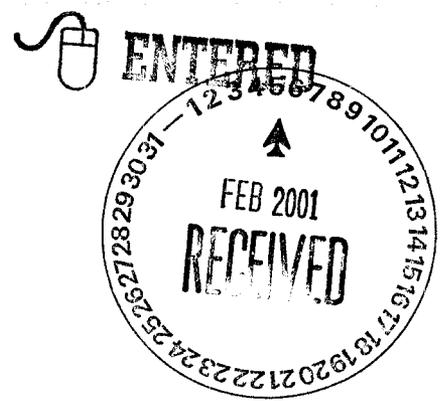




Department of Energy

Carlsbad Area Office
P. O. Box 3090
Carlsbad, New Mexico 88221
February 1, 2001



Steve Zappe, Project Leader
Hazardous & Radioactive Materials Bureau
New Mexico Environment Department
2044 – A Galisteo
Santa Fe, New Mexico 87502-6110

RE: Transmittal of the Revised Final Audit Report for the Las Alamos National Laboratory (A-00-16)

Dear Mr. Zappe:

This letter transmits the Revised Final Audit Report for the Los Alamos National Laboratory including the CBFO responses to the comments on the previous submittal and the associated objective evidence as required by Section II.C.2.c of the WIPP Hazardous Waste Facility Permit. Also included is a redline/strikeout copy of the revised report and B6 checklist to assist you in your review. The initial audit was conducted on September 25-28, 2000 with the Final Audit Report revised on February 1, 2001 to address NMEDs comments of January 8, 2001.

I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment for knowing violations.

If you have any question concerning this audit report, please contact Sam Vega at (505) 234-7423.

Sincerely,

Dr. Inés R. Triay
Manager

Enclosure

CBFO:QA:MLC:VW:01-0628:UFC:2300

*Revised report in box
in WIPP Library*



Printed on recycled paper

010204



Steve Zappe

-2-

cc: w/o enclosure
T. Harms, DOE-HQ
K. Watson, CBFO
S. Vega, CBFO
L. Chism, CBFO
H. Johnson, CBFO
J. Plum, CBFO
J. Kieling, NMED
J. Bearzi, NMED
R. Dinwiddie, NMED
H. Herrera, WTS
L. Steven, WTS
M. Gavett, LANL
P. Rodgers, LANL

cc: w/enclosure
M. Gerle, WTS (Operating Record)
C. Walker, Techlaw

Department of Energy Carlsbad Field Office
Response To
“NMED Comments On The Final Audit Report
Of The Los Alamos National Laboratory (LANL)”

NMED Item 1

“The B6 Checklist (Tables B6-1, B6-3, B6-4, B6-5 and B6-6) contains numerous references to specific information provided as Tabs in the report. However, some of the information apparently referenced is not included. Further, the referenced, and in some cases included, information is sometimes not that which was reviewed during the audit.”

Checklists B6-1 through B6-6 were reviewed for missing information as well as adequate reference to the corresponding objective evidence with the following results.

- *The objective evidence referenced in the B6 checklists were filed in their corresponding tab numbers under the reviewed section. In addition, referenced objective evidence was filed within the specific folders that pertained to the area in which the objective evidence was reviewed. Tabs have been added in the B6 checklists and the applicable objective evidence copied and inserted within the new tabbed locations. For example, added Data Report LA00-HGAS-016, and Tabbed as Tab GEN 21.*
- *All objective evidence referenced within the B6 checklists was reviewed and evaluated during the audit by various team members. Audit sub-teams review objective evidence within the specific area assigned and through discussions may utilize and or reference information from other sub-teams as long as the other sub-team verified that the objective evidence complied with the specific checklist attribute. In the future each sub-team will be instructed that only objective evidence reviewed by that sub-team or verified as pertaining to the specific attribute within the checklist will be listed in the B6 checklist.*

“The checklist indicates that Tab GEN 4 contains data packages LA00-HGAS-015 and LA00-HGAS-016. However, only LA00-HGAS-015 is included. In addition, based on information available to the NMED observer, LA00-HGAS-016 was not reviewed during the actual audit.”

The audit sub-team did review both of these data packages. The Headspace Gas sub-team reviewed LA00-HGAS-016 and therefore it was referenced on the B6 checklist as TAB GEN 4 after discussions between the two sub-teams. To provide clarity, Data Report LA00-HGAS-016 was also added as Tab GEN21 and B6-1 was revised to reflect this change.

