

Allen, Pam, NMENV



From: Maestas, Ricardo, NMENV
Sent: Friday, February 03, 2012 10:53 AM
To: Allen, Pam, NMENV
Subject: FW: analysis of the proposed ORNL audit
Attachments: ORNLAuditAnalysisRevision4.doc



Email and attachment in the WIPP file

From: Kliphuis, Trais, NMENV
Sent: Tuesday, January 24, 2012 8:18 AM
To: Maestas, Ricardo, NMENV; Hall, Timothy, NMENV; Holmes, Steve, NMENV
Cc: Kieling, John, NMENV
Subject: FW: analysis of the proposed ORNL audit

From: Conniewalk@aol.com [<mailto:Conniewalk@aol.com>]
Sent: Monday, [REDACTED]
To: Kliphuis, Trais, NMENV
Cc: rwood@trininc.com; Conniewalk@aol.com
Subject: analysis of the proposed ORNL audit

FOR INTERNAL USE AND REVIEW ONLY

Hello Trais

Attached please find our draft review and analysis of the ORNL recertification audit. The intent of the draft deliverable is to provide background information about the audit program and evaluation and analysis of the ORNL proposed audit in light of the permit requirements and previous audit performance elements. It includes five review items; you're probably already very familiar with the permit's audit requirements and the audit process (Items 2 and 3), so Items 1, 4, 5, and 6 contain the review elements you might be most interested in. Please note that while the deliverable offers suggestions, it is not our intent to state policy as that is outside of our review scope.

Trinity's QA audit team reviewed this deliverable and noted that compliance audits require on-site observation of activities and interview of onsite personnel. A "desk top" review (which includes review activities performed away from the generator site) is used by QA programs to perform program audits, verifying that the plans and procedures contain all the upper level requirements. The permit makes mention of QA programs and QA auditors are present during audit activities, so NMED may wish to further investigate this QA link with respect to performance of compliance audits away from the generator site (QA was not directly addressed in the attached review). Further, our reviewer noted that since a new audit must be performed prior to re-initiation of waste ship, it was unclear whether this audit was necessary unless aspects of the characterization program were to continue (i.e. AK). The reviewer suggested that performance of a full compliance audit is required once characterization is resumed to ensure that a complete compliance audit is performed and to ensure no questions are raised about the applicability of the "desk top" review.

I will be available via email and my cell (303 946 3840) tomorrow morning, and I will be at the office during the afternoon (303 526 0954). Please feel free to call with any questions.

thanks

Connie Walker

Trinity Engineering Corporation



DRAFT REVIEW OF ORNL RECERTIFICATION AUDIT TECHNICAL AND REGULATORY ANALYSIS

The CBFO recently notified NMED that the ORNL recertification audit, slated to take place in February, 2012, will not be conducted at ORNL because waste characterization activities at the site have been suspended as of July, 2011. Instead, the audit will be performed in Carlsbad with an audit later at ORNL to evaluate “waste characterization activities” when said activities resume. Trinity Engineering Associates was asked to review this letter with respect to the audit program and technical/regulatory acceptability of the approach which appears to separate the audit into some components here-to-for performed exclusively at the generator site.

The purpose of this review is to evaluate the technical and/or regulatory acceptability of the proposed ORNL audit approach. As per Trinity’s contract, policy determinations are not offered. We note that NMED personnel indicate that the Permittees intend to submit a permit modification request consolidating all audits into a single audit (or group of audits) to be held at the WIPP site only, with no generator site audits to be performed. Based on the current permit language and without additional information pertaining to the proposed modification, this appears to be a significant change from the existing audit approach implemented by CBFO and as presented in the permit. While not directly supporting the presumed PMR, the ORNL audit “separation” and performance of portions of the audit at WIPP instead of at the generator site advocates the shift of at least some audit activities away from the generator site, which appears to be a component of the presumed forthcoming modification request.

The Permit uses DOE when establishing who is responsible for the audit program. Typically, NMED refers to the Permittees with respect to permit activities, so the two designations refer to the same entity.

