Level 3 Requirements The QA Level 3 program is defined as standard commercial practice. A documented QA Level 3 program is not required. QA Level 3 components or processes do not require a Quality Level 3 designation on any documentation or system requirements. QA Level 3 governs all activities that are not designated as QA Level 1 or QA Level 2.

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QA-4 (QA-7) In Section 11.1.1.4, "Organizational Structure and Staffing Interfaces," the applicant states, "The various IIFP departments and contractors of IIFP perform quality-related activities." Consistent with the acceptance criteria in NUREG 1520 Revision 1, Section 11.4.3.8, clarify the meaning of this sentence and provide a description of these quality related activities.

RESPONSE: "Quality-related activities" will be revised to "management measures." In the License Application, the next paragraph of the subject paragraph states "Configuration management is implemented through or otherwise related to other management measures. Key interfaces and relationships to other management measures are described below.

- Quality Assurance - The QA program establishes the framework for CM and other management measures for IROFS and items that affect the function of the IROFS.
- Records Management - Records associated with IROFS and items affecting IROFS are generated and processed in accordance with the applicable requirements of the QA Program and provide evidence of the conduct of activities associated with the CM of those IROFS.
- Maintenance - The maintenance requirements are established as part of the design basis, which is controlled under CM. Maintenance records for IROFS and items affecting IROFS shall provide evidence of compliance with preventive and corrective maintenance schedules.
- Training and Qualifications - Training and qualifications are controlled in accordance with the applicable provisions of the QA Program. Personnel qualifications and/or training to specific processes and procedures are management measures that support the safe operation, maintenance, or testing of IROFS. Also, work activities that are themselves IROFS, (i.e., administrative controls) are included in procedures; and personnel shall be trained and qualified to these procedures. Training and qualification requirements and documentation of training may be considered part of the design basis controlled under CM.
- Incident Investigation/Audits and Assessments -Audits, assessments, and incident investigations are described in Sections 11.5, "Audits and Assessments," and 11.6, "Incident Investigations and Corrective Action Process." Corrective actions identified as a result of these management measures may result in changes to design features, administrative controls, or other management measures (e.g., operating procedures). The Corrective Action Program is described in Section 11.6, Incident Investigations and Corrective Action Process. Changes are evaluated under the provisions of CM through the QA Program and procedures. Periodic assessments of the CM program are also conducted in accordance with the audit and assessment program described in Section 11.5.
- Procedures - Operating, administrative, maintenance, and emergency procedures are used to conduct various operations associated with IROFS and items affecting IROFS and are reviewed for potential impacts to the design basis. Also, work activities that are themselves IROFS, (i.e., administrative controls) are contained in procedures."

NUREG 1520 Revision 1, Section 11.4.3.8, addresses the other QA elements as Organization; QA Program; Design Control; Procurement Document Control; Instructions, Procedures, and Drawing Control; Document Control; Control of Purchased Items; Identification and Control of Items; Control of Processes; Inspection; Test Control; Control of Measuring and Test

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Equipment; Handling, Storage, and Shipping; Inspection, Test, and Operating Status; Control of Nonconforming Items; Corrective Action; Quality Assurance Records; and Audits.

NRC Follow-up Question (4): In Question QA-4, please clarify if the text explaining the relationships and interfaces will be added to the license application.

NRC FOLLOW-UP QUESTION RESPONSE (4): The subject relationships and interfaces are already stated in the license application in section 11.1.1.4 referred to in question QA-4.

License Documentation Impact: The first sentence of the second paragraph of the License Application, Revision A, Section 11.1.1.4 will be revised as follows to clarify the meaning of the subject sentence:

The various IIFP departments and contractors of IIFP perform ~~quality-related activities~~ management measures as those summarized below. The primary IIFP contractors are responsible for development of their respective QA Programs and CM elements, which are consistent with the requirements of the IIFP QA Program for those activities determined to be within the scope of the IIFP QA Program. The interfaces between contractors and IIFP or among contractors are documented. IIFP and contractor personnel have the responsibility to identify quality problems. If a member of another area disagrees, that individual is instructed to take the matter to appropriate management. The disagreement may either be resolved at this level or at any level up to and including the ~~INIS~~ IIFP President.

License Documentation Impact: A final paragraph will be added to LA Rev A, Section 11.1.1.4, subsection "Procedures" to provide a reference to the description of these management measures as follows
(Note: QAPD Section numbering may have changed in response to RAI-QAPD-1.)

A description of the QA elements is provided in the Appendix A of the License Application, "Quality Assurance Program Description." The location of each QA element described in the QAPD is shown below.

Quality Assurance Elements

Organization	Section A.1
Quality Assurance Program	Section A.2
Design Control	Section A.3
Procurement Document Control	Section A.4
Instructions, Procedures, and Drawings	Section A.5
Document Control	Section A.6
Control of Purchased Items and Services	Section A.7
Identification and Control of Materials, Parts, and Components	Section A.8
Control of Special Processes	Section A.9
Inspection	Section A.10
Test Control	Section A.11
Control of Measuring and Test Equipment	Section A.12
Inspection, Test, and Operating Status	Section A.13
Control of Nonconforming Items	Section A.14

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Corrective Action	Section A.15
Quality Assurance Records	Section A.16
Audits	Section A.17

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QA-5 (QA-8) Consistent with the acceptance criteria in NUREG 1520 Revision 1, Section 11.4.3.1 and Section 11.5.1.3, provide the following information.

A. In Section 11.1.2, "Design Requirements," the application states, "The associated design documents are subject to interdisciplinary reviews and design verification. Changes to the design are evaluated to ensure consistency with the design basis." Clarify if these sentences are referring to IROFS or QL-1 or QL-2 items.

RESPONSE: The entire paragraph from the License Application reads as follows: "IROFS and any items that affect the function of the IROFS are designated as QA Level 1 or QA Level 2 (see Section 11.8). The associated design documents are subject to interdisciplinary reviews and design verification. Changes to the design are evaluated to ensure consistency with the design basis. Computer codes used in the design of IROFS are also subject to these design control measures, with additional requirements as appropriate for software control, verification, and validation." Thus, these sentences are referring to IROFS and the QL-1 or QL-2 items comprising the IROFS. Revisions are made to the subject sentence in LA, Revision A, Section 11.1.2 to clarify the meaning of that statement.

License Documentation Impact: The IIFP License Application, Revision A, Section 11.1.2, paragraph three will be revised as follows:
(Note: Section 11.8 reference changed to new subsection 11.8.2.2 to more specifically identify location.)

IROFS and any items that affect the function of the IROFS are designated as QA Level 1 or QA Level 2 (see ~~Section~~ subsection 11.8.2.2). The ~~associated~~ design documents associated with IROFS are subject to interdisciplinary reviews and design verification. Changes to the design are evaluated to ensure consistency with the design basis. Computer codes used in the design of IROFS are also subject to these design control measures, with additional requirements as appropriate for software control, verification, and validation.

