

WP 13-QA.04

Revision 17

Quality Assurance Department Administrative Program

Cognizant Department: Quality Assurance

Approved by: Jon Hoff



**Quality Assurance Department Administrative Program
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1.0 INTRODUCTION

This program document provides guidance and uniformity to the administrative practices of the Washington TRU Solutions LLC (WTS) Quality Assurance (QA) Department. This administrative program currently addresses the indoctrination, training, and qualification of QA Department personnel, personnel contracted to perform WTS QA functions, QA program responsibilities, special processes, interfaces, assessments, QA implementing procedures, QA Department document review, and Conduct of Operation (CONOPS) activities.

This process produces the following records:

- EA13QA04-4-0, WTS Quality Assurance Personnel Indoctrination and Training Record
- QAA-01, Lead Auditor Authorization Card
- QAA-02, Quality Assurance Surveillor Authorization Card
- QAE-01, Quality Engineer Authorization Card
- QAI-01-1, Quality Assurance Receipt Inspector Qualification Card
- QAI-01-2, Quality Assurance Source Inspector Qualification Card
- QAI-01-3, Quality Assurance Plant Inspector Qualification Card

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

2.0 QUALIFIED SUPPLIERS LIST ^{35, 36}

The Qualified Supplier List (QSL) Program defines the requirements for products and services in support of Quality Level (QL) 1 and 2 activities as determined through the application of WP 09-CN3005, Graded Approach to Application of QA Controls. This Program is managed and maintained by the QA Department, in accordance with WP 13-QA3012, Supplier Evaluation/Qualification.

3.0 TRAINING AND INDOCTRINATION ^{1, 2, 3}

This section defines and standardizes the training and indoctrination for WTS QA personnel. This section contains information for QA personnel regarding assigned tasks, QA organization functions, and instructional or reading requirements to familiarize personnel with fundamental QA methodologies, applications, and skills, including CONOPS principles.

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The QA Department follows the guidelines of WP 14-TR.01, WIPP Training Program, with the Original Lead Auditor Authorization Card, Inspector Qualification Cards, Quality Engineer Authorization Card, and Quality Assurance Surveillor Authorization Card being maintained by Technical Training. Qualification/Requalification exams are controlled and administered by Technical Training.

3.1 Responsibilities

The QA Manager will ensure implementation of the QA Department indoctrination and training program as stated in this section. Additionally, the QA Manager will conduct indoctrination of all QA section managers and ensure completion of EA13QA04-4-0.

QA section managers will conduct indoctrination of section personnel and ensure completion of EA13QA04-4-0. QA management will evaluate the training and experience gained with a former employer or certification/qualification by nationally recognized authorities. This evaluation may be used to support the employee's qualification.

QA personnel will complete the requirements on EA13QA04-4-0 as identified by QA management. Each individual assigned to the department will coordinate scheduling with the QA Training Coordinator for required classes for achieving and maintaining applicable qualifications. Employees must submit copies or originals of documentation substantiating their training, experience, and certification/qualification to QA management for evaluation for meeting WTS QA requirements.

3.2 General Requirements ²⁰

Personnel assigned to the QA Department will complete EA13QA04-4-0 within 60 days of assignment to the QA Department.

Indoctrination will consist of a discussion of:

- WTS QA Department functions and charter.
- The QA Department's and employees' responsibilities, work assignments, and authority.

QA personnel will complete the appropriate required reading in EA13QA04-4-0, and document by initialing and dating the appropriate block.

The employee's manager will verify completion of requirements by signing and dating EA13QA04-4-0.

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3.3 Specific Requirements ^{5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20}

Personnel who perform the following job functions will be trained and qualified in accordance with this document to meet the requirements of WP 13-1, Washington TRU Solutions LLC Quality Assurance Program Description:

- Lead Auditor (Reference Attachment 1, Requirements for Lead Auditors, for specific qualification requirements.)
- Inspector (Reference Attachment 2, Requirements for Inspectors, for specific qualification requirements.)
- Quality Engineer (Reference Attachment 3, Authorization Card(s) for Quality Engineers at WIPP.)
- Quality Assurance Surveillor (Reference Attachment 4, Requirements for Quality Assurance Surveillors, for specific requirements.)
- WTS Quality Assurance Contracted Personnel (Reference Attachment 5, Authorization Card for WTS Quality Assurance Oversight Contracted Personnel, for specific requirements.)