“The checklist indicates that Tab GEN 5 contains RTR data packages LA00-RTR-006 and LA00-RTR-008. However, only LA00-RTR-006 is included and neither of the cited packages was reviewed during the audit. The RTR package reviewed during the audit, as made available to the NMED observer, was actually LA00-RTR-009.”

LA00-RTR-006 and LA00-RTR-008 were reviewed by the sub-team assigned to RTR and included in the RTR section as a reference based upon discussions between the two sub-teams. Batch data report LA00-RTR-009 was reviewed by the sub-team assigned to this specific area

and therefore has been included in Tab GEN 33 and listed in checklist B6-1. To provide clarity, Batch Data Report LA00-RTR-008 found under Tab RTR12 was copied and inserted into the General Information Section under GEN Tab 23.

“The checklist indicates that Tab GEN 6 contains VE data packages LA00-VE-004 and LA00-VE-005. Again, only LA00-VE-004 is included in the copy made available to the NMED observers. Further, VE data packages reviewed during the audit included LA00-VE-03 and LA00-VE-006, in addition to those listed above.”

Review of the auditor’s notes indicate that LA00-VE-003, 004, 005 and 006 were reviewed during the audit. Therefore, Batch Data Reports LA00-VE-003, 005, and 006 have been copied and inserted in GEN tabs 29 & 30, 26 & 27, and 31 & 32 respectively.

“Also, there are confusing entries in the B6 checklists where the cited procedure, objective evidence and /or comments do not appear to be in agreement with the WAP requirement being evaluated. Three examples out of the numerous instances encounter are:”

Checklists B6-1 through B6-6 were reviewed for consistency and agreement in citations. To address this issue, entries were added, including additional procedure references, additional clarifying statements and additional objective evidence.

“For Item 28 on Table B6-1, reference to Tab CDA7 is included in the comments column. CDA7 relates to a revision to Procedure TWCP-QP-1.1-028, R.6. However, no reference to this procedure is included in those listed under Procedure Documented for this same item. Further, the issues addressed in CDA7 do not appear to be directly addressed by Item 28.”

Procedure TWCP-QP-1.1-028, R6 has been added to B6-1 checklist Item 30 E - Procedure Documented Column. The statement was added that VE results were not always being sent to RTR and this situation was corrected during the audit under Tab CDA7 under the “Comment Column”. The reference to CDA7 were deleted from Item 28 or Checklist B6-1.

“For Item 30, the topic covered is meeting Data Quality Objectives (DQOs) for five specific areas. The location cited does not include the procedure that addresses evaluation of DQOs (Procedure TWCP-QP-1.1-024, R4. In addition, the Objective Evidence citation refers to the Waste Stream Profile Form (Tab GEN1) rather than the Draft Characterization Information Summary (Tab GEN2) where the DQO information is actually provided.”

Procedure TWCP-QP-1.1-024 R4 has been added to Item 30. Moved adequacy “Y” to line-up with Items 30 and 30.A. Entered Tab GEN2 for objective evidence for Item 30. Moved Tab GEN1 reference to Item 30.A. Entered “n/a” under “Item Reviewed” column for Items 30.B and 30.C. Entered explanatory statement that “Homogeneous Solids were not in the scope of the audit for Items 30.B and 30.C under the “Comment Section”.

“For Item 31, Procedures TWCP-QP-1.1-024, R4 and TWCP-QP-1.1-010, R9 are not cited despite being directly applicable and included in the comments discussion for TAB CDA6.”

QP-1.1-024 R4 and QP-1.1-010, R9 have been added to procedure column for Item B.6-31.

“It appears that careful review and potential revision of the B6 checklist is required to accurately cite those documents included in each TAB of the report and the documentation used as objective evidence to support the audit conclusions, and to address any entries that do not appear to match WAP/B6 checklist requirements.”

Checklists B6-1 through B6-6 were reviewed and revised as necessary to provide clarity, to accurately cite documents included in the referenced tabs, and to ensure that the objective evidence supports the checklist attributes.

NMED Item 2.

