Independent Oversight Review of the Implementation Verification Review Processes at the Oak Ridge Office of Environmental Management for Building 3019

February 2012

Office of Safety and Emergency Management Evaluations
Office of Enforcement and Oversight
Office of Health, Safety and Security
U.S. Department of Energy

Table of Contents

Acronyms

ALARA	As-Low-as-Reasonably-Achievable
CFR	Code of Federal Regulations
CRAD	Criteria, Review and Approach Document
DNFSB	Defense Nuclear Facilities Safety Board
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
EM	DOE Office of Environmental Management
FHA	Fire Hazards Analysis
FMH	Fissile Material Handler
FMHS	Fissile Material Handler Supervisor
FR	Facility Representative
HSS	DOE Office of Health, Safety and Security
HVAC	Heating, Ventilation, and Air Conditioning
IVR	Implementation Verification Review
LOI	Line of Inquiry
MSA	Management Self-Assessment
NCSA	Nuclear Criticality Safety Approval
ODP	Operations Data Package
OEP	Operations Evolution Package
ORO-EM	Oak Ridge Office of Environmental Management
POA	Plan of Action
RA	Readiness Assessment
RWP	Radiological Work Permit
SAC	Specific Administrative Control
SARP	Safety Analysis Report for Packaging
SCMS	DOE Office of Science Management System
SER	Safety Evaluation Report
SSC	Structure, System or Component
SSO	Safety System Oversight
STC	Shielded Transfer Cask
TSR	Technical Safety Requirement
USQ	Unreviewed Safety Question
UTB	UT-Battelle, LLC
VOG	Vessel Offgas
ZPR	Zero Power Reactor

Independent Oversight Review of the
Implementation Verification Review Processes at the
Oak Ridge Office of Environmental Management for Building 3019

1.0 PURPOSE

This report documents the independent review of implementation verification review (IVR) processes at the Oak Ridge Office of Environmental Management (ORO-EM) conducted by the Office of Enforcement and Oversight (Independent Oversight) within the Office of Health, Safety and Security (HSS). The review involved evaluation of established IVR processes and implementation of the newly revised documented safety analysis (DSA) and technical safety requirements (TSRs) at the Building 3019 Complex (formerly referred to as the Radiochemical Development Facility) operated by Isotek Systems, LLC (Isotek). The review was performed by the HSS Office of Safety and Emergency Management Evaluations during two phases, with the first phase performed during October 3-7, 2011 and the second phase conducted during November 29 – December 8, 2011 and was carried out within the broader context of an ongoing program of assessments of the execution of IVRs at U.S. Department of Energy (DOE) sites with hazard category 1, 2, and 3 nuclear facilities. The objective of this assessment was to evaluate the extent to which the ORO-EM and Isotek have developed and executed appropriate methods for verifying and re-verifying implementation of new or substantially revised facility safety basis hazard controls.

2.0 BACKGROUND

Title 10 Code of Federal Regulations (CFR) 830.201, *Performance of Work*, states, "A contractor must perform work in accordance with the safety basis for a hazard category 1, 2, or 3 DOE nuclear facility and, in particular, with the hazard controls that ensure adequate protection of workers, the public, and the environment." In addition, 10 CFR 830, Subpart A, *Quality Assurance Requirements*, establishes requirements for conducting activities that may affect safety at the ORO-EM facilities, including performing work in accordance with hazard controls, using approved instructions or procedures, conducting tests and inspections of items and processes, and independently assessing the adequacy of work performance.

In February 2008, the Defense Nuclear Facilities Safety Board requested that DOE evaluate the need to conduct "independent validations on a recurring basis" to ensure that facility equipment, procedures, and personnel training related to safety basis controls have not degraded over time. In response, the Department conducted an evaluation that led to the conclusion that the existing requirements for implementation of safety controls and DOE policy for oversight of the implementation of nuclear safety requirements were appropriate. That evaluation also concluded there was no explicit requirement to validate safety basis hazard controls, so the Department committed to develop guidance on the validation of safety controls and to add that guidance to the Department's directives.

A DOE working group developed a "best practices guide" for the independent validation of safety basis controls. In November 2010, the guidance for performing IVRs was incorporated in DOE Guide 423.1-1A, *Implementation Guide for Use in Developing Technical Safety Requirements*, Appendix D, *Performance of Implementation Verification Reviews (IVRs) of Safety Basis Controls*.

3.0 SCOPE

At the Oak Ridge Reservation, ORO-EM provides direction and oversight for the design and operation of nuclear facilities involved in environmental cleanup activities for the DOE Office of Environmental Management (EM). Isotek is the primary contractor responsible for the management and operation of Building 3019, which is categorized as a hazard category 2 nuclear facility pursuant to DOE-STD-1027, *Hazard Categorization and Accident Analysis Techniques for Compliance with DOE Order 5480.23*, *Nuclear Safety Analysis Reports*. Building 3019 is located on the Oak Ridge National Laboratory campus, which is managed and operated by UT-Battelle, LLC (UTB).

In the first phase of Independent Oversight's review (October 2011), Independent Oversight assessed the establishment and execution of both ORO-EM and Isotek processes and activities for verifying the implementation of changes to facility safety basis hazard controls. The scope of the initial phase included Objectives 1 and 2 in the HSS criteria, review and approach document (CRAD) HSS CRAD 45-39, Rev. 1, *Implementation Verification Review of Safety Basis Hazard Controls: Inspection Criteria, Activities, and Lines of Inquiry*. The goal was to determine whether processes have been established that provide assurance that safety basis hazard controls are maintained and hazard control changes are correctly implemented, and whether the contractor and site office have developed and implemented appropriate methods for performing IVRs or similar reviews. The first phase of the assessment was accomplished by reviewing the documentation that establishes and governs the ORO-EM and Isotek IVR processes (for example, work instructions, procedures, forms, and checklists) and interviewing key ORO-EM and Isotek facility personnel responsible for developing and executing the IVR processes.

The second phase of the review (November and early December 2011) addressed the remaining objectives (3 through 6) in HSS CRAD 45-39 through observation of the DOE readiness assessment (RA) for the startup of programmatic transfer of Zero Power Reactor (ZPR) materials from Building 3019. This review focused on assessing the implementation of IVR processes and evaluating the effectiveness of both the contractor and site office in verifying implementation of the safety basis controls. Independent Oversight's tailored review of IVR implementation at Building 3019 included shadowing and observation of site office personnel during the DOE RA and their review of safety basis control implementation.

The scope of Independent Oversight's second phase review activities included verification that Isotek had effectively incorporated the safety basis hazard controls into implementing procedures and work control documents and adequately implemented the facility training and qualification program associated with the reviewed safety basis controls. Independent Oversight also examined the extent to which both ORO-EM and Isotek implemented appropriate methods for performing implementation verifications through the processes for scheduling and conducting readiness reviews and other related IVR activities. To verify that the IVR and RA processes are effective, Independent Oversight evaluated a selection of safety basis controls from the two most recent revisions of DSA and TSRs and from the shipping container safety analysis report for packaging (SARP), which establish the safety basis for the programmatic transfer evolution. Since the current safety basis hazard controls do not include limiting conditions for operation and do not address safety systems other than passive design features, Independent Oversight's evaluation was focused on verifying that specific administrative controls (SACs) are implemented such that they adequately meet the functional requirements and expectations of the safety basis and that selected safety management programs effectively support the startup of operations.

4.0 RESULTS

Objective 1: Processes have been established that provide assurance that safety basis hazard controls are maintained and hazard control changes are correctly implemented.

ORO-EM

Independent Oversight reviewed ORO-EM processes to determine whether the processes adequately assess the contractor's implementation of new and revised safety basis documents and provide sufficient information to confirm the ongoing effectiveness of contractor processes for the implementation of safety basis requirements.

ORO-EM has an established procedure for executing its responsibilities for review and approval of safety basis documents. This procedure, EM-3.5, *Safety Basis Document Review*, addresses the process for review and approval of safety basis documents, but it does not include responsibilities or instructions for oversight of the implementation of safety basis hazard controls. Nevertheless, through the integrated project team (established by the U-233 disposition program), ORO-EM assembled an oversight team to conduct formal shadowing of Isotek's implementation of changes to the safety basis hazard controls resulting from the transition of Building 3019 from surveillance and maintenance to operations. (See opportunity for improvement **L3-1**.)

The ORO-EM integrated assessment program, described in procedure EM-3.3, *Integrated Assessment Program*, provides an adequate foundation for oversight of implementation of safety basis hazard controls, including oversight of IVR processes. The procedure provides for the establishment of an integrated assessment schedule that includes both three-year and annual schedules. Roles and responsibilities are clearly established, with primary responsibility for schedule development assigned to the Federal project directors and division directors. Assessment elements include safety basis change and implementation verification and adequacy of the contractor's IVR. The procedure identifies both formal and informal assessments and provides instructions for their conduct and documentation; however, it does not identify any processes to periodically re-verify implementation of safety basis hazard controls. Given the previously static condition of Building 3019 (surveillance and maintenance) until the implementation of the revised DSA and TSRs to support new operations, the lack of periodic re-verification has been acceptable. Although the procedure identifies IVRs as an element to be included in the assessment program, no specific responsibilities for scheduling assessments of the contractor's implementation of IVRs were identified. (See opportunity for improvement **L3-1**.)