1. Genesis of the Permit Audit Program

The WIPP Permittees must comply with RCRA waste characterization requirements including those presented in 40 CFR Part 264.13 (c), that requires facilities accepting offsite waste to specify, in its waste analysis plan “the procedures which will be used to inspect and, if necessary, analyze each movement of hazardous waste received at the facility to ensure that it matches the identity of the waste designated on the accompanying manifest or shipping paper”. A typical RCRA WAP includes procedures used to identify and collect a “representative sample” of the waste for this purpose. EPA guidance (1994) was examined by NMED as part of the WIPP permitting process, and this document states “Waste analysis involves identifying or verifying the chemical and physical characteristics of a waste by performing a detailed chemical and physical analysis of a representative sample of the waste or, in certain cases, by applying acceptable knowledge of the waste”. Guidance also states that the treatment, storage or disposal facility (i.e. WIPP) must “conduct proper waste analysis... to ensure that your waste is managed properly.... Therefore, to ensure compliance with RCRA you should conduct a full-scale, or under certain circumstances an abbreviated-scale, sampling, and laboratory testing program for all wastes prior to managing the wastes.” Full-scale analysis refers to implementation of a

comprehensive analytical suite, while “fingerprint analysis” utilizes a more abbreviated analytical suite to identify select or representative constituents. Fingerprint analysis is used to verify that the waste matches the expected hazardous waste. Note that RCRA allows characterization by acceptable knowledge, but the burden is on the TSD to ensure that the characterization information provided by the generator is accurate.

The Permittees did not propose any on-site fingerprinting or other analysis to verify the characterization performed at the generator site because the Permittees committed to a “stay clean” approach for the WIPP (i.e. no analysis onsite) and because of ALARA considerations/concerns associated with sampling and analyzing mixed waste. Instead, the Permittees indicated that a series of waste characterization activities would be performed at their generator sites that the Permittees would regularly audit to ensure that the WAP characterization requirements were met. This approach was included (with modifications) in the original WIPP permit as an acceptable alternative to fingerprint analyses. As such, the WIPP does not operate under a “typical” WAP wherein waste analysis is performed at the disposal facility (full or fingerprint analysis); instead, the permit WAP applies to characterization requirements implemented at the generator sites, with the Permittees ensuring that these requirements are followed by performing at-generator audits.

In summary, the audit process replaced the “fingerprint” analysis typically performed at RCRA TSD facilities. Instead, the Permittees verify compliance with the WAP via generator site audit, rather than perform at-WIPP characterization of waste shipments to substantiate characterization information provided by the generators.

2. Permit Audit Requirements

The requirement to audit is presented in Part 2 of the Permit, and audit requirements are described in Permit Attachments including Attachments C, C4 and C6. The permit requires that DOE conduct an initial audit of each site prior to certifying the site for shipment of waste to WIPP. The audits are performed to ensure that the operators of each generator/storage site and DOE approved laboratory that plan to transport transuranic (TRU) mixed waste to the WIPP facility conduct sampling and analysis of wastes in accordance with the current WAP. Audits are performed at least annually after the initial audit, and NMED may observe these audits to verify that the Permittees have implemented the current WAP and that generator/storage sites have implemented a QA program for the characterization of waste and meet applicable WAP requirements. The permit is silent regarding suspension or termination of characterization activities at a site, save for reporting/recordkeeping requirements for records associated with waste characterization. Note that Attachment C6 specifies audits must be performed “at” a waste characterization site.

Audit requirements are detailed in Permit Part 2, and Attachments C, C4 and C6. Key elements of each are summarized below.