An authorization or qualification card (or section of a card pertinent to the specific duties to be performed) for each job function will be completed and approved by QA management for each candidate before performing any related activities.

The authorization or qualification card and related records will be retained by Technical Training in accordance with WP 14-TR.01. ⁴

4.0 SPECIAL PROCESSES ^{21, 22}

The QA Manager will identify special processes performed by the QA Department, based on the following criteria. Processes shall be considered to be special processes if they meet any one or a combination of the following criteria:

- The results are highly dependent on the control of the process.
- The results are highly dependent on the skill of the operator.
- The quality of the results cannot be readily determined by inspection or test of the product.

The QA Department shall develop and maintain special process implementing procedures that:

- Specify requirements for qualification of personnel, processes, and equipment.

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- Specify necessary conditions for performing the special process.
- Ensure that special process parameters are controlled, and that specified environmental conditions are maintained.

Nondestructive Examination is a special process.

5.0 QA PROGRAM RESPONSIBILITIES

The QA Department shall be responsible for defining the overall structure of, integrating, and ensuring the effective implementation of the QA program, in accordance with WP 13-1.

The WTS General Manager has overall responsibility for development and implementation of the QA program.²⁴

The QA Manager has overall authority and responsibility to execute the QA function delegated by the WTS General Manager. The QA Manager has the following responsibilities and authorities:²⁹

- Develop, establish, and interpret the overall WTS QA policy and ensure effective implementation.
- Maintain liaison with QA organizations from other Waste Isolation Pilot Plant (WIPP) participants and other affected organizations.
- Ensure QA Department involvement in decisions or commitments which directly affect nuclear safety or waste isolation at WIPP.
- Prepare, maintain, and improve WP 13-1.
- Prepare and maintain QA plans and procedures that implement the QA program.
- Review WTS procedures that implement the QA program.
- Schedule and conduct QA independent oversight, including assessments, to verify the organization's achievement of quality and assure the effective implementation of the QA program.
- Evaluate the adequacy of, and approve, supplier QA programs.
- Track and perform trend analysis of quality problems, and report quality problem areas.
- Provide for the administrative processing of documentation concerning conditions adverse to quality.

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- Review, concur, or approve corrective actions for significant conditions adverse to quality.
- Have direct access to responsible management at a level where appropriate action can be effected.
- Be sufficiently independent from cost and schedule considerations.
- Have the organizational freedom to effectively communicate with other senior management positions.
- Have no assigned responsibilities unrelated to the QA program that would prevent appropriate attention to QA matters.
- Interface with the U.S. Department of Energy (DOE)/Carlsbad Field Office (CBFO) staff, participants, and other stakeholders on QA matters.
- Assist other departments and sections with quality planning, documentation, measurement, problem identification, and the development of problem solutions.
- Provide guidance to all applicable subordinate organizations concerning identification, control, and protection of QA records.
- | • Maintain effective control of QA operational activities by working to the basic
| elements of WP 04-CO, Conduct of Operations.
- Have sufficient authority, access to work areas, and organizational freedom to:
 - Identify quality problems.
 - Participate in development of solutions.
 - Verify implementation of solutions.
 - Ensure that unsatisfactory conditions are controlled until proper disposition has occurred.
- **Disseminate information pertinent to quality performance, including:** ²⁵
 - The status of development and implementation of the QA program.
 - The status and resolution of significant quality problems.
 - The lessons learned from significant quality problems and adverse conditions.

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- Quality management practices and improvements.
- Trend analysis results.

