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IECEx OPERATIONAL DOCUMENT

IEC System for Certification to Standards relating to Equipment for use in Explosive Atmospheres (IECEx System)

IECEx Certified Equipment Scheme –

Guidelines on the Management of Assessment and Surveillance programs for the assessment of Manufacturer's Quality Management Systems, in accordance with the IECEx Scheme.

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0 Introduction

The IECEx System provides for the assessment and surveillance of Manufacturer's Quality Management Systems and the issue of an IECEx Quality Assessment Report in accordance with IS0/IEC 80079–34.

The purpose of this document is to provide guidance upon the methodology, thereby, providing the opportunity for IECEx Certification Bodies to conduct assessments and audits of manufacturer's quality management systems in a uniform manner.

This document is based on work conducted by the European Notified Bodies Group for ATEX and in turn is based upon *ISO 19011:2018 Guidelines for quality and/or environmental management systems auditing.*

NOTE ISO 19011: 2018 uses the term "audit" throughout but IECEx 02 uses the separate terms "assessment", "surveillance" and "audit". For the purpose of this document the term "audit" is considered to be an activity that comprises part of the processes of both "assessment" and "surveillance".

This Edition 5.0 replaces Edition 4.0 as approved via ExMC ballot on ExMC/2223/DV (refer ExMC/2235/RV for ballot result details.

1 Scope

This document provides guidance on the fundamentals of conducting assessment and surveillance visits as a means of verifying a manufacturer's compliance with the IECEx quality management system requirements.

2 Normative references

The following publications contain provisions, which, through reference in this text, constitute provisions of this Operational Document. At the time of publication, the referenced documents were valid and available as published. Where the reference is undated or where no edition for a referenced document is specified the latest currently published version shall apply. The Ex Management Committee shall decide the timetable for the introduction of revised editions of the publications.

ISO 9000: 2015 Quality management systems -- Fundamentals and vocabulary

ISO19011: 2018 Guidelines for quality and/or environmental management systems auditing.

ISO/IEC 80079-34: 2018 Explosive atmospheres – Part 34: Application of quality management systems for equipment manufacture

IECEx OD 003-2 – Assessment procedures for IECEx acceptance of applicant Ex Certification Bodies (ExCBs), Ex Testing Laboratories (ExTLs) and Additional Testing Facilities (ATFs) – Part 2: Assessment, surveillance assessment and re-assessment of ExCBs and ExTLs operating in the IECEx 02, IECEx Certified Equipment Scheme

IECEx OD 060 - IECEx Guide for Business Continuity – Management of Extraordinary Circumstances or Events Affecting IECEx Certification Schemes and Activities

IAF ID 3, IAF Informative Document for Management of Extraordinary Events or Circumstances Affecting ABs, CABs and Certified Organizations

IAF MD 4, IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.

3 Terms and Definitions

For the purpose of this document, the terms and definitions given in ISO 9000: 2015, ISO 19011: 2018, ISO/IEC 80079-34:2018, ISO/IEC 17000:2020 and below, shall apply.

3.1 Audit

An activity based on a systematic, independent and documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.

NOTE: Whilst "audit" applies to management systems, "assessment" applies to conformity assessment bodies as well as more generally. The assessment process includes auditing.

3.2 Product Audit

An audit (3.1) to determine whether the product is in compliance with the type described in the IECEx Assessment and Test Report.

3.3 Audit Criteria

Set of policies, procedures or requirements used as a reference.

3.4 Audit Evidence

Records, statements of fact or other information, relevant to the **audit criteria** (3.3) and which are verifiable.

NOTE: Audit evidence can be qualitative or quantitative.

3.5 Audit Finding(s)

Result of the evaluation of the collected **audit evidence** (3.4) against **audit criteria** (3.3).

NOTE: Audit findings can indicate either conformity or nonconformity with audit criteria.

3.6 Audit Conclusion(s)

Outcome of an **audit** (3.1), reached by the audit team after consideration of the audit objectives and all **audit findings** (3.5).

3.7 Audit Client

Organisation or person requesting an **audit** (3.1).

3.8 Auditee

Organisation being audited.

3.9 Auditor

Person with the **competence** (3.15) to conduct an **audit** (3.1).

3.10 Audit Team

One or more auditors conducting an **audit** (3.1).

NOTE 1 One auditor of the audit team is appointed as audit team leader.

NOTE 2 The audit team can include auditors-in-training and, where required, technical experts.

NOTE 3 Observers can accompany the audit team but do not act as part of it.

3.11 Technical Expert

Person who provides specific knowledge or expertise to the lead auditor with respect to the subject being audited.

NOTE 1 Specific knowledge or expertise includes those on the organisation, process, product, or activity to be audited, as well as language or cultural guidance.

NOTE 2 A technical expert does not act as an auditor in the audit team.

3.12 Audit Programme
Set of one or more **audits** (3.1) planned for a specific time frame and directed toward a specific purpose.

3.13 Audit Plan
Description of the on-site activities and arrangements for an **audit** (3.1).

3.14 Audit Scope
Extent and boundaries of an **audit** (3.1).

NOTE The scope typically includes a description of physical locations, organisational units, activities and processes, as well as the time period covered.

