

## Air Monitoring Directive – Summary of Feedback and Responses for Chapter 8 (Audit)

The following feedback was received following the 60-day public review of the Draft Air Monitoring Directive Chapter 8 which took place over June to August 2014.

Chapter 8 - Audit		
Comment	Response from ESRD	Action Taken
1	Paragraph 4 (Wording/grammar) Last sentence “if the results <u>of</u> an audit...”	Agreed.  Change made as suggested.
2	Aud 2-C, Aud 2-E (now an AMD requirement) Although it is desirable to have a representative of the person responsible attend the audit, it may not always be possible for the entire day. Can the allowance be made that should the audit not be attended for a portion without being in non-compliance with the AMD? The intent of this clause in the 2007 Protocol was to maximize the chance for learnings and to mitigate any minor findings that may lead to an audit failure. The implementation of this clause came to be interpreted as, should the auditee choose to leave, there can be no disputing the audit findings or the condition the station was left in.	If the auditee chooses to leave then chances of immediate consultation of the audit findings is lost. If it is deemed that auditee leaving will have no impact on the audit then it should not be an issue. Since more than one parameter can be audited at a time, prolonged absences should be discouraged in case issues with the DAS, documents etc. come up.  Changed back to reflect current Audit Protocol “must be present at minimum during the initial and final stages of the audit of each ambient air monitoring station”.  Added guidance stating that the auditee should be present for all stages of the audit and if the auditee chooses to leave during an audit, the opportunity for immediate on-site correction of any minor deficiencies is forgone.
3	Aud 3-A (modify a new clause) For in-situ calibrators that do not leave a station and are only used in one station, should the annual station audit serve to meet this clause?	An annual station audit cannot meet the requirements of Aud 3-A since. There may be instances where a station cannot be visited once per year.  No change. All calibrators are required to be cross-checked annually against a standard.
4	Aud 3-B (objection/clarify) Does AEMERA guarantee to have the capacity to audit all calibration systems once per year? Although auditees cannot reasonably wait till the last week or so before their “year is up” to attempt to schedule an audit it is also the case that a non-compliance to the AMD should not be a result of scheduling conflicts or lack of capacity by the AEMERA audit lab. There may have to be some sort of allowance for a couple of reschedules that take it past the one year mark and still be compliant as long as the scheduling process started before the 12 month window was up.	This is currently not an issue. Auditees will need to make arrangements with the AEMERA audit lab to fit with their schedules.  No change.

5	<p>Aud 4-E (modify a new clause) Data may not always need to be invalidated. In some cases data may be corrected after an audit failure and still be valid. Suggest wording similar to the first part of clause Aud 4-F.</p>	<p>Aud 4-E requires that data be invalidated “back to the time that data can be demonstrated as valid. Aud 4-H adds “when acceptable, resubmit corrected data”. If data is corrected, it is assumed to then be valid.</p>	<p>No change.</p>
6	<p>5.0 (wording/grammar) “...AMD requirements have not been not met”. Remove second “not”.</p>	<p>Agreed.</p>	<p>Change made as suggested.</p>
7	<p>Aud 5-L (modify a new clause) At the time this was jointly developed by AENV, Airsheds and contractors it was agreed the cost of this 3<sup>rd</sup> party assessment would be shared equally between the Person responsible and the Department. This sharing of costs should be reflected in this clause, since this point of the process is normally reached through mutual agreement.</p>	<p>The agreement referred to is not explicitly mentioned in the Audit Chapter, since AEMERA will now be conducting ambient audits and AEMERA was not part of the agreement between ESRD/AENV and contractors. This requires more dialogue with AEMERA.</p>	<p>No change.</p>
8	<p>Appendix B (objection) Continuous analyzers bullets 1, 2 and 6.  Failure at 10% is OK for calibration systems but it’s too stringent at 10% for analyzers. Usually hard to meet for certain gases. Suggest sticking with 15%.</p>	<p>10% is now in place because the limit on daily spans is +/- 10% (Chapter 7 – Calibration) and if this is not met, the person responsible is required take corrective action.</p>	<p>No change.</p>
9	<p>There is some confusion regarding the difference between “third party” and AEMERA audits. It states in 1.0 Purpose that audits are conducted by AEMERA. The wording in the definition is confusing.</p> <ul style="list-style-type: none"> <li>- does this mean that facilities will no longer be required to hire a third party contractor to do the audits?</li> <li>- Is there a certain criteria or standard that AEMERA’s auditors have to meet?</li> <li>- Does the failure of an audit mean that there has been a contravention or is uptime only affected?</li> <li>- Is there still an annual third party review in addition to AEMERA audit?</li> </ul>	<p>Facilities can still do third party audits if they so choose or as part of their QAP. ESRD’s auditors have transitioned to AEMERA – they will follow the same criteria and process. Failures can be considered in contravention if data has been adversely affected due to the failure and it has been over an extended period of time. AEMERA audits may not be annual (see response in comment #3 above).</p>	<p>No change.</p>
10	<p>Section 2.2 Delivery: Aud 2-D states that “the person responsible or station operator must have data averages available at the ambient monitoring station while the audit is being conducted.”</p> <ul style="list-style-type: none"> <li>- clarification on the expectations of this clause is needed as DHS data does not go back to ambient monitoring station</li> </ul>	<p>The audit requires that data that has been collected and processed be available at the site while the audit is being conducted. How the facility handles this requirement is up to the facility/operator.</p>	<p>No change.</p>