B. *(QA-9) In Section 11.1.2, "Design Requirements," the application states, "During the check and review, emphasis is placed on assuring conformance with applicable codes, standards and LA design commitments." Clarify what is "check and review" and to which documents the sentence is referring.*

RESPONSE: In the previous paragraph to the one in question, the following is found which provides clarification for "check and review" process: "A qualified individual who specifies and includes the appropriate codes, standards, and licensing commitments within the design documents prepares each design document, such as a calculation, specification, procedure, or drawing. This individual also notes any deviations or changes from such standards within the design documentation package. Each design document is then checked by another individual qualified in the same discipline and is reviewed for concept and conformity with the design inputs. These design inputs are in sufficient detail to permit verification of the document. The manager having overall responsibility for the design function approves the document. The Configuration Manager ensures that the designated engineering organization documents the entire review process in accordance with approved procedures."

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Earlier in License Application Section 11.1.2, "Design Requirements," the following is found to clarify the documents to which this process is applied: "Design requirements are documented in design requirement documents i.e. calculations, safety analysis, design criteria, engineering drawings, system descriptions, technical documents, and specifications. The design requirements and basis of design documents are controlled under the design control provisions of the CM program as described above and are subject to the same change control as analysis, specifications, and drawings.

Modifications are made to the subject statements in Section 11.1.2 to provide clarification of the "check and review" process and to clarify which documents the sentence is referring.

License Documentation Impact: Paragraph six of the License Application, Revision A, Section 11.1.2 will be revised as follows:

During the check and review, process described above, emphasis is placed on assuring conformance with applicable codes, standards and LA design commitments. The individuals in engineering assigned to perform the check and review of ~~a~~ design requirements documents (calculations, safety analysis, design criteria, engineering drawings, system description, technical documents specifications, etc.) have full and independent authority to withhold approval until questions concerning the work have been resolved. Design reviews, alternative calculations, or qualification testing accomplishes verification of design. The basis for a design, such as analytical models, theories, examples, tables, codes and computer programs must be referenced in the design document and their application verified during check and review. Model tests, when required to prove the adequacy of a concept or a design, are reviewed and approved by the responsible qualified individual. Testing used for design verification shall demonstrate adequacy of performance under conditions that simulate the most adverse design conditions. The tests used for design verification must meet all the design requirements.

C. *(QA-10) In Section 11.1.2, "Design Requirements," the application states, "In accordance with these procedures, the report is forwarded for appropriate review to the responsible manager..." Clarify to which report the sentence refers.*

Response: The report refers to nonconformance reports. To assist in clarifying that, the first two statements of the paragraph in question read: "When deficiencies are identified which affect the design of IROFS, such deficiencies are documented and resolved in accordance with approved Corrective Actions procedures. In accordance with these procedures, the report is forwarded for appropriate review to the responsible manager, who coordinates further review of the problem and revises all design documents affected by the deficiency as necessary." The subject statement in the LA Section 11.1.2 will be revised to clarify to which report the sentence refers.

License Documentation Impact: Paragraph 10 of the IIFP License Application, Revision A, Section 11.1.2, will be revised as follows:

When deficiencies are identified which affect the design of IROFS, such deficiencies are documented and resolved in accordance with approved Corrective Actions procedures. In

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accordance with these procedures, the nonconformance report (NCR) is forwarded for appropriate review to the responsible manager, who coordinates further review of the problem and revises all design documents affected by the deficiency as necessary. Where required, the responsible manager forwards the report to the engineers in other areas, who coordinate necessary revisions to their affected documents.

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QA-6 (QA-14) In Section 11.2.2.4, "Functional Testing – Post-Maintenance Testing," the application states, "This test is performed, with acceptable results, prior to returning the equipment into service." Consistent with the acceptance criteria in NUREG 1520 Revision 1, Section 11.4.3.2, clarify the intent of this sentence. (i.e. what happens if the test fails or the results are not acceptable?)

RESPONSE: Section 11.2.2.4, "Functional Testing – Post-Maintenance Testing" will be modified to include revisions to clarify that if acceptable results are not obtained during testing, equipment cannot be returned to service and corrective action is taken.

License Documentation Impact: The subject statement and former paragraph one in License Application, Revision A, Section 11.2.2.4, will be revised to read as follows:

~~Post-Maintenance Testing~~ Post-maintenance testing ~~(PMT)~~ is established to provide assurance that IROFS will perform their intended function following maintenance activities. ~~This test~~Post-maintenance testing confirms that the maintenance performed was satisfactory, the identified deficiency has been corrected, and the maintenance activity did not adversely affect the reliability of the item. ~~This test~~Post-maintenance testing is performed~~, with~~ until acceptable results are obtained, prior to returning the equipment to service. If acceptable results are not obtained, corrective action is taken and documented via the nonconformance report (NCR) process. The engineering discipline will dictate the path forward in the NCR process. See Sections 11.2.2.2 and 11.2.2.3 for additional information on actions taken prior to returning the IROFS to service.

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QA-7 *(QA-21) Section 11.3.8, "Evaluation of Training Effectiveness," includes the statement, "Unacceptable individual performance is transmitted to the appropriate line manager." Consistent with the requirements in NUREG 1520 Revision 1, Section 11.4.3.3, clarify if this statement is misplaced in this section instead that in Section 11.3.10, "Periodic Personnel Evaluations/Needs for Retraining."*

RESPONSE: NUREG 1520, Section 11.4.3.3 covers all aspects of "Training and Qualifications." The subject statement could indeed provide further clarification for the "Periodic Personnel Evaluations/Needs for Retraining" section in the License Application which presently reads in part as follows: "When the results of the evaluation dictate, retraining or other appropriate actions are provided. Continuing training is also required due to plant modifications, procedure changes, and QAP changes that result in new or revised information." However, the subject statements provides appropriate clarification in the present location within the "Evaluation of Training Effectiveness" section providing information on the evaluation of the overall training program effectiveness. If the trainee does not meet the evaluation criteria provided in that section, line management is notified.

License Documentation Impact: The subject statement will be retained in LA Rev A, Section 11.3.8; and LA Rev A, Section 11.3.10 (paragraph two) will be revised to add the subject statement as follows:

Personnel performing activities related to IROFS are evaluated periodically to determine whether they are capable of continuing their activities that are related to IROFS. The evaluation may be by written test, oral test, or on-the-job performance observation by the supervisor. The results of the evaluation are documented. Unacceptable individual performance is transmitted to the appropriate line manager for investigation and corrective action where appropriate. When the results of the evaluation dictate, retraining or other appropriate actions are provided. Continuing training is also required due to plant modifications, procedure changes, and QA ~~P~~program changes that result in new or revised information.

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QA-8 *(QA-25) Section 11.5.3 of the application, "Conduct of Audits and Assessments," states, "Audits are conducted on an annual basis." Section 11.5.5, "Scheduling of Audits and Assessments," states "The frequency of audits and assessments is based upon the status and safety importance of the activities being performed and upon work history." Consistent with the requirements in NUREG 1520 Revision 1, Section 11.4.3.5, modify sections as necessary to make them consistent with each other.*

RESPONSE: The subject paragraph in LA Rev A, Section 11.5.3 is modified to ensure consistency with NUREG 1520 Revision 1, Section 11.4.3.5 and IIFP Section 11.5.5.