ORO-EM procedure EM-2.1, *Startup and Restart of Oak Ridge Reservation Environmental Management Program Work*, includes appropriate instructions for the conduct of startups and restarts, and incorporates recent changes to the governing DOE order. It identifies the roles and responsibilities for implementation and establishes an adequate set of processes for conducting readiness reviews, including operational readiness reviews, RAs, and oversight reviews. The oversight review process has been established to address situations in which no readiness review is required but oversight of the contractor is desirable. The instructions include the possibility of incorporating IVR activities in the plan of action (POA). Overall, the instructions provide sufficient direction to support the planning, conduct, and reporting of readiness activities.

Isotek Services, LLC

Independent Oversight reviewed Isotek's procedures and processes for implementing and maintaining the safety basis hazard controls at their facilities in order to determine whether those processes and/or procedures include an IVR or similar process for implementing new or revised safety basis documents. The review also assessed these processes and procedures to determine whether they provide an

appropriate level of planning and formality for re-verification of safety basis hazard controls and for verification of the implementation of safety basis requirements prior to the startup of new or modified facilities with new or revised safety basis documents.

Isotek procedure ISO-OPS-210, *Implementation Validation Review Process*, adequately defines the process for implementing safety basis documents. It includes responsibilities, prerequisites, instructions for performing an IVR, generic CRADs and lines of inquiry (LOIs), an IVR plan outline, and a declaration of readiness prerequisites checklist. The sample CRADs and LOIs and the declaration of readiness prerequisites checklist are comprehensive and thorough. In addition to these items, the procedure states that the Operations Manager is responsible for ensuring that a safety basis compliance matrix is created. Although the procedure references separate duties for a Facility Manager and an Operations Manager, these position responsibilities have been combined and are being performed by one person. Independent Oversight conducted an interview with the Facility/Operations Manager, who was knowledgeable of the duties required for both positions. (See opportunity for improvement **L3-2**.)

Isotek Procedure ISO-SAF-204, *Safety Basis Documentation*, describes the overall process for safety basis development, including the requirement to perform an annual review and submit the results to DOE. It also includes implementation planning guidelines and recommendations, including the development of document-specific implementation plans and the performance of management assessments and/or IVRs as deemed appropriate. Responsibility for implementing the safety basis is assigned to the Facility Manager. The procedure addresses numerous safety basis topics including the need to evaluate safety structures, systems, and components (SSCs) for potential degradation; the selection of SACs; DOE conditions of approval; and justification for continued operation. The procedure adequately addresses the development and maintenance of safety basis documentation.

Procedure ISO-OPS-200, *Operational Readiness Reviews and Readiness Assessments*, has been updated to comply with DOE Order 425.1D. It addresses implementation of the safety basis through the CRADs in the POA. Guidance is provided for conducting a startup/restart activity description and activity score sheet, which are used to determine the appropriate level of readiness review and the authorization authority. The startup/restart activity description includes as one factor the effect of the proposed activity on the safety basis. The procedure also addresses startup notification reports, POA development, independence of team leaders, contractor readiness review implementation plan development, the conduct of management self-assessments (MSAs), the use of MSA affidavits, preparation of the declaration of readiness memorandum, and conduct of the readiness review. The readiness declaration memorandum worksheet states that the facility safety basis documentation should be approved, implemented, and validated before the independent review, and the readiness review final report must address the implementation of safety basis requirements.

Isotek procedure, ISO-OPS-210 specifically addresses the IVR process and the other processes and procedures that support the implementation of new or revised safety basis documents. These processes and procedures provide an appropriate level of planning and formality for verification of the implementation of safety basis requirements prior to the startup of new or modified facilities with new or revised safety basis documents. No specific processes or procedures were identified for re-verification of safety basis hazard controls at periodic intervals, other than the annual update requirement. Also, no assessment schedule was provided to show that safety basis controls are periodically re-verified, although, as noted, the previously static nature of operations and the earlier facility safety basis may have made re-verification unnecessary, as determined by Isotek. However, as the facility transitions into an operational mode, Isotek should consider whether formalizing these processes would help ensure that the safety basis implementation remains current. (See opportunity for improvement **L3-3**.)

Objective 2: The contractor and site office have developed and implemented appropriate methods for performing IVRs or similar reviews.

Independent Oversight reviewed the ORO-EM and Isotek IVR methods to determine whether they adequately address the implementation of safety basis hazard controls. The review also examined whether review criteria and approaches are sufficient for the scope of the review and appropriately tailored to the hazard controls being verified, and whether the review activities are sufficiently well documented (per procedures) to support the conclusions of the review.

ORO-EM

Past ORO-EM integrated assessment schedules did not specifically address the oversight of contractor IVRs or independent verification of the implementation of hazard controls at Building 3019, but the annual surveillance schedule for the Facility Representatives (FRs) includes two surveillance topics, TSR implementation and SACs, that address verification of hazard controls. ORO-EM personnel also conduct monthly reviews of aspects of the Isotek criticality safety program. In addition, the ORO-EM Engineering Division assessment schedule for fiscal year 2012 includes assessments of SACs and surveillance requirements. As noted above, formal oversight of the IVR for the implementation of the latest revision to the DSA and TSR was conducted by the ORO-EM integrated project team using functional area subject matter experts.

Independent Oversight reviewed the reports of several ORO-EM oversight activities of safety basis hazard controls that were conducted during the past fiscal year. Formal evaluation of SACs, including a small sample at Building 3019, was conducted and appropriately documented early last fiscal year. In addition to oversight of facility operational activities, the FR conducted two specific walkthrough surveillances of TSR implementation; one included interviews of building operations personnel, and the other documented a review of the flow down of requirements into the implementing procedures. In addition, the FR reviewed the report of the Isotek IVR for revision 5 to the DSA and TSR, though this did not include independent verification of implementation. These less-formal oversight activities are also appropriately documented.

Isotek Services, LLC

Procedure ISO-OPS-210, *Implementation Validation Review Process*, requires the preparation of a safety basis compliance matrix, the development of an IVR plan, preparation of the declaration of readiness prerequisites checklist, issuance of a final IVR report, and the disposition of findings. Independent Oversight reviewed the implementation validation review reports for revisions 4 and 5 of the Isotek safety basis documents for Building 3019. Both documents contained the results of the IVR, as well as the IVR plan. Independent Oversight interviewed the team leader for the revision 5 IVR and the upcoming revision 6 IVR, and confirmed that he was both well qualified and independent of the DSA and TSR development and implementation processes. The revision 4 and 5 IVRs addressed the adequacy of implementation of the safety basis documents, but did not evaluate the adequacy of the safety basis documents themselves. The IVR for revision 5 identified five pre-implementation findings and two post-implementation findings; the post-implementation findings were considered to be minor discrepancies or changes, and thus did not impact the implementation of the safety basis controls. Both IVR reports contained the plan for the implementation validation review, IVR performer resume, CRAD, LOIs, and list of findings. The review criteria and approaches were appropriately tailored and included the revised DSA controls, design features, SSCs, and the DOE conditions of approval. The IVR reports for both revision 4 and revision 5 contained sufficient documentation to support the conclusions of the review.

As required by ISO-OPS-200, Isotek prepared a startup/restart activity description that described the changes in hazards and their effect on the safety basis, as well as describing the process and procedure

changes. Isotek concluded that the ZPR activity is essentially a restart of a similar previous activity and proposed an independent contractor RA as the contractor readiness activity. Isotek prepared ISO-OPS-POA-004, *Plan of Action (POA) for Readiness Assessment for Programmatic Transfer of Zero Power Reactor (ZPR) Materials*, which was subsequently revised to add the staging locations and a shielded box to the scope of the overall restart activity. The POA provides a thorough description of the activity, including the movement of solid fissionable material and the move plan for the shipments. Per discussion with the Isotek Facility Manager, movement of the canisters will be controlled by an evolution plan that will be reviewed by a data review committee before any material is moved. The POA identifies prerequisites for the core requirements, including the implementation of facility safety documentation. The MSA process included the use of affidavits to document readiness in each of the core requirements, which proved effective in documenting implementation. The contractor conducts bi-weekly meetings, one of which was observed by the Independent Oversight team, to provide information on the status of progress on the Accelerated ZPR Campaign Milestone Schedule. Project milestones include the MSA, IVR, and the contractor and DOE RAs. The status of affidavit completion, as well as punch list and critical path items, was discussed.

The scope of the RA covered the activities between removing the locking device and lowering the loaded and closed shipping container onto the loading pad. Type B package QA plans and Safety Analysis Reports often include specific requirements for securing the packages on the means of conveyance. Considering this, Independent Oversight inquired whether the scope of the RA should also cover the activities associated with the loading and tie-down of the shipping containers in the transport vehicle. In response, Isotek prepared a white paper (ISO-OPS-WP-006) that concluded the loading and tie-down of the package in a transport vehicle is a routine shipment activity, and thus outside the scope of the restart review. This conclusion was based upon the Nuclear Regulatory Commission Certificate of Compliance, which certified that the shipping container meets the requirements of 10 CFR 71, *Packaging and Transportation of Radioactive Material*, and the SARP conclusion that "there are no tie-down devices which are a structural part of the shipping container." This reasoning was acknowledged and accepted by the review team.

Objective 3: Contractor IVRs or similar reviews and site office oversight activities are sufficient to verify that safety basis hazard controls have been effectively incorporated into implementing administrative and operating procedures and work control documents.