Department managers support the QA program by performing the following: ²⁶

- Provide the necessary planning, organization, direction, control, resources, and support to achieve their defined objectives.
- Plan, perform, and improve the work.
- Establish and implement policies and procedures that control the quality of work in accordance with the QA program.
- Provide technical and QA training for personnel performing work.
- Ensure compliance with applicable regulations, DOE Orders, requirements, and laws.
- Ensure that personnel adhere to procedures.
- Halt unsatisfactory evolutions if necessary to ensure that cost and schedule do not override environmental, health, safety, and quality considerations.
- Develop, implement, and maintain plans, policies, and procedures that implement applicable portions of the QA program.
- Identify, investigate, report, and correct quality problems.
- Disseminate information pertinent to quality performance. ²⁵

Managers are responsible for defining quality requirements for work and supporting the achievement of quality. ²³ Management empowers employees by delegating authority and decision making to the lowest appropriate level of the organization. ²⁷

Workers are responsible for achieving and maintaining quality in their work, and for promptly reporting to management any condition adverse to quality. ^{28, 32}

QA assessors are responsible for independently assessing and verifying the quality of work. ²³

6.0 INTERFACES

Where more than one organization is involved in the execution of activities covered by the WIPP QA program, the responsibility and authority of each organization shall be clearly established and documented. The external interfaces between organizations, the internal interfaces between organizational units, and interface changes shall be

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documented. Interface responsibilities shall be defined and documented, and shall include the requirements for management, performance, and assessment.³³

Individuals or organizations responsible for the work may delegate that work to other individuals or organizations; however, the individuals or organizations making the delegation shall retain overall responsibility for that work.³¹

Differences of opinion involving QA program requirements will be brought to the attention of the responsible manager and the QA Manager. If not resolved, these differences will be elevated progressively to higher levels of management, as necessary.³²

7.0 QA IMPLEMENTING PROCEDURES³⁰

WTS shall incorporate into its QA program documents and implementing procedures, the requirements described in the CBFO Quality Assurance Program Document (QAPD) (DOE/CBFO-94-1012), WIPP Hazardous Waste Facility Permit Waste Analysis Plan (WAP), Quality Assurance Project Plans (QAPjP), Certification QA Plans, Waste Acceptance Criteria (WAC) (DOE/WIPP 02-3122), and TRUPACT-II Certification of Compliance (NRC Docket 71-9218), including TRUPACT-II Authorized Methods for Payload Control (TRAMPAC), as applicable.

When the CBFO QAPD, or other applicable requirements document, is revised, WP 13-1, QA project plans, and implementing procedures shall be evaluated and appropriately revised to ensure that the WTS QA program meets the applicable requirements of the CBFO QA program.

8.0 ASSESSMENTS

8.1 Management Assessments

WTS managers perform Management Assessments to evaluate the performance of their organizations. These assessments are performed in accordance with WP 15-GM1000, Management Assessments.

8.2 Independent Assessments

WTS QA Department performs Independent Assessments (audits and surveillances) that measure item and service quality, adequacy of work performance, and promote improvement through emphasis on line organization's achievement of quality.

8.3 Findings and Corrective Actions

WTS QA uses the Issues Management System/WIPP Form to document and track findings noted during assessments. Findings noted at supplier facilities during external audits are documented directly into the site Commitment Tracking System (CTS) to track corrective actions through completion.

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9.0 QUALITY ASSURANCE DOCUMENT REVIEW

The QA Department reviews documentation associated with quality-affecting items, services, and activities to ensure that applicable requirements of the WTS QAPD are addressed. (Reference WP 09-CN3005 for determination of quality-affecting classification.)

QA review requirements apply (but are not limited) to:

- Electronic document system review process defined in WP 15-PS3002, WTS Controlled Document Processing.
- QL determination defined in WP 09-CN3005.
- Procurement reviews defined in WP 15-PC3609, Preparation of Purchase Requisitions.
- Supplier evaluations defined in WP 13-QA3012.
- Work Orders and Preventive Maintenance Instructions per WP 13-QA1006, Quality Assurance Plant Inspections.
- Engineering Change Proposals per WP 09-CN3024, Configuration Management Board/Engineering Change Proposal.

EA13QA04-5-0, Quality Assurance Screen, provides a guideline to QA elements to be considered during the review. WP 13-1 contains the detailed requirements for the listed QA elements and is used in conjunction with EA13QA04-5-0 to verify that applicable QAPD requirements are addressed in the document being reviewed.

