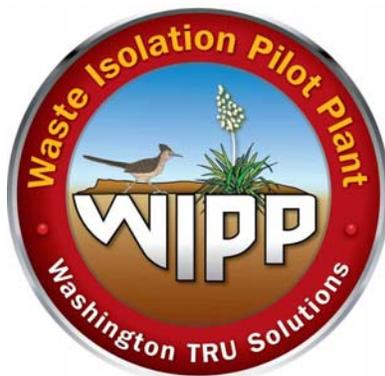


WP 13-QA.03
Revision 17

Quality Assurance Independent Assessment Program

Cognizant Department: Quality Assurance

Approved by: Martin Keathley



**Quality Assurance Independent Assessment Program
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ABBREVIATIONS AND ACRONYMS

ALARA	as low as reasonably achievable
CAM	continuous air monitor
CAQ	condition adverse to quality
CBFO	Carlsbad Field Office
CCP	Central Characterization Project
CDA	corrected during assessment
CFR	Code of Federal Regulations
CH	contact-handled
CMS	Central Monitoring System
CTS	commitment tracking system
DBE	design basis earthquake
DNFSB	Defense Nuclear Facilities Safety Board
DOE	U.S. Department of Energy
HEPA	high-efficiency particulate air (filter)
HERE	Horizontal Emplacement and Retrieval Equipment
HVAC	Heating, Ventilation, and Air Conditioning
ISM	Integrated Safety Management
NDE	nondestructive examination
NRC	U.S. Nuclear Regulatory Commission
P-A	Price-Anderson
PM	preventive maintenance
PPE	personal protective equipment
QA	Quality Assurance
QAPD	Quality Assurance Program Description
QSL	Qualified Suppliers List
RH	remote-handled
SDD	System Design Description
SSCs	Systems, Structures, and Components
VSS	Vital Safety System
WHB	Waste Handling Building
WIPP	Waste Isolation Pilot Plant
WTS	Washington TRU Solutions LLC

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1.0 INTRODUCTION ¹

The purpose of this document is to define and prescribe quality assurance (QA) methods and techniques used to identify, schedule, plan, perform, report, and close independent assessments, and to identify the resulting records.

This document applies to Washington TRU Solutions LLC (WTS) QA personnel qualified to lead and/or perform independent assessments. It also applies to cognizant managers of organizations being assessed.

Independent assessments may be performed as audits or surveillances. Audits are generally larger, more formal assessments of quality program elements or supplier programs. Surveillances are generally smaller assessments of specific activities, but may also be expanded and performed on quality program elements. Where the term "assessment" is used in this document, it applies to both audits and surveillances. Where actions apply only to an audit or surveillance, it will be so stated.

Assessments may contain elements of inspections, testing, monitoring work in progress, and checking to support the reviews that comprise assessment activities.

Assessments evaluate the adequacy of program documents and implementation, including effectiveness of established programs, and processes for compliance with WP 13-1, Washington TRU Solutions LLC Quality Assurance Program Description (WTS QAPD), other QA program documents, and purchase order requirements, as applicable. Assessments focus on improving items, services, and processes by emphasizing the achievement of quality by line organizations. Regularly scheduled program assessments may be supplemented by or integrated with additional technical assessments (e.g., surveillances and limited scope audits).

Assessments are performed using reviews, interviews, observation and monitoring, and checks. Actual and/or potential deficiencies are noted. Timeliness of corrective actions is evaluated. Supplier assessments verify conformance to applicable purchase orders and the QA requirements imposed by contract, or evaluate potential for providing products or services in compliance with WTS QA requirements. Scheduling is based on frequency required by regulation, ongoing project activities (e.g., previous audit results, adverse trends, or requests from other line organizations), and capabilities. Internal assessment findings and associated corrective actions are entered and tracked in the Issues Management (WIPP Form) System in accordance with WP 04-IM1000, Issues Management Processing of WIPP Forms (EA04IM1000-1-0). External assessment findings are tracked to completion as audit findings in the WTS Commitment Tracking System (CTS).

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The following records are generated as a result of using this document:

- WTS QA Independent Assessment Subject Master Table
- Approved Audit Schedule
- Audit Plan
- Assessment Checklist
- Audit Report
- Audit follow-up documentation
- Surveillance Report
- Surveillance follow-up documentation
- Independent Assessment Record File Completion Checklist
- Technical Specialist/Auditor Participation Indoctrination for Quality Assurance Audits (Attachment 12)

All records generated by this document will be handled, stored, and dispositioned in accordance with the responsible department's/section's Records Inventory and Disposition Schedule.

2.0 RESPONSIBILITIES

The Assurance Programs manager is responsible for:

- Implementation of this document.
- Ensuring that assessment personnel have sufficient authority and organizational freedom to carry out their assigned responsibilities.
- Approval of the assessment schedules.
- Qualification of lead auditors and Quality Assurance Surveillors (surveillors) in accordance with WP 13-QA.04, Quality Assurance Department Administrative Program.
- Assignment of assessment team leaders.
- Concurrence with assessment team selection.
- Assignment of surveillors.

The lead assessor is responsible for:

- Selecting the assessment team.
- Approving assessment checklists.
- Organizing and directing the assessment.

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- Reporting the assessment results.
- Providing information on status and/or findings to the CTS Coordinator, Price-Anderson (P-A) Coordinator, and the Qualified Suppliers List (QSL) Coordinator (for external supplier assessments).

The surveillor is responsible for:

- Performing surveillances.
- Organizing and directing the surveillance.
- Reporting the surveillance results.
- Providing information on status and/or findings to the CTS Coordinator, P-A Coordinator, and the QSL Coordinator (for external supplier assessments).

3.0 DEFINITIONS

Corrected During the Assessment (CDA) - An isolated condition adverse to quality (CAQ) requiring only remedial action to correct and for which resolution can be verified through review of objective evidence prior to the exit meeting.