3.15 Competence
Demonstrated capability to apply knowledge and skills.

3.16 Initial Assessment
Activities related to the notification of a manufacturer to determine whether the manufacturer and applicable manufacturing locations(s) meet all the requirements of the relevant clauses of the specified standard necessary for granting notification as to whether they have effectively implemented, including documentation review, site audit at the manufacturers' premises and manufacturing locations(s), preparation and consideration of the audit report and other relevant activities necessary to provide sufficient information to allow a decision to be made as to whether notification shall be granted. Audit results shall be recorded on a Quality Assessment Report (QAR).

3.17 Surveillance
Surveillance of a manufacturer's quality management system takes place on a regular basis as defined in this document. The surveillance audit should be product based with audit results being recorded on an approved Surveillance Audit Report.

The purpose of surveillance programmes is to:

- verify that the approved quality management system and associated product quality plans, continues to be implemented; and:
- consider the implications of any changes to the system, initiated as a result of changes in the manufacturers operation; and
- confirm continued compliance with ISO/IEC 80079-34.
- evaluate any addition manufacturing, external providers , sub-external providers where critical requirements of ISO/IEC 80079-34 are being performed.

3.18 Re-Assessment
Verification of the effectiveness of the organisation's (Manufacturer, Manufacturing Locations, Trade Agents, Local Assessmblers etcetera) quality management system to ensure compliance with IECEx requirements. In most cases it is unlikely that a period greater than three years for periodic re-assessment of the manufacturer's quality management system would satisfy this requirement. The re-assessment should provide for a review of past performance of the system over the period of the notification. The re-assessment program shall take into consideration the results of the above review and shall at least include a review of the quality management system documents and a site audit (which may replace or extend a regular surveillance audit). It shall at least ensure

- the effective inter-action between all elements of the system
- the overall effectiveness of the system in its entirety in the light of changes in operations
- demonstrated commitment to maintain the effectiveness of the system.

3.19 Quality Assessment Report.

Upon the acceptance of the assessment, the Certification Body shall. Issue an IECEx Quality Assessment Report (QAR) and have this registered on the official IECEx Website www.iecex.com

4 Principles of auditing

Auditing is characterised by its reliance on a number of principles. These make the audit an efficient and reliable tool in support of management policies and controls, providing information on which management can act to improve its performance. Adherence to these principles is a prerequisite for audit conclusions that are relevant and sufficient, such that auditors working independently from one another will reach similar conclusions in similar circumstances.

Three of these principles relate primarily to personal characteristics of the auditors themselves. These are:

i. **Ethical conduct** - *the foundation of professionalism*
The role of the auditor is one of trust, integrity, confidentiality and discretion.

ii. **Fair presentation** - *the obligation to report truthfully and accurately*
Audit findings, audit conclusions and audit reports reflect truthfully, accurately and completely the audit activities. Any unresolved or diverging opinions between the audit team and the auditee and any obstacles encountered are reported.

iii. **Due professional care** - *application of reasonable care in auditing*
Auditors exercise a degree of care appropriate to the importance of the task they perform and to the confidence placed in them by audit clients and other interested parties. Having the necessary competence is an important prerequisite.

The remaining two principles of auditing relate primarily to the audit process. An audit is, by definition, independent and systematic and these characteristics are closely linked to the following two principles of auditing:

iv. **Independence** - *the basis for the impartiality and objectivity of the audit conclusion*
Audits are objective and independent. Audit team members are free from bias and conflict of interest.

v. **Evidence** - *the rational basis for reaching audit conclusions*
Audit evidence is verifiable. It is based on samples of the information available, since an audit is conducted during a finite period of time and with finite resources. However, the use of sampling is appropriate to the confidence placed in the audit conclusions.

5 Managing an audit programme

5.1 Introduction

An IECEx Certification Body having a need to conduct audits shall implement and manage an efficient and effective audit programme. The purpose of an audit programme is to assist the IECEx Certification Body in providing the resources necessary to facilitate the conduct of individual audits on a complete and timely basis.

The IECEx Certification Body's management shall grant the authority for managing the audit programme.

Managing the audit programme includes:
a) establishing the objectives and extent of the audit programme
b) establishing the responsibilities, resources and procedures
c) ensuring the implementation of the audit programme

d) monitoring and reviewing the audit programme
e) ensuring that appropriate audit programme records are maintained.

