

3. Conducting Audits

To ensure continuity of compliance, this process shall be followed when conducting on site audits in conjunction with the Audit Programme (V5). Should any part of the audit be undertaken remotely, this shall be carried out in line with W17 process.

For XAIS-PTSPAS, the audit plan shall follow the requirements in line with process W15 and as specified in the relevant Guidelines and Criteria documents.

For UKCA marking W11 process will be followed

XAIS-PTS shall ensure that all audit activities are conducted by personnel with appropriate competence. The evidence obtained during audits shall be sufficient to enable the auditor to make an informed decision on the conformity of the audit requirement.

4. Conducting the Opening Meeting

A formal opening meeting shall be held with the client's management and where appropriate those responsible for the functions / processes to be audited. The purpose of the opening meeting, usually conducted by the audit team leader is to provide a short explanation of how the audit activities will be undertaken, the degree of detail shall be consistent with the familiarity of the client with the audit process and shall consider:

- Introductions of the participants, including an outline of their roles
- Confirmation of the scope of certification
- Confirmation of the audit plan (including type and scope of audit, objectives and criteria), any changes and other relevant arrangements with the client, such as date and time for the closing meeting, interim meetings between the audit team and the client's management
- Confirmation that the evidence as seen is confidential
- Confirmation of formal communication channels between the audit team and the client
- Confirmation that the resources and facilities needed by the audit team are available
- Confirmation of relevant work safety, emergency, and security procedures for the audit team
- Confirmation of availability, roles and identities of any guides and observers
- The method of reporting, including, and grading of audit findings
- Information about the conditions under which the audit may be prematurely terminated
- Confirmation that the audit team leader and audit team representing XAIS-PTS is responsible for the audit and shall be in control of executing the audit plan including audit activities and audit trails
- Confirmation of the status of findings of the previous review or audit, if applicable
- Methods and procedures to be used to conduct the audit based on sampling
- Confirmation of the language to be used during the audit
- Confirmation that, during the audit the client will be kept informed of audit progress and any concerns
- Opportunity for the client to ask any questions

5. Communication During the Audit

The audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between audit team members and periodically communicate the progress of the audit and any concerns to the client.

The audit team leader shall report to the client and if possible, XAIS-PTS Management if during the audit evidence indicates that audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety) to the audit to determine appropriate action.

It may be the case that reconfirmation or modification of the audit programme is required or to the objectives or scope or termination of the audit. The audit team leader shall report the outcome to XAIS-PTS management.

The audit team leader shall review with the client any need for changes to the audit scope which becomes apparent as onsite auditing activities progress and report this to XAIS-PTS Management.

6. Observers Technical experts and Guides

6.1 Observers

The presence of observers during an audit shall have been agreed by XAIS-PTS prior to the audit and shall be documented in the audit visit plan and report.

The audit team shall ensure that observers do not influence or interfere in the audit process or outcome of the audit.

6.2 Technical experts

The role of technical experts during an audit activity shall be agreed to by XAIS-PTS and client prior to the conduct of the audit. A technical expert shall not act as an auditor in the audit team. The technical experts shall be accompanied by an auditor. The technical experts can provide advice to the audit team for the preparation, planning or audit.

6.3 Guides

Each auditor shall be accompanied by a guide, unless otherwise agreed by team leader and the client. Guides shall be assigned to facilitate the audit. The audit team shall ensure that guides do not influence or interfere in the audit process or outcome of the audit.

Where appropriate the auditee can also act as the guide.

Guides may assist the audit process by:

- Establishing contacts and timing for interviews
 - Arranging visits to specific parts of the site/organisation
 - Ensuring that site safety rules and security procedures are known and respected by audit team members
 - Witnessing audit on behalf of client
- Providing clarification or information as requested by an auditor

7. Obtaining and Verifying Information

During the audit, information relevant to policy statement / commitment to the standard, audit objectives, scope, and criteria (information relating to interfaces between functions, activities, and processes) shall be obtained by appropriate sampling and verified to become audit evidence. Example of information collection methods can include interviews, observation of processes and activities, review of documentation or other known means.