Finding - A condition, applicable to the program or process being audited, that deviates from specified requirements defined by codes, standards, or other established specifications (a clear violation of a clear requirement).

Observation - A condition that, if left unattended, could become a deviation from established acceptance criteria; or a suggestion that, if enacted, could strengthen the existing program.

4.0 PREPARATION FOR ASSESSMENTS

4.1 QA Independent Assessment Identification

Waste Isolation Pilot Plant (WIPP) program elements or activities requiring independent assessment are found in:

- WP 13-1, Washington TRU Solutions LLC Quality Assurance Program Description
- DOE/CBFO 94-1012, *U.S. Department of Energy Carlsbad Field Office Quality Assurance Program Document*
- Hazardous Waste Facility Permit NM4890139088-TSDF

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Additional programs, processes, or activities important to compliance application, nuclear safety, waste characterization, or the isolation of waste within the disposal system require independent assessments to verify adequate and effective performance. These programs are found in:

- Defense Nuclear Facilities Safety Board (DNFSB) Recommendation 2000-2, *Configuration Management Vital Safety Systems*
- DOE/WIPP-04-3310, *WIPP Environmental Policy Statement*
- DOE/WIPP-07-3372, *Waste Isolation Pilot Plant Documented Safety Analysis*
- DOE/WIPP-07-3373, *Waste Isolation Pilot Plant Technical Safety Requirements*
- EFCOG *Contractor Guide For Performance of Effectiveness Reviews*
- WTS procedures that prescribe assessments

Activities which affect the following require independent assessments, in accordance with the contractor assurance system established by U.S. Department of Energy (DOE) Order 226.1A, Implementation of Department of Energy Oversight Policy:

- Environment, safety, and health (e.g., protection of the environment, workers, and the public from damage or injury)
- Safeguards and security
- Emergency management
- Cyber security

Independent assessments performed in accordance with the contractor assurance system include evaluations of compliance with the following, as applicable:

- Laws
- Regulations
- National standards
- DOE directives
- DOE-approved plans and program documents (e.g., authorization basis documents and quality assurance program)
- Site-specific procedures/manuals

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- Criteria review and approach documents
- Contractual performance objectives, and other contractually mandated requirements

The scope and frequency of audits scheduled and performed in accordance with the contractor assurance system must ensure that:

- Assessments required by applicable DOE directives, including environment, safety, and health, safeguards and security, emergency management, and cyber security, are being performed;
- The effectiveness of safety management programs, including programs that are credited in the safety basis, is being assessed adequately;
- Deficiencies are being self-identified; and
- Corrective actions are being taken in a timely and effective manner.

Supplier audits are based on requests for new suppliers to be added to the WTS QSL; those suppliers currently on the QSL which are due for reevaluation, or have their authorized scope changed; and suppliers providing products or services under Title 10 *Code of Federal Regulations* (CFR) Part 71, that require a facility audit every three years. These requests and reevaluations are processed in accordance with WP 13-QA3012, Supplier Evaluation/Qualification.

The Assurance Programs manager or assigned cognizant individual will:

- Review WIPP requirements documents and identify needs for independent assessments based on both written requirements for independent assessments and other programs or processes that affect safety, storage of waste, or the environment, the importance of which necessitates assurance of compliance.
- Upon notification from a QA procurement reviewer (WTS or CCP [Central Characterization Project]) or a WTS Contracting Officer that a project is scheduled to begin or is ongoing, evaluate the need for initial and follow-on independent assessments based on this Section 4.0.
- Review the potential assessment to be added using the criteria in the Assessment Priority Determination Tables (provided in Attachment 1). Document a decision for either an audit or a surveillance on the WTS QA Independent Assessment Subject Master Table (example provided in Attachment 2). This table is controlled by Assessment Services and each revision, with date, is a record. A copy is located on the network in WQNRA on the Torreón server, under the folder "Assessment Planning," subfolder "Assessment Subject Master Table."

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- Determine a frequency at which the assessment should be performed. If established by the requirement, that frequency is to be used. If not established by requirement, determine an adequate frequency based on relative risk, hazards, and complexity of the processes and activities to be evaluated. Also consider the scope and coverage of previous oversight activities, and historical performance. Document the frequency on the WTS QA Independent Assessment Subject Master Table.

4.2 QA Independent Assessment Scheduling

The scheduling of audits and surveillances is a continuing function of the identification in the previous section. Audits will be scheduled to begin as early in the life of a project or activity as practicable, and will continue at intervals consistent with the schedule for accomplishing the work. Certain surveillances may be scheduled on a repetitive basis, and others may be requested on an as-needed basis.

The Assurance Programs manager or assigned cognizant individual will:

- Evaluate the timing of the first, or next, occurrence for the assessment to be scheduled against all current or planned assessments. Consider resources, date required, time available, known regulatory oversight preparedness needs, associated historical issues, and client expectations, then schedule the assessment to best accommodate the need.
- Document external (supplier) audits on the WTS Quality Assurance Fiscal Year External Audit Schedule (example supplied in Attachment 3), completing all necessary fields as applicable. Suppliers of parts and materials, and services regulated by 10 CFR 71, Subpart H, will require the performance of a site audit on a triennial basis. (Reg. Guide 7.10, Section 18.2)
- Document internal audits on the WTS Quality Assurance Fiscal Year Internal Audit Schedule (example supplied in Attachment 3), completing all necessary fields as applicable.
- Develop additional informal schedule tools to track assessments, as necessary.

The Assurance Programs manager will:

- Review and approve internal and external audit schedules and revisions.
- Revise or update QA audit schedules, as applicable, to reflect current needs.
- Approve any extensions, cancellations, or other changes to the audit schedules prior to deviating from the approved schedule and place documentation of the approved extension or cancellation in the appropriate audit schedule file.

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- Distribute audit schedules to the Carlsbad Field Office (CBFO), affected WTS management, applicable assessment personnel, and the assessment file.

