DOE F 1325.8

United States Government

Department of Energy
Carlsbad Area Office

memorandum

ENTERED

DATE: July 28, 1999

REPLY TO ATTN OF: CAO:QA:MLC 99-0894 UFC 2300.00

SUBJECT: CAO Audit Report A-99-19

TO: Gerry Streier, TRUtech

On June 7-10, 1999, the Carlsbad Area Office (CAO) performed Audit A-99-19 of the TRUtech waste characterization activities. The audit team determined that TRUtech's quality assurance (QA) program was adequate in the flowdown of requirements from the CAO Quality Assurance Program Document (QAPD), Quality Assurance Program Plan (QAPP), and Waste Acceptance Criteria (WAC) into TRUtech implementing procedures. The audit team also concluded that the TRUtech QA Program was satisfactorily implemented and effective for the processes that were evaluated during the audit. The technical processes (NDA and NDE) that were evaluated during this audit, however, were concluded to be inadequate, unsatisfactorily implemented and ineffective. The overall (QA and Technical) program conclusions, however, are that the programs are adequate and marginal in the area of implementation and effectiveness.

Three (3) Corrective Action Reports (CARs) were issued and provided under separate cover.

If you have any questions or comments, please contact me at (505) 234-7423.

M. Lea Chism

for Samuel A. Vega
CAO QA Manager

Attachment

JUL 1999
RECEIVED

990721

cc w/attachment:
L. Chism, CAO
D. Armstrong, NVO
A. Colarusso, NVO
S. Monroe, EPA
M. Eagle, EPA
S. Nolan, Bechtel-NV
B. Foster, Bechtel/NV
M. Griffin, Bechtel/NV
T. Krause, TRUtech
N. Seguin, TRUtech
B. Walker, EEG
D. Winters, DNFSB
S. Zappe, NMED
T. Bowden, CTAC

U.S. DEPARTMENT OF ENERGY
CARLSBAD AREA OFFICE

AUDIT REPORT

OF

TRUtech Mobile Characterization Systems

Performed for
The
NEVADA TEST SITE

LAS VEGAS, NEVADA

AUDIT NUMBER A-99-19

June 7-10, 1999

TRU WASTE CHARACTERIZATION AND CERTIFICATION

Prepared By: _____ **Date:** 7-21-99
Pete V. Rodriguez
Audit Team Leader

Approved By: M. Lea Chism **Date:** 7/28/99
for Samuel A. Vega
CAO QA Manager

Reviewed By: M. Lea Chism **Date:** 7/28/99
for M. E. Bennington
CAO Waste Certification Manager

1.0 EXECUTIVE SUMMARY

Carlsbad Area Office (CAO) Audit A-99-19 was conducted to evaluate the adequacy, implementation, and effectiveness of the TRUtech Transuranic (TRU) Waste Characterization and Certification activities. This audit was a follow-up to CAO Audit A-99-10 of TRUtech conducted in January 1999, and was performed in conjunction with an Environmental Protection Agency (EPA) inspection of the Real-Time Radiography (RTR) and Nondestructive Assay systems utilized by TRUtech.

The audit was conducted at the TRUtech field operating site at Area 5 of the Nevada Test Site (NTS) near Las Vegas, Nevada, June 7-10, 1999. The audit team determined that TRUtech's quality assurance (QA) program was adequate in the flowdown of requirements from the CAO Quality Assurance Program Document (QAPD), Quality Assurance Program Plan (QAPP), and Waste Acceptance Criteria (WAC) into TRUtech implementing procedures. The audit team also concluded that the TRUtech QA program was satisfactorily implemented and effective for the processes that were evaluated during the audit. The technical processes (Nondestructive Assay [NDA] and Nondestructive Examination [NDE]) that were evaluated during this audit, however, were concluded to be inadequate, unsatisfactorily implemented and ineffective. The overall (QA and Technical) program conclusions, however, are that the programs are adequate and marginally implemented and marginally effective. The adequacy, implementation and effectiveness of evaluated technical processes are detailed in Section 5.0 and Attachment 2.