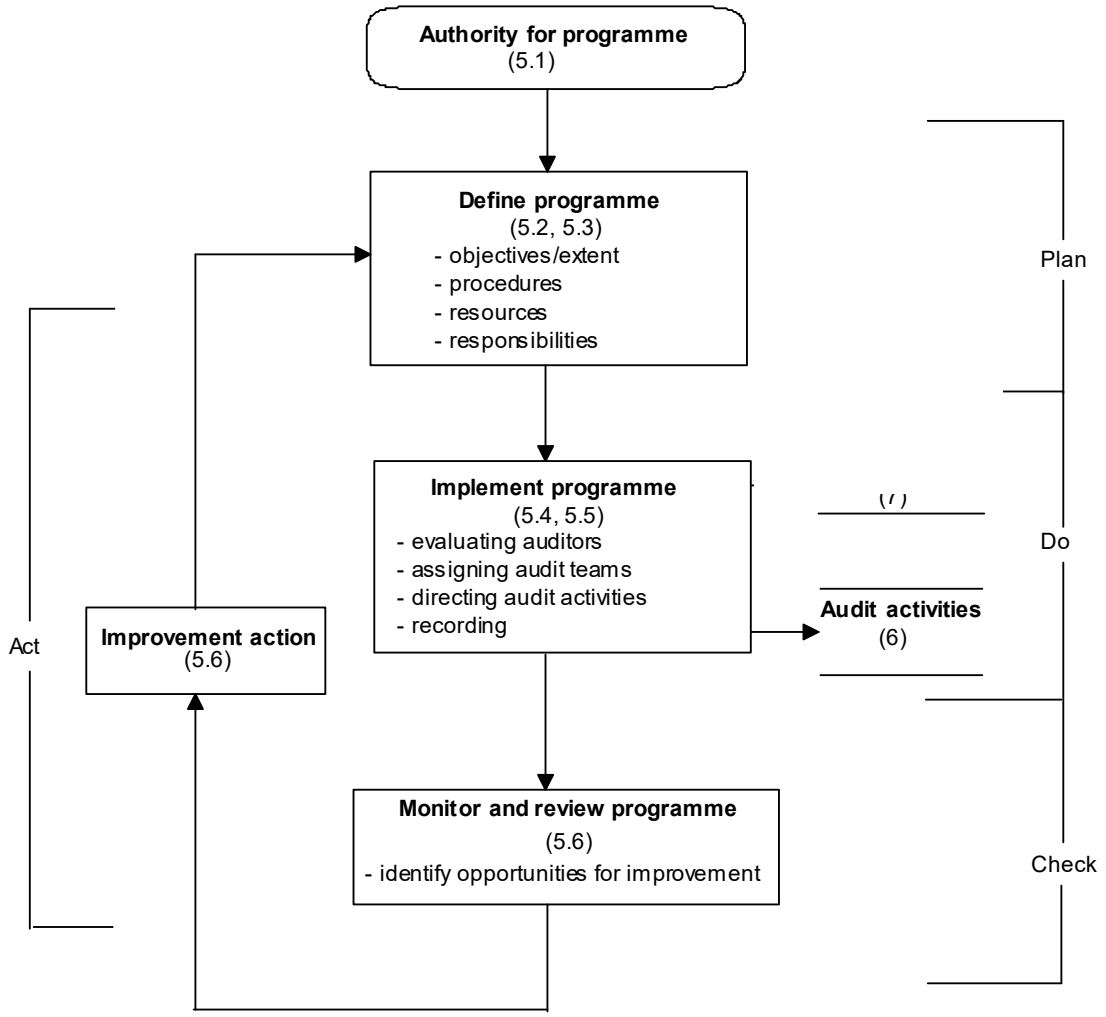


Figure 1 - illustrates the application of the Plan-Do-Check-Act cycle to the management of an audit programme

Note: The numbers in this and all subsequent figures refer to the relevant clauses of this document.

5.2 Audit programme objectives and extent

5.2.1 Objectives of the audit programme

The objective of the audit programme is to establish that the manufacturer is complying with ISO/IEC 80079-34, and with respect to the certificates listed or to be listed on the IECEx On-line system. Depending on their size, nature and complexity, organisations may meet the objectives in a single audit.

The objective can be based on consideration of:

a) conformity of the product with the type described in the IECEx Test Report and with the requirements of the IEC Standard, which apply to it.
b) management priorities
c) commercial intentions
d) management system requirements supporting conformity of the product
e) legal and contractual requirements
f) external provider evaluation
g) customer requirements
h) potential risks to the organisation.

5.2.2 Extent of the audit programme

An audit programme can vary in size, nature and complexity. The extent of the programme will be influenced by:

a) scope, objective, duration and frequency of each audit to be conducted
b) size, nature and complexity of the organisation audited
c) the number, importance, complexity, similarity and locations of the activities to be audited
d) standards, legal and contractual requirements, policies, procedures and other audit criteria
e) accreditation and registration/certification
f) the results of previous audits or a previous audit programme review
g) language, cultural and social issues
h) concerns of interested parties
i) significant changes to any organisations, activities or functional areas.

5.2.2.1 Scope of initial assessment, surveillance and re-assessment

a) Initial assessments and re-assessments:

For initial assessments and re-assessments all requirements of ISO/IEC 80079-34 apply. These assessments may be conducted in whole or part at the manufacturer's premises, as well as other manufacturing location(s)/production site(s) if applicable.

It is the CB (Certification Body) responsibility to determine what level of assessment is required for external providers / sub-external providers that are responsible for critical operations and requirements laid down in ISO/IEC 80079-34. Examples of critical operations include, but are not limited to:

- Design and development changes
- Assembly / sub-assembly of product
- Routine Testing / Final testing of product
- Labelling of product
- Inspection and control of critical operations.

"Storage" and "handling" are activities included in the definitions of "Manufacturing Location" and "Production Site." Storage and handling are critical operations only in cases where improper storage or handling of parts or assemblies may potentially impact the certification or safety of the final product. It is not the intent of this clause to require assessment of locations whose sole function is the storage of finished goods inventory after final assembly and packaging.