4.3 QA Independent Assessment Planning

Assessments include audits and surveillances. Direction regarding assessments applies to both audits and surveillances. The term "assessor" denotes the person performing either the audit or surveillance, as appropriate. Any direction specific to either audits or surveillances is indicated where applicable.

The Assurance Programs manager will:

- Direct an assessment coordinator to maintain the Independent Assessment schedule and tracking documents. The log (see example in Attachment 11) will be used to issue assessment numbers, and collect certain information regarding the assessments. The schedules (example, see Attachment 3) contain certain deliverable information.
- Assign a qualified lead auditor to lead/perform audits. Determine if an audit team is necessary due to size or complexity of the scope.
- Assign a qualified surveillor or qualified lead auditor to perform surveillances.

The assessment coordinator will:

- Develop and maintain an independent assessment log for systematically issuing unique numbers to assessments performed by WTS QA. The log is to contain, at a minimum, the assessment number, assessment subject or manufacturer, date performed, assessor identification, and status.
- Develop and maintain schedules that contain the anticipated audits for a specific time frame. The anticipated assessments are identified in the WTS QA Independent Assessment Subject Master Table with their respective performance frequencies. As the audits are performed, collect applicable information and enter into the appropriate document.
- Prepare copies of the schedules for record or contract deliverable purposes, as necessary.

The lead auditor/surveillor will:

- Obtain from the assessment coordinator an audit or surveillance number that denotes the type of assessment ("I" or "E" for internal or external audit, or "S" for surveillance, the fiscal year, and a sequential number beginning with 01 (e.g., I06-01, E06-01, S06-01).

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- Contact the cognizant individual for internal audits/surveillances or the supplier for external audits/surveillances to determine any safety/security issues and precautions of which the team should be aware. This includes Personal Protective Equipment (PPE), badging, logistics information, etc. Document the safety/security issues and precautions in the audit plan.
- Select an assessment team, if a team is needed, based on the scope, complexity, or special nature of the work being assessed, technical expertise, availability, experience, and the prospective assessor's ability to provide an objective contribution.
- Consider the following:
 - Personnel having direct responsibility for performing the activities being assessed shall not be involved in the selection of the team. Team members shall have the authority and be independent from the items and/or processes being audited. Independent assessors shall be trained/indoctrinated in accordance with WP 13-QA.04, technically qualified and knowledgeable of the items and activities being audited, and/or perform under the supervision of a lead auditor.
 - During audits, technical specialists shall be used when evaluating the adequacy of technical processes. Technical specialists will be indoctrinated by the lead auditor commensurate with the scope, complexity, or special nature of the work being audited, and of the audit process associated with their duties. This indoctrination will be documented on Attachment 12. Attachment 12 may also be used to indoctrinate other auditors from the assessment group, at the discretion of the lead auditor.
 - External peers or subject matter experts may be used as necessary to support assessment activities.
- Ensure that the team members collectively have appropriate training and experience commensurate with the scope of the assessment.
- Indoctrinate the audit team to the audit process, as needed, and their associated tasks before the audit. Include a review of potential hazards and plan accordingly for proper PPE, ALARA (as low as reasonably achievable), and additional controls deemed necessary. Document the indoctrination.
- Prepare the audit plan, for both internal audits and external supplier audits, using guidance in Attachment 4, and obtain QA management approval. The audit plan will include purpose, scope (including the work to be assessed and related corrective actions since previous assessments), requirements, audit personnel, organizations to be notified, applicable documents, written procedures to be used, schedule, safety/security issues and precautions, and background.

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Background should include previous findings, Corrective Action Requests, and weaknesses noted within the intended scope. For external supplier assessments, obtain supplier history from the QSL file or Coordinator.

- Review, with team members, any plan generated, pertinent background information that includes previous audit or oversight results, applicable procedures, and applicable technical documents so that team members are familiar with the work being assessed.
- If the assessment is external, notify the affected organization or company management by correspondence of the scheduled assessment, identifying the scope of the assessment. The notification need not include the audit checklist.
- Determine, with QA management, when internal surveillances are to be formally announced prior to performance. In such cases, notify the organization to be surveilled by correspondence of the surveillance, its scope, and schedule.

Assessor(s) will:

- Refer to the WTS QA Independent Assessment Subject Master Table for identification of requirements documents from which assessment criteria should be developed.
- Develop the criteria to be used during the assessment based on approved requirements; will also consider the following when developing criteria:
 - For internal assessments, include criteria, as applicable, to assess application of Integrated Safety Management (ISM) in accordance with Management Policy MP 1.28, Integrated Safety Management, and WP 15-GM.03, Integrated Safety Management System Description. The Safety Management Responsibilities section of the latter document provides a source from which criteria can be generated. For internal assessments, the intention is to review the ISM controls in evidence or exhibited in the activity being assessed. For external assessments, ISM controls may be considered regarding the hazards that the assessor could encounter (e.g., anticipated hazards mitigated by adequate PPE).
 - Although Graded Approach is assessed separately, consider possible criteria in accordance with WP 09-CN3005, Graded Approach to Application of QA Controls.
 - Consider Conduct of Operations criteria applicable to the activity being assessed.
 - Consider environmental controls or environmental response to unusual occurrences applicable to the activity being assessed.

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- Consider software controls applicable to the activity being assessed.
- When assessing a WIPP Vital Safety System (VSS), develop criteria from the applicable portion of Attachment 9, Vital Safety System Criteria Considerations.
- For an audit, develop the audit checklist(s) under the direction of the lead auditor using the guidance in Attachment 5. Checklist line items are generally written as directions to verify conformance of the activity being evaluated with established requirements, or as questions whether or not the activity being evaluated conforms with the requirement.
- For a surveillance, the criteria may be identified briefly on the Surveillance Report or on a detailed checklist to be filed with the assessment. Examples of brief criteria include, "observe actions based on steps XX through and including YY," or "observe waste hoist lifting activity for adherence to Procedure XXX, Revision Y, Section ZZ," or "review 15 WIPP Forms for adequacy, completeness, and implementation of corrective actions," etc. Criteria typically are found in QA manuals and program plans, procedures, previous assessments and corrective action documents, and contract requirements.
- For Effectiveness Reviews of completed corrective actions for 'significant' WIPP Forms, P-A externally-reportable issues, etc., develop criteria using the EFCOG *Contractor Guide For Performance of Effectiveness Reviews*.