In addition, for Environmental Audits to BS EN ISO 14001:2015, Legal Compliance requirements shall be evaluated and confirmed that the client has a demonstrably effective EMS to ensure legal compliance through its:

- 1) public environmental policy commitment to legal compliance (4.2).
- 2) identification and having access to applicable legal requirements and other requirements related to its environmental aspects (4.3.2 a).
- 3) how those legal requirements apply to the organisation's environmental aspects (4.3.2 b).
- 4) objectives/targets/programs (4.3.3)
- 5) how legal obligations are routinely managed and monitored (4.4.6 and 4.5.1).
- 6) evaluation of legal compliance (4.5.2).
- 7) corrective and preventive actions where necessary (4.5.3).
- 8) internal audit (4.5.5); and
- 9) management review (4.6).

All information as seen during the audit shall remain confidential to the client and no copies shall be taken for audit proof. The auditor shall make notes / reference to document contents only in relation to

certification validation requirements. All necessary steps shall be taken by auditors to protect and safeguard customer property during their assessment

All auditors both XAIS-PTS personnel and outsourced personnel shall ensure that all audit evidence information shall be handled with utmost confidentiality with respect to data transfer and handling of information in forwarding/supplying XAIS-PTS Certification office with the information

8. XAIS-PTS PAS on Site Audits

XAIS-PTS PAS assessment and certification requirements are carried out in line with XAIS-PTS SG Guidelines and Criteria Documents. The assessment process is carried out in the stages as detailed within the Guidelines document. Once issue of XAIS-PTS PAS Certificate the annual assessment process cycle commences. Details of requirements are included within the Appendix section of the relevant Guidelines and Criteria Document. The cycle audits are carried out in with XAIS-PTS Guidelines and Criteria Documents and Processes are followed as per W15.

9. Identifying and Recording Audit Findings

Audit findings, whether conforming or non-conforming shall be summarised within the audit report with its supporting audit evidence. Nonconforming findings shall also be summarised on the Corrective action summary form. Details shall be identified, classified (minor / major), and recorded to enable informed certification decision to be made or certification to be maintained.

Details contained within the audit report for conformity will include:

- description of or reference to audit criteria against which conformity is shown
- audit evidence to support conformity and effectiveness, if applicable
- declaration / conclusion of conformity / compliance / effectiveness of the process

Opportunities for improvement or observations may be identified and recorded without recommending specific solutions, unless prohibited by the requirements of the management system certification scheme. Audit findings which are non-conforming shall not be recorded as opportunity for improvement.

A nonconformity finding shall be recorded against a specific requirement of the audit criteria and contain a clear statement of the category (minor or major) of the nonconformity and identify in detail the objective evidence on which the nonconformity is based.

When findings are raised, the following will be considered:

- follow-up of previous audit records and conclusions
- requirements of the audit client
- accuracy, sufficiency, and appropriateness of objective evidence to support audit findings
- extent to which planned audit activities are realised and planned results achieved
- findings exceeding normal practice, or opportunities for improvement
- sample size.
- categorization (minor / major) of the audit findings.

During an audit, it is possible to identify findings related to multiple criteria. Where an auditor identifies a finding linked to one criterion on a combined audit, the auditor should consider the possible impact on the corresponding or similar criteria of the other management / FPC / process systems.

The auditor may raise either:

- a) separate findings for each criterion; or
- b) a single finding, combining the references to multiple criteria.

Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor shall refrain from suggesting the cause of the nonconformity or their solution.

The client shall analyse the cause of the nonconformity and describe the appropriate corrective action to be taken or planned to be taken to eliminate the non-conformity within the defined time.

The audit team leader shall attempt to resolve any diverging opinions between the audit team and the client, concerning audit evidence or findings, any unresolved points shall be recorded.