For this objective, Independent Oversight reviewed the facility's operating procedures to determine whether they adequately implement the hazard controls and maintain operation of the facility within the established safety basis. Operating procedures that contain safety basis hazard controls were reviewed to verify that they adequately implement hazard controls and operating evolutions were observed to verify that the procedures can be executed as written. In addition, Independent Oversight shadowed the performance of the DOE RA and verified that the procedures and processes in place for scheduling and conducting readiness reviews are effectively implemented.

ORO-EM

As discussed above, the ORO-EM POA for the startup of programmatic transfer of ZPR materials included a series of contractor and DOE reviews to verify readiness. These reviews comprised an Isotek MSA followed by a contractor RA, which was shadowed by a DOE MSA team, and finally a DOE RA. The POA incorporated the minimum core requirements established by the DOE startup and restart order and adequately described the scope of the review. The POA also established an appropriate set of prerequisites, including completion of the contractor RA and DOE MSA and correction of the identified deficiencies. The plan identified the team leader and the startup authority. A table in the plan set out the breadth and scope of the review for each of the core requirements, which were appropriate for this startup.

ORO-EM conducted an MSA for the startup in conjunction with the contractor RA. The scope of the MSA included the adequacy of the Isotek RA, readiness of Building 3019 personnel and systems, and completion of the DOE prerequisites from the POA. The MSA team consisted of five members supporting a deputy and team leader, who performed their review using a suitable set of CRADs for each functional area included in the review. The assessment approach included document reviews, interviews, observations of performance demonstrations, and observation of the Isotek RA. Individual review forms for each functional area adequately support the completed review. The DOE MSA team concluded that the contractor RA was satisfactorily conducted and that Isotek was ready to start up and safely conduct the ZPR movements. The DOE MSA team did not identify additional findings beyond those identified by the contractor RA; however, the team upgraded five of the contractor RA findings and observations to pre-start findings, and also upgraded one observation to a post-start finding. Overall, the assessment final report provides well documented conclusions and evidence of a thorough review of the Isotek RA and readiness to start up.

Following the contractor RA and DOE MSA, the DOE RA was conducted in accordance with an approved implementation plan that adequately fulfilled the DOE POA. The implementation plan provided an appropriate level of discussion to guide the team through the review and was supplemented by an indoctrination and briefings provided by the team leader. The scope and breadth of the RA discussed in the implementation plan appropriately matched the DOE POA. The RA included a documentation review, interviews, walk downs, and observation of performance demonstrations for all the major activities in the ZPR material movement. Notably, the DOE RA team developed two scenarios for off-normal events, one of which was injected without advance notice during the performance demonstrations. The RA was appropriately conducted using the implementation plan CRADs to guide the review of the functional areas, which included criticality safety, facility safety, operations, fire protection, radiation protection, training and qualification, emergency preparedness, worker safety and health, maintenance management, restart readiness, DOE oversight, and quality assurance. The facility safety functional area included a review of the contractor's IVR report. The five team members and supporting subject matter experts were adequately independent and qualified to evaluate the assigned functional areas.

The DOE RA team concluded that Isotek had adequately demonstrated its ability to safely conduct the ZPR movement operations and that the previous reviews were adequately performed and documented. In its report, the team identified two pre-start findings, which are indicated to have been adequately closed, and one post-start finding along with eleven observations. The pre-start findings relate to failure to perform unreviewed safety question (USQ) reviews of the operations evolution plan (OEP) and forms and the lack of two independent actions to verify that the correct storage vault is opened. The post-start finding addresses an inconsistency in the SAC for lift height restrictions and the descriptions of the control in the DSA and the supporting calculation. Although this is a post-start finding, it must be corrected before the shielded transfer cask (STC) is used.

Independent Oversight observed the performance of the DOE RA, witnessed all of the operating performance demonstrations and a number of the interviews, and independently reviewed many of Isotek's implementing documents. Independent Oversight also asked follow-up questions during the interviews as appropriate. The DOE RA team closely observed the performance demonstrations and, as noted above, included off-normal events to gauge the operator's ability to respond. The interviews were probing, and the questions posed were appropriate to the topical areas. The team's final report provides an appropriately detailed discussion of the RA results. Overall, the DOE RA team adequately executed its implementation plan and provided a critical assessment of the previous reviews and Isotek's readiness to proceed with operations.

Isotek Services, LLC

DSA and TSR Revision

The implementation plan for the latest revisions of the Building 3019 complex DSA and TSR is documented in ISO-OPS-008, *Documented Safety Analysis and Technical Safety Requirements Implementation Plan for Building 3019 Complex*, which is updated from previous revisions as the documents change. The plan identifies the actions needed to implement the credited controls and assumptions identified in the safety basis and incorporates changes associated with the ZPR shipping campaign, as well as other updates to the DSA. It assigned responsibility for implementation of safety basis documents to the facility Operations Manager, including development of an implementation plan, preparation of implementing operations procedures, determination of the proper level and scope of the IVR, creation of a safety basis implementation/action matrix, preparation and maintenance of a flow down matrix, declaration of readiness, assignment of personnel to perform the IVR, and submittal of the implementation statement to DOE. The implementation actions also include conducting a contractor RA and supporting a DOE RA. For the revised portions of the safety basis, the implementation action matrix identifies the changes in the DSA, along with the implementation action. Attachment 7.1 provides the implementation actions matrix, and Attachment 7.2 identifies the training associated with the implementation of the safety basis changes. Although Independent Oversight requested the safety basis compliance matrix for the entire DSA, none was provided. The DOE RA team identified, as an issue, the lack of a safety basis compliance matrix for the complete safety basis. (See opportunity for improvement **L3-4**.)

Following completion of the DSA and TSR implementation plan, Isotek completed an independent IVR, as required by ISO-OPS-210. The plan for the IVR had four objectives: requirements flow down is complete, safety basis controls and requirements are implemented in command media, facility personnel are knowledgeable of the changes and controls, and requirements are implemented. The conclusion of the IVR was that each of the objectives was met, but the review identified five pre-implementation and three post-implementation findings, all of which were corrected before the IVR report was issued. The report documented the LOIs and briefly summarized the review activities (interview or document review), though it did not include a detailed discussion of the findings. In addition to the DSA and TSR implementation plan, Istotek developed and completed verification and implementation checklists for both nuclear criticality safety approvals (NCSAs) associated with the ZPR shipment operations: NCSA No. 004, *SNM Storage and Vault Access*, and NCSA No. 12, *Container Handling*.

Readiness Assessments

Before declaring its readiness to proceed with ZPR movement operations, Isotek completed a contractor MSA and an independent readiness review. In the contractor MSA, Isotek implemented a structured approach to achieving readiness by developing a series of affidavits to demonstrate and document readiness in the functional areas. Following the MSA, a contractor RA was conducted in accordance with Isotek procedures and executed as specified in an appropriate implementation plan. The RA was completed by an independent team of technical experts following an implementation plan that addressed the core requirements and CRADs from the DOE-approved POA. The team, consisting of a team leader and five technical experts, evaluated 11 functional areas, including criticality safety, facility safety analysis, training and qualification, emergency preparedness, worker safety and health, maintenance management, restart readiness, DOE oversight, radiation protection, conduct of operations, and quality assurance. The facility safety analysis functional area included verification that an implementation matrix and the administrative controls described in the DSA were in place, but did not address the requirements of the transportation package SARP or specifically mention the IVR. The quality assurance functional area also did not address requirements related to the SARP. The contractor readiness review team identified one pre-start and one post-start finding (along with three findings that were designated as "non-

RA" – not directly affecting ZPR shipping activities) and 15 observations. As noted above, the DOE MSA team, which shadowed the contractor RA team, revised and upgraded six of these findings and observations. For the most part, the contractor RA was adequately documented and the report provided satisfactory evidence to support the team's conclusion that Isotek was ready to commence the DOE RA.

Safety Management Programs and Operating Processes

Independent Oversight also reviewed several of the safety management programs and operating processes that maintain facility operations within the safety basis.

Isotek's operating procedure ISO-OPS-001, *General Operations*, contains appropriate instructions for implementing TSR administrative controls, conducting general operations, and completing periodic round sheets. The precautions and limitations section addresses several administrative controls that are suitably linked to the TSR requirement, as required by the document control procedure. These controls include minimum staffing, emergency actions, and periodic verification of vessel off gas (VOG) header vacuum. The procedure also delineates Facility Manager TSR responsibilities (with links to the TSR requirement), including the Facility Manager's responsibility to remain "available to the facility" to meet the definition in the TSR. The procedure establishes daily, weekly, monthly, and annual round sheets and provides instructions for completing the rounds, annotating out-of-specification readings, and notifying supervision. The daily round sheet records the cell VOG system differential pressure per TSR administrative control 5.8.11.1 and establishes an appropriate reporting limit. The procedure also provides for monthly inspection of (cell cover) drain holes per the applicable nuclear criticality safety approval.

Independent Oversight also verified the implementation of several safety management programs described in the TSRs and found that non-safety devices and equipment used during ZPR movement operations are controlled and tested per the applicable program and implementing procedures. For example, in addition to the verification of adequate VOG differential pressure during the daily rounds discussed above, ISO-OPS-104 requires that the VOG downstream header pressure and high efficiency particulate air filter differential pressure be recorded at least once during each day's evolutions and that the air flow into the tube vault is measured upon opening.

The DOE RA team identified concerns about the fire protection program related to configuration management of the systems and emergency planning communications. The current version of the pre-fire plan was updated using a fire hazards analysis (FHA) that was created prior to the air-gapping of the intermediate sprinklers. Later revisions of the FHA were not transmitted to the UTB Fire Department. The RA team noted that Isotek needed to improve coordination with the UTB fire protection program to ensure that pre-fire plans are consistent with the current configuration.