5.0 ASSESSMENT PERFORMANCE

The lead auditor/surveillor will:

- For audits and external surveillances (optional for internal surveillances), conduct an entrance meeting with the assessment team and appropriate personnel representing the assessed organization(s). The entrance meeting is intended to introduce the assessors, explain the purpose, scope, and schedule for the assessment, and establish interfaces and contacts with the organization being assessed.
- For Effectiveness Reviews of completed corrective actions for 'significant' WIPP Forms, P-A externally reportable issues, etc., perform the assessment using criteria developed from the EFCOG *Contractor Guide For Performance of Effectiveness Reviews*.

The assessment team will:

- Evaluate the applicable quality program element(s) by examining objective evidence, observing activities in progress, examining items (including components, specimens, and machinery, etc.), and/or interviewing personnel responsible for the activity. Include technical evaluations of the applicable procedures, instructions, activities, and items, as appropriate. Objective

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evidence related to the planning and technical aspects of the work performance is to be examined to the depth necessary to determine if these elements are being implemented effectively.

- Review previous corrective actions, as applicable, to evaluate implementation and effectiveness when recurring problems are found.
- Observe, to the extent possible, actual operations to verify conformance to requirements.
- Record the results of the evaluations performed on the assessment checklist or surveillance report, as applicable.
- Record, on the assessment checklist or surveillance report, as applicable, objective evidence examined, including all documents reviewed, with sufficient detail so that any conditions or practices may be noted in the report with adequate detail. Include, as applicable, document number, title, and revision.
- Record, on the assessment checklist or surveillance report, as applicable, the results of observations of processes or items, including the quantity of items examined to indicate the size or breadth of the examination. Identify the items, where possible.
- Record, on the assessment checklist or surveillance report, as applicable, the names of personnel interviewed.
- Submit concerns noted during the assessment process to the lead auditor/surveillor at the end of each day, or as directed, using a format similar to the example in Attachment 10. Include a description of the concern, the name of the individual with whom the concern was discussed, and the requirement not met (if applicable). Concerns communicated during the assessment are considered working documents and will not be retained in the assessment file. Valid concerns will be documented in the assessment report.
- Inform the lead auditor/surveillor of progress and/or problems with assigned tasks periodically during the assessment.
- Notify immediately the lead auditor/surveillor if conditions are identified during an internal audit or surveillance that qualify as an event or potentially reportable occurrence under the requirements of 10 CFR Part 21, 10 CFR Part 71, WP 12-ES3918, Reporting Occurrences in Accordance with DOE Order 231.1A, etc.
- Notify immediately the lead auditor/surveillor if conditions are identified that are believed to be unsafe. If an internal assessment condition requires immediate work stoppage, proceed as directed in MP 1.2, Work Suspension and Stop-Work

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Direction. During external assessments, notify the supplier management, or their designated point-of-contact.

- Acknowledge and track any 'finding' conditions that are corrected during the assessment. Verify that the actions completed correct the condition and are capable of preventing recurrences.

The lead auditor/surveillor will:

- Notify QA management and the management of the assessed organization as soon as practicable if conditions are discovered that could have a significant adverse impact on prior work or affect work in progress, or if conditions require prompt attention. If conditions require immediate attention as defined in WP 12-ES3918 or MP 1.2, perform action as directed by the appropriate document.
- Notify the management of the assessed organization as soon as practicable of any issues identified, to assure accuracy, and allow opportunity for resolution during the assessment.
- Notify Packaging Manager of issues that affect nuclear packaging (TRUPACTs, HalfPACTs, etc.) or are otherwise potentially reportable to the U.S. Nuclear Regulatory Commission (NRC), to allow them to screen for reportability under 10 CFR Part 21 or 10 CFR Part 71, etc.
- For audits and external surveillances, conduct an exit meeting with appropriate personnel representing the assessed organization(s). The exit meeting is intended to provide a general overview of the evaluation of the program element and any issues requiring attention.

QA management will notify the CBFO of any deficiencies in DOE requirements (e.g., conflicting, unclear, or incomplete requirements contained in a DOE Order or other DOE document) identified through QA assessments.

6.0 ASSESSMENT REPORTING

The reporting of the assessment, if performed as an audit or external surveillance, will follow the guidance provided in Attachment 6; and, if performed as an internal surveillance, will use the example provided in Attachment 8.

Assessments that involve sensitive (e.g., permit- or personnel-related) information are to be coordinated through the WTS Legal Counsel. The lead auditor/surveillor and QA management will determine the necessary reviewers (i.e., WTS Legal Counsel, etc.) for proper processing of such assessment information.

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The lead auditor/surveillor/manager will:

- Prepare the assessment report with the assistance, as necessary, of the assessment team, and sign the report.
- Ensure that the assessment report includes the following, as appropriate:
 - Assessment purpose and scope (surveillances to include criteria used)
 - Identification of assessors
 - Identification of personnel contacted
 - Identification of documents reviewed, including revision indicator
 - Summary statement(s) indicating program (or program element) adequacy, implementation, effectiveness (applicable to scope), and a brief statement of ISM evaluations performed
 - Commendable practices or situations (if any are identified)

NOTE

Internal assessment finding issues (conditions adverse to quality) are to be issued on the Issues Management WIPP Form in accordance with WP 04-IM1000. Corrections will be made within the WIPP Form process; however, the issue also must be similarly stated in the assessment report to allow both the assessment report and WIPP Form to be stand-alone documents. (A suggestion is to 'copy and paste' the text from one to the other.)

