



**Department of Energy**

Carlsbad Area Office  
P. O. Box 3090  
Carlsbad, New Mexico 88221

December 20, 1999

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Mr. Stephen D. Page, Director  
Radiation Protection Division  
Environmental Protection Agency  
401 M Street, S. W.  
Washington, D. C. 20460

Dear Mr. Page:

The Carlsbad Area Office acknowledges your letter of October 26, 1999, that contained the EPA Inspection Report of the CAO audits of MCS, TRUtech, and NTS conducted on June 7 -11, 1999. The Inspection Report indicates that EPA has eleven findings and ten concerns that require CAO response. Our responses are enclosed.

Please note that NTS will not be allowed to ship transuranic waste to WIPP until final approval is granted by both CAO and EPA.

If you have any questions on this matter, please contact Sam Vega of my staff at (505) 234-7423.

Sincerely,

Dr. Inés R. Triay  
Manager

Enclosure

cc w/enclosure:  
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**ATTACHMENT I****RESPONSES TO EPA ISSUES IDENTIFIED IN THEIR MCS, TRUtech, AND  
NTS INSPECTION REPORT****EPA QA Concerns Related to Mobile Characterization Systems (MCS) [EPA  
Report Section 7.1]**

EPA did not require response to MCS Concern Nos. 1, 2, and 3. [EPA Report Subsections 7.1.1, 7.1.2, and 7.1.3]

**MCS Concern No. 4 [EPA Report Subsection 7.1.4]**

*Procedure MCS-055, Revision E, Section 6.3.7.2, first sentence, states lifetime records will be transferred to the DOE Site Project Office, but the second sentence of this section states lifetime records will be transferred to the management of the waste site, i.e. Bechtel-Nevada. The inspection team is concerned that section 6.3.7.3 does not provide clear direction regarding which organization will receive the MCS lifetime records.*

**CAO Response to MCS Concern No. 4**

Turnover of lifetime QA records by MCS, either directly to DOE or it's site contractor, is sufficient and should be considered equivalent. The records are required to be part of the site Records Identification and Disposition System (RIDS). The end result will be the same regardless of which organization initially receives the records.

**EPA QA Findings and Concerns Related to TRUtech [EPA Report Section 7.2]**

EPA did not identify any QA findings or concerns related to TRUtech.

**EPA QA Concerns Related to the Nevada Test Site (NTS) [EPA Report Section 7.3]****NTS Concern No. 1 [EPA Report Subsection 7.3.1]:**

*The EPA is concerned that dual storage was not completed for all records. In addition, records could be checked out from either of the dual storage areas with no assurance that both copies of a record would not be checked out at the same time.*

**CAO Response to NTS Concern No. 1:**

The concern was identified by CAO during the audit. NTS corrected the concern prior to completion of the audit. The CAO audit report (A-99-20) identifies the concern as being Corrected During the Audit (CDA). In addition, the CAO audit report provided a recommendation that NTS only allow QA records to be checked out from one storage location. CAO considers this item to be closed.

**ATTACHMENT I****NTS Concern No. 2 [EPA Report Subsection 7.3.2]:**

*The EPA inspection team is concerned that the records access list was not current and no letter of delegation was on file assigning the records coordinator responsibilities.*

**CAO Response to NTS Concern No. 2:**

This concern was identified by CAO during the audit. NTS corrected the concern prior to the completion of the audit. The CAO audit report (A-99-20) identifies the concern as being Corrected During the Audit (CDA). CAO considers this item to be closed.

**NTS Concern No. 3 [EPA Report Subsection 7.3.3]:**

*In reviewing training records, the EPA inspection team did not observe objective evidence that one of the supervisors had completed the required reading based on NTS procedure L-E10.329.LL.WC. Other instances were noted where evidence was not observed that employees had read applicable procedures. The EPA inspection team is concerned that if objective evidence is not documented or available, this would be a violation of CAO flow-down requirements and NQA-1 requirements.*

**CAO Response to NTS Concern No. 3:**

This concern was identified by CAO during the audit. CAO issued a Corrective Action Report (CAR 99-074) addressing the training issues. CAO will perform follow up verification activities to assure that the identified training issues have been corrected and that measures have been taken to prevent recurrence of the problem.

**NTS Concern No. 4 [EPA Report Subsection 7.3.4]:**

*Although NTS audits are scheduled annually, only one was performed during the past two years. Consequently, only one trend analysis was available for review. The EPA inspection team is concerned the Bechtel Nevada has not dedicated sufficient quality assurance staff to satisfy the completion of WIPP certification requirements.*

**CAO Response to NTS Concern No. 4:**

This concern was a nonconforming condition. NTS generated an internal nonconformance report (NCR) documenting that they had not reported the trend analysis nonconformance in a timely manner. CAO CAR 99-072 also identifies the NTS failure. CAO will perform follow up activities to assure trend analysis reporting is occurring as required.