ISO-MNT-212, *Measuring and Test Equipment*, supports SAC implementation and operations by ensuring that tools, gauges, instruments and devices are properly controlled and calibrated. The maintenance manager maintains a recall status database that identifies the equipment, including the identification number, last calibration date, and next due date. Examination of a number of tools and instruments during the performance demonstrations provided evidence that the recall system is effectively implemented. In addition, in a number of instances, the operating procedures record the measuring and test equipment data to verify that the instruments are within their calibration interval and to document their use. Radiological protection instruments were also found to be appropriately labeled as calibrated and functionally checked in accordance with radiological protection procedures.

The hoisting and rigging program is governed by ISO-OSH-219, which establishes requirements to protect personnel and equipment during hoisting and rigging evolutions. This procedure is identified as a reference in the DSA and TSR implementation plan, though the plan indicates that no specific changes

were required to the procedure for revisions 5 or 6 of the TSRs. The procedure includes appropriate marked references to the TSR requirements, and the attached hoisting and rigging checklist includes the restrictions in SAC MH-3. The lifts that are to be conducted as part of the ZPR canister movements have all been incorporated as pre-engineered production lifts in the appropriate operating procedures. Review of the operating procedures and observation of the performance demonstrations provided evidence that the requirements for pre-engineered lifts are effectively implemented as required in ISO-OSH-219; however, the hoisting and rigging procedure precautions are not incorporated in the appropriate operating procedures, such as ISO-OPS-223. In addition, the operating procedure does not caution against changing the lift equipment without an appropriate review. (See opportunity for improvement **L3-5**.)

The quality assurance requirements for the ZPR shipping program are identified in a compliance matrix that cross-references the quality assurance requirements from 10 CFR 71 to the quality assurance criteria and Isotek implementing documents. Independent Oversight identified three procedures that provide instructions for the use and handling of the 5X22 shipping containers. Although these procedures and processes, as a whole, address most requirements in the SARP and 10 CFR 71, they are not clearly integrated to ensure that appropriate quality assurance records are consistently generated, captured, and maintained. ISO-OPS-229, *Receipt of Empty 5X22 Shipping Containers*, contains instructions for receiving and inspecting empty 5X22 packages, and ISO-OPS-225, *5X22 Shipping Container Handling Procedure*, provides instructions for loading the ZPR canisters into the shipping containers and preparing them for shipment. ISO-OPS-225, which is discussed further under Objective 4, identifies a completed attachment as "records," but does not identify the three-year records retention requirement. ISO-WMP-210, *Receipt of Empty 5X22 Shipping Containers and Transport of ZPR Plates to the Device Assembly Facility*, provides detailed instructions for receiving and inspecting empty containers, generating the shipping paperwork, marking the containers, and opening and closing the containers. It also contains a thorough list of records and indicates a three-year retention requirement "after material is accepted by the carrier," but in relation to the generation of records, ISO-WMP-210 does not reference either of the two operating procedures and does not require the completion or use of the receiving inspection checklists (ISO-F-329) that have been prepared to guide the initial receipt of shipping containers from the Y-12 National Security Complex or return from the Device Assembly Facility. ISO-OPS-229 and ISO-WMP-210 are also not listed as implementing documents in the quality assurance program compliance matrix. None of the procedures identifies quality control hold points. (See finding **L2-1** and opportunity for improvement **L3-6**.)

Radiological Control

Independent Oversight reviewed as-low-as-reasonably-achievable (ALARA) plans for the operations personnel and support personnel, and interviewed the Isotek radiological control manager. A detailed calculation, ISO-SAF-CALC-030, provided a comprehensive analysis of potential hazards and accident scenarios for the operations. An additional calculation, ISO-SAF-CALC-029, assessed the impacts of an unmitigated inhalation dose for collocated workers and offsite dose from various accident scenarios. The Independent Oversight team reviewed these documents and found the methodology and assumptions to be sound. The results indicated that the potential doses to collocated workers and off site individuals were below applicable limits and guidance. It was noted that the inhalation dose calculations did not address the impact of an inhalation dose to the immediate workers. Both the Federal project manager and the radiological control manager acknowledged that the hypothetical dose would be very high, however, considering the multiple layer containment (welded ZPR fuel plates, aluminum wrapping foil, and sealed canister) and the handling limitations in the movement plan, a substantial rupture and significant airborne release during close proximity handling were not considered credible. Consequently, active airborne monitoring will be provided during the operations, but no need for respiratory protection or full anti-contamination clothing is expected.

Anticipated external doses to the workers have been estimated based on previous measurements of the material containers. Given appropriate applications of standard time, distance, and shielding strategies, the external dose rates should be manageable resulting in acceptable doses. Discussions with the radiological control manager and review of the draft ALARA plans and draft radiological work permits (RWPs) showed that Isotek has addressed this issue and developed appropriate controls. The ALARA plans covering the initial phases of the work with just the ZPR canisters are appropriate for the work scope; RWPs for movement of the ZPR canisters have been completed. An additional ALARA plan covering the movement of the non-ZPR canisters is under development, and a draft RWP has been prepared. The Independent Oversight team observed RA interviews with the Isotek radiological control manager and radiological control technicians and observed demonstration of the movement and packaging processes. It was clearly demonstrated that the radiological control processes and staff were well integrated with operations. It was further apparent that the staff is well trained and knowledgeable of the required tasks. The implementation of the radiological control program as observed appears to satisfy the regulatory requirements of 10 CFR 835.

The RA team noted early concerns with respect to application of an RWP used for the demonstration of canister movements. One concern was that the RWP included training requirements that were not satisfied for some of the observers. Another concern was that the RWP for non-ZPR canister movement referenced an ALARA plan that was still in draft form. These issues were resolved when it was recognized that these RWPs were noted to be "draft" documents for demonstration purposes.

The RA team subject matter expert identified some potential areas for improvement in the form of good work practices. Most of these were viewed as potential enhancements that would be desirable in the unlikely event of an unexpected upset condition (for example, a ruptured container), rather than necessary steps to mitigate anticipated radiation conditions. These areas for improvement included a stricter adherence to contamination control practices, a more formally defined and posted fixed boundary for high to low dose areas, more active communication of measured dose rate conditions during canister movements, considering placement of the active continuous air monitor systems, additional air sampling closer to the work zone may be a useful precaution, and more active use of data recording during measurements. These observations were also noted by Independent Oversight and recognized as potential good practices/enhancements rather than regulatory requirements. These as well as other precautions to prevent a container rupture during an upset condition should be actively considered in the context of possible lessons learned based on a recent incident at another DOE facility which was also preparing ZPR elements for transport.

Objective 4: Contractor IVR or similar processes and site office oversight activities are sufficient to verify that safety SSCs and design features are installed, inspected, and maintained as described in the safety basis documentation.

Revision 6 of the Building 3019 DSA and TSRs does not identify any active safety SSCs. Consequently, Independent Oversight reviewed only a sample of the configuration control and installation processes intended to ensure that design features match design documents, including design calculations, design descriptions, and design drawings. The DSA, TSR, and SARP were also reviewed to determine whether in-service tests and inspections for design features are specified, where appropriate.

ORO-EM

ORO-EM performed a thorough review of the safety basis revision associated with the programmatic transfer of ZPR material, as documented by their safety evaluation report (SER)-ISO-3019-SBT-06-012. The SER addressed the deletion of selected design features for safety (it is noted that one of these design features for safety was later reinstated). No DOE conditions of approval were identified. The SER documented the involvement of the DOE FR in the review process, as well as the DOE lead safety basis

reviewer. The DOE FR is routinely involved in the safety basis review and approval process and is knowledgeable of the administrative controls associated with the design features for safety. The DOE FR is supported by subject matter experts for fire protection; radiological control; heating, ventilation, and air conditioning (HVAC); criticality safety; and industrial safety. Assessments for safety system oversight (SSO) are scheduled through the ORION system. As discussed under Objective 3, DOE oversight of the contractor's readiness processes, as well as self-assessments, has been thorough and well-documented.

Isotek Services, LLC

Currently, several passive, safety class design features are identified as hazard controls in the DSA and TSRs, but there are no active safety class or safety significant systems that require periodic surveillance tests. Independent Oversight verified that processes for configuration control of the passive safety design features are in place. The configuration item list, ISO-CI-3019, identifies the safety class and safety significant SSCs, as well as other designated SSCs, that are configured items. The list includes the passive safety systems (design features) identified in the DSA and TSRs and was recently revised to include the ZPR lifting devices and new Isotek drawing numbers. The list includes the applicable drawings for the configured items, and as changes are made, the list is revised as part of the modification process. A walk down of the STC and its lifting device revealed that it matched the drawing referenced in the configured items list. Although the configured items list is mostly complete, no drawings were listed for the tube vault upper closures. In addition, no specific in-service tests or inspections for conformance of the passive design features with the TSRs were identified. (See opportunities for improvement **L3-7** and **L3-8**.)