It is not the intent of this clause to require CBs to audit external providers or sub-external providers. It is however the responsibility of the CBs to evaluate if external providers / sub-external providers responsible for requirements of ISO/IEC 80079-34 have the necessary quality management systems and quality plans in place to ensure the requirements of ISO/IEC 80079-34 are being met. Examples of evaluations of external providers / sub-external providers can include:

- Review of a current ISO certificate with the proper scope
- Audits performed by the Manufacturer
- Audits performed by another CB
- Audits by the CB
- Components covered by the IECQ Scheme

Reassessments should be scheduled for a date approximately two months prior to the Valid Until date of the QAR and shall be planned and conducted in due time to enable for timely renewal before the Valid Until date. Details on the requirements for the Valid Until Date are defined in IECEx OD 011-2.

b) Surveillance:

The surveillance visits at the manufacturer's premises shall include:

- the system maintenance elements, which are internal audit, management review and preventive and corrective action
- customer complaints
- changes to the documented system
- areas subject to change
- selected elements of the certification/registration standard
- other selected areas as appropriate.
- identification of any new manufacturing locations / production sites
- review of external providers and/or sub-external providers performing critical operations.
- re-assessment is defined in clause 3.18 of this document.

NOTE: Where a manufacturer has a certified quality management system with an appropriate scope, certified by a recognised body (Type A or C manufacturer), then the scope of assessment/surveillance may be restricted to assessing the effectiveness of that quality management system with respect to the certificates listed or to be listed upon the on-line notification system.

5.2.2.2 Audit programme for IECEx Certification Bodies

5.2.2.2.1 Initial and Re-assessments

IECEx Certification Bodies have essentially 3 types of customer, concerning initial or re-assessments:

TYPE (A) a manufacturer requiring an initial assessment or re-assessment prior to the issue of an IECEx QAR, where the manufacturer has a certified quality management system, for example, to ISO 9001:2015 requirements, with an appropriate scope certified by a recognised body. (The scope does not necessarily need to include protection concepts)

TYPE (B) a manufacturer requiring an initial assessment or re-assessment prior to the issue of a QAR, where the manufacturer does not have a certified quality management system for example, to ISO 9001:2015 requirements, or a certified quality management system with an inappropriate scope. (The scope does not necessarily need to include protection concepts)

TYPE (C) a manufacturer requiring initial assessment or periodic surveillance, where the manufacturer has also contracted the IECEx Certification Body in its capacity as an ISO 9000 Certification provider to integrate the two activities i.e. an IECEx Quality Assurance assessment and a certified quality management system for example, to ISO 9001:2015 requirements. (The scope does not necessarily need to include protection concepts)

IECEx Certification Bodies are required to take into consideration the factors listed in clause 5.2.2 of this document. The “complexity” factor given in 5.2.2 b) is one of the major issues for IECEx Certification Bodies in that products include equipment (electrical and non-electrical) along with protective systems, components and devices required for contributing to the safe functioning of equipment and/or protective systems, all of which covers a wide range of technologies.

Therefore, as a guide to the amount of resource (in auditor days) that should be spent conducting initial assessments, based upon the number of protection concepts, number of Ex personnel located onsite, and if there is a Certified Quality management system in place the following table(s) are provided. These tables are only supplied as guidelines. It is the IECEx auditor’s responsibility to ensure that the appropriate time is spent to ensure that audits cover all requirements of ISO/IEC 80079-34 and any issued certificates on the online system.

WITH CERTIFIED QUALITY MANAGEMENT SYSTEM
(Manufacturing Types (A) and (C))

	AUDITOR(s) TIME ON SITE IN PERSON DAYS		
No. OF PROTECTION CONCEPTS LISTED ON MANUFACTURER’S APPLICATION OR IECEx ON-LINE CERTIFICATE(S)	25 OR LESS Ex PERSONS ON SITE	100 OR LESS Ex PERSONS ON SITE	100 OR MORE Ex PERSONS ON SITE
1	1	1	1 - 2
2 - 3	1 – 1 1/2	1 – 1 1/2	2
4 - 5	2	2 - 3	3 - 4
6+	2 - 3	3	3 - 4

WITHOUT CERTIFIED QUALITY MANAGEMENT SYSTEM
(Manufacturing Type (B))

	AUDITOR TIME ON SITE IN PERSON DAYS		
No. OF PROTECTION CONCEPTS LISTED ON THE MANUFACTURER’S APPLICATION OR IECEx CERTIFICATE(S)	25 OR LESS Ex PERSONS ON SITE	100 OR LESS Ex PERSONS ON SITE	100 OR MORE Ex PERSONS ON SITE
1	2	2	2 - 3
2 - 3	2 - 3	2 - 3	3
4 - 5	2 - 3	3 - 4	3 - 4
6+	3 - 4	4	5

*The above times do not include the time spent by technical experts.

Protection concepts as referenced in the above tables are represented and identified by the different technologies, i.e. Ex d, Ex i, Ex n etc., as used for equipment certified under the IECEx Scheme.

These guidance times may be varied at the auditor's discretion provided that all protection concepts are subject to adequate assessment / surveillance. For example, the duration may be extended where there is not a common language, a large number of certificates are involved or reduced if processes are similar for several different products but with a minimum of one auditor day for an initial assessment.