“The Audit Report Acceptable Knowledge (AK) Checklist is not sufficiently specific as it does not provide commentary or examples of implementation in some instances, and in other instances inaccurately or inadequately sites examples of implementation. As a result, the AK checklist does not adequately demonstrate that the AK auditor examined each of the required checklist elements in sufficient detail, even though the NMED observer noted that many of the elements in question were examined during the audit. Examples of specific deficiencies include, but are not limited to, the following items:”

To address this issue additional references were added such as Process AK Reports, since they contain the detailed AK information. TWCP-PLAN-027-001 R3 Sampling Plan has been added to items in the B6 checklist. Comments were added to either the “Item Reviewed” column or the “Comment” column explaining why the item is “n/a”.

“The audit team recognized that the AK percent accuracy was not covered on the DQO review form, and this was remedied during the audit (see Tab CDA6). However, simply adding a checklist line on the DQO form does not fully address the issue. Other generator sites prepare an AK accuracy report or summary sheet that specifically addresses all drums used to calculate waste matrix code and hazardous waste code changes, so that an actual percent value for accuracy is achieved. AK accuracy (Attachment B3, Section B3-9) must be reported as the “degree of agreement between an observed sample result and the true value,” and must include “the percentage of waste containers which require reassignment to a new waste matrix code and/or designation of different hazardous waste codes based on the reevaluation of acceptable knowledge and sampling and analysis data”. Tab CDA6 does not indicate that this level of detail in the AK auditor reviewed this type of information, and that it should have been included as evidence on the AK checklist.”

The audit team members assigned to this area reviewed, evaluated and determined that Procedure TWCP-QP-1.1-024 R5, Interim Change 1 was adequate and implemented including the requirements contained in Section 7.8 of the procedure. Procedure TWCP –QP-1.1-024 R5 Interim Change 1, Section 7.8 States “Use the information in the WMC Discrepancy List to calculate the accuracy of AK for the waste stream lot. The AK accuracy is given by the ratio of number of containers originally assigned to the waste stream, but moved to another waste stream on the basis of RTR, to the number of containers originally assigned to the waste stream.” This calculation is performed by the Site Project Manager or designee prior to signing the Waste Stream Characterization DQO Review form (attachment 4 of the procedure) and

including it in the WSPF for the appropriate waste stream lot. Interim Change 1 to this procedure was issued as resolution to CDA 6. This resolution added a requirement for the Site Project Manager to fill in the AK accuracy as determined in paragraph 7.8 of above referenced procedure in step 18 of the Waste Stream Characterization DQO Review form (attachment 4 of the procedure).

“The permit (Attachment B, page B-2) defines a waste stream “as waste material generated from a single process or from an activity that is similar in material, physical form, and hazardous constituents.” Clearly, both the TA-55-19 and TA-55-20 wastes include several process activities that can be traced to the drum level, and justification for combining several processes into mixed/non mixed streams is not included in AK documentation referenced in the Audit Report and the AK checklist. This information must be included to ensure that the AK auditor agreed with the waste stream designation.”

Waste stream TA-55-20 comprises approximately 7% of the combined total of waste streams TA-55-19 and TA-55-20. LA-UR-004291 “Acceptable Knowledge Summary Report For Waste Streams TA-55-19 and TA-55-20, Sections 2.1 and 2.2 describes the facility, mission, waste form and content description of TA-55-19 and TA-55-20. The origin of the waste is from the same facility, and is covered by the Process AK reports for the various operations. Waste stream TA-55-20 is known to contain no hazardous constituents, and other than that, is identical to the waste in stream TA-55-19. Since waste streams TA-55-19 and TA-55-20 are identical except for the hazardous constituents, these two waste streams were addressed in one acceptable knowledge summary report to facilitate managing and maintaining the information in a consistent manner. In addition, waste stream TA-55-20 does not fall under the requirements of the WAP since it contains no hazardous constituents. Therefore it was understood that verbatim compliance to the WAP requirements (e.g., An AK Summary Report for each Waste stream) would not be required in this type of situation. This justification has been added to the B6-3 checklist.

“The AK checklist does not document whether the AK auditor examined the completeness of the AK Summary Form (Tab AK1, Attachment 1), which is included in the Characterization Information Summary and provided to WIPP with the Waste Stream Profile Form (WSPF). For example, the AK Summary Form does not appear to be complete with respect to all information obtained through the acceptable knowledge process (e.g., hazardous waste codes assigned, etc.), and the AK Summary Form does not include discussion of AK-cited references on the WSPF. This presents a somewhat incomplete AK picture, and should be rectified.”