- Part 2: Section 2.3.2: 2.3.2. Audit and Surveillance Program. This Section of the permit says the Permittees will not disposal of waste at WIPP from a generators/storage site until the site and/or laboratory has been successfully audited

(and as required by 20.4.1.500 NMAC incorporating 40 CFR §264.13). NMED may observe these audits, and will be provided the final audit report as specified in Attachment C6. The NMED Secretary shall approve DOE's final audit report by written notification to DOE that the applicable characterization requirements of the WAP at a generator/storage site and or DOE approved laboratory have been implemented. Elements that must be audited as specified in Section Part 2 Section 2.3.1 include sampling and analysis activities, i.e. applicable method requirements, quality control, equipment testing, inspection, maintenance, and equipment calibration and frequency standards for the procedures specified in Permit Attachment C1 (Waste Characterization Sampling Methods). Statistical methods presented in Attachment C2 must be examined for compliance as well as QAOs and data validation techniques described in Attachment C3 and AK requirements presented in Attachment C4. Development of a QAPjP (Attachment C5) and the WDS are also audited.

- Attachment C, Section C-5a (3), Audit and Surveillance Program. The attachment states that “an important part of the Permittees’ verification process is the Audit and Surveillance Program”, the focus of which is compliance with the WAP and Permit. This audit program addresses all AK implementation and waste sampling and analysis activities, from waste stream classification assignment through waste container certification, and ensures compliance with SOPs and the WAP. Attachment C states that audits ensure waste containers and their associated documentation are adequately tracked throughout the waste handling process. Operator qualifications are verified and implementation of QA/QC procedures is surveyed. A final report that includes generator/storage site or DOE approved laboratory audit results and applicable WAP-related corrective action report (CAR) resolution is provided to NMED for approval, and is kept in the WIPP facility operating record until closure of the WIPP facility. Attachment C reiterates that an initial audit will be performed at each generator/storage site performing waste characterization activities prior to the formal acceptance of the waste stream profile form and will be performed at least annually thereafter. The audits let NMED verify, through audit observation, that the Permittees have implemented the WAP and the generator/storage sites have implemented a QA program for the characterization of waste and meet applicable WAP requirements.
- Attachment C4, Section C4-3g, Audits of Acceptable Knowledge. Attachment C4 specifies the audit process with respect to AK, but the description also applies to the audit process as a whole. Attachment C4 specifies that DOE conduct an initial audit of each site prior to certifying the site for shipment of TRU mixed waste to the WIPP facility. This initial audit establishes an approved baseline that is reassessed annually DOE. These audits verify compliance with the requirements specified in the WAP (Permit Attachment C), including compliance with AK requirements specified in Attachment C4 : “The audits will be used to verify compliance with the compilation, application, and interpretation requirements of acceptable knowledge information specified in this Permit at all sites, and to evaluate the completeness and defensibility of site specific acceptable knowledge documentation related to hazardous waste

characterization.” This means that an AK audit must be site specific and conducted “at all sites”. Attachment C4 describes the AK audit process including use of checklists, items to be examined, qualifications of the audit team members, and the requirement to audit “at least one waste stream from the Summary Category Group(s) (SCGs) being audited, and will audit acceptable knowledge traceability for at least one container from the audited Summary Category Group(s).” General audit processes, meetings, closeout, and report requirements are also addressed

- Attachment C, Section C6-1- C6-4, Introduction- Audit Conduct. The Waste Isolation Pilot Plant (WIPP) Audit and Surveillance Program shall ensure that: 1) the operators of each generator/storage site (site) and U.S. Department of Energy (DOE) approved laboratory that plan to transport transuranic (TRU) mixed waste to the WIPP facility conduct sampling and analysis of wastes in accordance with the current WIPP Waste Analysis Plan (WAP) (Permit Attachment C), and 2) the information supplied by each site to satisfy the waste screening and acceptability requirements of Section C-4 of the WAP is being managed properly. DOE conducts these audits and surveillances at each site and DOE approved laboratory performing these activities in accordance with a standard operating procedure (SOP). Attachment C6 presents the audit process (see Item 3).

3. General Overview of Audit Process

The audit process is described in permit attachment C6. The general process described in this section is typically followed, and permit compliance is documented via completion of the C6 checklist for each technical element. Permit Attachment C6 presents the audit process and is summarized as follows:

1. The purpose of the audit program is to ensure that the operators of each generator/storage site and DOE labs conduct sampling and analysis in accordance with the WAP, and to ensure that “screening and acceptability” requirements of Permit Attachment C-4 (AK) are met.
2. The permit states that the DOE will conduct these audits and surveillance at each site and approved laboratory.