**ATTACHMENT I****NTS Concern No. 5 [EPA Report Subsection 7.3.5]:**

*The NTS audit procedures do not require the lead auditor to sign the audit report, as required by Element 18, although the report reviewed was signed by the lead auditor. The EPA inspection team is concerned that this requirement should be addressed by an audit procedure.*

**CAO Response to NTS Concern No. 5:**

NTS does have a project-specific procedure that requires the lead auditor to sign the audit report. Procedure L-A20.027, Revision 0, (effective May 5, 1999), paragraph 4.2.3.1 states that, "The Lead Auditor shall prepare and sign an audit report." This procedure was in place at the time of the CAO audit. CAO considers this issue to be closed.

**EPA QA Finding and Concern Related to the Carlsbad Area Office (CAO) [EPA Report Section 7.4]****CAO Finding No. 1 [EPA Report Section 7.4.1]:**

*NQA-1, Element 1, Organization, states quality assurance personnel "shall have direct access to responsible management at a level where appropriate action can be effected. Such persons or organizations shall report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule consideration."*

*However, the CAO QAPP (Interim Change, dated November 15, 1996), Section 3.1.1, second paragraph, third sentence, states " Facilities may combine the positions of technical supervisor and QA [quality assurance] officer." Based on the very nature of his/her position a technical supervisor is not independent of cost and schedule considerations and, therefore, cannot fulfill a quality assurance function on activities for which he/she is responsible.*

**CAO Response to Finding No. 1:**

This issue has been previously addressed with EPA. The combining of the technical supervisor and QA review occur only at the data generation level. This review level (level I) is a quality *control* check to assure that the independent technical review has been completed and the documentation requirements have been met. A detailed independent quality *assurance* review occurs during the project level (level II) review. The project level review is performed by the Site Project Quality Assurance Officer (SPQAO). The SPQAO is sufficiently independent of cost and schedule considerations to perform the required quality assurance review functions.

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### CAO Concern No. 1 [EPA Report Subsection 7.4.2]

*MCS uses Lotus Notes® database to manage all quality assurance records, thus creating a paperless documentation system. Therefore, all original MCS quality assurance records, both lifetime and non-permanent, are in an electronic format. Procedure MCS-055, Revision E, Section 6.3.7.3 states, "Lifetime records...shall be converted into a text readable format..." The CAO QAPP, however, does not define the format requirements for text readable format as it applies to electronic quality assurance records.*

*The EPA inspection team is concerned that CAO should define the software and media format requirements for electronic quality assurance records to ensure consistency and, ultimately, accessibility to these records in the future. By the very nature of this concern, the inspection team believes that hardware requirements should also be established by the CAO QAPP to ensure that machines will be available to read electronic quality assurance records in the prescribed software format as well as media format (e.g., 3.5-inch diskette, CD-ROM, digital video disk, etc.). In lieu of prescribed formats for software and media, CAO should prescribe how electronic quality assurance records will be transitioned from one format to the next as information technology changes and advances in the present and the future.*

#### CAO Response to Concern No. 1:

CAO will provide additional guidance concerning electronic records management in a future revision to the CAO Quality Assurance Program Document (QAPD).

### **EPA Technical Findings Directed at Mobile Characterization Services (MCS), TRUtech, and the Nevada Test Site (NTS) [EPA Report Section 2 (Technical), Subsection 9.1]**

#### **Technical Finding 9.1.1**

*No replicate drum counts had been performed by the TRUtech gamma spectroscopy system. Gamma spectroscopy is an integral part of the overall assay system, and replicate drums should be run for all components of the assay system.*

#### **CAO Response to Technical Finding 9.1.1**

CAO issued CAR 98-050 to identify this concern. To date the CAR is still open. TRUtech's assay systems have not yet been approved by CAO. CAO will verify compliance of the assay systems prior to approval of TRUtech.

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### Technical Finding 9.1.2

*The TRUtech systems did not report  $^{234}\text{U}$  unless the  $^{234}\text{U}$  was present in very high quantities. TRUtech determined that the sensitivity of their assay program to  $^{234}\text{U}$  was 3 orders of magnitude less than the sensitivity to  $^{239}\text{Pu}$ , and recommended that a more sensitive detection method for  $^{234}\text{U}$  be employed for waste streams where  $^{234}\text{U}$  was expected. The poor sensitivity to  $^{234}\text{U}$  in effect means that  $^{234}\text{U}$  is not being quantified as required.*

### CAO Response to Technical Finding 9.1.2

CAO issued CAR 99-078 to document this concern. To date, the CAR is still open. TRUtech's assay systems have not yet been approved by CAO. CAO will verify compliance of the assay systems prior to approval of TRUtech.