Results of the QA review are documented as applicable for the specific type of review (e.g., record procedure review in the electronic document system). Identified discrepancies shall be satisfactorily addressed before final QA approval of the reviewed document.

10.0 CONDUCT OF OPERATIONS

The organization and administration of the Quality Assurance operations for the WIPP site is intended to achieve a high level of safety and performance that is accomplished through effective control of operational activities by working to the basic elements of WP 04-CO, Conduct of Operations.

This includes but is not limited to the following CONOPS protocol:

- Maintaining a back-shift turn-over manual and supporting documents
- Maintaining a back-shift turn-over log

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- Identifying vendor/supplier safety parameters, expectations and conducting safety briefs, as needed
- Conducting independent verifications, as required
- Determining safety/security issues associated with internal/external assessment activities. Ensure that the assessor or team is aware of these issues, and provided with appropriate logistics information regarding equipment necessary to maintain compliance with the basic elements of Conduct of Operations (e.g., Personal Protective Equipment).

11.0 REFERENCES

NRC Docket 71-9218, *Certificate of Compliance for TRUPACT-II Package*

TRAMPAC, TRUPACT-II Authorized Methods for Payload Control (TRAMPAC)

DOE-CBFO-94-1012, U.S. Department of Energy Carlsbad Field Office *Quality Assurance Program Document*

DOE/WIPP 02-3122, *Contact-Handled Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant*

WP 04-CO, Conduct of Operations

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

WP 09-CN3024, Configuration Management Board/Engineering Change Proposal

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

WP 13-QA.03, Quality Assurance Independent Assessment Program

WP 13-QA1006, Quality Assurance Plant Inspections

WP 13-QA3012, Supplier Evaluation/Qualification

WP 14-TR.01, WIPP Training Program

WP 15-GM1000, Management Assessments

WP 15-PC3609, Preparation of Purchase Requisitions

WP 15-PS3002, WTS Controlled Document Processing

EA13QA04-4-0, WTS Quality Assurance Personnel Indoctrination and Training Record

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EA13QA04-5-0, Quality Assurance Screen

QAA-01, Lead Auditor Authorization Card

QAA-02, Quality Assurance Surveillor Authorization Card

QAE-01, Quality Engineer Authorization Card

QAI-01-1, Quality Assurance Receipt Inspector Qualification Card

QAI-01-2, Quality Assurance Source Inspector Qualification Card

QAI-01-3, Quality Assurance Plant Inspector Qualification Card

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Attachment 1 - Requirements for Lead Auditors

The following requirements for Lead Auditor certification shall be documented on the Lead Auditor Authorization Card, Form QAA-01. Obtain a blank original QAA-01 from Technical Training and, when completed and signed by QA management, forward to Technical Training for processing in accordance with WP 14-TR.01. ³⁴

Scoring System ¹⁰

The prospective Lead Auditor shall have verifiable evidence that a minimum of ten credits have been accumulated under the following scoring system:

1. Education (four credits maximum)
 - a. An associate's degree from an accredited institution scores one credit or, if the degree is in engineering, physical sciences, mathematics, or QA, scores two credits; or
 - b. A bachelor's degree from an accredited institution scores two credits or, if the degree is in engineering, physical sciences, mathematics, or QA, it scores three credits. In addition, score one more credit for a master's degree (or higher) in engineering, physical sciences, business management, or QA from an accredited institution.

2. Experience (nine credits maximum)

For technical experience in such areas as scientific investigation, site characterization, nuclear waste management, production, transportation, engineering, manufacturing, construction, operation, maintenance, or experience applicable to the auditing organization's area of responsibility, score one credit for each full year, with a maximum of five credits for this aspect of experience.

- a. If two years of this experience have been in a nuclear field, score one additional credit; or
- b. If two years of this experience have been in QA, score two additional credits; or
- c. If two years of this experience have been in auditing or assessment, score three additional credits; or
- d. If two years of this experience have been in nuclear-related QA, score three additional credits; or
- e. If two years of this experience have been in nuclear-related QA auditing or assessment, score four additional credits.