9.1 Definitions:

Opportunity for Improvement / Observation

OFI - Opportunity for Improvement – relates to processes/areas meeting the management system, but which could be improved. No formal obligation is required to investigate or respond.

Obs - Observation – non-compliance that poses no risk to the operation of the management system, but it is recommended that action is taken within the 12-month period (prior to next assessment). No formal response is required.

Minor Non-Conformity

Non-compliance that affords no great risk to the effective operation / functioning of the management system / product(s) placed on the market / processes performed when corrective action is implemented, and the root cause is analysed. The auditor shall make a judgement based on the nonconformity for whether the non-conformity shall be dealt with before the next assessment or corrective action shall be submitted with the Corrective Action Form within the agreed limited time frame (example 2 months) to allow XAIS-PTS to conduct desk review.

Major Non-Conformity

Non-compliance that affects the operation/functioning and/or the effectiveness of the management system / operations / production controls / process performed in such a way that it does not comply with the relevant standard and/or have a major impact of materials/goods placed on the market. Major non-compliance corrective action can only be closed out by either submission of evidence, with the corrective action form to XAIS-PTS or for a re-visit to be carried out to ensure corrections/corrective action(s) have been carried out within the agreed time frame (example one month).

10. Preparing Audit Conclusions

Prior to the close out meeting the audit team under the responsibility of the audit team leader shall review the audit findings and audit observation details from each audit team member and any other appropriate information obtained during the audit against the audit objectives and audit criteria and classify the nonconformities, agree upon the audit conclusions, taking into account the uncertainty inherent in the audit process and agree any necessary follow up actions ensuring they confirm the appropriateness of the audit programme or identify any modification required for future audits (e.g. scope, audit time or dates, surveillance frequency, audit team competence)

11. Conducting the Closing Meeting

A formal closing meeting shall be held with the client's management and where appropriate those responsible for the functions / processes to be audited.

The closing meeting shall be formal and conducted by the audit team leader. He/she will present the audit conclusions, including recommendations regarding certification. Any nonconformities shall be presented in such a manner that they are understood, a time frame for responding shall be agreed, the degree of detail shall be consistent with the familiarity of the client with the audit process:

- Attendees of the closing meeting shall be recorded
- Advise the client that the audit evidence obtained was based on a sample of the information; thereby introducing an element of uncertainty
- The method and timeframe of reporting, including any grading of audit findings
- XAIS-PTS's process for handling nonconformities including any consequences relating to the status of the client's certification and additional costs for re-visits

- The timeframe for the client to present a plan for correction and corrective action for any nonconformities identified during the audit

XAIS-PTS's post audit activities

- Information about the complaint handling and appeal process
- Give the client opportunity to ask any questions regarding audit findings. Any diverging opinions between the audit team and client shall be discussed and resolved where possible, if unable to resolve, details shall be recorded and referred to XAIS-PTS
- certification management.
- Refer to 3-year audit recertification / audit plan for next visit
- Notify client of additional costs for any cancelled audits

12. Audit Report

XAIS-PTS shall provide a written report for each audit to the client. The audit team may identify opportunities for improvement but not specific solutions. Ownership of the audit report shall be maintained by XAIS-PTS.

The audit team leader shall ensure that the audit report is prepared from all evidence as submitted from the audit team and shall be responsible for its content. The audit report shall provide an accurate, concise and clear record of the audit to enable an informed certification decision to be made and shall include or refer to the following

- identification of XAIS-PTS
- name and address of client and client's representative
- the type of audit (e.g. initial, surveillance, recertification audit or special audit)
- audit criteria
- audit objectives
- audit scope particularly identification of the organisation or functional units or processes audited and the time of the audit
- any deviation from the audit plan and their reasons
- any significant issues impacting on the audit programme
- identification of audit team leader, audit team members and any accompanying persons
- date and places where audit activities (on site or off site, permanent or temporary sites) were conducted
- audit findings, reference to evidence, conclusions, consistent with the requirements of the type of audit
- any unresolved issues, if identified
- where applicable, whether the audit is combined, joint or integrated
- a disclaimer statement indicating that auditing is based on a sampling process of the available information
- recommendation from the audit team
- the audited client is effectively controlling the use of the certification documents and marks, if applicable
- verification of effectiveness of taken corrective actions regarding previously identified nonconformities