### Technical Finding 9.1.3

*The reported uncertainties for TRUtech are excessively high for drums with low  $^{239}\text{Pu}$  fissile gram equivalents in the 1 gram range, and the cause of these excessively high uncertainties is not understood by TRUtech. The cause of the high uncertainties must be understood, and TRUtech must demonstrate that no systemic problem exists with the methods for calculating uncertainty before the total measurement uncertainties for the TRUtech system can be accepted.*

### CAO Response to Technical Finding 9.1.3

CAO issued CAR 98-050 to identify this concern. To date, the CAR is still open. TRUtech's assay systems have not yet been approved by CAO. CAO will verify compliance of the assay systems prior to approval of TRUtech.

### Technical Finding 9.1.4

*The TRUtech job responsibilities document, M50851, does not describe the technical reviewer position. The technical reviewer position was described in the APNEA Operations Plan, M50723, but this description had not yet been carried through to the position description document.*

### CAO Response to Technical Finding 9.1.4

The TRUtech "Job Responsibilities and Training Requirements" document M50851, is a guidance document. Documents M50851 and M50723 were not within the scope of CAO Audit A-99-19. TRUtech procedure TT-QP-018, titled: "Data Generation Level Data Reviews, Validation, Verification, and Reporting" describes the governing requirements for all independent technical reviewers. CAO considers this issue to be closed.

**ATTACHMENT I****Technical Finding 9.1.5**

EPA did not require a response to this finding.

**Technical Finding 9.1.6**

*Bechtel-Nevada's procedure "TRU Waste Examination, Segregating, and Repacking," L-E10.312.WWC. Rev. 3, 05/17/99, does not require the VE expert to assess the accuracy of the TRUCON code, matrix parameter category, and/or IDC obtained through RTR. The QAPP requires that VE is used to verify at a minimum both matrix parameter categories and matrix parameter weights (Rev. 1C, 11/15/96, Section 5, p. 18/27, and Section 10, p. 6/11). Section 4.3.4.6 of Bechtel-Nevada's VE Procedure ("TRU Waste Examination, Segregation, and Repacking," L-E10.312.WWC. Rev. 4, May 17, 1999) requires the WEF Supervisor to review the vendor's RTR and submitted data report prior to the performance of VE to confirm radiography.*

**CAO Response to Technical Finding 9.1.6**

At the time of the audit, the Waste Examination Facility (WEF) was in a stop work mode. Verification of the implementation of procedure L-E10.312.WWC could not be performed. CAO issued an Observation addressing this concern. NTS has not been approved by CAO. Compliance to the requirements of the procedure will be verified prior to approval.

**Technical Finding 9.1.7**

*Site personnel did not produce documentation that the site had correctly calculated the miscertification rate on an annual basis. The QAPP, Rev 1C, 11/15/96, p. 18/27, requires that the miscertification rate be determined each year. Section 4.5.1.3 of "Data Management for TRU Waste Characterization," L-E10.325.WWC, Revision 0, P.7) requires the site to determine the miscertification rate on an annual basis.*

**CAO Response to Technical Finding 9.1.7**

The miscertification rate is required to be calculated on an annual basis. At the time of the audit, NTS had not yet been in WIPP operation for a year. An Observation was documented in audit report A-99-01 to identify this concern. CAO will verify that the miscertification rate has been properly calculated prior to approval of the site.

**Technical Finding 9.1.8**

*The results of comparisons of RTR and VE had not been provided by BN NTS to either MCS or TRUtech. The QAPP, Rev. 1C, 11/15/96, Section 10, p. 6/11, requires the results of visual examination to be transmitted to the radiography facility.*

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### CAO Response to Technical Finding 9.1.8

CAO issued CAR 99-076 to address this concern. To date, this CAR is still open. NTS has not yet been approved by CAO. Corrective actions will be verified prior to CAO approval.

### Technical Finding 9.1.9

*TRUtech records images on an optical disk; no audio is recorded. Section 10 of the QAPP, p. 1/11, states that an audio/videotape of the radiography examination must be obtained for 100 percent of the retrievably stored waste container. Page 2/11 states that audio/videotaping is a required component of the radiography system.*

### CAO Response to Technical Finding 9.1.9

CAO issued CARs 99-070 and 99-077 to document this concern. To date, these CARs are still open. TRUtech and NTS have not yet been approved by CAO. The corrective actions for this concern will be verified prior to approval of NTS and TRUtech.