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Attachment 1 - Requirements for Lead Auditors

3. Professional Competence or Accomplishment (two credits maximum)

For certification of competency in engineering, science, or QA specialties, issued and approved by a state agency or national professional or technical society, score two credits.

4. Rights of Management (two credits maximum)

When determined appropriate, the organization performing the qualification may grant up to two credits for other performance factors applicable to auditing that are not explicitly called out in this section (such as leadership, sound judgment, maturity, analytical ability, tenacity, past performance, and completed QA training courses).

[Training](#) ¹²

Prospective Lead Auditors shall be trained to the extent necessary to ensure their competence in skills as established by the organization responsible for performing audits and assessments. Training in the following areas shall be accomplished, and its completion verified, based upon management evaluation of the particular needs of each prospective Lead Auditor:

- Knowledge and understanding of WP 13-1 and other program-related procedures, codes, standards, regulations, DOE Orders, and regulatory guides
- General structure of QA plans and implementation procedures, as a whole, and as related to specific elements of WP 13-1
- Auditing or assessment fundamentals, objectives, and techniques of examining, questioning, evaluating, and reporting; and methods of identifying, evaluating effectiveness of, following up, and closing corrective action items
- Audit planning in functional areas of nuclear QA

[Audit Participation](#) ¹³

The prospective Lead Auditor shall have participated in a minimum of five QA audits within a period of time NOT to exceed three years prior to the date of the qualification. At least one of the five QA audits shall be a nuclear audit and shall have been performed within the last year.

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Attachment 1 - Requirements for Lead Auditors

[Communication Skills](#) ¹¹

The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the candidate's manager.

[Examination](#) ^{14, 15}

The prospective Lead Auditor shall pass an examination that evaluates the comprehension of and ability to apply the audit knowledge described in this section. The test shall be oral, written, practical, or any combination of these methods. The development and administration of the examination for a Lead Auditor is the responsibility of the QA Department. The QA Department may delegate administrative duties related to this responsibility. The QA Department (or designee) shall:

- Maintain the integrity of the examination through confidentiality of files and, where applicable, proctoring of examinations.
- Develop and maintain objective evidence regarding the type and content of the examination.

[Certification](#) ^{9, 16}

Lead Auditors will be certified by the QA organization and Technical Training as being authorized (qualified) to lead audits and assessments. This certification will document the:

- Name of the organization performing the certification.
- Name of the Lead Auditor.
- Date of certification or recertification.
- Basis of certification (such as education, experience, communication skills, and training).
- Signature of the designated representative of the organization responsible for certification.

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Attachment 1 - Requirements for Lead Auditors

Proficiency Maintenance

Lead Auditors shall maintain their proficiency through one or a combination of the following: ¹⁷

- Regular and active participation in the audit process
- Review and study of codes, standards, QA implementation procedures, instructions, and other documents related to QA program auditing or assessment
- Participation in training programs

QA management shall evaluate the proficiency of Lead Auditors annually. Based on the evaluation, management shall choose to extend the qualification, require retraining, or require requalification. Management evaluations shall be documented. ¹⁸

Lead Auditors who fail to maintain their proficiency for a two-year period shall be required to requalify in accordance with the Lead Auditor Qualification requirements of this procedure. Participation in only one nuclear QA audit is required for this requalification. ¹⁹

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Attachment 2 - Requirements for Inspectors

The following requirements for Quality Assurance Inspector certification shall be documented on the applicable form, Quality Assurance Receipt Inspector Qualification Card, QAI-01-1, Quality Assurance Source Inspector Qualification Card, QAI-01-2, and Quality Assurance Plant Inspector Qualification Card, QAI-01-3. Qualification cards are to be obtained and completed in sequential order. Obtain blank original qualification cards from Technical Training and, when completed and signed by QA management, forward to Technical Training for processing in accordance with WP 14-TR.01.³⁴

Training²

The need for a formal training program shall be determined, and such training activities shall be conducted as required to qualify personnel who perform such inspections and tests. On-the-job training shall also be included in the program, as appropriate, with emphasis on first-hand experience gained through actual performance of inspections and tests.