5.2.2.2.2 Surveillance Assessments

Surveillance assessments shall be carried out as follows:

a) For sites not covered under an ISO 9001 registration with an appropriate scope that has been issued by a body accredited by an IAF signatory organisation, surveillance audits should be conducted every 12 months and the period between audits shall not exceed 14 months.
b) For sites covered under an ISO 9001 registration with an appropriate scope that has been issued by a body accredited by an IAF signatory organisation, Quality management system surveillance audits should be carried out every 18 months and the period between audits shall not exceed 20 months.

Audit intervals should be based on the date of the initial audit of the site per OD 011-2 to ensure consistent, regular surveillance activities.

NOTE: Per Clause 8.3.2 of IECEx 02, a QAR has a validity of three years. Therefore, in situation (a), the site will have an initial audit, then a surveillance audit within 12 to 14 months after the initial audit, another surveillance audit within 24 to 26 months after the initial audit, and a reassessment audit within 36 months after the initial audit. In situation (b), the site will have an initial assessment, then a surveillance audit within 18 to 20 months after the initial audit, and a reassessment audit within 36 months after the initial audit.

Additional surveillance / assessments may be conducted at the discretion of the IECEx Certification Body based on the manufacturer's / manufacturing location's / production site's performance and results of previous surveillance / audit results.

5.3 Audit programme responsibilities, resources and procedures

5.3.1 Responsibilities

Responsibility for managing an audit programme should be assigned to (an) individual(s) who has (have) a general understanding of audit principles, of auditor competence and the application of audit tools and methods. They should also have technical and business understanding relevant to the activities to be audited.

Those assigned the responsibility for managing the audit programme should:

a) define, implement, maintain, and improve the audit programme
b) identify and provide resources for the programme.

5.3.2 Resources

When identifying resources for the audit programme, consideration should be given to:

a) financial resources necessary to develop, implement, manage and improve audit activities
b) audit tools and methods
c) availability of auditors and technical experts
d) processes to achieve and maintain auditor competence, and to improve auditor performance
e) auditor competence appropriate to the particular audit programme objectives
f) time, travel and other auditing needs.

5.3.3 Procedures

Audit programme procedures should be established and should address, for example:

a) planning and scheduling audits
b) assuring the competence of auditors and audit team leaders
c) selecting appropriate audit teams
d) conducting audits
e) performing audit follow-up.

5.4 Audit programme implementation

The implementation of an audit programme should include:

a) documenting the audit programme and communicating it to relevant parties;
b) co-ordinating and scheduling audits and other audit programme activities
c) establishing and maintaining a process for the initial evaluation of auditors and the on- going evaluation of training needs and continuing professional development of auditors
d) ensuring the appointment of audit teams
e) providing required resources to the audit teams
f) ensuring the conduct of audits according to the audit programme
g) ensuring the control of records of the audit activities
h) ensuring review and approval of audit reports, and ensuring their distribution to the audit client and other specified parties
i) ensuring audit follow-up, if applicable.

5.5 Audit programme records

Records of all IECEx audits shall be maintained by the IECEx Certification Body to demonstrate the operation of the audit programme and shall include:

a) results of audit programme review
b) audit records, such as:
   - audit plans
   - audit reports
   - nonconformity reports; and
   - corrective and preventive action reports
c) audit personnel records, covering subjects such as performance evaluation, audit team selection and training.

5.6 Audit programme monitoring and reviewing

The effectiveness of an IECEx Certification Body's auditing programme shall be monitored by the ExCB itself and at appropriate intervals reviewed and included as part of their internal quality management system review, to assess whether its objectives and those of the IECEx Scheme have been met. This audit programme review should be carried out to assess the audit programme effectiveness and identify opportunities for improvement.

Monitoring should be carried out by using performance indicators that measure, for example:

- the ability of the audit teams to meet audit objectives
- conformity with audit programmes and schedules
- feedback from audit clients, auditees and auditors
- time to close audit programme corrective actions.

This audit programme review should consider for example:

- results and trends from monitoring
- conformity with procedures
- evolving needs and expectations of interested parties
- audit records
- alternative or new auditing practices.

Results of the audit programme review can lead to corrective actions and improvement of the IECEx Certification Body's audit programme.

6 Audit Activities

6.1 Introduction

This clause contains guidance on managing and conducting audits, including the selection of audit team members.

After completion of an audit, audit follow-up actions can take place (see clause 6.8).

6.2 Initiating the audit

6.2.1 Audit objectives, scope and criteria

Within the overall objectives of an audit programme, an individual audit should be based on defined objectives, scope and criteria.

The objective for the audit programme is to establish that the manufacturer is complying with ISO/IEC 80079-34 with respect to all the certificates listed on the online notification system, and kept up-to-date by the IECEx Certification Body planning and conducting the audit programme. An individual audit that is part of a surveillance programme may address only part of a quality management system.