The audit team was unable to verify the completion of effective corrective actions for Corrective Action Reports (CARs) 98-049 and 98-050 identified during TRUtech audit A-98-20 June 1998 and CAR 99-030 identified during audit A-99-10 in January 1999. Complete and effective corrective action(s) were verified, however, for CAR 99-025, identified during audit A-99-02 in December 1998.

The team identified four additional conditions adverse to quality resulting in the issuance of three CARs that require TRUtech corrective action in the areas of RTR, NDA and records. Two isolated deficiencies requiring only remedial corrective action were Corrected During the Audit (CDA). Two Recommendations were identified and are being offered for TRUtech management consideration.

2.0 SCOPE AND LIMITATIONS

The audit team evaluated the adequacy, implementation, and effectiveness of technical and quality assurance processes related to the TRUtech TRU Waste Characterization and Certification activities.

The following QA program elements were evaluated in accordance with the CAO QAPD:

Organization
QA Program Implementation and Grading
Interface Control
Personnel Qualification and Training
Nonconformances and Corrective Actions
Documents and Records
Procedure Development
Procurement
Measuring and Test Equipment
Audits and Assessments
Software Quality Assurance
Data Validation

The following TRU Waste characterization technical processes were evaluated in accordance with the CAO QAPP:

Nondestructive Assay (NDA)
Real - Time Radiography (RTR)
Data Validation (Level I)

Evaluation of the TRUtech TRU Waste Characterization Program (TWCP) implementing documents and activities was based on current revisions of the following documents:

TRUtech Quality Assurance Project Plan (QAPjP), TT-DOC-001

TRUtech Team Mobile Systems Program Transuranic Waste Certification Plan, TT-DOC-002

Related TRUtech technical and quality assurance implementing procedures (see Attachment #3 for specific documents)

3.0 AUDIT TEAM AND OBSERVERS

AUDITORS/TECHNICAL SPECIALISTS

Beth Bennington	Waste Certification Manager, CAO
Sam Vega	Management Representative, CAO
Pete Rodriguez	Audit Team Leader, CTAC
Dave Kimbro	Auditor, CTAC
Stephen Hans	Auditor, CTAC
Jack Walsh	Auditor, CTAC

Chet Wright	Auditor, CTAC
Jim Bresson	Technical Specialist, CTAC
Kerry Watson	Technical Specialist, CTAC

OBSERVERS/INSPECTORS

Sheila Lott	CTAC Observer
Mark Doehnert	EPA Observer
Willie Most	WID Observer
Ben Walker	EEG Observer
Howard Finkel	ICF (EPA Inspector)
Don Hammer	ICF (EPA Inspector)
Scott Monroe	EPA Inspector
Dave Stuenkel	Trinity Engineering (EPA Inspector)
Gary Walvatne	TechLaw (EPA Inspector)
Ray Wood	Trinity Engineering (EPA Inspector)
Bill Vocke	TechLaw (EPA Inspector)

4.0 AUDIT CONDUCT AND AUDIT PARTICIPANTS

TRUtech personnel involved in the audit process and other individuals contacted during the audit are identified in Attachment 1. A preaudit meeting was held in the DOE Nevada Support Facility conference room on June 7, 1999. A daily meeting was held with TRUtech management and staff to discuss issues and potential deficiencies. The audit was concluded with a postaudit meeting held in Area 5 at the NTS on June 10, 1999.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Adequacy, Implementation, and Effectiveness

The audit team determined that TRUtech's QA program was adequate in the flow down of requirements from the CAO QAPD, QAPP, and the WAC into the TRUtech implementing documents. The audit team concluded that the TRUtech QA Program was satisfactorily implemented and effective.

The audit team performed follow-up verifications of Corrective Action Reports (CARs) 98-049 and 98-050, identified during TRUtech audit A-98-20 in June 1998, and CAR 99-030, identified during audit A-99-10 in January 1999. However, due to incomplete and incorrect documentation provided by TRUtech, closure of these CARs cannot be completed at this time. Verification of corrective action completion will be attempted when TRUtech submits revised corrective action plans and documentation.