License Documentation Impact: The IIFP License Application, Revision A, Section 11.5.3, paragraph three will be revised as follows:

Audits are performed in accordance with a written plan that identifies and schedules audits to be performed. Audit team members shall not have direct responsibility for the function and area being audited. Team members shall have technical expertise or experience in the area being audited and are indoctrinated in audit techniques. ~~Audits are conducted on an annual basis.~~ The frequency of audits is based upon the status and safety importance of the activities being performed and upon work history. Major activities, as described in Section 11.5.4, are audited or assessed on a periodic basis.

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QA-9 *(QA-27) Section 11.7 of the application, "Records Management and Document Control," states, "The principal elements of each of the records management and document control programs and a brief description of the manner in which the functions associated with each element shall be performed along with a list of the types of records that are retained for the duration of the NRC License at the site." Consistent with the requirements in NUREG 1520 Revision 1, Section 11.4.3.7, clarify what was meant by this sentence.*

RESPONSE: The subject sentence should have read as follows: "The principal elements of each of the records management and document control programs and a brief description of the manner in which the functions associated with each element *are* performed *are provided below*, along with a list of the types of records that are retained at the site for the duration of the NRC License." The applicable statement and paragraph in the LA is modified to clarify the meaning of the sentence and to specify the location in the LA of (1) lists and descriptions principal elements of the records management and document control programs, and (2) the types of records.

License Documentation Impact: In response, paragraph one of the IIFP License Application, Revision A, Section 11.7 will be revised as follows:

Records management and document control programs are established to ensure records and documents required by the QA Program are appropriately managed and controlled. These programs provide administrative controls that establish standard methods and requirements for collecting, maintaining, and disposing of records. These programs also ensure that documents are controlled and distributed in accordance with identified written requirements and authorizations. The administrative controls for the generation and revision of records and documents are contained in site implementing procedures. The principal elements of each of the records management and document control programs and a brief description of the manner in which the functions associated with each element ~~shall be performed~~ are provided below along with a list of the types of records that are retained at the site for the duration of the NRC License ~~at the site~~. The principal elements with the brief description are listed and described in Sections 11.7.1.1 through 11.7.1.14, and the types of records are identified in Section 11.7.1.12. The principal elements for Document Control are described in Sections 11.7.2.1 through 11.7.2.13.

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QA-10 (QA-6) In Section 11.1.1.1, "Scope of Structures, Systems, and Components," the application states, "These documents include documentation related to IROFS that is generated through functional interface with QA, maintenance, and training and qualifications of personnel. Consistent with 70.62(d) clarify why other management measures (e.g. procedures, incident investigations, audits and assessments, and records management) are not mentioned.

RESPONSE: The functional interface with QA would include the other management measures as procedures, incident investigations, audits and assessments. Section 11.1.1.4, "Organizational Structure and Staffing Interfaces," states, "Configuration management is implemented through or otherwise related to other management measures. Key interfaces and relationships to other management measures are described below." Those interfaces identified and described included Quality Assurance, Records Management, Maintenance, Training and Qualifications, Incident Investigations, Audits and Assessments, and Procedures.

License Documentation Impact: License Application, Revision A, Section 11.1.1.1, final paragraph will be revised as follows to include those interfaces identified in Section 11.1.1.4:

These documents include documentation related to IROFS that is generated through functional interface with QA (procedures, incident investigations, audits and assessments, etc.), maintenance, records management and document control, and training and qualifications of personnel. Configuration management procedures will provide for evaluation, implementation, and tracking of changes to IROFS, ~~and~~ processes, equipment, computer programs, and activities of personnel that impact IROFS.

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QA-11 (QA-11) In Section 11.1.4, "Document Control," the application states, "Procedures are established which control the preparation and issuance of documents such as manuals, instructions, drawings, procedures, specifications, design documents, procurement documents, and supplier-supplied documents, including any changes." Consistent with Section 11.4.3.1 of NUREG-1520, "Configuration Management," clarify that the following documents are included in this description: ISAs, all procedures that are IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant deems part of CM.

RESPONSE: This stated documentation is included in the IIFP Configuration Management program. Within the Configuration Management Policy (License Application Section 11.1.1) under Section 11.1.1.1, "Scope of Structures, Systems, and Components," the following is stated:

"The scope of Structures, Systems, and Components (SSCs) under CM includes all IROFS identified by the ISA of the design basis and any items which may affect the function of the IROFS. Design documents subject to CM include calculations, safety analyses, design criteria, engineering drawings, system descriptions, technical documents, and specifications that establish design requirements for IROFS. During the design phase, these design documents are maintained under CM when initially approved.

The scope of documents included in the CM program expands throughout the design process. As drawings and specification sections related to IROFS or items affecting the functions of IROFS are prepared and issued for procurement, fabrication, or construction, these documents are included in CM.

During construction, initial startup, and operations, the scope of documents under CM similarly expands to include, as appropriate:

- vendor data;
- test data;
- inspection data; and
- initial startup, test, operating and administrative procedures as applicable to IROFS

These documents include documentation related to IROFS that is generated through functional interface with QA, maintenance, and training and qualifications of personnel. Configuration management procedures will provide for evaluation, implementation, and tracking of changes to IROFS, and processes, equipment, computer programs, and activities of personnel that impact IROFS."

Section 11.1.1.4 further clarifies the following. "Operating, administrative, maintenance, and emergency procedures are used to conduct various operations associated with IROFS and items affecting IROFS and are reviewed for potential impacts to the design basis. Also, work activities that are themselves IROFS, (i.e., administrative controls) are contained in procedures."

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Section 11.4 states the following: "All activities involving IROFS and QA level 1 and 2 items (See Section 11.8.2.2) are conducted in accordance with approved procedures. As noted throughout this document, procedures are used to control IROFS activities to ensure the activities are carried out in a safe manner and in accordance with regulatory requirements."

Section 11.4.2.1 states: "Site managers have the responsibility for identifying which tasks are included in procedures within their areas of control. Procedures are required where actions are taken necessary to prevent or mitigate the consequences of accidents described in the ISA. As a minimum, a procedure is required for any task or activity that affects QA Level 1 and QA Level 2 SSCs."

License Documentation Impact: License Application, Revision A, Section 11.1.4 will be revised to add a final paragraph as follows to add subject clarification.

Document control encompasses those documents that are relied on for safety, e.g. the ISA, all procedures that pertain to IROFS, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others that the applicant deems part of CM. See Section 11.1.1.1, "Scope of Structures, Systems, and Components," for a general accounting of the documents subject to configuration management during design, construction, and operations of the IIFP Facility. A more detailed listing of documents under configuration control during design is provided in Section 11.1.2, "Design Requirement" and Section 11.1.3, "Configuration Management Controls on the Design Requirements." Documentation under CM during construction is delineated in Section 11.1.5.2 below. Similarly, Section 11.1.5.3 provides a discussion of documentation under CM during the operations phase.

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QA-12 (QA-15) Section 11.2.2.4, "Functional Testing," includes the requirements for functional testing, preoperational testing and post maintenance testing. Consistent with the acceptance criteria in NUREG 1520 Revision 1, Section 11.4.3.2, clarify if there will be any periodic or special testing as part of the maintenance program.

RESPONSE: The Functional Testing Section is revised to address functional testing requirements during pre-operational testing and operational testing. Presently pre-operational testing is adequately addressed. Operational testing includes periodic testing and special testing. Post-maintenance testing is being incorporated into operational testing.