The auditor reviewed the Acceptable Knowledge Summary Report for Waste Streams TA-55-019 and TA-55-20, LA-UR-4291, 8/31/00 (Tab AK 1) as evidenced by its reference within the B6-3 Checklist. It is standard practice that when an auditor lists a document in this manner, the entire document is reviewed unless otherwise stipulated. In regards to the lack of completeness that was noted within the above comment, it is acknowledged that Attachment 1 “Acceptable Knowledge Summary” is incomplete without a completed Waste Generation Summary Diagram, (see QP-1.1-021 attachment 5 located within the LANL Procedures Folder). A completed Waste Generation Summary Diagram listing the hazardous waste codes assigned was included as part of the Acceptable Knowledge Summary Report for Waste Streams TA-55-019 and TA-55-20, LA-UR-4291, 8/31/00 as Attachment 9.

“AK information is intended to provide an accurate, detailed accounting of waste characterization information pertaining to each waste stream. Although LANL has a significant body of AK information, these data were apparently inappropriately or inadequately assembled and assessed, as evident by the significant number of errors in AK documentation and the appropriate issuance of a corrective action report (CAR) by CBFO. These errors ranged from typographical errors and incomplete road mapping (which impacts traceability) to incomplete inclusion/justification of hazardous waste codes, which resulted in corrective actions that included hazardous waste code reassignment, reassignment of drums to different waste streams, etc. Therefore, it is unclear why the Audit Report states on page 14 that “investigation of the impacts on data identified no impact on past data,” when the CAR report states on page 1 of 8 (addendum) of Response to CAO-CAR-00-036 (Tab CAR2) that “the reviews have identified the need to change applicable EPA Hazardous Waste Numbers for specific waste streams and may also require movement of payload containers to different waste streams.” While this has not impacted shipment of waste to WIPP under the permit because these waste streams have yet to be certified, these issues certainly have the potential to impact past data. These conflicting conclusion need to be reconciled with more detailed information on the AK checklist.”

The conclusions within the Audit Report on page 14 did not provide enough detail to adequately address the issue. The specific section of the Audit Report has been revised to accurately reflect that the conditions adverse to quality had no impact on completed work to date in regards to the certification process since the waste streams affected have not been submitted to WIPP for approval under the WAP. However, the report has also been revised to acknowledge that past data may have been impacted and that these conditions were addressed during the remedial actions taken and the action taken as a result of the independent technical review of the TA-55 AK reports. Both the remedial actions taken and the actions taken as a result of the independent technical review are documented in Table 1, 2 and 3 of the LANL Corrective Action Plan. Any corrections related to changing applicable EPA Hazardous Waste Numbers of specific waste streams or any required movement of payload containers to different waste streams will be completed prior to shipment as part of the normal certification process. No change to the B6-3 checklist was deemed necessary since the checklist references the CAR 00-036 and the CAR and all attachments are included under TAB CAR 2.

“During the audit, as observed by NMED contractor personnel, discussions took place between the auditors and LANL staff concerning the confirmation and subsequent AK document revision using the actual analytical results for hazardous constituents. At the time of the audit, it appeared to have been determined that procedural revisions were necessary to ensure that adequate communication, review, and confirmation of AK prior to shipment of waste would be performed. As presented in the Audit Report text and checklist, the only revision made even related to this issue was a minor modification to Procedure TWCP-QP-1.1-024, R4, inserting a requirement to determine AK percent accuracy (see first bullet in this comment). This revision does not address the concern identified during the audit. Determining the percent accuracy in no way ensures that adequate confirmation will be performed or that revisions to AK documentation shall take place. In addition, failure to address this issue renders inaccurate the conclusions drawn in the Audit Report text indicating the absence of unresolved issues or Corrective Action needs.”