The technical processes (NDA/NDE) that were evaluated during this audit, however, were concluded to be inadequate, unsatisfactorily implemented and ineffective. The overall (QA and Technical) program conclusions, however, are that the programs are adequate and marginally implemented and marginally effective. The unverifiable CARs from the previous audits, coupled with the three CARs resulting from this audit were contributing factors in this overall (QA and Technical) program conclusion.

A follow-up verification of CAR 99-025, identified during TRUtech audit A-99-02 in December 1998, was also performed. This verification resulted in the recommended closure of CAR 99-025.

5.2 QA Program Audit Activities

Applicable QA program elements that were evaluated (see Section 2.0) were assessed by review of records, interviews, and observation of process activities. The audit team determined that not all documents designated to become QA records were identified. (CAR 99-079). The overall QA program, however, was determined to be adequate, satisfactorily implemented, and effective. A summary table of audit results is provided as Attachment 2. Details of audit activities, including specific objective evidence reviewed, are contained within the audit checklists. The checklists are maintained as QA records.

5.3 Technical Activities

Evaluations of the applicable TRUtech technical activities are summarized below. The procedures evaluated during the audit are listed in Attachment 3.

5.3.1 Nondestructive Assay (NDA)

The TRUtech NDA activities at the NTS were evaluated for adequacy of requirement flow down, for the implementation of TRUtech procedures, and for the effectiveness of the processes used to assay TRU waste drums. The NDA portion of this audit focused on issues related to Corrective Action Report (CAR-98-050), primarily on development of Total Measurement Uncertainty (TMU). The audit evaluated the Active Passive Neutron Examination and Assay (APNEA) nondestructive assay (NDA) system and a few activities performed by the WIT gamma system.

New Minimum Detectable Concentration (MDC) calculations were reviewed. The new data indicates that passive assay results were above the applicable MDC level and the MDC issue described in CAR 98-050 has been satisfactorily resolved. However, the APNEA TMU data for both active and passive modes of assay in the areas of self-shielding, active background and matrix effects were overly conservative and raise questions concerning the validity of the assay. Review of applicable assay data packages resulted in identification of several instances in which Low-Level Waste (LLW) was artificially raised to the status of TRU waste. The audit team determined

that TRUtech has not submitted an acceptable revision to their TMU document, therefore, CAR 98-050 will remain open until corrective actions are complete. The audit team also identified new deficiencies in the area of NDA (see CAR 99-078). The CAR identifies replicate isotopic ratio measurement not being performed in conjunction with APNEA Assays and the measurement of U-234 not being done unless present in large quantities.

Because of the open issues relating to CAR 98-050 and the newly issued CAR 99-078, the audit team concluded that the NDA implementing procedures are inadequate, that implementation is unsatisfactory, and the process not effective.

5.3.2 Data Validation and Reporting (Generation Level)

The evaluation included examination of data packages to assure that generation-level data reviews are being properly performed. The team determined that procedures (see Attachment 3: procedures 12, 22 and 23) were adequate and implemented and that the generation level data validation for NDA was effective. Review of radiography (RTR) data validated and released at the data generation level indicated that the data generation level reviews for RTR are not acceptable, (see section 5.3.3 for details.) Corrective actions for previously issued CAR 99-025, relative to NDA batch data reporting, were satisfactorily verified and the CAR will be recommended for closure. Two other CARs (98-049 and 99-030) relate to deficiencies in the data generation process for headspace gas batch data reports remain open due to incomplete and incorrect documentation that was provided by TRUtech.

5.3.3 Nondestructive Examination (NDE)

TRUtech Waste Inspection Tomography (WIT) operating procedures were reviewed, and the performance of radiography was observed to determine adequate flow-down of CAO requirements, satisfactory implementation of the procedures, and the effectiveness of radiography as performed using computed tomography. The WIT NDE system as configured at the time of the audit did not include an audio recording component. Failure to record the audio description of the waste examination process resulted in the generation of incomplete data as required per the QAPP, section 10.2.