Physical Examination⁸

The QA Department shall identify any special physical characteristics needed in the performance of each activity, including the need for initial and subsequent physical examination.

Certification⁷

Inspector qualification shall be certified in writing in an appropriate form and shall include the following information:

- Employer's name
- Identification of person being certified
- Activities certified to perform
- Basis used for certification, including such factors as (1) education, experience, indoctrination, and training; (2) test results, where applicable; and (3) results of capability demonstration
- Results of periodic evaluation
- Results of physical examination, when required

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Attachment 2 - Requirements for Inspectors

- Signature of employer's designated representative who is responsible for such certification
- The date of certification and date of certification expiration

Maintenance of Qualification ³

The job performance of inspectors shall be reevaluated for capability at periodic intervals not to exceed two years. ³⁷ If, during this evaluation, or at any other time, it is determined that the capabilities of an individual are not in accordance with the specified qualification requirements, that person shall be removed from inspection activity until such time as the required capability has been demonstrated.

Any person who has not performed inspection activities in their qualified area for a period of one year shall be reevaluated for the required capability in accordance with the above requirements.

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Attachment 3 - Authorization Card(s) for Quality Engineers at WIPP

Training

Training for Quality Engineers (QEs) at WIPP shall be performed and documented using Form QAE-01, Quality Engineer Authorization Card.³⁴

Obtain a blank original QAE-01 from Technical Training, and when completed and signed by QA management, forward to Technical Training for processing.

Maintenance

The job performance of QEs shall be reevaluated by the Manager, Oversight Programs, at periodic intervals not to exceed two years. If, during the evaluation, or at any other time, it is determined that the capabilities of an individual are not in accordance with the specified authorizations, that person shall be removed from witnessing activity until such time as the required capability has been demonstrated.

Implementation

The QAE-01* card shall be used as a means for authorizing the performance of inspector /quality engineering function(s) specified by the card including off-site and limited on-site* witness type activities, Quality Engineer reviews, and fabrication oversight planning.

* Limited on-site activities - When an Inspector is not available, a QE may be used to perform witness-type functions (based on QA management discretion).

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Attachment 4 - Requirements for Quality Assurance Surveillors

Training

The following requirements for Quality Assurance Surveillors shall be documented on Form QAA-02, Quality Assurance Surveillor Authorization Card: ³⁴

- The prospective Quality Assurance Surveillor shall read WP 13-QA.03, Quality Assurance Independent Assessment Program.
- QA management shall provide an orientation of the assessment process and requirements.
- The prospective Quality Assurance Surveillor shall pass the Lead Auditor examination (reference Attachment 1).

Obtain a blank original QAA-02 from Technical Training and, when completed and signed by QA management, forward to Technical Training for processing.

Maintenance

The job performance of Quality Assurance Surveillors shall be re-evaluated by the Manager, Assurance Programs, at periodic intervals not to exceed two years. If, during the evaluation, or at any other time, it is determined that the capabilities of an individual are not in accordance with the specified authorizations, that person shall be removed from performing the activity until such time as the required capability has been demonstrated.

Implementation

QAA-02 will be used for performing surveillances, in accordance with WP 13-QA.03.

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Attachment 5 - Authorization Card for WTS Quality Assurance Oversight Contracted Personnel

Training

Training shall be performed and documented using Form QAE-01, Quality Engineer Authorization Card.³⁴ Obtain a blank original QAE-01 from Technical Training, and when completed and signed by QA management, forward to Technical Training for processing.

Maintenance

The job performance of WTS contracted personnel shall be reevaluated by the Manager, Oversight Programs, at periodic intervals not to exceed two years. If, during the evaluation, or at any other time, it is determined that the capabilities of an individual are not in accordance with the specified authorizations, that person shall be removed from witnessing and/or oversight activity until such time as the required capability has been demonstrated.

Implementation

QAE-01 will be used for contract personnel performing fabrication oversight activities in accordance with WP 13-QA3020.