Note: DOE typically performs the AK portion of recertification audits at the CBFO office in Carlsbad, New Mexico, which is clearly not at the “generator storage site”. NMED representatives questioned whether this action violated the Permit and we believe this issue was discussed with the Permittees when the process was initiated. However, the Permittees pointed out that the AK element doesn’t require on-site testing (e.g. sampling and analysis) and the approach was not expressly prohibited by the permit. NMED did not require the Permittees to cease this approach in the interest of cost effectiveness and because, in the case of CCP: 1) all individuals associated with AK data and the AK process are available at the AK audit, and 2) the process does not involve interviews with site personnel or use of measurement equipment on-site. However, since Attachment C6 requires audits and surveillance at the generator/storage and labs to evaluate these

activities performed at these sites (e.g. sampling and analysis), then these elements of the characterization program must take place at the generator sites to be in full compliance with the permit.

3. Auditors use checklists, and the checklists for each site and DOE approved laboratory include, at a minimum, the appropriate checklists found in Tables C6-1 through C6-6 for the summary category groups undergoing audit.
4. The “DOE manager who oversees the audit program” ensures that audits are scheduled; this person designates the lead auditor and appoints auditors, ensures their training is up to date, reviews final audit reports, tracks deficiencies identified during the audit, and ensures that appropriate documents are in the operating record.
5. The lead auditor assigned by the DOE manager concurs with assigned auditors and technical specialists, develops the audit plan, coordinates preparation of completed C6 checklists, assigns audit areas to technical and QA specialists, “runs” or leads the audit at the site or DOE approved laboratory, records maintenance and transfer of records to the DOE manager.
6. Auditors and technical specialists are required to:
 - be appropriately trained,
 - prepare C6 checklists,
 - review AK documentation packages/test report data/ other data verification activities,
 - obtain “objective evidence” by means of observation, document reviews and conducting interviews of operators, analysts and technicians and others,
 - conduct inspection tours of waste generating stations, sampling areas and equipment, analytical laboratories, calibration facilities, and document control/record facilities,
 - complete the C6 checklist,
 - identify deficiencies and transmit those deficiencies to the audit team leader, and
 - prepare portions of the final audit report as requested by the ATL.
7. Audits will be conducted at least annually for each site involved in the waste characterization program. Both announced and unannounced audits will address results of previous audits, changes in programs/operations, new programs/operations, changes to key personnel.
8. Annual certification audits address contact-handled (**CH**) and remote-handled (**RH**) waste characterization activities if the site has approval or is seeking approval for such wastes. At a minimum, the audit evaluates acceptable knowledge documentation for CH and RH waste separately by Summary Category Group, as applicable. NOTE: The permit requires the Permittee audits to approve sites by SCG - that is, each new SCG a site characterizes must be approved through audit. Also, the permit requires that audits address both RH and CH SCGs. The Permittees originally assumed that audit of a CH

SCG also applied to the same SCG for RH waste, but RH and CH waste are not addressed separately at each audit.

9. Audits are performed as follows:

- Entrance meeting is conducted
- Audit performance by technical areas using approved audit checklists (C6)
- Daily caucuses to go over issues identified
- Final close-out (exit) meeting to transmit issues identified by the auditors to the generator sites.
- The audit report is prepared, approved, and issued to the site or DOE approved laboratory within 30 days of the completion of the audit by DOE. NMED receives a copy of the audit report upon issuance for information purposes, and a formal final audit report is provided to NMED for review and approval that includes WAP-related CAR resolution results and other information.
- The audited site or DOE approved laboratory responds to any deficiencies and observations within 30 days after receipt of any CARs and indicate the corrective action taken or to be taken. If the corrective action has not been completed, the response must indicate the expected date the action will be completed. CARs applicable to WAP requirements are resolved prior to waste shipment.
- Subsequent audits or specific verifications, announced or unannounced, determine whether the corrective action has been satisfactorily implemented.