ISO-OPS-225, *5X22 Shipping Container Handling Procedure*, includes the instructions for opening, preparing for canister insertion, leak testing, and closing the 5X22 shipping containers. It also implements the requirements of the Nuclear Regulatory Commission Certificate of Compliance (No. 9250), which requires the packages to be operated and prepared for shipment in accordance with chapter 7 and acceptance tested and maintained in accordance with chapter 8 of the application package (i.e., the SARP). The precautions and limitations in ISO-OPS-225 address a number of the requirements in the Certificate of Compliance, and for the most part, the instructions in the procedure attachments include the directions from chapter 7 of the SARP. The procedure also contains adequate steps to conduct the specified leak rate test, including signatures by the performing operator and supervisor review. However, the procedural steps, which follow the SARP instructions, do not ensure that the seal port test plug O-ring is present prior to installation, nor do they use independent or dual verification to ensure that this important pressure boundary (test port plug) is restored after the leak test. In addition, some directions from SARP chapter 7 are not included in ISO-OPS-225 or are not accurately reflected in the instructions. For example, the procedure prerequisites do not specifically address the "prior to every use" inspection requirements (SARP section 8.2.7.2) to verify that both the required maintenance and miscellaneous inspections have been completed. Also, though it appropriately requires inspection of the O-ring seating and mating surfaces, the procedure does not specify that the O-ring itself be inspected, as required by the SARP. Finally, the procedure specifies the torque value for the inner vessel lid bolts as 35 foot-pounds, while the torque specified in the SARP is 25-35 foot-pounds. (See finding **L2-2**.)

Objective 5: Contractor IVR or similar processes and site office oversight activities are sufficient to verify that SACs are implemented such that they adequately meet the functional requirements and expectations of the safety basis.

Independent Oversight verified that SAC implementing procedures have been prepared, reviewed, and approved to implement the functional requirements identified in the safety basis. The review team examined these procedures to determine whether they demonstrate that the SACs can accomplish their safety functions and continue to meet applicable SAC requirements and performance criteria.

Independent Oversight also observed performance of one of the SAC implementing procedures during the RA.

ORO-EM

ORO-EM performed a thorough review of the safety basis revision, as documented by SER-ISO-3019-SBT-06-012, which addresses the crediting of SACs to protect key assumptions, including which shield plugs could be removed, which canisters could be moved, and the maximum number of canisters allowed outside of a tube vault. Other topics in the safety basis review included: the treatment of hydrogen in the vaults; the criticality evaluation of ZPR shipping container activities; removal of decontamination and decommissioning activities from the DSA; classification of lead as a standard industrial hazard: and clarification of the minimum operations shift complement. No DOE conditions of approval were identified. The SER documents the involvement of the DOE FR in the review process, as well as the DOE lead safety basis reviewer. The DOE FR is routinely involved in the safety basis review and approval process and is knowledgeable of the SACs. The annual surveillance schedule for the DOE FRs includes two surveillance topics, TSR implementation and SACs, that address verification of hazard controls. The DOE FR provided a documented surveillance on the SACs for Building 3019. Similar to the SSCs related issues, the DOE FR receives support on SAC related issues from subject matter experts in fire protection, radiological control, HVAC, criticality safety, and industrial safety. SSO assessments are scheduled through the ORION system. As discussed under Objective 3, DOE oversight of the contractor's readiness processes, as well as self-assessments, is thorough and well-documented.

Isotek Services, LLC

Revision 6 to the DSA and TSRs provides the supporting analysis and hazard controls for the transition from surveillance and maintenance to operations involving ZPR canister movements. The primary safety basis hazard controls are SACs that limit the amount of material at risk in accidents to the analyzed quantities. These limits also implement the assumptions that were used to develop the criticality safety analyses and parallel the controls in the NCSAs. The changes to the DSA and TSRs include a revision to the SAC that controls the opening of the storage locations and the addition of two new SACs that control the specific canisters that can be moved and the number that can be out of storage at any given time. In addition, two SACs limit the movement of crane loads during lifting operations.

To support the ZPR canister shipments, Isotek developed ISO-OPS-012, *ZPR Plate Planning, Retrieval, Packaging, and Transportation Plan*, which provides a detailed plan to support preparation and execution of the shipments. ISO-OPS-WP-004, *Move Plan for ZPR Shipments*, supports the overall movement plan and provides a detailed plan for fissile material movements to support the safety analysis and the nuclear criticality safety evaluations. Independent Oversight reviewed these documents and found them to be comprehensive and to provide adequate support for the assessment that the SAC limits are sufficient to support the conclusion that a criticality event is not credible.

Isotek prepared an administrative procedure to develop the details of the ZPR canister movements. ISO-OPS-105, *Material Data Handling Data Management*, provides for the development of OEPs and operations data packages (ODPs), as well the collection of shipping data. This procedure lists the DSA and TSR controls and assumptions in the precautions and limitations section and appropriately includes references to the TSR and/or NCSA requirement, as required by the document control procedure. Using the procedure, the data manager prepares the OEP and ODP per the instructions and limitations of the TSR and NCSAs and assembles the appropriate operating procedures and attachments in the data package. The draft ODP is then submitted to a document review committee for review and concurrence. The OEP is reviewed by the Fissile Material Handling Supervisor (FMHS), and the combined ODP and OEP are provided to the Facility Manager for approval. The FMHS then completes the evolution per the evolution plan, including both initial and final confirmation of the number of canisters outside storage,

and places a date in the "completed" column of the OEP as each task is completed.

Three main operating procedures support the ZPR oxide plate canister retrieval, inspection, and shipment and are included in the ODP. The procedure for opening and securing storage vaults is ISO-OPS-104, *Opening and Securing Building 3019 Tube Vaults*. ISO-OPS-223, *Movement of Solid Fissionable Material*, provides instructions for fissile material handling within the Building 3019 complex and ISO-OPS-225, *Shipping Container Handling Procedure*, is used to open and close the 5X22 Type-B packages that are used for transporting the ZPR oxide canisters. Based on the OEP for the particular planned evolution, the main body of the procedure and the attachments needed to perform the evolution are included in the ODP. The ODP and OEP are developed using a procedurally established process; however, they contain executable steps and safety basis hazard controls, and the DOE RA team identified an issue regarding the lack of USQ review of the approved ODP and OEP associated modifications of the data forms.

Overall, the operating procedures are detailed and well written, and evolutions performed during the DOE RA demonstrate that they can be executed step-by-step. The procedures were reviewed and approved using a formal document preparation and approval process and were verified and validated using an appropriate process. The principal operating procedures are designated with a usage category of "In-Hand," which requires the procedure to be performed in a manner in which each step is read prior to its performance. During the demonstrations, the operators appropriately handled the procedures, read each step prior to performance, and performed the steps in sequence as required. The "three-way repeat back" was an effective communication tool. Operations were conducted safely and deliberately, and the operators demonstrated knowledge of the procedures and equipment and proficiency in the tasks. Additionally, a continuous air monitor alarmed during an evolution, and the operating personnel responded appropriately in accordance with the abnormal event procedure.

Although most SACs are adequately implemented in the main operating procedures, these procedures, which are used in performing safety-related tasks, are not recognized or designated as SAC implementing procedures in the DSA and TSR requirements implementation plan. Additionally, not all these safety-related steps are highlighted (marked with the TSR designation), as required by ISO-DOC-222 R0, *Procedure Development and Formatting*. For example:

- ISO-OPS-104 and ISO-OPS-223 do not reference any of the SACs in the precautions and limitations section even though the procedures are used to open and close the storage vaults and move fissile material, respectively.
- ISO-OPS-104 (step 6.3.1) describes the use of pre-engineered lifts in the procedure but does not identify this step as TSR-related.
- Several of the attachments to ISO-OPS-104 that contain the action steps for accessing the storage vault mark the steps related to the NCSA but do not mark these steps with the TSR number.
- ISO-OPS-223 does not identify the use of specific lifting equipment for the shielded transfer cask as a TSR-related SAC control, even though changing the rigging equipment could lead to a violation of the SAC lift height restriction in this pre-engineered lift.
- The OEP records the number of canisters outside of storage but does not mark these verification steps as TSR-related.

As noted by the DOE RA team, without appropriate markings, the operators are not alerted to the relationship of the particular steps to the safety basis, so safety-related controls could be removed or revised without sufficient review and analysis. (See opportunity for improvement **L3-9**.)

In addition to the weaknesses in marking safety-related procedural steps, the operating procedures do not sufficiently and consistently implement independent or dual verification steps for completing these safety-related actions. For example:

- ISO-OPS-104 specifies that independent verification will be used for accessing the storage vaults, but the verification is done by the FMHS, who (in the "read and perform" method) provides the direction to the operator and is involved in the initial selection process.
- ISO-OPS-223, Attachment 13.2, *Fissionable Material Movement Data Sheet*, specifies the retrieval vault and the destination vault but does not specify the use of either independent or dual verification for these steps. (Note: The locations are also listed on the OEP.)
- Similarly, ISO-OPS-223, attachment 13.11, *Retrieving a Canister from a Tube Vault Using the STC*, does not include dual or independent verification that the STC is over the correct vault.

The lack of effective verification techniques could reduce the level of expected operator performance for these safety-related steps. This issue also was identified by the DOE RA team for ISO-OPS-104. (See finding **L2-3**.)

In addition to the weaknesses discussed above, a potential inadequacy in the DSA and implementing control in the TSR was identified during the DOE RA. The material handling control for the movement of loads by the penthouse crane is implemented through a table that limits the height of a lifted load based on its indicated lift weight. The lift heights are based on an appropriately detailed, verified engineering calculation. The DSA indicates that the values in the table include a 20 percent margin of safety; however, it was discovered during the RA that the table in the TSR does not incorporate this margin of safety in every range of indicated lift weight. When informed of this concern by the DOE RA team, Isotek appropriately declared the situation a potential inadequacy in the safety analysis and implemented a suitable compensatory measure. This issue was identified as a post-start finding by the DOE RA team and must be resolved before the STC is used to move non-ZPR canisters using the STC.