License Documentation Impact: The subject section in License Application, Revision A, Section 11.2.2.4, "Functional Testing", subsection "Post-Maintenance Testing" will be revised. The "Post-Maintenance Testing" heading will be changed to "Operational Testing." New paragraphs will be added to address operational testing and special testing. Former paragraphs will be revised to address post-maintenance testing and to clarify the operational testing requirements of IROFS. The Operational Testing subsection will read as follows:

~~Post-Maintenance~~ Operational Testing

Operational testing consists of periodic testing and special testing. Periodic testing is conducted to monitor various facility parameters and to verify the continuing integrity and capability of facility IROFS. Special testing which may be conducted at the facility is testing which does not fall under any other testing program and is of a non-recurring nature.

The periodic testing program at the facility consists of testing conducted on a periodic basis to verify the continuing capability of IROFS to meet performance requirements. The facility periodic testing program begins during the pre-operational testing stage and continues throughout the facility's life. A schedule is established to ensure that all required testing is performed and properly evaluated on a timely basis. The schedule is revised periodically, as necessary, to reflect changes in periodic testing requirements and experience gained during plant operations. An integral part of the operational testing program is post-maintenance testing.

Post-maintenance testing ~~(PMT)~~ is established to provide assurance that IROFS will perform their intended function following maintenance activities. ~~This test~~ Post-maintenance testing confirms that the maintenance performed was satisfactory, the identified deficiency has been corrected, and the maintenance activity did not adversely affect the reliability of the item. ~~This test~~ Post-maintenance testing is performed~~, with~~ until acceptable results are obtained, prior to returning the equipment to service. If acceptable results are not obtained, corrective action is taken and documented via the nonconformance report (NCR) process. Engineering will dictate the path forward in the NCR process. See Sections 11.2.2.2 and 11.2.2.3 for additional information on actions taken prior returning the IROFS to service.

Special testing is testing conducted at the facility that is not a facility pre-operational test, periodic test, or post-maintenance test. Special testing is of a non-recurring nature and is conducted to determine facility parameters and/or to verify the capability of IROFS to meet performance requirements. The determination that a certain plant activity is a special test is intended to exclude those plant activities which are routine surveillances, normal operational

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evolutions, and activities for which there is previous experience in the conduct and performance of the activity.

~~PMT~~ Operational testing requirements of IROFS are developed and included in work packages, ~~where IROFS or~~ during the work planning process. The Plant Manager organization ~~Production Organization~~ may provide support to the Plant Engineering and Maintenance o~~O~~rganization in identifying ~~PMT~~ operational testing requirements. ~~PMT~~ Operational testing meets applicable codes and technical requirements and is conducted with specified acceptance criteria. The results of ~~the PMT~~ operational testing are documented and retained in the work package with other documentation generated during the maintenance evolution.

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QA-13 Section 11.2, "Maintenance," outlines the maintenance program to be implemented in the operations phase of the facility. Consistent with Section 11.4.3.2 of NUREG-1520, "Maintenance,"

A. (QA-16) Clarify how the maintenance function uses, interfaces with, or is linked to the various management measures.

RESPONSE: Various management measures are found throughout License Application Section 11.2. Examples of these management measures include:

- Establishment of Performance Criteria.
- Trending/Corrective Actions.
- Incident Investigations/Root Cause Determination.
- Lessons Learned
- Procedures.
- Records.
- Assessments.
- Feedback.
- Procedures/Control of M&TE
- Documented Management Measures within Procedures.

Section 11.2.1 of the LA will be modified to clarify how the maintenance function uses, interfaces with, or is linked to the various management measures.

Section 11.2.2.1, "Surveillance/Monitoring," will be modified to clarify how surveillance/monitoring uses, interfaces with, or is linked to the various management measures:

License Documentation Impact: The IIFP License Application, Revision A, Chapter 11, Section 11.2.1, "Maintenance Program," will be amended (1) to introduce the use of management measures to all IROFS (new paragraph one) and (2) to clarify how the maintenance function uses, interfaces with, or is linked to the various management measures. New paragraphs will be added and existing paragraphs the Section will be revised to read as follows:

A comprehensive Process Hazard Analysis was conducted as part of the ISA. Four types of IROFS controls were used to maintain an acceptable risk level. These included Passive Engineered Controls, Active Engineered Controls, Enhanced Administrative Controls, and Administrative Controls. The ISA identified management measures for IROFS, where applicable. See the ISA Summary (IIFP, 2009b) for additional details.

To provide for the continued safe and reliable operation of the facility IROFS, these management measures are implemented to ensure that the quality of these IROFS is not compromised by planned changes (modifications) or maintenance activities. Change ~~management~~ Control for modifications is described in Section 11.1.5 above. In maintenance of the facility, IIFP utilizes a systems-based program for planning, scheduling, tracking and maintaining records for maintenance activities ~~where those~~ affecting IROFS. Use of approved maintenance procedures for IROFS-related maintenance is a vital part of that program. The

details of maintenance procedure acceptance criteria, reviews, and approval are provided in Section 11.4, "Procedures Development and Implementation."

As applicable, contractors that work on or near IROFS identified in the ISA Summary will be required by IIFP to follow the same maintenance procedures described for the corrective, preventive, functional testing, or surveillance/monitoring activities listed ~~above~~below for the maintenance function.

Maintenance supervisors or Maintenance Planners provide the planning function in accordance with the work control process. Maintenance supervisors or Maintenance Planners are responsible for the planning of maintenance work activities and for maintaining a record of work accomplished. Listed below are methods or practices that will be incorporated into the work control process for the corrective, preventative, and functional-test maintenance elements. IIFP will prepare written procedures for performance of these methods and practices. These methods and practices include, as applicable:

- Authorized work instructions with detailed steps and a reminder of the importance of the IROFS identified in the ISA Summary;
- Parts lists;
- As-built drawings;
- A notification step to the Plant Manager organization~~Operations~~ function before conducting repairs and removing an IROFS from service;
- Radiation Work Permits;
- Replacement with like-kind parts and the control of new or replacement parts to ensure compliance with 10 CFR 21 (CFR, 2003a);
- Compensatory measures while performing work on IROFS;
- Procedural control of removal of components from service for maintenance and for return to service;
- Ensuring safe operations during the removal of IROFS from service; and
- Notification to the Plant Manager organization personnel that repairs have been completed.

The work control process includes provisions for

- Planning tasks to ready-to-work status;
- Ensuring that safety, safeguards, quality, and configuration management are properly and effectively implemented in performance of maintenance; and
- Closing out, including final validation of work performed and review of the acceptance tests.

Maintenance procedures involving IROFS commit to the ~~topics~~ management measures listed below for corrective and preventive maintenance, post-maintenance testing, and surveillance/monitoring maintenance activities:

- Pre-maintenance activities require reviews of the work to be performed, including procedure reviews for accuracy and completeness.