NMED representatives have also observed the following with respect to audit performance:

- CTAC provides both a technical and QA auditor for each functional area. For example, Dick Blauvelt addresses technical elements of AK, and any number of other auditors (e.g. Prissy Martinez) may address the QA aspects of AK.
- AK audits are addressed by “going through” the AK Summary and all related characterization documents required by CCP-TP-005, as well as other permit requirements pertaining to statistical selection of samples and programmatic requirements (i.e. WSPF generation). This includes interviews of those assembling and interpreting the AK data, as well as the SPM.
- RTR, VE, and HSG audits begin by interviewing the on-site characterization team and observing characterization activities that are ongoing, including HSG sampling, container RTR, etc. Note that this does NOT occur universally at each audit—if equipment is “down”, the auditor can’t observe the characterization process in action. In this instance, the auditors may examine tapes or other information in lieu of evaluating the operating equipment, but individuals (i.e. on-site operators) are available to answer questions.
- AK audits include assembly of all objective evidence necessary to demonstrate compliance with the C6 checklist; the checklist is also reviewed, item by item, to ensure that each requirements has been addressed

4. Overview of Proposed ORNL Approach

NMED received notification of the ORNL recertification audit on January 18, 2012. The notification states that the audit, to be performed on February 21-23, will “evaluate the adequacy, implementation and effectiveness of the ORNL/CCP technical and QA activities performed for characterization and certification of CH (S4000 and S5000) and RH (S5000) waste”, but will specifically deal only with waste activities performed from the date of the previous audit A-11-08 through the end of July, 2011. CBFO states that ORNL/CCP has not characterized any waste after July, 2011 and “no TRU waste characterization activities will be performed or evaluated at the ONRL during the audit” because CCP operations at ORNL have been “discontinued” (i.e. not terminated, but suspended). “When ORNL/CCP field activities resume at ONRL, an audit will be performed to evaluate waste characterization activities before ORNL/CCP is authorized to certify containers using data generated after July 2011”. This is interpreted to mean that the audit is being performed in February, 2012 to meet the annual audit requirement in the permit, but this audit will be incomplete because it cannot address on-site waste characterization activities. Full “recertification” would occur when on-site waste characterization activities resume. The scope of this later on-site audit is not specified in the letter.

5. Evaluation of the ONRL Audit Approach

The DOE notification letter clearly indicates that on-site characterization activities must be audited to comply with the permit. The Permittees also propose to audit “what they can” on the annual deadline, and the letter implies that this does not constitute a “full” audit, which would be accomplished when on-site activities are examined. The following questions are offered, with associated evaluations.

1. What is the scope of the recertification? Verification and AK activities only? Will those activities, as approved, continue even though on-site characterization is suspended?

>This question should be answered by the Permittees to understand what they intend to continue doing while the on-site systems are on suspension and identify exactly what will be addressed during the February recertification audit.

2. Does CBFO propose to perform a full “certification” audit once the characterization systems are up and running, or will the on-site audit address only those aspects that need to be performed on-site (i.e. characterization system operation, all on-site interviews, etc)?

>If only sampling and analysis methods are reviewed, then it is possible there would be two separate annual audit dates for the different components audited. This would complicate the audit process in terms of annual recertification dates. If, however, the Permittees would perform a full-scale audit at the generator site, then the annual audit clock would “start” with this audit.

3. Is the approach allowed by the current permit language? Note that the permit is silent with respect to “suspension” of activities or “partial” recertification, but is very clear that sampling and analysis (and related activities) must be performed AT the generator site.

>The permit requires annual audits, presumably of active sites with ongoing characterization activities. If ORNL intends to continue AK data assembly, verification of containers sampled and analyzed prior to July 2011, etc., then it appears necessary that these activities move forward under an approved and audited program. However, if ORNL intends to suspend ALL activities, then it would make more sense to forgo this audit and “restart” the process with a full audit when the generator site begins characterization again. Note that a full audit at the time of restart makes sense because it brings all activities in sync under a single annual recertification date. Again, the permit is silent with regard to this situation.