### Technical Finding 9.1.10

*When the MCS RTR operator comes across a container that the operator is unable to see through, the data form is marked as "passing" and annotated in the comment field to state that the operator was unable to see through the container. Although this is permissible for sludge drums, drums containing debris must be tagged, an NCR written, and the container opened for visual examination. Section 9 of MCS's "Radiography Inspection Operating Procedure," Rev. D, p 15/37, states, "Whenever the RTR operator identifies a drum in the S5000 waste matrix parameter category that cannot be penetrated by the RTR method because of the presence of lead shielding, a waste NCR is completed in accordance with MCS-053, Non-Conformance Reporting, Tracking, and Closure."*

### CAO Response to Technical Finding 9.1.10

MCS's radiography inspection operating procedure requires the generation of an NCR "whenever the RTR operator identifies a drum...that cannot be penetrated by the RTR method because of the presence of lead shielding." When MCS first encountered unusual opaque areas that did not appear to be lead shielding, Bechtel Nevada (NTS) was immediately notified. These drums were opened at the Waste Examination Facility and visually examined. The opaque areas were clearly related to the presence of inorganic absorption materials (i.e., vermiculite). Documented examinations of approximately 200 such drums demonstrated that the RTR operators could distinguish between these inorganic materials and lead shielding, therefore NTS directed that annotation of the data form was sufficient and that NCRs need not be generated for drums with opaque areas that are attributed to inorganic absorption materials. CAO concurs with this practice and, therefore, considers this finding to be closed.

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### Technical Finding 9.1.11

*NTS was not authorized by CAO to use the production version of the WWIS. WIPP data base operators have not maintained all of the fields contained in the test version of WWIS. Actual data submitted by NTS are rejected because analytical methods for which the site is approved are not contained in the reference tables in the WWIS test version. When the site attempts to submit data on a container that was characterized using one of these analytical methods, the data are rejected by WIPP because the site is not certified for certain methods.*

### CAO Response to Technical Finding 9.1.11

NTS has performed only a demonstration of the WWIS. The site has not yet been approved by CAO. CAO will perform verification activities to assure that NTS can utilize the WWIS before the site is approved.

### EPA Technical Concerns Related to Mobile Characterization Services (MCS), TRUtech, and the Nevada Test Site (NTS)

EPA did not require responses to technical Concerns 9.2.2, 9.2.4, and 9.2.5.

### Technical Concern 9.2.1

*Surveillance audits conducted by BN NTS identified a serious potential for miscertification of containers by TRUtech (Report #: BN-TRU-S99-03, 6/2/99). However, BN NTS' surveillance audit of TRUtech's nondestructive examination were conducted by reviewing videotapes for 100% of the TRUtech drums. These videotapes are of extremely poor quality and there is no audio portion. TRUtech records images on optical disks; BN NTS does not have an optical disk player to review the primary recording.*

### CAO Response to Technical Concern 9.2.1

CAO issued CARs 99-070, 99-072 and 99-077 to document this concern. To date, these CARs are still open. Corrective actions for this concern will be verified prior to approval of NTS.

### Technical Concern 9.2.3

*Although the MCS RTR operator is tested on a quarterly basis, the contents of the test drum are never changed, thereby limiting the usefulness of the test as a measure of the operator's performance.*

**ATTACHMENT I****CAO Response to Technical Concern 9.2.3**

There are no requirements that test drums include provision for changing the contents. However, this concern is a valid recommendation. In the future, CAO will monitor the process and make the necessary recommendations, if warranted.

**Technical Concern 9.2.6**

*The operator scans a complete batch of drums (i. e., 20 drums) and completes the data forms for the drums when convenient. The data forms should be completed and validated within 28 days. Drum NT98-0188 was initially examined on 8/27/98, the operator on 11/24/98 signed the data form, and an entry was corrected on 12/02/98.*

**CAO Response to Technical Concern 9.2.6**

CAO identified this issue in CAR 99-076. To date, the CAR is still open. Corrective actions related to this issue will be verified prior to CAO approval.

**Technical Concern 9.2.7**

*Neither MCS nor TRUtech RTR operators have received feedback from the visual examination of their drums. Section 10 of the QAPP, p. 6/11, stipulates that the results of the VE must be transmitted to the radiography facility.*

**CAO Response to Technical Concern 9.2.7**

CAO issued CAR 99-076 to address this concern. To date, this CAR is still open. NTS has not yet been approved by CAO. Corrective actions will be verified prior to CAO approval.