Please note that procedure TWCP –QP-1.1-024 R5, Interim Change 1 was the actual procedure reviewed during the audit. Procedure TWCP –QP-1.1-024 R5, Interim Change1, Section 7.8

States “Uses the information in the WMC Discrepancy List to calculate the accuracy of AK for the waste stream lot. The AK accuracy is given by the ratio of number of containers originally assigned to the waste stream, but moved to another waste stream on the basis of RTR, to the number of containers originally assigned to the waste stream.” This requirement is performed by the Site project Manager or designee prior to signing the Waste Stream Characterization DQO review form (attachment. 4 of the procedure) and including it in the WSDP for the appropriate waste stream lot. Interim Change 1 to this procedure was issued as resolution to CDA 6. This resolution added a requirement for the Site Project Manager to fill in the AK accuracy as determined in Section 7.8 of above referenced procedure in step 18 of the Waste Stream Characterization DQO review form (attachment 4 of the procedure).

Procedure TWCP-DTP-1.2-064, R2, Interim Change 1, Section 7.0 describes how to document reassignment of waste containers to different waste streams based on the results of characterization activities. Section 7.6 requires that if any changes to the AK are identified, that a change to the AK Summary report for the appropriate waste stream be submitted.

Based upon the above, it was determined by the audit team that only procedural change required to resolve the CDA 6 issue was addressed by Interim Change. No additional procedural changes were required to address the confirmation and subsequent AK document revision.

“The need to communicate, confirm, and revise, as necessary, the AK for a given waste stream based on actual analytical results for hazardous constituents must be addressed within LANL procedures in order to demonstrate compliance with the WAP. The Audit Report and B6 checklist must be revised to document both the deficiency and the resolution.”

Procedure TWCP-DTP-1.2-064, R2, Interim Change 1, Section 7.0 describes how to document reassignment of waste containers to different waste streams based on the results of characterization activities. Section 7.6 requires that if any changes to the AK are identified, that a change to the AK Summary report for the appropriate waste stream be submitted.

Based upon the above, it was determined by the audit team that no procedural changes were required to address the need to “communicate, confirm, and revise, as necessary, the AK for a given waste stream.”

NMED ITEM 3

“The Radiography checklist references Tab RTR 14 for information pertaining to RTR training, but Tab RTR 14 does not include much information pertinent to the specific items in the checklist elements. The comments column should more specifically address the checklist elements, indicating specific examined, information in these courses, etc, which support the checklist elements.”

Checklist B6-5 was reviewed and revised to include additional clarification regarding the checklist elements. Specifically, additional objective evidence was added to checklist items 237, 246 through 252, 259 and 260 to provide additional detail in support of the acceptability of the checklist elements.

NMED Item 4

“The Radiography checklist asks specific questions that are not addressed in the Item Reviewed column or Comments column. For example, the checklist (#253) asks whether the test drum was divided into layers with varying densities, or whether different test drums were examined; it also asks whether the test drum was representative of site waste matrix codes. However, the Item Reviewed portion of the checklist does not specifically address these checklist requirements, instead indicating that the auditor “confirmed proper contents” of the drum and viewed test drum videos. The checklist should clearly specify whether a single drum with multiple layers/densities was examined, or whether several drums were used, and whether the test drum was representative of site waste matrix codes and included all required elements.”

The auditor reviewed the Test Drum Assembly Inventory Sheets and determined that the test drums were divided into layers with varying packing densities, and representative of site waste matrix codes, including all required elements. For clarity a statement was added to the B6 checklist, Table B6-5 Item 253 as follows: Test drums are divided into layers with varying packing densities, and representative of site waste matrix codes, including all required elements. Copies of the Test Drum Assembly Inventory Sheets were added to the objective evidence as TAB RTR 26.

NMED Item 5

“The Visual Examination checklist (#286-293) states that miscertification rate calculations are not in the scope of the audit, but it is unclear why implementation of at least some aspects of miscertification were not in the scope of the audit. If the site is determining its site specific miscertification rate for the Summary Waste Category Group, then the initial miscertification rate of 11% should apply until this rate is established. The auditor should better explain circumstances surrounding why this is outside the scope of the audit. Additionally, if miscertification rate was in the process of being calculated, then a “mock” calculation should have been examined to ensure that the site knows how to perform miscertification rate calculations in their entirety. Without this information, it is difficult to agree that the site has fully demonstrated the ability to address miscertification rate calculations. Further, the site shipped non-hazardous waste to WIPP for much of 1999, and was required to calculate miscertification rates by EPA throughout this shipping period. Therefore, examples of implementation, though outside of the specified mixed waste stream, should have been available for review by the auditor and the checklist should reflect this Auditor review activity.”