Review of radiography data validated and released at the data generation level indicated that the independent technical reviewer, technical supervisor and QA officer failed to identify that the testing batch data was incomplete without the required audio recordings. The Completeness and Comparability Review of Quality Assurance Objectives for radiography as detailed in QAPP section 10.1 were not met without the audio recording of the radiography examination. Failure to meet these objectives had not been identified by TRUtech personnel; therefore, corrective actions had not been implemented as required.

As a result of TRUtech releasing incomplete radiography testing batch data and their failure to meet the required QAOs for radiography, this area was found to be unsatisfactory (see CAR 99-077). The audit team concluded that the NDE implementing procedures are inadequate, that implementation is unsatisfactory, and the process is not effective.

5.3.4 Software

The software used for processing, controlling, measuring, and statusing of hazardous, radioactive, and waste matrix materials was evaluated. The evaluation included a review of the changes to software made since the last CAO audit and a verification of the continuation of previous corrective actions from CAR 98-047. The evaluation focused on the control of software baselines, classification, and review of completed software documentation.

Software systems reviewed for TRUtech included the Active Passive Neutron Examination and Assay (APNEA) system. The software quality assurance procedure (see Attachment 3: procedure 6) was determined to be adequate, satisfactorily implemented, and effective.

6.0 CORRECTIVE ACTION REPORTS (CARs), DEFICIENCIES CORRECTED DURING THE AUDIT (CDAs), AND RECOMMENDATIONS

6.1 Corrective Action Reports

The following three CARs, initiated as a result of Audit A-99-19, have been transmitted to TRUtech under separate cover. A brief description of each CAR is provided below.

6.1.1 CAO CAR 99-077

Contrary to the requirements of the QAPP, Waste Inspection Technology Company (WITCO) has not put an audio recording system in place with the video recording for the waste inspection tomography system.

6.1.2 CAO CAR 99-078

Contrary to QAPjP requirements, replicate (one in 20) isotopic ratio measurements have not been performed in conjunction with APNEA assays, and measurement of U-234 has not been done unless present in large quantities.

6.1.3 CAO CAR 99-079

Contrary to the requirements of TT-QP-002, Paragraph 4.1.1, three APNEA procedures M50472, M50755, and M50764 do not identify documents designated to become QA

records. Those same APNEA procedures and WITCO procedures QP 7.1 through 7.16 did not identify the individuals responsible for submitting QA records to the records system.

6.2 Deficiencies Corrected During the Audit (CDA)

Two isolated deficiencies requiring only remedial corrective action were identified and corrected during the audit. One deficiency related to M&TE re-calibration and NCR/CAR closure. The second deficiency related to missing review comment documentation for three procedure revisions.

6.3 Recommendations

The following Recommendations are being presented for TRUtech management consideration:

1. Procedure TT-QP-007, *Managing Nonconformance and Corrective Actions and Analyzing Trends,* needs clarification regarding notification practices. A Quality Action request to revise the procedure and eliminate the multiple notification requirements was initiated by TRUtech.

2. The TRUtech training program could be enhanced through additional operator training or hands-on instruction in the area of waste generating practices and packaging configurations expected to be found in each matrix category at the site. It should also be noted that the review of operator training and qualification records did not disclose any discrepancies, and operator qualification is not an issue.

7.0 LIST OF ATTACHMENTS

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results
Attachment 3: Table of Procedures Audited

PERSONNEL CONTACTED DURING THE AUDIT

PERSONNEL CONTACTED				
NAME	ORG/TITLE	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Armstrong, Dennis	DOE/NV TRU Task	X		
Benard, Loni	BN-Procurement/Contracts Specialist	X		
Benardi, Richard	TRUtech/WITCO-WIT BIR Facility Manager	X	X	X
Calarusso, Angela	DOE/NV TRU Program Manager, WMD	X		
Cowley, Jan	BN-WMD Project Manager	X		
Foster, Bruce	BN-Assistant Project Manager	X		
Griffin, Michael	BN-Scientist – AK Expert	X		
Kotek, Larry	BN-Training Coordinator	X		
Krause, Tom	TRUtech Project Office Project Manager	X	X	X
Mellington, Stephen	DOE/NV, Acting AMEM	X		
Nolan, Steve P.	BN QAO Performance Assessment	X		
Nisius, David	TRUtech BIR Principal Scientist		X	
Ruth, Fred	BN-Records Coordinator/Senior Engineer	X		
Sequin, Nicole	TRUtech QA Officer	X	X	X
Spanger, Lorenz	TRUtech WCO/TCO		X	