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11	<p>Section 3.0 Calibration System and Gas Audits:                  Aud 3-A states that “the person responsible must cross-check the performance of all continuous ambient air monitoring station calibration systems against the auditor’s audit standards once per year at a minimum.”</p> <ul style="list-style-type: none"> <li>- “audit standards” have not been defined in this chapter – please provide clarity</li> </ul>	<p>All calibration systems and gases are directly referenced to SRM’s (Standard Reference Materials) that are used by the audit function.</p>	<p>No change.</p>
12	<p>Aud 3-A and Aud 3-B can be put together as one clause.</p> <ul style="list-style-type: none"> <li>- consider the following “The person responsible shall contact the auditor, at least once per year, to schedule an appointment to cross-check the performance of all continuous ambient air monitoring station calibration systems against the auditor’s standards.”</li> </ul>	<p>The wording suggested changes the requirement – only requires that the person responsible contacts and schedules an appointment.</p>	<p>No change.</p>
13	<p>Section 3.1 Calibration System Audit:                  Clarity is needed for this section:</p> <ul style="list-style-type: none"> <li>- are the facilities required to remove the calibration equipment and put it back?</li> <li>- where is the equipment delivered to?</li> <li>- is there downtime during delivery and testing of the equipment?</li> </ul>	<p>Yes. Facilities are required to remove the calibration equipment .                  Equipment is delivered to AEMERA’s audit lab in Edmonton.                  Downtime for analyzers – no. If the system is out extended periods of time and no daily spans are occurring then the potential for downtime can occur. There is no means of validating data.</p>	<p>No change.</p>
14	<p>Aud 3-F states that the person responsible shall supply a written report to the auditor when operation concerns are identified. It does not state, however, that the auditor is required to submit a report of the issues to the person responsible and that verbal communication of the concerns will be given.</p> <ul style="list-style-type: none"> <li>- auditors should be required to submit a report of operational concerns for facility records</li> </ul>	<p>Reports are issued when an audit is complete. If issues are addressed immediately there is documentation provided at the time of the issue. This is not a change from current practice.</p>	<p>No change.</p>
15	<p>Section 4.0 Audit Failure:                  This section does not specify downtime.</p> <ul style="list-style-type: none"> <li>- downtime is covered in 4.1 Data Handling. However, consider providing more clarity in Section 4.0.</li> </ul>	<p>Section 4.0 specifies what actions to take in response to an audit failure, while 4.1 specifies how to manage collected data after an audit failure. Audit failure doesn’t automatically translate to downtime. See Chapter 6 of the AMD (Data Quality) for uptime requirements for continuous ambient air analyzers.</p>	<p>No change.</p>
16	<p>Section 4.1 Data Handling                  This section does not state how the Directive would like facilities to validate the data. It only states what to do when there is invalid data.</p> <ul style="list-style-type: none"> <li>- please consider specifying how the Directive would like data to be validated</li> </ul>	<p>Data is validated using methods employed by the facility. Each operator will ultimately have a method, sometimes supplied by the DAS provider, that enables them to validate data. For data validation see Chapter 6 of the AMD (Data Quality Chapter).</p>	<p>No change.</p>