In preparing for an audit, the following shall be communicated to the auditee and recorded on the job file:

- The audit scope describes the extent and boundaries of the audit in terms of factors such as physical locations, organisational units, activities and processes to be audited and, where relevant, the time period covered by the audit.
- The audit criteria, i.e. ISO/IEC 80079-34
- Dates of the audit, as agreed with the auditee
- Membership of the audit Team

6.2.2 Feasibility of the audit

Those responsible for managing the audit programme should determine the feasibility of the audit, taking into consideration such factors as:

a) sufficient and appropriate information for planning the audit
b) adequate co-operation from the auditee
c) availability of time and adequate resources.

Upon receipt of an application from a manufacturer for an IECEx Certificate of Conformity, the IECEx Certification Body should:

1. ensure that the documentation as required by ISO/IEC 80079-34 as appropriate and the relevant IEC Standard is provided.
2. ascertain that sufficient and appropriate information regarding the manufacturer is available for example, size, location, status of quality management system.

An IECEx Certification Body is NOT permitted to issue an IECEx Quality Assessment Report (QAR) until a document review and site assessment have been satisfactorily completed.

Where products to be covered by an IECEx Certificate of Conformity are to be manufactured in different locations or countries, the IECEx Certification Body to whom the application for an IECEx Certificate of Conformity has been lodged (known as ExCB 'A') may engage other IECEx Certification Bodies to perform sites visits of the various manufacturing locations under the direction and control of ExCB 'A'.

An IECEx Certification Body is permitted to amend the scope of an existing QAR (without a site assessment visit) where the technology/processes are declared similar to those already covered.

6.2.3 Establishing the audit team

When the audit has been declared feasible, an audit team should be established and an audit team leader is appointed taking into account the competence needed to achieve the objectives of the audit. When there is only one auditor, the auditor should perform all applicable duties of an audit team leader.

Those responsible for managing the audit programme and/or the audit team leader, in consultation with the audit client and, if necessary, the auditee, should identify the resources necessary.

When deciding the size and composition of the audit team, consideration should be given to the following:

a) audit objectives, scope, criteria, location(s) and estimated duration
b) the overall competence of the audit team needed to achieve the objectives of the audit
c) requirements from accreditation/certification bodies, as applicable
d) the language of the audit and understanding of the auditee's social and cultural characteristics either through their own skills or through the support of a technical expert
e) the need to assure the independence of the audit team from the activities to be audited and to avoid conflict of interest
f) the ability of the audit team members to interact effectively with the auditee and to work together.

The process of assuring the competence of the audit team should comprise the following steps:

1) identifying the knowledge and skills needed to achieve the objectives of the audit
2) defining the criteria by which knowledge and skills are to be evaluated
3) selecting the audit team such that all of the knowledge and skills needed to conduct the audit and to achieve the audit objectives are present in the audit team. If not fully covered by the auditors in the team, the overall competence may be satisfied by including technical experts in the team.

Technical experts should operate under the direction of an auditor. The IECEx Certification Body should evaluate and record the required competencies of technical experts.

Both the audit client and auditee have a right to request the replacement of particular team members on reasonable grounds which should be communicated to those responsible for managing the audit programme. Any decisions to replace team members should be taken by those responsible for managing the audit programme. Examples of reasonable grounds can be conflict of interest situations (such as an audit team member having been a former employee of the auditee or having provided consultancy services) or previous unethical behaviour.

6.2.4 Initial contact with the auditee

The initial contact with the auditee can be informal or formal. Depending on the audit situation, those responsible for managing the audit programme or audit team leader should consider the following, as appropriate:

a) contacting the auditee to establish communication channels
b) providing information on proposed timing and audit team composition
c) requesting documents, including records, if needed, and
d) making arrangements for the audit.

Any need for accompanying persons such as observers or guides for the audit team should be mutually agreed.

6.3 Document Review

Relevant management system documents, including records, from the auditee, including any previous audit reports, should be reviewed to determine the conformity of the system components or processes, as documented, with audit criteria. The review, normally by the audit team leader or by one or more auditors assigned by the audit team leader, should take into account the size, nature and complexity of the organisation, and the objectives and scope of the audit. A preliminary on-site visit is an option to get a good overview of available information.

If the auditee's management system documentation is found to be inadequate, such that it is not commensurate with the audit scope or criteria, the audit client, those responsible for managing the audit programme and the auditee should be informed. Further resources should not be expended on the audit until such concerns are resolved to the satisfaction of those responsible for managing the audit programme in consultation with the audit client, the audit team leader and, if appropriate, the auditee.

6.4 Preparing for the on-site audit activities

6.4.1 Planning the on-site audit activities

The audit team leader should prepare a plan for the on-site audit activities. This plan should provide necessary information to the audit team, auditee and audit client. It also facilitates scheduling and co-ordination of the audit activities.

The level of detail provided in the audit plan, should be adapted to suit the scope and complexity of the audit. The details can for example differ between initial and subsequent surveillance visits.

The audit plan includes the audit objectives and scope which shall include a product audit and should include:

a) the audit criteria and any reference documents
b) the dates and places where the on-site audit activities are to be conducted
c) the identification of the organisational and functional units and processes to be audited
d) the expected time and duration for audit on-site activities, including meetings with the auditee's management and audit team meetings.