- Findings (conditions adverse to quality, if any are identified) - Identify findings in the report as directed in Attachments 6 and 8. Concisely describe in the report (and on the WIPP Form for internal findings) the specific condition that deviates from the requirements, with sufficient detail to enable remedial actions to be taken by the audited organization, and subsequent closure by QA. Clearly quote or state the requirement from which the deviation was noted. Group findings of a common nature together whenever possible so that systematic breakdowns can be identified. Evaluate findings based on the relative importance to indicate the degree of impact on compliance application, waste characterization, repository performance assessment, waste isolation, waste transportation, nuclear safety, environmental protection, or management and operation of the WIPP facility. Enter internal (WTS) conditions adverse to quality into the Issues Management System using the WIPP Form in accordance with WP 04-IM1000. Findings (except CDAs) noted on external audits and external surveillances are to be entered directly into the CTS.

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- Observations (if any are identified) - Concisely state either the condition observed that, if left unaddressed, could deteriorate into a finding, or the suggestion that could strengthen the existing program or process.
- Findings Corrected During Assessment (CDA) - Concisely describe the condition adverse to quality found, the requirement from which the condition deviated, and the action(s) taken to resolve the condition. Any internal issues considered to have been findings at the time they were identified, even though now closed, must be entered into the CTS to accommodate trending. These CTS items are to be entered as closed issues, for trending only.
- Include the following statement in external supplier audit reports:

(Name of Company) will be (select "retained on," "added to," "added to pending successful resolution of finding," or "removed from") the WTS QSL for (state the scope or limitations of products or services authorized).
- Include the following statement in audit reports for suppliers currently on the WTS QSL:

If the agreements and commitments contained herein are deemed by the supplier to involve a change in the order concerning work scope, price, or schedule, it is agreed that such work will not commence or continue until authorized by a written change notice. It is understood that if the supplier commences such work without a written change notice, it is at the supplier's risk.
- Using cover correspondence, issue the assessment report to all affected entities within 45 calendar days of conclusion of the audit:
 - Cognizant department manager (all reports)
 - P-A Coordinator (all reports)
 - CTS Coordinator (reports containing findings and/or CDAs)
 - Facility point-of-contact (external reports)
 - QSL Coordinator (external qualification or requalification audits)
 - Packaging Manager (reports affecting packaging)
 - Assessment Coordinator (all reports)

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- Lessons Learned Coordinator (reports containing findings determined by the lead auditor/surveillor/management to be potential Lessons Learned issues)
- QA assessment file for this assessment
- Others as designated by QA management

Because internal findings are transferred to WIPP Forms, internal reports are considered closed at the time of issue. For external audit reports, include direction to the supplier for responding to any findings.

- Jointly with the CTS Coordinator, ensure that external supplier audit findings are adequately entered into the CTS using the finding number as the "driver."
- Jointly with the CTS Coordinator, ensure that internal CDAs are entered into the CTS as closed items, for trending purposes.
- For external supplier qualification audits, complete the Supplier Evaluation/QSL Update Request Form in accordance with WP 13-QA3012, and forward to the QSL Coordinator.

It is recommended to electronically file a copy of the completed checklist and the report in the applicable assessment folder within "Assessment Reports" in the shared folder WQNRA on the Torreon server.

7.0 ASSESSMENT RESPONSE

The cognizant manager of the assessed WIPP organization will review the assessment (audit or surveillance) results assigned to their organization on the WIPP Form, and respond using the Issues Management (WIPP Form) process in accordance with WP 04-IM1000.

The facility contact (for external assessments) is expected to respond as directed in the issuing cover letter and report. Any request for extension of corrective action due date shall be reviewed by the Assurance Programs Manager or designee.

8.0 ASSESSMENT FOLLOW-UP

In accordance with WP 04-IM1000, the WIPP Form screening committee will assign the lead auditor/surveillor as a technical reviewer of actions/corrective action plans developed in response to a WIPP Form issued as the result of an internal audit/surveillance finding. As a technical reviewer, the lead auditor/surveillor/manager will be responsible for determining the long-term effectiveness of the corrective actions, and will be expected to sign the Correction Action Plan, so indicating, in accordance with WP 04-IM1000. Issues that cannot be resolved will be referred to management.

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External supplier audit or surveillance findings and the resulting supplier's committed actions will be tracked in the WTS CTS to assure completion and review. The lead auditor/surveillor/manager will review the supplier's actions, and report completion based on the supplier's approved commitment(s).

9.0 ASSESSMENT CLOSURE AND FILING

The lead auditor/surveillor/manager will:

- For external supplier audits or surveillances with findings, verify that the corrective actions were completed as committed, issue a closure letter to the supplier and any other affected organizations, and ensure that copies are distributed to the CTS Coordinator, QSL Coordinator (if applicable), and the P-A Coordinator.
- Review, using the file checklist (Attachment 7), the assessment file for completeness: purge working documents, sign the checklist, notify the assessment coordinator, and forward the complete file to the QA file. The assessment file is to include:
 - Audit Plan (for audits)
 - Completed Assessment Checklist (required for audits, or when used for surveillances)
 - Completed Assessment Report (including identification of documents reviewed and personnel contacted)
 - Assessment response (for external assessments)
 - Corrective Action completion, follow-up, and verification (for external assessments)
 - Other documentation determined to be necessary to support the assessment (closure correspondence, etc.)