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- ~~Steps that require a notification~~ Notification of all affected parties (Plant Manager's organization ~~production personnel~~ and other appropriate managers) is required before performing work and on completion of maintenance work. The discussion includes potential degradation of IROFS during the planned maintenance.
- Control of work described above is accomplished by maintenance personnel following comprehensive procedures ~~to be followed by maintenance technicians~~.
- Radiation Protection, Industrial Hygiene, Environment and Industrial Safety representatives provide personnel safety and radiological control requirements needed to perform work safely.
- Procedures address the qualifications of personnel authorized to perform the maintenance or surveillance.
- Procedures also address controls on and specifications of any replacement components or materials to be used as well as post-maintenance testing to verify operability of the equipment.
- Procedures address tracking and records management of maintenance activities.
- Quality Assurance performs inspections that are specified in work packages and procurement documents.

Written procedures for the performance of maintenance activities include the steps listed above. The details of maintenance procedure acceptance criteria, reviews, and approval are provided in Section 11.4.1.3, "Procedures Development and Implementation."

License Documentation Impact: Section 11.2.2.1, "Surveillance/Monitoring," will be modified to clarify how surveillance/monitoring uses, interfaces with, or is linked to the various management measures. Section 11.2.2.1 of the LA, Rev A will read as follows:

Surveillance/monitoring activities are utilized to detect degradation and adverse trends of IROFS so that action may be taken prior to component failure. The monitored parameters are selected based upon their ability to detect predominate failure modes of the critical components. Data sources include the following:

- surveillance,
- periodic and diagnostic test results,
- plant computer information,
- operator rounds,
- walk downs,
- as-found conditions,
- failure trending, and
- predictive maintenance

IIFP utilizes active engineered controls that are integrated into routine operations to the degree practical. The IROFS are monitored as a routine part of the operating process. IROFS associated with passive engineered systems are typically fixed physical design features to maintain safe process conditions. Availability and reliability of IROFS are maintained through pre-operational audits and periodic verifications as prescribed in the ISA, and includes consideration of the importance of the IROFS as well as available quality and reliability information.

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Surveillance/monitoring and reporting are required for IROFS and any administrative controls that could impact the functions of an IROFS. During surveillance/monitoring, maintenance utilizes the management measures delineated in the paragraphs below.

Plant performance criteria are established to monitor plant performance and to monitor IROFS functions and component parameters. These criteria are established by industry experience, operating data, surveillance data, and plant equipment operating experience. These criteria ensure the reliability and availability of IROFS. The performance criteria are also used to demonstrate that the performance or condition of an IROFS is being effectively controlled through appropriate predictive and repetitive maintenance strategies so that IROFS remain capable of performing their intended function.

Surveillances are included in the work control process to permit timely planning, scheduling, establishment of system or facility conditions, execution of the activity, and creation of documentation that identifies the results of the surveillance. The established frequencies are based on the IROFS degree of safety importance. Surveillance of IROFS is performed at specified intervals. The purpose of the surveillance program is to measure the degree to which IROFS meet performance specifications. The results of surveillances are trended, and when the trend indicates potential IROFS performance degradation, preventive maintenance frequencies are adjusted or other appropriate corrective action is taken.

Incident investigations may identify root causes of failures that are related to the type or frequency of maintenance. The investigation is to determine their specific or generic root cause(s) and generic implications, to recommend corrective actions, and to report to the NRC as required by 10 CFR 70.74 (CFR, 2009f) or to other regulatory agencies, accordingly. The record of IROFS failures required by 10 CFR 70.62(a)(3) (CFR, 2009c) for IROFS is reviewed as part of the investigation. See Section 11.6, "Incident Investigations and Corrective Action Process," for further details. The lessons learned from such investigations are factored into the surveillance/monitoring and preventive maintenance programs as appropriate.

Maintenance procedures prescribe compensatory measures, if appropriate, for surveillance tests of IROFS that can be performed only while equipment is out of service.

Records showing the current surveillance schedule, performance criteria, and test results for all IROFS will be maintained in accordance with the Record Management System.

Results of surveillance/monitoring activities related to IROFS via the CM program ~~is~~ are evaluated by the appropriate safety disciplines to determine any impact on the ISA and any updates needed.

B. (QA-17) Provide justifications for assignment of differing degrees of maintenance to individual IROFS, based on the item's contribution to the reduction of risk.

RESPONSE: A comprehensive Process Hazard Analysis was conducted as part of the ISA. Four types of IROFS controls were used to maintain an acceptable risk level. (See RAI-QA-13A for new paragraph one to be inserted in LA, Section 11.2.1). Integration of those types of IROFS controls is shown in Section 11.2.2.4 "Functional Testing," this text provides is an excellent

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example of how the maintenance function uses, interfaces with, or is linked to the various management measures (RAI QA-13A above):

License Documentation Impact: As stated above, the new first paragraph of LA Rev A, Section 11.2.1 will be revised as follows to provide justifications for assignment of differing degrees of maintenance to individual IROFS (See RAI-13A):

A comprehensive Process Hazard Analysis was conducted as part of the ISA. Four types of IROFS controls were used to maintain an acceptable risk level. These included Passive Engineered Controls, Active Engineered Controls, Enhanced Administrative Control, and Administrative Control. The ISA identified general high-quality management measures to all IROFS. See the ISA Summary (IIFP, 2009b) for additional details.

License Documentation Impact: The following will be added LA Rev A, Section 11.2.2.1 as a new second paragraph for this Surveillance/Monitoring section (Management measures applied to this maintenance function are provided above in the License Documentation Impact for RAI QA-13A. above.):

IIFP utilizes active engineered controls that are integrated into routine operations to the degree practical. The IROFS are monitored as a routine part of the operating process. IROFS associated with passive engineered systems are typically fixed physical design features to maintain safe process conditions. Availability and reliability of IROFS are maintained through pre-operational audits and periodic verifications as prescribed in the ISA, and includes consideration of the importance of the IROFS as well as available quality and reliability information.

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QA-14 (QA-19) Section 11.3.1, "Organization and Management of Training," states, "Training records are maintained to support management information needs associated with personnel training, job performance, and qualification." Consistent with Section 11.4.3.3 of NUREG-1520, "Maintenance," clarify if programmatic and individual training records will be maintained.

RESPONSE: Programmatic and individual training records are maintained as stated in License Application Section 11.3.1: "Records are maintained on each employee's qualifications, experience, and training. The employee training file shall include records of all general initial site training, safety training, technical training, and employee development training conducted at the facility. The employee training file shall also contain records of special company sponsored training conducted by others. The training records for each individual are maintained so that they are accurate and retrievable. Training records are retained in accordance with the records management procedures." The subject paragraph in LA, Section 11.3.1 will be revised to clarify that programmatic and individual training records will be maintained:

License Documentation Impact: The subject paragraph (four) in LA Rev A, Section 11.3.1 will be revised as follows:

Training programs and training records at the facility are the responsibility of the Training organization~~ Lead~~. Training attendance records, examinations, employee qualification records, and program needs are maintained in an accurate, auditable manner to document each employee's training. Training records are maintained to support management information needs associated with programmatic and individual~~personnel~~ training, job performance, and qualification. Records are maintained on each employee's qualifications, experience, and training. The employee training file shall include records of all general initial site training, safety training, technical training, and employee development training conducted at the facility. The employee training file shall also contain records of special company sponsored training conducted by others. The training records for each individual are maintained so that they are accurate and retrievable. Training records are retained in accordance with the records management procedures.