The report shall also contain

- A statement on the conformity and the effectiveness of the system under audit together with a summary of the evidence relating to
 - The capability of the system to meet applicable requirements and expected outcomes
 - The internal audit and management review process
- A conclusion on the appropriateness of the certification scope
- Confirmation that the audit objectives have been fulfilled

The written report is provided. XAIS-PTS shall retain ownership of the audit reports. The report confirms XAIS-PTS's Confidentiality, and that no XAIS-PTS representative will pass on any of the information that is gathered about the client, including the contents of reports to any other person or organisation without permission, unless as requested as part of a UKAS assessment or by a relevant regulatory body.

XAIS-PTS shall review the corrections, corrective actions and identified causes as submitted by the client to determine if these are acceptable. XAIS-PTS shall verify the effectiveness of any correction and corrective actions taken. The evidence obtained to support the resolution of nonconformities shall be recorded.

The client shall be formally informed of the result of the review and verification and advised if an additional full audit, an additional limited audit, or documented evidence (to be confirmed during future audits) will be needed to verify effective corrections and corrective actions.

Verification of effectiveness of corrections and corrective actions can be carried out based on a review of documented information provided by the client, or where necessary, through verification onsite. This activity would be carried out by a member of the audit team.

13. Recertification Audit planning

The purpose of recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole and to ensure continued relevance and applicability for the scope of certification.

Recertification shall be planned and conducted to evaluate the continued fulfilment by the client of all the requirements of the relevant management system standard or other normative document. This shall be planned and conducted in due time to enable for timely renewal before the certificate expiry date.

The recertification activity shall include the review of previous surveillance audit reports and consider the performance of the management system over the most recent certification cycle

Recertification audit activities may need to have a stage 1 in situations where there have been significant changes to the management system, the organisation, or the context in which the management system is operating (e.g. changes to legislation). Such changes can occur at any time during the certification cycle and XAIS-PTS may need to perform a special audit which may or may not be a two-stage audit

14. Recertification audit

The recertification audit process shall include an onsite audit that addresses:

- The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification
- Demonstrated commitment to maintain the effectiveness and improvement of the management system to enhance overall performance
- The effectiveness of the management system with regard to achieving the certified client's objectives and the intended results of the respective management system(s)

For any major non-conformity XAIS-PTS shall define time limits for correction and corrective actions. These actions shall be implemented and verified prior to the expiration of certification

When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of the new certificate can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision

If XAIS-PTS has not completed the recertification audit or is unable to verify the implementation of corrections and corrective actions for any major non-conformity prior to the expiry date of the certification, then recertification shall not be recommended, and the validity of the certification shall not be extended. The client shall be informed, and the consequences explained.

Following expiration of certification, XAIS-PTS can restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision and the expiry date shall be based on prior certification cycle.

15. Special Audits

15.1 Expanding scope

XAIS-PTS shall, in response to an application for extension to the scope of a certification already granted, undertake a review of the application, and determine any audit activities necessary to decide whether or not for the extension to be granted. This may be conducted in conjunction with a surveillance audit

15.2 Short Notice Audits

It may be necessary for XAIS-PTS to conduct audits of certified clients at short notice or unannounced to investigate complaints or in response to changes in the standards to which compliance of the product is certified or changes in ownership, structure or management of the client if relevant or in the case of any other information indicating that the product may no longer comply with the requirements of the certification system or as a follow up on suspended clients. In such cases

- a. XAIS-PTS shall describe and make known in advance to the client the conditions under which the short notice visit is to be conducted and
- b. XAIS-PTS shall exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.