Objective 6: Contractor personnel working at the facility are adequately trained and qualified to implement and maintain the safety basis hazard controls, and the site office personnel are sufficiently trained and knowledgeable to provide oversight of safety basis hazard control implementation.

Independent Oversight verified that training has been performed and documented in accordance with the latest revision of the facility safety basis and the implementing work instructions. Training documents and records were reviewed to determine the adequacy of the training to prepare personnel to perform their assigned tasks.

ORO-EM

Independent Oversight interviewed the DOE FR with primary responsibility for oversight of Building 3019 activities. The DOE FR is fully qualified to perform FR duties in accordance with the FR functional area qualification standard, and she presented a completed and signed qualification card. The DOE FR is well qualified to perform oversight of the safety basis hazard control implementation; her previous qualifications include chemical SSO, and she has been assigned responsibility for Building 3019 since September 2008. Her responsibilities include review of the safety basis documents, and she is required to be present when the approval authority reviews the documents. She is knowledgeable of the IVR process, is on distribution for the contractor IVR reports, and performed an assessment of an earlier IVR report. SAC reviews are included in the annual surveillance schedule for DOE FRs, and there was evidence that a SAC surveillance was completed in April 2011. The FR observed some of the readiness review evolutions and demonstrated knowledge of the safety basis hazard controls, including SACs. The DOE FR is supported by subject matter experts in fire protection, radiological control, HVAC, criticality safety, and industrial safety. DOE's independent readiness assessment also confirmed ORO-EM's readiness to perform line management oversight. The Independent Oversight review team did not assess the qualifications of ORO EM SSOs or other site office personnel.

Isotek Services, LLC

The implementation plan for revision 6 of the Building 3019 DSA and TSR includes an attached training plan that identifies the minimum training requirements for both operations and support personnel. Training modules were developed for the latest version of the TSR. Independent Oversight interviewed the Isotek training manager, who has a strong background in technical training, and also reviewed training modules developed for the Building 3019 TSR. Training modules were provided for Building 3019 TSR revision 6 delta briefing, and another for the complete set of Building 3019 TSRs. One training module is for support personnel and the other is for operations personnel. These training modules provide a clear overview of the facility safety basis, with emphasis on TSR compliance.

Isotek's procedure for conducting IVRs appropriately addresses training and qualification, as evidenced by the CRADS, LOIs, and checklist of prerequisites for declaring readiness. The IVR conducted for revision 6 of the DSA and TSR included the objective to verify that facility personnel are knowledgeable of safety basis controls and requirements, and the IVR included interviews of the training manager as well as document reviews. The subsequent readiness reviews focused on the overall training and qualification program. Isotek's readiness preparations incorporated an affidavit in the area of training, which included an approved training implementation matrix and training records. The contractor readiness review also reviewed the area of training and qualification, including document reviews, interviews, and observations of work performance. A review of the contractor forms for training and qualification provided evidence that a thorough assessment of the training and qualification processes had been conducted.

Independent Oversight observed interviews, watched evolutions, and reviewed a number of documents, including the training implementation matrix, the training program plan, the ZPR material handling training plan, and a white paper on fissile material handler (FMH) certification/qualification. Examples of training impact assessment, position training and qualification requirements, training modules and other training records were also reviewed. The ZPR material handling training plan identifies ZPR-specific training by position and states that the FMH and FMHS positions will be trained on the TSR and conditions of approval. Another section in the training plan addresses support personnel, but it does not include the FMH and FMHS positions even though the position training and qualification requirements for an FMH specify the training module for 3019 Complex TSR for Support Personnel. This is a discrepancy between the training plan and the position training and qualification requirement. Although the safety basis hazard controls are adequately addressed in both training modules, the training module for 3019 Complex TSR provides additional coverage of criticality safety controls and includes a more thorough examination, which would be appropriate for the FMHs. (See opportunity for improvement **L3-10**.).

DOE Order 426.2 requires that FMHs and FMHSs be certified. However, Isotek has determined that for this operation, the FMH and FMHS will have to meet qualification requirements rather than certification requirements. The Isotek nuclear criticality safety manager provided a white paper that documented the determination that FMHs can be qualified rather than certified, because the operation to remove and ship ZPR canisters is inherently safe from a nuclear criticality safety perspective. Thus, the operators for this particular operation are not handling significant quantities of fissionable material. (See opportunity for improvement **L3-11**.)

The LEARN database is used to notify staff of required training, document completion of training, maintain electronic copies of the position training and qualification requirements, provide status of training completion for individuals, and develop such performance indicators as overdue reports and training status. Personnel are required to document completion of training and required reading through the LEARN database, which is an effective tool for managing training information. ISO-F-178, *Required Reading Verification*, is used to document required reading when the person does not have access to the LEARN database. This form discusses the objectives of required reading as a training mechanism, which

is to inform and provide awareness. Required reading was used to ensure that operators were aware of changes in the operating procedures that were used in the practice evolutions, several of which had been revised within the past two days. The Isotek training program plan states that "documents (e.g. procedures and policies) related to the position may be identified for required reading." Although the evolutions were conducted successfully, the process of disseminating information through required reading was questioned with respect to its efficacy, timeliness, and retention of knowledge. (See opportunity for improvement **L3-12**.)

During interviews, the Isotek training manager, FMH, FMHS, and Facility Manager demonstrated a good understanding of the safety basis hazard controls. Independent Oversight observed evolutions involving the movement of simulated ZPR and non-ZPR canisters in accordance with the SACs, and the operators demonstrated knowledge of the controls and proficiency in following the procedures. Overall, Isotek's processes are sufficient to ensure that the training and qualification program adequately prepares personnel to implement and maintain the safety basis hazard controls. Facility personnel are well trained and knowledgeable of the SAC implementing procedures.

5.0 CONCLUSIONS

ORO-EM

ORO-EM procedures provide an adequate foundation for line management oversight of safety basis hazard control implementation, including oversight of IVR processes and conduct of readiness reviews in support of startups and restarts. ORO-EM also has an established procedure for executing its responsibilities for review and approval of safety basis documents. Formal oversight of the IVR for the implementation of the latest revision to the DSA and TSR was conducted by the DOE integrated project team that was responsible for the ZPR shipment project. ORO-EM then conducted an MSA and a DOE RA to verify Isotek's readiness to start ZPR movements. The DOE MSA was appropriately documented and provided evidence of close oversight of the contractor's RA and appropriate expectations for performance. Independent Oversight observed the DOE RA and found that overall the DOE RA team adequately executed its implementation plan and provided a critical assessment of the previous reviews. Further, the DOE RA provided evidence of effective ORO-EM oversight of Isotek's readiness to proceed with operations. Nonetheless, the ORO-EM RA team would have benefited from including one or two more full-time members and specifically including the implementation of the SARP requirements in the POA and implementation plan. Although it is evident that ORO-EM is providing appropriate oversight for the current implementation, they have not formally assigned responsibility for scheduling and performing line oversight of contractor IVRs. The DOE FR is fully qualified to perform FR duties in accordance with the DOE FR functional area qualification standard and has several years of experience as an FR and SSO. The DOE FR is routinely involved in the review of safety basis documents, conducts surveillances in accordance with the annual surveillance schedule for DOE FRs, and is supported by a staff of subject matter experts.

Isotek Services, LLC

The Isotek IVR procedure adequately defines the process for implementing safety basis documents and implements an appropriate level of planning and formality for the IVR process. The implementation of safety basis hazard controls is adequately addressed by the Isotek IVR processes and procedures for IVRs, DSA implementation plans, and readiness reviews. The review criteria and approaches were appropriately tailored and sufficient, and verification methods adequately addressed the implementation of hazard controls and conditions of approval. The IVR plan for the DSA changes supporting ZPR movement included a safety basis compliance matrix and a training plan, and training modules were developed specifically for implementation of the safety basis documents. Facility personnel were familiar

with the processes and methods for conducting IVRs, and IVR reports were sufficiently documented to support the reviewer's conclusions. There was no evidence of processes for periodically re-verifying the implementation of safety basis hazard controls, aside from the annual review, update, and implementation of safety basis revisions.

Isotek has established and implemented an adequate set of procedures and processes governing the implementation of the DSA and the processes for startup and restart. The affidavit process provided an effective mechanism for documenting readiness to proceed with the contractor and DOE RAs. The Isotek contracted independent RA was sufficiently rigorous to validate Isotek's declared readiness and was adequately documented, although the DOE MSA team appropriately upgraded some of the findings. Isotek personnel actively supported the timely completion of the DOE RA and demonstrated, through the performance of all the planned movement evolutions, that the facility and personnel are cognizant of the SAC requirements and ready to start operations. Nevertheless, weaknesses were identified in the integration of quality assurance processes with the operating procedures, implementation of some SARP requirements, and use of dual or independent verification when appropriate.

Although the processes and procedures were generally adequate for ensuring that safety basis hazard controls are maintained and correctly implemented, some findings and opportunities for improvement were identified. Three findings were identified for Isotek, the first two of which are related to the shipping container procedures. The third finding is related to the practice for independent verification. Of the 12 opportunities for improvement, one is related to the need for ORO-EM to formalize the processes for conducting IVRs. The 11 opportunities for improvement for Isotek include issues with maintaining and verifying safety basis controls, highlighting TSR controls, inspecting passive safety features, performing hoisting and rigging, and training.