10.0 REFERENCES

10 CFR Part 21, "Reporting of Defects and Noncompliance"

10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

Reg. Guide 7.10, Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material (NRC)

DNFSB Recommendation 2000-2, *Configuration Management Vital Safety Systems*

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DOE O 226.1A, Implementation of Department of Energy Oversight Policy

Hazardous Waste Facility Permit, Waste Isolation Pilot Plant, Permit #NM4890139088
TSD, Issued by New Mexico Environment Department

DOE/CBFO 94-1012, *Carlsbad Field Office Quality Assurance Program Document*

DOE/WIPP 04-3310, *WIPP Environmental Policy Statement*

DOE/WIPP-07-3372, *Waste Isolation Pilot Plant Documented Safety Analysis*

DOE/WIPP-07-3373, *Waste Isolation Pilot Plant Technical Safety Requirements*

EFCOG *Contractor Guide For Performance of Effectiveness Reviews*

MP 1.2, Work Suspension and Stop-Work Direction

MP 1.28, Integrated Safety Management

WP 04-IM1000, Issues Management Processing of WIPP Forms

WP 09-CN3005, Graded Approach to Application of QA Controls

WP 09-CN3025, Annual System Walkdown/Requalification

WP 12-ES3918, Reporting Occurrences in Accordance with DOE Order 231.1A

WP 13-1, Washington TRU Solutions LLC Quality Assurance Program Description

WP 13-QA.04, Quality Assurance Department Administrative Program

WP 13-QA3012, Supplier Evaluation/Qualification

WP 15-GM.03, Integrated Safety Management System Description

EA04IM1000-1-0, WIPP Form

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Attachment 1 - WTS QA Internal Assessment Priority Determination Tables

Determine whether the assessment will be performed as an audit or surveillance using the tables below:

- Review the assessment to be performed against the criteria in the Risk and Hazard Table to determine a numeric value.
- Review the assessment also against the criteria in the Importance and Complexity Table to determine a numeric value.
- Multiply the two numeric values.
- Use the Assessment Priority Table and the number derived from the previous bullet to determine the priority of the assessment to be performed and schedule the type of assessment indicated.

Risk and Hazard Table	
Description	Probability and Consequence Level
If not performed, improbable undetected impact on environment safety, health, safeguards and security, emergency management, cyber security, or QA	1
If not performed, possible minor undetected impact on environment, safety, health, safeguards, and security, emergency management, cyber security, or QA	2
If not performed, possible major undetected impact on environment, safety, health, safeguards, and security, emergency management, cyber security, or unknown status of QA program, or possible continuation of negative trend or repetitive nonconformance	3

Importance and Complexity Table	
Description	Importance and Complexity Level
Necessary to verify actions in document other than a requirement-source or implementing procedure	1
Necessary to verify an action required by an implementing procedure	2
Necessary to complete an assessment required by an implementing procedure	3
Necessary to complete an assessment required by an implementing procedure, and complex in nature	4
Necessary to complete a specific program assessment requirement, or commitment (both non-complex and complex in nature)	4

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Attachment 1 - WTS QA Internal Assessment Priority Determination Tables

Assessment Priority Table		
Derived Numeric Value	Priority	Action
1-4	Low	Schedule Surveillance
5-8	Medium	Schedule Surveillance or Audit
9-12	High	Schedule Audit

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Attachment 3 - Example of QA Fiscal Year External and Internal Audit Schedules

**WTS QUALITY ASSURANCE
FISCAL YEAR 2007 EXTERNAL AUDIT SCHEDULE**

Supplier/Location Audit	Product/Service	Lead Auditor	Audit Number	Remarks
ACME Manufacturing 123 Any Street Anywhere, NM	Pipe, flanges, fittings	Lead Auditor Name	E07-01	Completed October 2006
Jones Cal Services 456 Busy Highway Big City, NM	Calibration Services	Lead Auditor Name		Scheduled January 2007

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Signatures on last printed page: Manager, Assurance Programs, and Manager, Quality Assurance

**WTS QUALITY ASSURANCE
FISCAL YEAR 2007 INTERNAL AUDIT SCHEDULE**

Audit Title and Audit Criteria	Scheduled	Lead Auditor (when determined)	Audit Number (when determined)	Status
Personnel Qualification	March 2007			

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Signatures on last printed page: Manager, Assurance Programs, and Manager, Quality Assurance

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Attachment 4 - Audit Plan Guidance

WASHINGTON TRU SOLUTIONS LLC
QUALITY ASSURANCE AUDIT PLAN
Title of audit (subject)

Audit number

Audited organization(s) (and location if supplier audit)

1. Purpose and Scope of the audit
2. Applicable Requirements Documents
WP 13-1, WTS Quality Assurance Program Description
(Any others, including regulatory documents containing requirements)
3. Procedure(s) to be used to perform the audit
WP 13-QA.03, Quality Assurance Independent Assessment Program
4. Audit Team
Lead Auditor
Team Auditors (if any)
Technical Expertise (if any)
Anticipated Observers (if any)
5. Schedule
Pre-Audit Meeting
Audit Activities
Post-Audit Meeting
6. Background
Previously reported findings (if any)
Previous corrective action issues (if any)
Previously reported weaknesses (if any)
7. Hazards, Safety/security issues
Precautions
Badging, logistics information
PPE (if any)

Signatures:

Prepared by: _____
(Printed Name)
Lead Auditor

Approved by: _____
(Printed Name)
Manager, Assurance Programs

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Attachment 5 - Example of WTS Quality Assurance Assessment Checklist

(The following table is shown on first page only, followed by the second table as space allows.)

WTS Quality Assurance Assessment Checklist	
Organization Assessed: _____	Assessment Number: _____
Requirements Documents: _____	Dates of Assessment: _____
Assessor(s): _____	Key: S=Satis., U=Unsat., N=N/A

(The top row of the following table is a header to be shown on each page to which this table expands with usage.)

Item	[Type in Assessment # here] Assessment Item	Reference Document(s)	Key	Assessor Comments
	(Add rows as needed)			

(The following signature line is shown on the last page only, following the end of the above table.)

Approved by: _____ Date: _____
Lead Auditor/Surveillor (print name and sign)

Notes: Refer to the WTS QA Independent Assessment Subject Master Table for identification of requirements documents from which assessment criteria should be developed.
 Review any corrective actions committed as a result of the previous assessment; develop criteria to evaluate their effectiveness.
 Develop criteria that evaluates a broad range of the requirements with enough detail to be meaningful in verifying compliance and effectiveness.
 Develop criteria to evaluate effectiveness of Graded Approach and the ISM system.