The permit is silent with respect to temporary suspension of waste shipments but clearly specifies the frequency and scope of typical audits and the requirement to audit at generator sites. Therefore, it appears to be NMED’s prerogative as to how to interpret this activity and to set precedence with regard to what is acceptable under the current permit language. For example, the permit requirement to audit “at least annually”, could clearly not be accomplishable if a portion of the system is shut down. NMED may then choose to interpret the permit “annual” requirement to terminate when a program was completely shut down, and an “initial audit” would then be required when it started up again. Similarly, NMED may allow continuance of a portion of a program (that has been appropriately audited) while another portion is under suspension, and NMED could determine the “scope” of the restart audit if an existing portion of the program (i.e. AK) has continued while on-site characterization was suspended. In short, this situation may be an opportunity to clarify NMED’s position as to auditing requirements when site characterization activities start and stop.

Does this open the door for audit performance at WIPP only, with no performance of audits at the generator site? If the ORNL notification letter language means that an on-site (at ORNL) audit is required to audit the site sampling/analysis and other on-site activities, then the letter acknowledges the requirement to audit measurement activities “on site” and proposed approach does not open the door for full and “at WIPP only” audits. It does, however, support the notion that those activities which do not require the input of site personnel or review of at-site equipment can be held separately, so long as all individuals, documents, and other requirements are fully available to the auditor. Note that the AK portion of recertification audits is already being performed at the WIPP site, separate from the generator site audit. The reason for this separation of the AK portion of the audit was primarily cost based, the argument being that the files necessary to conduct the audit are in Carlsbad, CCP personnel are in Carlsbad, and there is no need to interact with site personnel because the characterization entity, CCP, obtains all information from the site for their CCP program. It is true that most if not all AK files can be made available to the AK Auditor at the Carlsbad office through electronic file transmission (but this could occur anywhere). CCP personnel are located throughout the country, and AK personnel, including the CTAC AK auditor, are typically flown to Carlsbad (so cost savings in that regard are for only those individuals stationed in Carlsbad). The need for AK auditors to interact with site personnel is case by case: NMED has felt that LANL personnel offer insight to waste characterized by CCP and this interaction is important, but other sites (like NTS) have limited AK data and no longer have individuals available to interview, so the CCP files are “all

that there are”. In short, precedence has already been set for the separation of at least some portions of audits to locations other than the generator site because the AK portion of recertification audits is currently performed in Carlsbad.

Does this audit support a single at-WIPP audit approach? While the approach opens the door for the performance of more audit activities away from the generator site, it does not directly support the contention that one audit can address all generator sites with no generator site audit activities. However, the approach does press toward a gradual shift of activities away from generator sites, which is a component of the single at-WIPP audit approach.

6. Suggestions/conclusions:

1. NMED could contact the Permittees to clarify the following:
 - Intent and scope of the recertification audit. Identify the portions of a “typical” audit that will be covered under the RTR, VE, HSG, and WDS elements shown in the audit notification letter. Is the audit intended to allow certain aspects of the program (i.e. AK) to continue even though generator site characterization has been suspended? Or will all activities cease and restart later when generator site activities resume?
 - What areas and activities will be addressed in the later audit to be performed when field activities resume? Will it be a partial or full-scale audit?
 - If the second audit is a partial audit, how does CBFO intend to get the two “parts” of the audit in sync with respect to meeting the annual recertification requirement?
2. Discuss the permit requirement that audits be performed at the generator site (C6 requirement), and how they interpret this requirement with respect to those elements that aren’t being held at the generator site.
3. Once the intent of the audit is understood, NMED should determine whether this approach is appropriate from a “what makes sense” perspective, keeping in mind the Permit requirement to audit at generator sites, but also mindful of the precedence set with AK wherein this portion of the audit is held separate from the site.
4. NMED could choose to present their determination in some sort of written correspondence if management wants to take this approach—this will document the approach and will therefore be available to the public through a freedom of information act request. However, the “way” the determination is documented or agreed upon is a policy determination that should be made by NMED. It is also possible that both parties might agree that a PMR is in order to clearly present the approach; particularly if a “stop – start” approach to waste characterization is project to occur continually given the current economy.