Quality Assurance (Management Measures)

QA-15 (QA-22) Section 11.4.1.2, "Administrative Procedures" provides a list of the activities that will be covered by administrative procedures. Consistent with Section 11.4.3.4 of NUREG-1520, "Maintenance," clarify if existing or planned procedures will direct the following activities: construction, radiation safety, and criticality safety.

RESPONSE: Procedures for construction are not addressed in Chapter 11. The Design and Build (BD) contractor chosen by IIFP must possess existing construction procedures. The DB contractor would use those procedures during the construction phases of the IIFP Facility.

Radiation safety procedures are identified in the referenced listing in Section 11.4.1.2. Radiological Safety Training on these procedures is discussed in Section 11.3.7.2.

Criticality Safety procedures will not be applicable for the IIFP Facility since the facility will only process depleted uranium.

NRC Follow-up Question (5): In Response to Question QA-15, please clarify if the procedures chosen by the DB contractor for the construction phases will be reviewed and approved by IIFP.

NRC FOLLOW-UP QUESTION RESPONSE (5): During the selection process of the DB contractor, review of contractor QA procedures is integral in the evaluation of the prospective bidders. The DB contractor field procedures will not be approved by IIFP since the DB contractor is more knowledgeable in those areas than IIFP personnel.

License Documentation Impact: License Application, Revision A, Section 11.4.1.2, (revised paragraph one and add two additional paragraphs) will be amended, including a heading title change to modify the listing of subject activities and to address the need for construction and criticality safety procedures:

11.4.1.2 Management Control (Administrative) Procedures

~~Administrative~~ Management control procedures deal with policy or programs and administrative systems, provide programmatic requirements, and do not normally involve manipulation of equipment. ~~Administrative~~ Management control procedures are used to perform activities that support production~~,~~ and control process with IROFS and/or hazardous chemicals incident to the processing of licensed material. Site-wide safe work practices (such as lockout/tagout, confined space entry, exclusion area requirements, radiation or hot work permits, industrial safety, and environmental issues) apply to workers, visitors, contractors, and vendors. These management control procedures include~~ing~~ management measures such as the following:

- Configuration management;
- Industrial ~~Safety~~safety, radiation safety, chemical safety, and fire safety;
- Quality a~~A~~ssurance;
- Design control;
- Facility~~Plant~~ personnel training and qualification;
- Audits and assessments;
- Incident investigations;

Quality Assurance (Management Measures)

- Record keeping and document control;
- Reporting; and
- Procurement

Procedures for construction will be an integral part of the procedures of the Design and Build (DB) contractor chosen by IIFP. The DB contractor will use those procedures during the construction phases of the IIFP Facility.

Additionally, criticality safety procedures will not be applicable for the IIFP Facility since the facility will only process depleted uranium.

Quality Assurance (Management Measures)

QA-16 (QA-23) Section 11.4.1.3, "Maintenance Procedures" describes the controls for the maintenance procedures. Consistent with Section 11.4.3.4 of NUREG-1520, "Maintenance,"

A. Clarify if pre-maintenance activities will involve reviews of the work to be performed, including procedure reviews for accuracy and completeness.

RESPONSE: The first sentence of the first paragraph of License Application Section 11.4.1.3 "Maintenance procedures," states: "Maintenance, including testing, and calibration, of facility IROFS is performed in accordance with approved written procedures, documented instructions, checklists, or drawings that conform to applicable codes, standards, specifications, and other appropriate criteria." Pre-maintenance activities would include review of those procedures.

License Documentation Impact: LA Rev A, Section 11.4.1.3 will be revised to clarify that pre-maintenance activities involve reviews of the work to be performed, including procedure reviews for accuracy and completeness. The fourth paragraph of the subject section reads as follows:

Maintenance procedures address:

- Preventive and corrective maintenance of IROFS;
- Surveillance (includes calibration, inspection, and other surveillance testing);
- ~~Post-maintenance~~Functional testing of IROFS; and
- Requirements for pre-maintenance activity involving reviews of the work to be performed and reviews of procedures for accuracy and completeness.

B. Clarify if the maintenance procedures will include steps that will require notification of all affected parties before performance of work and on completion of maintenance of work, including the discussion of potential degradation of IROFS during planned maintenance.

RESPONSE: Section 11.4.3.4 of NUREG 1520, "Procedures," specifies for maintenance procedures that "Steps require notification of all affected parties (operators and supervisors) before performance of work and on completion of maintenance work. The discussion includes potential degradation of IROFS during the planned maintenance." The IIFP License Application, Revision A, Section 11.4.1.3, fifth paragraph states the following: "The administrative control of maintenance is maintained as follows:

- A comprehensive maintenance program for the facility's IROFS is established to assure safe, reliable, and efficient operation.
- Personnel performing maintenance activities are qualified in accordance with applicable codes and standards and procedures.
- Maintenance is performed with written procedures that conform to applicable codes, standards, specifications, and other appropriate criteria.
- Maintenance is scheduled so as not to jeopardize facility operation or the safety of facility personnel.
- Maintenance histories are maintained on facility IROFS.
- The administrative control of facility modifications is maintained as in Section 11.1.5, "Change Control".

Quality Assurance (Management Measures)

The last bullet in paragraph five formerly referenced Section 11.1, "Configuration Management" and will be modified in license documentation impact

The sixth paragraph Section 11.4.1.3 is modified to include the requirements of subject notification of all affected parties before performance of work and on completion of maintenance of work and an additional paragraph is added to identify the location of additional information on requirements for maintenance procedures.

License Documentation Impact: IIFP LA, Rev A, Section 11.4.1.3, the fifth paragraph, last bullet will be revised to reflect reference to Section 11.1.5 "Change Control and the sixth paragraph will be revised and an additional paragraph will added. These paragraphs will read as follows.

The administrative control of maintenance is maintained as follows:

- A comprehensive maintenance program for the facility's IROFS is established to assure safe, reliable, and efficient operation.
- Personnel performing maintenance activities are qualified in accordance with applicable codes and standards and procedures.
- Maintenance is performed with written procedures that conform to applicable codes, standards, specifications, and other appropriate criteria.
- Maintenance is scheduled so as not to jeopardize facility operation or the safety of facility personnel.
- Maintenance histories are maintained on facility IROFS.
- The administrative control of facility modifications is maintained as in Section 11.1.5, "~~Configuration Management~~Change Control."

Maintenance procedures are reviewed by the various safety disciplines, including fire, radiation, and industrial and chemical process safety. The procedures describe, as a minimum, the following:

- Pre-maintenance activities will involve reviews of the work to be performed including procedure reviews for accuracy and completeness;
- Steps that require notification of all affected parties (operators and appropriate supervisors) before performing work on completion of maintenance work (The discussion includes potential degradation of IROFS during the planned maintenance.);
- Controls on and specification of any replacement components or materials to be used, to ensure like-kind replacement;
- Post-maintenance testing to verify operability of the equipment;
- Tracking and records management of maintenance activities; and
- Safe work practices (e. g., lockout/tag-out, confined space entry, control of exclusion area, radiation or hot work permits, and fire, chemical, and environmental requirements).

See Section 11.2.1 for additional information on requirements for maintenance procedures.