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Attachment 6 - Audit Report Guidance

Washington TRU Solutions LLC

Quality Assurance (select either **Internal** or **External**) **Audit Report**
[Descriptive, yet concise **title** - if external, provide company and address]
[**Audit Number**]

I. **Executive Summary:** Concise summary (generally one page or less), written in paragraph format including brief mention of organization audited (include location for external supplier) and audit date, abbreviated purpose and scope, results in general terms, conclusion of program adequacy (including ISM), any commendable situations noted, and any major issues requiring further action.

II. **Audit Details**

Purpose and Scope (more detailed than the Executive Summary)
Criteria used (identify or make reference to checklist, and specifically address ISM)
Audit Team
Inclusive dates of audit
Location(s) of audit
Conclusion(s) regarding compliance, effectiveness, and ISM evaluations performed. Include a statement addressing the number of findings, observations, and/or "CDAs." An acceptable method would be, "The assessment resulted in 2 Findings, 0 Observations, and 3 issues closed during the assessment."
Commendable practices or activities (if applicable)

[Include the following statement, as applicable, in assessment reports containing findings.]

Response to Findings (external supplier audits only) - When responding to audit findings, the following elements are required to be addressed:

- Cause of nonconformance
- Interim actions planned to correct the nonconformance
- Evaluation of the extent of the condition beyond that cited in the report
- Actions planned to prevent recurrence
- Schedule of implementation/completion

Findings (are to be numbered as [audit no.]-F-[sequential number beginning with 01], and internal findings are to also cross-reference to the WIPP Form Number. Example - "S04-027-F-01 issued as WF04-120")

- Condition noted
- Requirement not met

Observations (numbered as [assessment no.]-O-[sequential number beginning with 01])

- Condition (noted, or considered to be an improvement)

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Attachment 6 - Audit Report Guidance

Attachment 1 Table of Personnel Contacted

- [A]** Attended Audit Entrance Meeting
- [B]** Contacted During the Audit
- [C]** Attended Audit Exit Meeting

Personnel Contacted	A	B	C
(Add rows as needed)			

Attachment 2 Table of Documents Reviewed

Document Identification	Document Title or Description
(Add rows as needed)	

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Attachment 7 - Example of Independent Assessment Record File Completion Checklist

INDEPENDENT ASSESSMENT RECORD FILE COMPLETION CHECKLIST	
Assessment No. _____	
	<u>Complete</u>
Assessment Plan (required for audit, optional for surveillance)	<input type="checkbox"/>
Assessment report	<input type="checkbox"/>
Assessment response (if external assessment contained findings)	<input type="checkbox"/>
Assessment Checklist (required for audit)	<input type="checkbox"/>
Closure letter (if external assessment contained findings)	<input type="checkbox"/>
Other	
_____	<input type="checkbox"/>
I have reviewed the above listed records and verified their completeness and legibility.	
[Type or Print Name here] _____	
Lead Auditor/Surveillor	Signature
	Date

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Attachment 8 - Example of Surveillance Report

Washington TRU Solutions Quality Assurance (make this a header row)			
Surveillance Report Number:		Date:	
Subject		Organization(s) Surveilled	
Scope			
Surveillor(s)			
Requirement References (include revision no.)			
Surveillance Criteria		[] Checklist on file in QA	
Personnel Contacted (* indicates persons to whom a copy of this report is to be distributed)			
Documents reviewed [] See Attachment			
Details/Results/Conclusions [] WIPP Form(s) identified in Findings			
_____ [Print and Sign] Lead Auditor/Surveillor		_____ [Print and Sign] Date	
_____ [Print and Sign] Manager, Assurance Programs		_____ [Print and Sign] Date	
Comments			
cc: Manager of assessed organization, WIPP Form Coordinator (if containing findings), P-A Coordinator, Assessment Coordinator, CTS Coordinator (if containing findings), Packaging Manager (if containing packaging issues)			
Page 1 of (total)			

Make the top row a header to appear on every page.
Insert pagination (page X of Y) at the bottom center

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Attachment 9 - Vital Safety System Criteria Considerations

Refer to WP 09-CN3025, Annual System Walkdown/Requalification, for additional VSS walkdown information.

General for VSS assessments - Timely closure of modifications, Cognizant Engineer walkdowns, periodic maintenance performed as required in System Design Descriptions, maintenance performed in accordance with manufacturer recommendations, combustible materials in the disposal circuit in the underground, software QA

Assessment Boundary Definition 1:

Waste Handling Building (WHB) components associated with providing confinement including Tornado doors. (The elements are described in System Design Description [SDD] CF02.)

Safety function: Confinement barriers. The building is: (1) preventing release of radioactive material in case of a radiological accident; (2) withstand design basis earthquake (DBE) and snow/ice loading to prevent damage to the waste containers within the buildings; (3) noncombustible construction/dissipate lighting; (4) RH Hot Cell Complex provides radiological shielding (includes walls, floors, ceiling, leaded glass viewing window, shield valves, plugs, and shield door).

Assessment Boundary Definition 2:

Central Monitoring System (CMS) components associated with the shift-to-filtration activation. (The elements are described in SDD CM01.)

Safety Function: Support underground shift-to-filtration to mitigate the consequences of underground accidents that could result in a release of radioactive material to the environment.

Assessment Boundary Definition 3:

WHB Contact-Handled (CH) Area Heating, Ventilation, and Air Conditioning (HVAC) associated with confinement ventilation. (The elements are described in SDD HV01.)

Safety Function: Provide differential pressure between the CH area of the WHB and the outside atmosphere. The CH area of the WHB is maintained sub-atmospheric. The confinement function is designed to mitigate the consequences of a release of airborne radioactive material in the CH area by providing a barrier to environmental release.

Assessment Boundary Definition 4a:

Fire Protection, Fire Suppression. For the purpose of this assessment, the Fire Suppression System for the CH/RH area of the WHB is defined as the following:

- The sprinkler system of the CH/RH area of the WHB. (The elements are described in SDD FP02.)