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17	<p>Section 5.4 Third Party Review</p> <p>This section states that once a third party is engaged, data may be flagged back to the previous audit that was passed. However, flagged data may not necessarily be invalid.</p> <ul style="list-style-type: none"> <li>- please provide some clarity in this paragraph</li> <li>- in what circumstances would a third party be engaged?</li> </ul>	<p>A third party is mutually agreed upon when resolution cannot be attained through normal communication. Data can be flagged invalid until it can be proven valid. This sometime runs into extended periods of time – back to the previous audit or some other timeline back to valid data.</p>	<p>No change.</p>
18	<p>Section 2.1</p> <p><i>“Audits may be conducted with minimum notification. Prior arrangement to gain access to the monitoring station will be made with the station operator no earlier than the business day immediately prior to the audit day, or the Friday prior to a week-long audit of a monitoring network.”</i></p> <p>Shell recognizes that as little as one day notice may be given but it is unclear why operators will not under any circumstances be given more than one day notice. We suggest re-wording this statement to the following:</p> <p>“...Prior arrangement to gain access to the monitoring station can be made with the station operator with as little as one business day notice...”</p>	<p>The main reason for this notification period, as short as it may be, is that there will be little chance of altering the as found conditions of the equipment. This has been a major issue in the past hence the short timeline.</p> <p>This is not a change from current practices.</p>	<p>No change.</p>
19	<p>Section 2.2, Aud 2-C</p> <p><i>“The person responsible or station operator must be present at the ambient air monitoring station during all stages of the audit, including a pre audit meeting, for each ambient air monitoring station audited.”</i></p> <p>Given the one business day notice period specified in Subsection 2.1, it may not always be possible to have the station operator present in all situations. As Shell relies on our monitoring companies to run the stations on our behalf, we would prefer to have the technical staff from these companies present at the audit. Unfortunately, our monitoring companies cannot guarantee that they will always have technical staff available within 24-hours’ notice. For this reason, Shell recommends that the notice period be extended to 48 hours.</p>	<p>If the auditee chooses to leave then chances of immediate consultation of the audit findings is lost. If it is deemed that auditee leaving will have no impact on the audit then it should not be an issue. Since more than one parameter can be audited at a time, prolonged absences should be discouraged in case issues with the DAS, documents etc. come up.</p>	<p>Changed back to reflect current Audit Protocol “must be present at minimum during the initial and final stages of the audit of each ambient air monitoring station”.</p> <p>Added guidance stating that the auditee should be present for all stages of the audit and if the auditee chooses to leave during an audit, the opportunity for immediate on-site correction of any minor deficiencies is forgone.</p>
20	<p>Section 3.1, Aud 3-C</p> <p><i>“For a calibration systems audit, the person responsible shall deliver calibration systems to the auditor with sufficient time in advance of the audit appointment so that equipment is fully operational and all gases are at room temperature by the scheduled audit start time.”</i></p> <p>For the person responsible to be able to comply with this requirement, the auditor should ensure sufficient (rather than "minimum" as per Section 2.1) notice is given to the person responsible.</p>	<p>This requirement pertains to bringing calibration systems into AEMERA’s audit lab, not on site audits. The person responsible makes an appointment to bring in their calibration system as per clause Aud 3-B.</p>	<p>No change.</p>

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21	<p>Page 30, APPENDIX B AUDIT ASSESSMENT CRITERIA The word "marginal" is missing from this sentence”</p> <p>“Results very near the failure criteria will be considered <u>marginal</u>. The station operator should investigate the causes of these marginal results in order to minimize future failures.”</p>	Agreed	Change made as suggested.
23	<p>Section 2.1 Preparation “Prior arrangement to gain access to the monitoring station will be made with the station operator no earlier than the business day immediately prior to the audit day, or the Friday prior to a week-long audit of a monitoring network.”</p> <p>No earlier than the day prior? (SEE Aud 2-C)</p>	<p>The main reason for this notification period, as short as it may be, is that there will be little chance of altering the as found conditions of the equipment. This has been a major issue in the past hence the short timeline.</p> <p>This is not a change from current practices.</p>	No change.
24	<p>Section 2.2 Delivery “Aud 2-C The person responsible or station operator must be present at the ambient air monitoring station during all stages of the audit, including a pre audit meeting, for each ambient air monitoring station audited.”</p> <p>Given the amount of notice that will be given for the audit (&lt;24 hours), 2.1 and 2.2 are incompatible. We cannot guarantee that suitable technical staff will be available at any station in the province on this kind of schedule.</p>	<p>If the auditee chooses to leave then chances of immediate consultation of the audit findings is lost. If it is deemed that auditee leaving will have no impact on the audit then it should not be an issue. Since more than one parameter can be audited at a time, prolonged absences should be discouraged in case issues with the DAS, documents etc. come up.</p>	<p>Changed back to reflect current Audit Protocol “must be present at minimum during the initial and final stages of the audit of each ambient air monitoring station”.</p> <p>Added guidance stating that the auditee should be present for all stages of the audit and if the auditee chooses to leave during an audit, the opportunity for immediate on-site correction of any minor deficiencies is forgone.</p>
25	<p>Definitions “Calibration system”</p> <p>It is understood from conversations with AEMERA that calibration gas audits (Section 3.2) will be considered as a calibration system audit (Section 3.1) However; this is not how the new directive reads.</p> <p>The current definition of "calibration system" does not allow for sub-division and the new guidelines list "calibration system audit" and "calibration gas audit" separately. They are therefore separate entities. If AEMERA wants to solve this, it is suggested that either the phrase "or part thereof" needs adding to the definition of calibration system or a phrase similar to Aud 3-D(a) needs adding after Aud 3-G.</p>	<p>The definition of calibration systems is all inclusive: “calibration system” means the calibrators, standard gases, gas cylinder regulators, zero air systems, flow measurement devices, calculations, calculators and procedures used to conduct a calibration of air analyzers;</p> <p>If an auditee wants to book cylinder gas audit as part of the calibration system, then AEMERA will continue to do so as was done in the past through the Department.</p>	Change definition of “calibration system” to specifically include “calibration gases”.

26	<p>Page 6 - 2.1 Preparation                  “Prior arrangement to gain access to the monitoring station will be made with the station operator no earlier than the business day immediately prior to the audit day, or the Friday prior to a week-long audit of a monitoring network.”</p> <p>In certain situations, there may be issues in making the necessary resources available.</p>	<p>The main reason for this notification period, as short as it may be, is that there will be little chance of altering the as found conditions of the equipment. This has been a major issue in the past hence the short timeline.</p> <p>This is not a change from current practices.</p>	<p>No change.</p>
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