Quality Assurance (Management Measures)

QA-17 (QA-28) Section 11.7.1. "Records Management," establishes the elements and requirements of the records management program applicable to QA Level 1 and QA Level 2 SSCs and activities; or to ESH, financial, quality, emergency response or investigation related records as required by regulations or approved procedures. In accordance with Section 11.4.3.7 of NUREG-1520, "Records Management,"

A. Please clarify if there are implementing procedures that (1) assign responsibilities for records management, (2) specify the authority needed for records retention or disposal, (3) specify which records must have controlled access and provide the controls needed, (4) provide for the protection of records from loss, damage, tampering, and theft or during an emergency, and (5) specify procedures for ensuring that the records management system remains effective.

RESPONSE: License Application Section 11.7.1 states: "The Records functional organization is responsible for the administration of the records management program. The managers and functional organizations that generate the records are responsible for ensuring compliance with the records management program. This program is implemented through procedures that provide guidance for the program elements.

The IIFP License Application, Revision A, Section 11.7.1 is modified to re-affirm records requirements are included in implementing procedures:

License Documentation Impact: The first paragraph will split into two paragraphs will additional wording added to the new second paragraph of LA Rev A. Section 11.7.1 will be revised as below:

The following elements and requirements of the records management program shall be applied to QA Level 1 and QA Level 2 SSCs and activities; or to ESH, financial, quality assurance, emergency response or investigation related records as required by regulations or approved procedures. These elements may be also applied to commercial quality and other plant activities where determined by facility management or required by procedure. The records management program provides direction for the handling, transmittal, storage, and retrieval of records. Records media may include microfilm, electronic (magnetic or optical), or hard copy. Records are categorized and handled in accordance with their relative importance to safety and storage needs. The Record functional organization is responsible for the administration of the records management program. The managers and functional organizations that generate the records are responsible for ensuring compliance with the records management program. ~~This program is implemented through procedures that provide guidance for the following program elements.~~

The IIFP QA Program Description requires procedures for reviewing, approving, handling, identifying, retention, retrieval and maintenance of quality assurance records. These records include the results of tests and inspections required by applicable codes and standards, construction, procurement and receiving records, personnel certification records, design calculations, purchase orders, specifications and amendments, procedures, incident investigation results and approvals or corrective action taken, various certification forms, source surveillance and audit reports, component data packages, and any other QA documentation required by specification and procedures. Implementing procedures assign responsibilities for records management, specify the authority needed for records retention or disposal, specify which

Quality Assurance (Management Measures)

records must have controlled access and provide the controls needed, provide for the protection of records from loss, damage, tampering, and theft or during an emergency, and specify procedures for ensuring that the records management system remains effective. Implementing procedures will include:

- Assign responsibilities for records management,
- Specify the authority needed for records retention or disposal,
- Specify which records must have controlled access and provide the controls needed,
- Provide for the protection of records from loss, damage, tampering, and theft or during an emergency, and
- Specify procedures for ensuring that the records management system remains effective.

Records management ~~This program~~ is implemented through procedures that provide guidance for the following program elements.

B. Please clarify if records of IROFS failures will be maintained and updated in accordance with 10 CFR 70.62(a)(3).

RESPONSE: Records of IROFS failures will be maintained and updated in accordance with 10 CFR 70.62(a)(3). Section 11.7.1.12 is revised to clarify records of IROFS failures are maintained and updated in accordance with 10 CFR 70.62(a)(3) and to show the linkage to Section 11.6.1.

License Documentation Impact: LA Rev A, Section 11.7.1.12 will be revised, inserting a new paragraph two to read as follows:

Records of IROFS failures will be maintained and updated in accordance with 10 CFR 70.62(a)(3). See Section 11.6.1 on incident investigations for additional records requirements.

Quality Assurance (Management Measures)

QAPD-1 The QAPD does not address requirements for criteria such as Control of Special Processes; Test Control; and Inspection, Test, and Operating Status. Consistent with NUREG-1520 Revision 1, Section 11.4.3.8, please clarify if the application of these measures to IROFS are appropriate.

RESPONSE: The application of Control of Special Processes; Test Control; and Inspection, Test, and Operating Status to IROFS are appropriate for the QAPD for the IIFP Facility. In response the IIFP License Application, Revision A and the License Application, Revision A, Appendix A will be amended to include these topics. Due to revisions, Sections and subsections will be renumbered in sequence, accordingly.

License Documentation Impact: "Control of Special Processes" will be added as a new paragraph to LA, Rev A, as new Section 11.8.9 (to be inserted before former11.8.15, "Inspection") and to the LA, Rev A, Appendix A as new Section A.9, (to be inserted before former A.9.1, "Inspection") each will read as follows:

11.8.9 Control of Special Processes

Special processes affecting quality of items and services are controlled. Procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means are used to control special processes. These means assure that special process parameters are controlled and that specified environmental conditions are maintained.

Special processes that control or verify quality (such as, those used in welding, heat treating, and nondestructive examination) are performed by qualified personnel using approved written procedures in accordance with specified requirements, codes, or standards. Special process procedures prescribe the necessary equipment, process parameters, calibration, and acceptance criteria. Records are maintained of currently qualified personnel, processes, and equipment for special processes. See LA Appendix A.9.

A.9 Control of Special Processes

A.9.1 General

A system is established for the control of special processes within the scope of the QA Program Description. This system establishes the requirements for the control of special processes.

A.9.2 Responsibilities

The engineering discipline is responsible for determining special processes, providing technical requirements for identified special processes, and reviewing and concurring with all

special process procedures including the utilization and application of nondestructive examination (NDE) procedures.

The Quality Assurance Manager is responsible for the qualification on NDE personnel, including welder/brazing qualifications.

Line Managers ensure that identified special processes are performed by qualified personnel, using qualified and approved procedures or documents of a type appropriate to the circumstances.

A.9.3 Requirements

Special processes affecting quality of items and services such as welding, heat treating, and nondestructive examination are controlled.

Policies, plans, procedures, instructions, drawings, checklists, travelers, work orders, or other appropriate means are used to control special processes.

These special processes ensure special process parameters are controlled and specified environmental conditions are maintained.

Special processes that control or verify quality (that is, those used in welding, heat treating, and nondestructive examination) are performed by qualified personnel using approved written policies, plans, and/or procedures in accordance with specified requirements, codes, or standards.

When the outcome of the process is highly dependent on personal skills, such individuals are certified in accordance with specified requirements.

When the outcome is highly dependent on control of process parameters, the process and equipment are pre-qualified in accordance with specified requirements.

Special process policies, plans, and/or procedures prescribe the necessary equipment, process parameters, calibration, and acceptance criteria.

Records are maintained of currently qualified personnel, processes, and equipment for special processes.

License Documentation Impact: "Test Control" will be added as a new paragraph to LA, Rev A, as new Section 11.8.11 (to be inserted after 11.8.15, "Inspection") and to the LA, Rev A, Appendix A as new Section A.11, (to be inserted after former Section and subsections for A.9.1, "Inspection") each will read as follows:

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11.8.11 Test Control

Tests required for conformance verification of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated.