Commentary evidence to clarify B6-6 Items 286 - 293. Additional objective was added in the form of a mock-up miscertification rate determination per procedure TWCP-DTP-1.2-015, R4 for items 286, 287, 289, and 292. This mock-up miscertification rate determination was evaluated for compliance during the review and revision process of the B6 checklist.

NMED Item 6

“NMED observers noted that the HSG Method Detection Limit was obtained in a manner different than the permit intended. Los Alamos based their approach on a CAO clarification, but the clarification was inaccurate and did not adequately reflect permit requirements. The checklist

and/or audit report should address this observation in the appropriate location, including how the Auditor examined and assessed this situation.”

The method detection limit (MDL) was derived from the analysis of seven spiked samples. All the samples were analyzed on the same day. The requirement for analysis of samples used for determination of the MDL on non-consecutive days applies only to FTIR methods per the permit language and Clarification 10. LANL uses GC/MS, not FTIR, so the requirement for performing MDL analyses on non-consecutive days does not apply. For clarity, a comment was added to the B6-4 checklist item 219.

NMED Item 7

“In several instances, checklists indicate that an item is “not applicable,” but does not explain why the checklist element is not applicable. The reader might attempt to presume why elements are not applicable, but the checklists should specifically address why elements are not applicable.”

The B6 checklists were reviewed and explanations added as necessary to explain “n/a” entries.

NMED Item 8

“Although the Audit Report states that a CAR is a concern that is not addressed or corrected during the Audit, the Audit Report should specify in greater detail the criteria for designating CARs, observations, and recommendations. NMED has consistently made this comment (RFETS Approval, March 9, 2000; Hanford Approval, June 15, 2000; INEEL Approval, July 17, 2000), but the Permittees have failed to incorporate this recommendation.”

The Final Audit Report has been revised to provide greater detail for the criteria for designating CARs, CDAs, observations, and recommendations.

NMED Item 9

“The B6 checklist indicates throughout that repackaged waste was not within the scope of the audit. However, NMED observers reviewed information pertaining to repackaged waste during the audit, as did the audit team members. In addition, the checklist contains specific references to procedures pertaining to repackaged waste, immediately following statements that repackaged waste is not within the scope (See Item 30 on Table 6-1 for one example).

Based on the available information, the status of repackaged waste under this audit is unclear. If repackaged waste has been determined to be outside the scope of the audit by the audit team after completion of the audit, the Audit Report and B6 checklist must be reviewed and revised to provide a full justification for this finding, as well as clear explanations and references in each section of the checklist where repackaged waste is addressed.”

Item 30 on Table B6-1 does not address repackaging of waste or reference repackaging batch data reports, only Items 41 and 43 of Table B6-1 and items 151 and 159 of Table B6-3 list repackaging batch data reports. These data reports pertain to the loading of SWBs only and do not pertain to repackaging as addressed within the WAP. For clarity a comment was added to checklists B6-1 and B6-3.

NMED Transmittal Letter Items:

“NMED understands that the audit teams perform procedural adequacy reviews prior to site audits, but the results of these reviews are not shared with NMED. While NMED assumed the results were not shared because the auditors ensured the site rectified any procedural problems prior to audit, NMED has observed that some procedural changes are still required during audit. NMED believes it would be appropriate to share the results of this adequacy review with out staff prior to the audit.”

This request has been noted and will be acted upon in future audits by providing one reference book containing the applicable B6 checklists with the first two columns completed for the NMED observers.

“Additionally, NMED has observed that audit team members vary in their use of the B6 checklist during site audits. Some auditors complete their checklists during the course of audit interviews, others complete them at the end of each day, while others appear to wait until after the conclusion of the site visit to complete them. Permit Attachment B6 (Section B6-4) requires auditors to use “approved audit checklists that include the checklists in Tables B6-1 to B6-6 for the summary category groups undergoing audit,” and to complete the checklists during the audit.”

All auditors were notified and reminded of this requirement. During future audits, the ATL will ensure that the auditors complete their B6 checklist in a timely manner.

“Please indicate revisions to any text in the Audit Report and checklists with redline/strickout annotation.”

Changes to the Audit Report and checklists have been annotated.