The audit plan can also include, as appropriate:

e) the identification of the sites, activities, and management system processes that are essential to meeting audit objectives in order to allocate appropriate resources to critical areas of the audit
f) the identification of the auditee's key representative participating in the audit
g) the working and reporting language(s) of the audit where this is different from the native language of the auditor(s) and/or the auditee
h) the identification of roles and responsibilities of the audit team members and any accompanying persons
i) the audit report topics (including any methods of nonconformity gradings), format and structure, expected date of issue and distribution
j) logistical arrangements (travel, on-site etcetra)
k) matters related to confidentiality
l) any arrangements for audit follow-up actions.

The plan is to be presented to the manufacturer prior to conducting all certification audits but may not be necessary for all surveillance audits.

Any objections by the auditee should be resolved among the audit team leader, the auditee, the audit client and ExCB management before continuing the audit.

The audit plan should be sufficiently flexible to permit changes, such as any changes in emphasis, which can become necessary as the on-site audit activities progress. Any revised audit plan should be agreed among the parties concerned before continuing the audit.

6.4.2 Audit teamwork assignments

When an audit is conducted by an audit team comprising more than one auditor, the audit team leader, in consultation with the audit team, should assign to each team member responsibility for auditing specific management system processes, functions, sites, areas or activities. Such assignments should take into account the need for auditor independence, competence and efficient use of resources as well as different roles and responsibilities of auditors, auditors-in-training, and technical experts. Changes to the work assignments can be made to ensure the achievement of the audit objectives.

The audit team members should review the relevant information related to their audit assignments and prepare any work documents necessary for those assignments.

6.4.3 Work documents

Work documents used by the audit team for the purpose of reference and/or recording the proceedings of the audit can include:

a) audit procedures, checklists and audit sampling plans
b) forms for recording information, supporting evidence, records of audit findings and meetings.

The use of work documents, such as checklists and forms, should not restrict the extent of audit activities.

Work documents, and any records resulting from their use, should be retained, at least until audit completion. The requirements for the retention of documents, including records, after audit completion, are described in clause 6.6.3. Those records involving confidential or proprietary information should be suitably safeguarded at all times by the audit team members.

6.5 On-site audit activities

6.5.1 Opening meeting

An opening meeting should be held to confirm the audit plan, clarify how the audit activities will be undertaken, and to establish communications. The opening meeting should be held with the auditee's management or, where appropriate, those responsible for the functions or processes to be audited. The opening meeting should also include opportunity to the auditee to ask any questions.

The meeting should be formal and records of the attendance should be kept. The meeting should be chaired by the audit team leader and the following items considered, as appropriate:

a) introduction of the participants, including an outline of their roles
b) confirmation of the audit objectives, scope and criteria
c) confirmation of the audit timetable and other relevant arrangements with the auditee, such as the date and time for the closing meeting, any interim meetings between the audit team and the auditee's management, and any late changes
d) methods and procedures to be used to conduct the audit, advising the auditee that the audit evidence will only be a sample of the information available and that therefore there is an element of uncertainty inherent in all audits
e) confirmation of formal communication links between the audit team and the auditee
f) confirmation of the language to be used during the audit
g) confirmation that during the audit, the auditee will be kept informed of audit progress
h) confirmation that any resources and facilities needed by the audit team are available
i) confirmation of matters relating to confidentiality

j) confirmation of relevant work safety, emergency and security procedures for the audit team
k) confirmation of availability, roles and identities of any guides
l) method of reporting including any grading of non-conformities
m) information about conditions on which the audit can be terminated
n) information about any appeal system on the conduct or outcome of the audit.

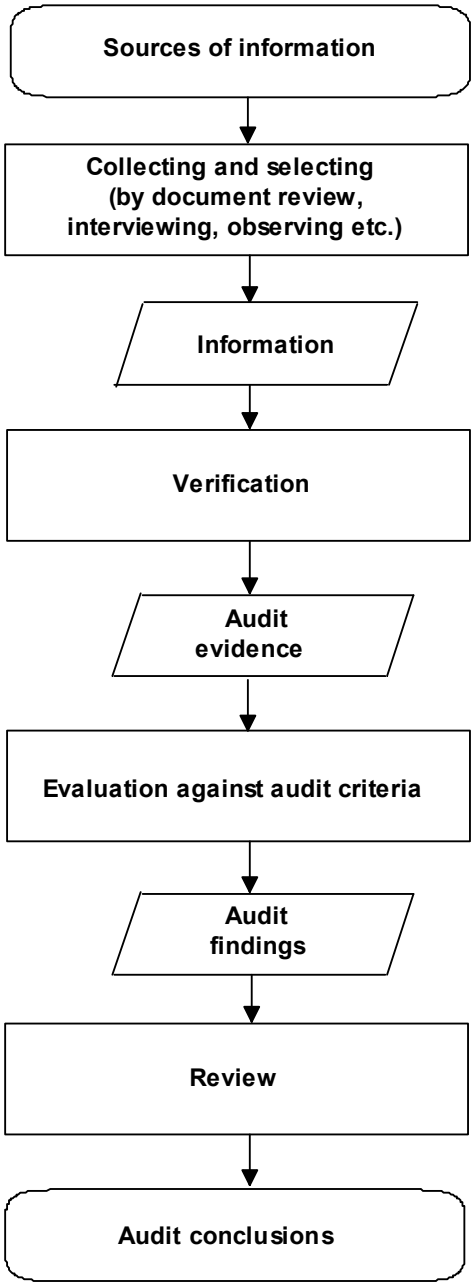
6.5.2 Roles and responsibilities of guides

Where guides are assigned, they should assist the audit team and act on the request of the audit team leader. Their duties can include ensuring that rules concerning site safety and security procedures are known and respected by the auditors, and they can also witness the audit on behalf of the auditee. Guides should not influence or interfere with the conduct of the audit except where, with the agreement of the auditor, the guide can provide clarification or assist in establishing correct information.