6.0 FINDINGS AND OPPORTUNITIES FOR IMPROVEMENT

The ORO EM team uses the established definitions from the Science Management System (SCMS) procedure as the standard for issues management processes. During the review, Independent Oversight identified several issues, most of them representing opportunities for improvement. These issues are characterized in accordance with the DOE Office of Science Management System (SCMS) procedure for issues management and are annotated in this report by level and number (for example, L2-1). The SCMS issues management process identifies a Level 2 finding as an "issue that represents a nonconformance and/or deviation with implementation of a requirement" and a Level 3 finding as an "issue where it is recognized that improvements can be gained in process, performance, or efficiency already established for meeting a requirement." Level 3 findings closely approximate opportunities for improvement, which according to Independent Oversight protocols "are suggestions offered by the Independent Oversight appraisal team that may assist line management in identifying options and potential solutions to various issues identified during the conduct of the appraisal." The findings and opportunities for improvement are summarized below and are provided to ORO-EM for evaluation and follow-up in accordance with ORO-EM procedures and processes. The opportunities for improvement (as with Level 3 findings) are not mandatory and do not require formal resolution by management through the corrective action process.

Level 2 Findings: Isotek

Independent Oversight identified three Level 2 findings for Isotek Services, LLC.

L2-1: Procedures for receiving, handling, and shipping the 5X22 containers are not sufficiently integrated to ensure that all packaging quality assurance requirements are met, as required by 10 CFR 71, *Packaging and Transportation of Radioactive Material*.

L2-2: ISO-OPS-225, *5X22 Shipping Container Handling Procedure*, does not ensure that all directions for loading the 5X22 package established in the SARP are implemented, as required by the Certificate of Compliance and 10 CFR 71, *Packaging and Transportation of Radioactive Material*.

L2-3: Dual or independent verification is not always used where appropriate to ensure that safety-related tasks are completed accurately, as required by DOE-STD-1186, *Specific Administrative Controls*, and DOE Order 422.1, *Conduct of Operations*.

Level 3 Findings

Independent Oversight identified 12 opportunities for improvement (Level 3 findings), one for ORO-EM and 11 for Isotek Services, LLC.

ORO-EM

L3-1: As a means to ensure that safety basis hazard controls are adequately implemented and periodically re-verified, consider revising the ORO-EM procedures to establish roles, responsibilities, and methods for routinely scheduling and periodically conducting independent verification of contractor implementation of TSR controls for all EM projects.

Isotek Services, LLC

L3-2: Isotek should update procedure ISO-OPS-210, *Implementation Validation Review Process,* to reflect the current management organization.

L3-3: As the facility transitions into an operational mode, Isotek should consider formalizing processes to re-verify safety basis hazard controls and schedule periodic assessments of safety basis control implementation.

L3-4: To facilitate verification of flow down and maintenance of safety basis controls to the implementing operating procedures, consider developing a safety basis implementation matrix for the complete DSA, rather than limiting the matrix to the changes from the previous revision.

L3-5: To ensure that hoisting and rigging requirements are properly implemented and maintained in the operating procedures, consider revising the procedures to include the appropriate precautions and limitations and requiring reviews of the lift plans before changing any rigging equipment.

L3-6: Consider using a traveler and checklist for each 5X22 container to ensure that all relevant documentation is developed and retained for three years following its last use.

L3-7: To ensure that potential changes are appropriately reviewed, verify that the configured items list includes appropriate reference to all drawings for safety class SSCs.

L3-8: Since most passive safety features are not included in routine documented tests or verifications and could be subject to modification or degradation; consider conducting periodic documented inspection or verification of the condition or integrity of passive structures, penetrations, seals, and windows.

L3-9: Consider adding the principal operating procedures to the list of safety basis implementing procedures and adding references to the TSR SAC where appropriate.

L3-10: Consider revising the position training and qualification requirement for the fissionable material handlers to require that they be trained to the more comprehensive TSR training module.

L3-11: Avoid using the FMH and FMHS designation for the ZPR campaign operators.

L3-12: Consider revising procedures to clarify when required reading is appropriate, especially with regard to changes to operating procedures.

7.0 FOLLOW-UP ITEMS

As part of its regular oversight activities, Independent Oversight will follow the closure of the findings identified above and monitor the execution of the ZPR material movement.

Appendix A
Supplemental Information

Dates of Review

Onsite Review: October 3-7, 2011
November 29 – December 8, 2011

Office of Health, Safety and Security Management

Glenn S. Podonsky, Chief Health, Safety and Security Officer
William A. Eckroade, Principal Deputy Chief for Mission Support Operations
John S. Boulden III, Director, Office of Enforcement and Oversight
Thomas R. Staker, Deputy Director for Oversight, Office of Enforcement and Oversight
William E. Miller, Deputy Director, Office of Safety and Emergency Management Oversight

Quality Review Board

William Eckroade
John Boulden
Thomas Staker
William Miller
Michael Kilpatrick
George Armstrong
Robert Nelson

Independent Oversight Site Lead for ORNL

Timothy Mengers

Independent Oversight Reviewers

Timothy Mengers – Lead
David Odland
Terry Olberding

Appendix B
Documents Reviewed, Interviews, and Observations

Documents Reviewed

- EM-2.1, Startup and Restart of Oak Ridge Reservation Environmental Management Program Work, Rev. 4, 10/11
- EM-2.2, Safety Systems Oversight, Rev. 3, 11/09
- EM-2.5, EM Facility Representative Training and Qualification Program, Rev. 3, 1/11
- EM-2.9, Safety System Oversight Training and Qualification Program, Rev. 0, 5/11
- EM-3.5, Safety Basis Document Review, Rev. 2, 11/09
- EM-3.2, Facility Representative Program, Rev. 6, 2/11
- EM-3.3, Integrated Assessment Program, Rev. 7, 1/11
- U-233 Disposition Program Management Plan, Rev. 0, 5/11
- WALK-H4C-8/24/2011-59187, Review of Isotek Implementation Validation Review (IVR) Report for Safety Basis Revision 5 Documents, 8/11
- WALK-H4C-9/1/2011-13340, Review of Building 3019 Complex Implementation Validation Review (IVR) Process Procedure, 9/11
- WALK-H4C-4/21/2011-35564, 3019 Complex Specific Administrative Controls (SACs) – (Surveillance), 4/11
- WALK-H4C-3/17/2011-49045, Building 3019 Complex Technical Safety Requirements (TSRs) – (Surveillance), 3/11
- EM-97: T. Noe, Surveillance Schedule, 6/24/2010
- EM-94: Kelly, Surveillance Schedule, 7/15/2011
- Facility Representative Monthly Report, 7/31/2011
- Facility Representative Monthly Report, 8/31/2011
- Facility Representative Monthly Report, 9/30/2011
- ORO-EM Engineering Division – Assessment Schedule (Draft), 10/6/2011
- Assessments and Reviews at Building 3019 (Printout), 10/6/2011
- REV-MJ8-10/13/2010-47765, 3019 NCSE Evaluation Review, 10/10
- ORO-EM Nuclear Safety Team Assessment Report, Management Assessment of Specific Administrative Controls at Oak Ridge Environmental Management Facilities, 12/10
- Letter to John Eschenberg from James Bolon, Declaration of Readiness to Proceed for the Programmatic Transfer of Zero Power Reactor Materials Project, 11/29/11
- Letter to James Bolon from John Eschenberg, Approval of Building 3019 Complex Training Implementation Matrix, 8/16/11
- Letter to James Bolon from Wendy Cain, Approval of the Isotek Systems LLC Submittal of ISO-NCS-002, R3, Nuclear Criticality Safety Program Description and Approval of Deviation from Double Contingency Principle, 8/19/11
- Orion Rev-W2V-8/25/2011-41125, Implementation Plan for Readiness Assessment for Programmatic Transfer of Zero Power Reactor (ZPR) Materials, Oak Ridge National Laboratory, Rev. 0, 11/11
- DOE-SER-ISO-3019-SBT-06-012, Final Safety Evaluation Report, Rev. 4, 09/11
- Orion Number: REV-W2V-8/25/2011-97778, Management Self-Assessment for the Activity of Programmatic Transfer of Zero Power Reactor (ZPR) Materials at Oak Ridge National Laboratory, Final Report, 11/11
- Isotek, LLC, Readiness Assessment for Programmatic Transfer of Zero Power Reactor (ZPR) Materials, Final Report, 11/11
- ISO-SAF-003, Technical Safety Requirements for the Building 3019 Complex, Rev. 6, 9/23/11
- ISO-SAF-003, Technical Safety Requirements for the Building 3019 Complex, Rev. 5, 4/11