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Attachment 9 - Vital Safety System Criteria Considerations

- The yard fire water piping supplying the sprinkler system. (The elements are described in SDD FP01.)
- The fire water supply system. (The elements are described in SDD FP01.)
- The water storage tanks. (The elements are described in SDD WD02.)

Safety Function: The Fire Protection System is designed to extinguish fires in the WHB before they become large enough to impact CH/RH waste.

Assessment Boundary Definition 4b:

Fire Detection and Alarm in areas that are associated with waste handling. For the purpose of this assessment, the associated Fire Detection and Alarm System are defined as the Fire Detection and Alarm System of the CH/RH area of the WHB. (The elements are described in SDD FP03.)

Safety Function: The Fire Protection Detection and Alarm is designed to provide industrial safety functions.

Assessment Boundary Definition 5:

Underground Room Exit Alpha Continuous Air Monitors (CAMs). (The elements are described in SDD RM01.)

Safety Function: The room exit alpha CAMs are to provide a shift-to-filtration signal to the CMS upon detection of radiation levels that exceed the predetermined threshold in accordance with the guidelines described in 10 CFR Part 835 and DOE Order 5400.5.

Assessment Boundary Definition 6:

Waste Hoist Systems, Structures, and Components (SSCs) that prevent uncontrolled movement of the Waste Hoist. (The elements are described in SDD UH06.)

Safety Function: Prevent uncontrolled movement of the Waste Hoist.

Assessment Boundary Definition 7:

Underground Ventilation Filtration System to provide dynamic ventilation in the WIPP underground and support High Efficiency Particulate Air (HEPA) filtration of underground ventilation air. This system is comprised of the mine surface ventilation (700 and 860) fans, the shift-to-filtration controls, and the associated HEPA filtration. (The elements are described in SDD VU01.)

Safety Function: The function of the Underground Ventilation Filtration System is to mitigate the consequences of underground accidents that could result in a release of radioactive material to the environment.

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Attachment 9 - Vital Safety System Criteria Considerations

Assessment Boundary Definition 8:

Waste Handling Equipment that is directly used to handle waste, including the TRUPACT-II Unloading Dock (TRUDOCK) bridge cranes, forklifts, facility pallets, underground transporters, conveyance loading cars, and push-pull devices. (The elements are described in SDD WH02.)

Safety Function: The function of the waste handling equipment is to reduce the probability of an accident, such as the fire resistant construction aspect of forklifts used in waste handling. The design provides equipment which reduces the likelihood of a drum drop or breached drum.

Assessment Boundary Definition 9:

Waste Handling Equipment that is used directly to provide shielding, handle waste drums, or handle waste canisters. This includes equipment in the Hot Cell Complex, the shield valve and shield door interlocks and controls, Hot Cell cranes and grapples, overhead powered manipulators, manipulators, swipe systems, facility cask, underground fire suppression equipment, shield plug and facility canister configuration, and Horizontal Emplacement and Retrieval Equipment (HERE) unit. (The elements are described in SDD WH03 and SDD WH05.)

Safety Function: The function of the waste handling equipment is to reduce the probability of an accident and to provide shielding protection for the worker. The design provides equipment that reduces the likelihood of a drum or canister drop or breach and reduces the likelihood that shielding designed to protect the worker is not in proper configuration.

Assessment Boundary Definition 10:

WHB Remote Handled (RH) HVAC associated with confinement ventilation. (The elements are described in SDD HV02.)

Safety Function: Provide differential pressure between the different zones of the RH and CH areas of the WHB and the outside atmosphere. Different zones of the RH area of the WHB (excluding the RH Bay) are maintained sub-atmospheric. The confinement function is designed to mitigate the consequences of a release of airborne radioactive material in the RH area by providing a barrier to environmental release. The Hot Cell Complex is designed to be more negative than any other portion of the WHB in accordance with the "as low as reasonably achievable" (ALARA) principle.

Assessment Boundary Definition 11:

Radiation detection equipment interlocked with the shield door controls.

Safety Function: The design provides equipment that ensures that the shielding designed to protect the worker is in proper configuration.

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Attachment 10 - Example of Concerns Form

Assessment Number: _____ Date: _____

ASSESSOR: _____ Checklist Activity (Item No.): _____

CONCERN NO.: _____

I WHAT IS THE CONCERN?

CONCERN DISCUSSED WITH WHOM: _____

II REQUIREMENT(S) NOT MET (if applicable) (Name, Revision, Paragraph):

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Attachment 11 - Example of WTS QA Independent Assessment Log

**WTS QUALITY ASSURANCE
INDEPENDENT ASSESSMENT LOG**

Assessment Number	Subject/Manufacturer	Location	Date Performed	Lead Auditor/ Surveillor	Assessment Team	Results Findings/CDAs/ Observations	Status of External Findings
E05-06	Supplier X	Wichita, KS	5/10/2005	(Name)	(Names)	8 Findings 1 CDA 2 Obs.	All findings closed 5/10/05, QA:05:00287

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Attachment 12 - Technical Specialist/Auditor Participation Indoctrination for Quality Assurance Audits

**Technical Specialist/Auditor Participation Indoctrination
for Quality Assurance Audits
Audit XXX0XX
(Audit Title)**

In preparation for participation as a Technical specialist/Auditor, this documentation serves as a record that the below listed individual has been indoctrinated per the requirements of the WTS QAPD, and procedure WP 13-QA.03.

Items discussed:

- Applicable portion of the WTS QAPD
- Applicable section of WP 13-QA.03, which includes audit checklist preparation and completion, documentation required during the audit process, and the audit report format.
- Applicable requirements documentation associated with this audit.
- Expectations of an Auditor.

Experience Background:

(Enter short biography for each specialist [auditor as desired] detailing previous experience and qualifications.)

Technical Specialist/Auditor:

Print Name

Signature

Lead Auditor:

Print Name

Signature