Tests include design verification tests, acceptance tests, pre-operational and operational tests, post-maintenance, and special tests. Planning for tests may include mandatory hold points, as required. Test procedures contain the following information, as appropriate:

- Test purpose or objectives, responsibilities, characteristics to be tested, hold points, and test methods to be employed;
- References and related documents;
- Provisions for ensuring that prerequisites for a given test have been met, to include, as applicable: calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, and provisions for data acquisition;
- Adequate instrumentation is available and suitable environmental conditions are maintained;
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria; and
- Qualifications for test personnel.

Test records contain the following information: item tested, test date, tester or data recorder, type of observation, test procedure or reference, results and acceptability, actions taken in connection with any deviations noted, and person evaluating the results. See LA Appendix A.11.

A.11 Test Control

A.11.1 General

A system is established for design verification testing, acceptance testing, pre-operational and operational testing, post-maintenance testing, and special testing of IROFS. This system provides measures to ensure that this testing is completed satisfactorily.

Requirements for the certification of personnel who perform design verification testing, acceptance testing, pre-operational and operational testing, post-maintenance testing, and special testing of IROFS are identified.

A.11.2 Responsibilities

The Engineering organization is responsible for providing technical criteria for testing, evaluation of test results, and resolution of deficiencies identified from these tests.

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Line managers are responsible for the conduct of testing activities under their cognizance which are in accordance with procedures consistent with these requirements.

A.11.3 Requirements

Tests required for conformance verification of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed.

Characteristics to be tested and test methods to be employed are specified.

Test results are documented and their conformance with acceptance criteria is evaluated.

Tests required to collect data, such as for siting or design input, shall be planned, executed, documented, and evaluated.

Tests include design verification tests, acceptance tests, pre-operational and operational tests, post-maintenance tests and special tests. Planning for tests may include mandatory hold points, as required.

Test policies, plans, and/or procedures contain the following information, as appropriate:

- Test purpose or objectives, responsibilities, characteristics to be tested, hold points, and test methods to be employed;
- References and related documents;
- Provisions for ensuring prerequisites for a given test have been met, to include, as applicable, calibrated instrumentation, appropriate equipment, trained personnel, condition of test equipment and the item to be tested, and provisions for data acquisition;
- Adequate instrumentation is available and suitable environmental conditions are maintained;
- Provisions for documenting and evaluating the test results for conformance with acceptance criteria; and
- Qualifications for test personnel.

In lieu of test policies, plans, and procedures, appropriate methods of related documents [such as American Society for Testing and Materials (ASTM), external manuals, maintenance instructions, or approved drawings] may be used. Such documents must include adequate instructions to ensure the required quality of work.

Test records contain the following information:

- Item tested; test date;
- Tester or data recorder;

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- Type of observation;
- Test policy, plan, procedure, or reference;
- Results and acceptability;
- Actions taken in connection with any deviations noted; and
- Person evaluating the results

License Documentation Impact: "Inspections, Test, and Operating Status" will be added as a new Section to LA, Rev A, as Section 11.8.13 (to be inserted after former 11.8.16, "Control of Measuring and Test Equipment") and to the LA, Rev A, Appendix A as new Section A.13, (to be inserted after former Section and Subsections for A.10.1, "Control of Measuring and Test Equipment") each will read as follows:

11.8.13 Inspection, Test, and Operating Status

Requirements are established for IIFP to identify the status of inspection and test activities. Status indicators are also provided for indicating the operating status of IROFS systems and components to prevent inadvertent operation. Policies, plans, and procedures are established to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item.

Status indicators (for example, physical location and tags, markings, work controlling documents, stamps, inspection records, or other suitable means) are utilized when required. This includes indicating the operating status of systems and components to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels, and stamps is specified. See LA Appendix A.13.

A.13 Inspection, Test, and Operating Status

A.13.1 General

A system establishes requirements for IIFP to identify the status of inspection and test activities. Status indicators are also provided for indicating the operating status of IROFS systems and components to prevent inadvertent operation.

A.13.2 Responsibilities

The Quality Assurance Manager is responsible for providing a status-indicating system for inspections performed in accordance with these requirements.

Line managers participating in testing and operational activities are responsible for the development and implementation of status-indicating systems consistent with these requirements.

A.13.3 Requirements

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Policies, plans, and procedures are established to ensure that the status of inspection and test activities are either marked or labeled on the item or in documents traceable to the item. This activity is required when it is necessary to ensure that required inspections and tests are performed, and to ensure items that have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Status indicators (for example, physical location and tags, markings, work controlling documents, stamps, inspection records, or other suitable means) are utilized when required. This includes indicating the operating status of systems and components (for example, tagging valves and switches) to prevent inadvertent operation. Authority for the application and removal of tags, markings, labels, and stamps is specified.

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QAPD-2 Section A.7.1.3.3 of the Quality Assurance Program Description states that "The criteria and methods shall identify the critical characteristics that are essential to ensure the item will perform its intended IROFS function." Consistent with 10 CFR Part 21, "Reporting of Defects and Noncompliance," dedication occurs after receipt when the item is designated for use as a basic component. Please clearly describe the dedication process; and, if critical characteristics will be verified, please identify those methods.

RESPONSE: The QAPD is revised to describe the dedication process and methods to verify critical characteristics.

License Documentation Impact: Former Section A.7.1.3.3 of the Quality Assurance Program Description (LA, Rev A, Appendix A) new Section number A.7.3.3 will be revised to add new second and third paragraphs which will read as follows:

~~A.7.1.3.3~~A.7.3.3 Commercial Grade Items

Methods shall be established for determining whether an item can be purchased as commercial grade and dedicated for use in an IROFS application. The criteria and methods shall identify the critical characteristics that are essential to ensure that the item will perform its intended IROFS function.

QL-1 and QL-2 items may be procured as commercially available items provided they are subjected to a dedication process. Items and services that are not relied on for safety may be designated as QL-2 or QL-3 and may be procured as commercially available items. The dedication process is described below.

In accordance with 10 CFR 21 (CFR, 2009c), the procurement process procedures include requirements that IIFP confirm each supplier/vendor approved to provide basic components has an approved process in place that implements the requirements of 10 CFR 21. In cases where commercial-grade items are to be procured and then dedicated for use as IROFS or parts thereof, the procurement process procedures include requirements that IIFP define to the supplier those elements of the supplier's process controls that are mandatory and any other requirements necessary to ensure critical characteristics will be met. Those requirements for verifying acceptability of critical characteristics could encompass inspection, tests, or analyses after delivery, supplemented as necessary by one or more of the following:

- Commercial grade surveys,
- Product inspections or witness at hold-points at the manufacturer's facility, and
- Analysis of historical records for acceptable performance.

As a minimum for acceptance of commercial grade items, receipt inspection will be performed to provide reasonable assurance that the item received is the item ordered. Receipt inspections are performed:

- to determine that damage was not sustained during shipment,
- that the item received is the item ordered,
- that inspection and testing was performed by the supplier as required by Engineering,

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- to ensure conformance with manufacturer's published requirements, and
- to ensure that required documentation is received and is acceptable

Commercial grade items are identified in the contract or purchase order by the manufacturer's published product description. Alternate commercial grade items are allowed provided Engineering provides verification that the alternate commercial grade item will perform its intended IROFS function.