- ISO-SAF-002, Documented Safety Analysis for the Building 3019 Complex, Rev. 6, 9/11
- ISO-OPS-008, DSA and TSR Implementation Plan for Bldg 3019 Complex, , Rev. 3, 9/11
- ISO-OPS-008, DSA and TSR Implementation Plan for Bldg 3019, Rev. 2, 4/11
- Implementation Validation Review Report For Revision 4 to Isotek Safety Basis Documents, 4/30/10
- Addendum A to Implementation Validation Review Report For Revision 4 to Isotek Safety Basis Documents, 9/29/10
- Implementation Validation Review Report for Revision 5 to Isotek Safety Basis Documents, Rev. 1 8/23/11
- Implementation Validation Review Report for Revision 6 to Isotek Safety Basis Documents, 11/9/2011
- ISO-NCS-002, Nuclear Criticality Safety Program Description Document, Rev. 3, 7/11
- ISO-NCS-WP-002, Fissionable Material Handler Certification/Qualification, Rev. 0, 7/11
- Guidance for Determining if Personnel Handling Fissionable Materials Require Certification, 7/3/96
- ISO-OPS-POA-004, Plan of Action for Readiness Assessment for Programmatic Transfer of Zero Power Reactor (ZPR) Materials, Rev. 0, 8/11
- ISO-OPS-POA-004, Plan of Action for Readiness Assessment for Programmatic Transfer of Zero Power Reactor (ZPR) Materials, Rev. 1, 9/11
- ISO-OPS-012, ZPR Plate Planning, Retrieval, Packaging, and Transportation Plan, Rev. 1, 8/11
- ISO-OPS-104, Opening and Securing Building 3019 Tube Vaults, Rev. 6, CN-1, 11/23/11
- ISO-OPS-105, Material Handling Data Management, Rev. 4, 11/23/11
- ISO-OPS-200, Readiness Reviews, Rev. 2, 7/28/11
- ISO-OPS-210, Implementation Validation Review Process, Rev. 1, 1/19/10
- ISO-OPS-223, Movement of Solid Fissionable Material, Rev. 1, 11/28/11
- ISO-OPS-225, 5x22 Shipping Container Handling Procedure, Rev. 1, 11/23/11
- ISO-OPS-227, Shipping Pallet Loading Station Operation, Rev. 0, 11/1/11
- ISO-OPS-229, Receipt of Empty 5X22 Shipping Containers, Rev. 0, CN-2, 12/11
- Nuclear Criticality Safety Evaluation for Storage
- Nuclear Criticality Safety Evaluation for Handling
- ISO-F-169, Verification Checklist for NCSE/NCSA Implementation, Rev. 0,
- Training Modules 60713 and 60714, 3019 Technical Safety Requirements (TSR) Rev 6 Delta Briefing
- Training Module 60603 R4, 3019 Technical Safety Requirements (TSR) for Support Personnel
- Training Module 60602 R4, 3019 Technical Safety Requirements (TSR)
- ISO-OPS-WP-004, Move Plan for ZPR Shipments
- ISO-OPS-WP-006, Review of ZPR Material Movement Readiness Assessment Scope to Include 5x22 Shipping Container Loading and Tie-Down on Commercial Carriers, 10/19/11
- Shipping Container Certificate of Compliance
- ISO-BUS-LST-020 Isotek Organizational Structure, Functions, and Authorities – Business, R1
- ISO-MLD-109 R7 Roles and Responsibilities
- ISO-MLD-LST-020 Isotek Organizational Structure, Functions, and Authorities – Management/Company Level, Rev. 2
- ISO-OPS-LST-020 Isotek Organizational Structure, Functions, and Authorities – Operations, Rev. 1
- ISO-ORR-LST-020 Isotek Organizational Structure, Functions, and Authorities – Readiness, Rev. 0
- ISO-SAF-LST-020 Isotek Organizational Structure, Functions, and Authorities – Nuclear Safety, Rev. 1
- ISO-SQS-LST-020 Isotek Organizational Structure, Functions, and Authorities – Safety, Quality and Security, Rev. 0
- ISO-OSH-002, Perchlorates Safety Program Description, Rev. 1

- ISO-RAD-AP-001 ALARA PLAN: ZPR Plate Transfer, Rev. 0
- ISO-RAD-AP-002 ALARA PLAN: Indirect Support Personnel ZPR Plate Transfer, Rev. 2
- Radiological Work Permit 3019A-200113, Rev. 1, 12/1/2011
- Radiological Work Permit 3019A-200116, Rev. 1, 12/1/2011 (draft)
- ISO-SAF-204, Safety Basis Documentation, Rev. 3, CN-1
- Startup Restart Activity Description for Transfer of ZPR Material (SRAD)
- Position Training and Qualification Requirements for Fissionable Material Handler, 9/23/11
- Operations Supervisor Initial QualCard RO5
- Operations Technician Initial QualCard RO8
- Building 3019 Facility Manager Qualification Cards
- ISO-F-374, Training Impact Assessment, 9/30/11
- ISO-OPS-ODP-11-RA1-FTO, Operations Data Package
- ISO-OPS-ODP-11-RA2-FTO, Operations Data Package
- ISO-OPS-ODP-11-RA3-FTO, Operations Data Package
- ISO-TRN-003, Zero Power Reactor Material Handling Training Plan, Rev. 1, 10/11
- Plan of Action for Department of Energy Readiness Assessment of the Isotek Systems, LLC Programmatic Transfer of Zero Power Reactor (ZPR) Materials at the Oak Ridge National Laboratory, Rev. 0, 10/11
- Implementation Validation Review Report for Revision 6 to Isotek Safety Basis Documents, Rev. 0, 11/11
- ISO-SAF-002, Documented Safety Analysis for the Building 3019 Complex, Rev. 6, 9/11
- ISO-SAF-003, Technical Safety Requirements for the Building 3019 Complex, Rev. 5, 4/11
- ISO-SAF-003, Technical Safety Requirements for the Building 3019 Complex, Rev. 6, 9/11
- SER-ISO-3019-SBT-012, Safety Evaluation Report for the Building 3019 Complex, Rev. 4, 9/11
- ISO-OPS-008, Documented Safety Analysis and Technical Safety Requirements Implementation Plan for Building 3019 Complex, Rev. 4, 10/11
- ISO-OPS-104, Opening and Securing Building 3019 Tube Vaults, Rev. 6, CN-1, 11/11
- ISO-OPS-223, Movement of Solid Fissionable Material, Rev. 1, 11/11
- ISO-OPS-105, Material Handling Data Management, Rev. 4, 11/11
- ISO-CI-3019, Buildings 3019-A and B Configuration Item List, Rev. 9, 11/11
- NCSA No. 004, SNM Storage and Vault Access, Rev. 2, 11/11
- NCSA No. 012, Container Handling, Rev. 0, 10/11
- ISO-ENG-CALC-006, 3019 Storage Well Crane Drop Analysis, Rev. 0, 3/29/11
- ISO-OPS-210, Implementation Validation Review Process, Rev. 1, CN-2, 12/09
- ISO-OPS-001, General Operations, Rev. 7, CN-3, 10/11
- ISO-OSH-219, Hoisting and Rigging, Rev. 3, CN-1, 11/11
- CRO-10016-M, Bldg 3019 Penthouse Transfer Cask Inspection Assembly, Rev. 1, 7/11
- ISO-MNT-212, Measuring and Test Equipment, Rev. 3, 9/11
- Calibration Report for X178577 (Mettler Balance), 4/11
- Calibration Report for Air Velocity Meter M210091, 5/11
- Calibration Recall Database (Informal), 11/11
- ISO-OPS-001, General Operations, Rev. 7, Cn-3, 10/11
- ISO-DOC-001, Document Control, Rev. 4, CN-1, 6/11
- ISO-OPS-000, Conduct of Operations Plan, Rev. 7, 11/11
- ISO-DOC -220, Document Review and Approval Process, Rev. 2, 6/11
- ISO-WMP-002, Isotek Transportation Plan, Rev. 1, 6/11
- ISO-F-110, Validation Checklist
- ISO-ENG-229, Modification Process, Rev. 2, 10/11

- ISO-CI-3019, Buildings 3019-A and B Configuration Item List, Rev. 9, 11/11
- ISO-WMP-210, *Receipt of Empty 5X22 Shipping Containers and Transport of ZPR Plates to the Device Assembly Facility*, Rev. 0, 11/11
- ISO-F-329, Receiving Inspection Checklist (for 5X22 Shipping Containers), no date
- ISO-DOC-222 R0, Procedure Development and Formatting, R0, 6/14/11

Interviews

- Acting Director, ORO-EM Facility Operations Division
- Director, ORO-EM Engineering Division
- ORO-EM U-233 Federal Project Director
- DOE Project Manager/Contracting Officer's Representative
- Isotek Facility Operations Manager
- Isotek Radiological Controls Manager
- Isotek Training Manager
- Isotek Facility Modification Manager and IVR Team Lead
- Isotek Criticality Safety Manager
- Isotek Document Control and Records Manager
- DOE Facility Representative
- Isotek Operations Supervisor
- Isotek Facility Manager (backup)
- Isotek Work Planner
- Isotek Fire Protection Engineer
- Isotek Readiness Manager
- Isotek Nuclear Safety Manager
- Isotek Quality Assurance Manager
- Isotek Maintenance Manager
- Isotek Safety Analysis Engineer
- Isotek Fire Protection Lead
- ORNL Fire Chief
- Isotek Operations Supervisor
- Isotek Data Manager

Observations

- DOE/EM Integrated Project Team Meeting
- Isotek Milestones Schedule Meeting
- Toured 3019 Operational Area
- Evolution OEP-RA-1, Move a ZPR oxide canister from a storage vault to an empty staging vault and move a non-ZPR oxide canister from the same storage vault to the Cell 3 weigh station and store in a different vault
- Evolution OEP-RA-2, Move a ZPR oxide canister from a staging vault to a 5x22 Shipping Container and transfer container to Cell 5 temporary staging area
- Evolution OEP-RA-3, Move a closed, loaded 5x22 Shipping Container from the Cell 5 staging area to the Shielded Pallet Loading Station in the South Yard
- Receipt of 5X22 Container