PERSONNEL CONTACTED				
NAME	ORG/TITLE	PREAUDIT MEETING	CONTACTED DURING AUDIT	POST AUDIT MEETING
Streier, Gerry	TRUtech Program	X	X	X
Sygitowicz, Lee	BN-Waste Management Program Manager	X		

CAO Audit A-99-19 Detail Summary

Evaluation Area	Concern Classification				QA Evaluation		Technical
	CARs	CDAs	Obs	Rec	Adequacy	Implementation	Effectiveness
Organization					A	S	E
QA Program Implementation					A	S	E
Interface Control					A	S	E
QA Grading					A	S	E
Qualification &Training				9	A	S	E
Document Control		5			A	S	E
Records	99-079 (6)				A	S	E
Procurement					A	S	E
Procedure Development					A	S	E
Software					A	S	E
Audits & Assessments					A	S	E
NCRs/CARs				2	A	S	E
M&TE		3&4			A	S	E
NDA / Level I Data Validation	99-078 (7 & 8)				NA	U	NE
NDE / Level I Data Validation	99-077 (1)				NA	U	NE
TOTALS (QA Program)	1	2		2	**A**	**S**	**E**
TOTALS (NDA/NDE)	2				**NA**	**U**	**NE**
COMBINED (QA/TECH.)TOTALS	**3**	**2**		**2**	**A**	**M**	**M**

Definitions

E = Effective
S = Satisfactory
I = Indeterminate
U= Unsatisfactory

CAR = Corrective Action Report
CDA = Corrected During Audit
NE = Not Effective
M = Marginal

Obs = Observation
Rec = Recommendation
A = Adequate
NA = Not Adequate

TRUtech PROCEDURES AUDITED

NUMBER	PROCEDURE NUMBER	REVISION	TITLE
1.	TT-DOC-001	0.1	TRU Waste Characterization Quality Assurance Project Plan (QAPjP)
2.	TT-DOC-005	1	Training, Qualification, and Certification Plan
3.	TT-QP-001	0	Document Control
4.	TT-QP-002	3	Records Management
5.	TT-QP-003	1	Controlling Procurement of Items and Services
6.	TT-QP-004	0.1	Software Quality Assurance
7.	TT-QP-006	0.1	Implementing the Graded Approach
8.	TT-QP-007	1	Managing Nonconformance and Corrective Actions and Analyzing Trends
9.	TT-QP-008	1	Conducting Assessments and Audits
10.	TT-QP-010	0.1	Conducting Preliminary Site Visits
11.	TT-QP-015	1.0	Developing Procedures for Process Control
12.	TT-QP-018	0.1	Data Generation Level, Data Review, Validation, Verification, and Reporting
13.	TT-QP-019	0.1	Equipment Testing, Inspection, and Maintenance
14.	WIT-QP 7.1	4	WIT NDE with DR
15.	WIT-QP 7.2	4	WIT NDE with CT
16.	WIT-QP 7.3	4	WIT NDE with CT Volume-Rendering
17.	WIT-QP 7.7	4	WIT NDE and NDA Data Fusion
18.	WIT-QP 7.8	4	WIT DR Calibration
19.	WIT-QP 7.9	4	WIT CT Calibration
20.	WIT-QA 7.13	4	WIT NDE Maintenance
21.	WIT-QP 7.15	4	WIT Operator Training
22.	M50471	E	APNEA Characterization With Surrogate Drums
23.	M50472	F	APNEA Waste Drum Assay Procedure