6.5.3 Collecting and verifying information

Figure 3 provides an overview of the process steps from collecting information to reaching audit conclusions.

Figure 3 - Flowchart of the process from collection of information to reaching of audit conclusions.



Information relevant to the audit objectives, scope, and criteria, including information relating to interfaces between functions, activities, and processes should be collected during the audit. It should be verified by the auditor(s) and can then be considered to be audit evidence. Audit evidence should be identified as such and recorded.

NOTE The audit evidence will inevitably be only samples of the information available, since an audit is conducted during a finite period of time and with limited resources. There is thus an element of uncertainty inherent in all audits, and those acting upon the audit conclusions should be aware of this uncertainty.

The sources of information chosen can vary according to the scope and complexity of the audit and can include:

a) interviews
b) observations of activities and the surrounding work environment and conditions
c) documents, including, for example, policy, objectives, plans, procedures, instructions, product certificates and notifications, specifications, drawings, contracts orders
d) records, such as inspection records, minutes of meetings, reports or logbooks on customer complaints and other relevant communication from external parties, audit reports, monitoring programmes and results of measurements
e) data summaries, analyses, metrics and performance indicators
f) records of the basis of relevant auditee's sampling programmes and the procedures for ensuring effective quality control of sampling and measurement processes
g) reports from other sources, for example, customer feedback, external reports and vendor external providers ratings
h) computerised data bases and web sites.

Practical Help – *Interviews*

Interviews are one of the important means of collecting information and should be carried out in a manner adapted to the situation and person interviewed. However, the auditor should consider the following:

a) interviews should be held with persons from different levels and functions, and especially with persons performing activities or tasks within the scope of the audit
b) whenever possible, the interview should be conducted during normal working hours and at the normal workplace of the interviewed person
c) every attempt should be made to put the interviewed person at ease prior to the interview;
d) the reason for the interview and any note taking should be explained
e) interviews can be initiated by asking the persons to describe their work
f) the results from the interview should be summarised and reviewed with the interviewed person
g) questions that bias the answers (leading questions) should be avoided
h) the interviewed persons should be thanked for their participation and co-operation

6.5.4 Audit findings

Collected audit evidence should be evaluated against the audit criteria to generate the audit findings. An audit finding can indicate either conformity or nonconformity with audit criteria. If so decided, audit findings can be graded in accordance with the audit plan.

An audit team should meet as needed to review the audit findings at appropriate stages during the audit.

Conformities should be summarised to at least indicate locations, functions, processes, or requirements that were audited.

Individual audit findings of conformity should also be recorded and supported with audit evidence.

Nonconformities should be recorded and supported by audit evidence. Nonconformities should be reviewed with an appropriate auditee representative to obtain acknowledgement of the audit evidence. The acknowledgement indicates that the audit evidence is accurate, and that the nonconformity is understood. Every attempt should be made to resolve any divergence of opinion concerning the audit evidence and/or findings, and unresolved points should be recorded.

The audit team leader shall determine whether it is possible for the auditee to correct any nonconformities raised, prior to the completion of the audit.

6.5.5 Communication during the audit

Dependent upon the scope and complexity of the audit, it can be necessary to make formal arrangements for communication during the audit.

An audit team should confer at least daily in order to exchange information, assess audit progress, and reassign work between auditors as needed.

During the audit, the audit team leader should periodically communicate the status of the audit and any concerns to the auditee and audit client, as appropriate. Any evidence collected in the audit that suggests a significant risk exposure should be reported immediately to the auditee and, as appropriate, to the audit client.

Where the available audit evidence indicates that the audit objectives are unattainable, the audit team leader should report the reasons to the audit client and the auditee to determine the appropriate action. Such action can include reconfirmation of the audit plan, termination of the audit or a change in the audit objectives.

Any concern about an issue outside the audit scope should be noted and reported to the audit team leader, for possible communication to the audit client and auditee. Any need for changes in the audit scope which may become apparent as on-site auditing activities progress should be reviewed with and approved by the audit client and, as appropriate, the auditee.

6.5.6 Preparation for the closing meeting

The audit team should confer prior to the closing meeting in order to:

a) review the audit findings and any other appropriate information collected during the audit
b) prepare a list of audit findings, if appropriate
c) reach consensus on the audit conclusions
d) agree on roles and tasks for the closing meeting
e) prepare recommendations, if specified by the audit objectives
f) discuss subsequent audit follow-up, if appropriate.

In many instances a simplified approach can be taken for the audit team review, depending on the audit objectives and scope and the audit team size.

6.5.7 Closing meeting

A closing meeting should be held to present audit findings and conclusions in such a manner as to ensure that they are understood and acknowledged by the auditee, and to agree, if appropriate, on the time period for the auditee to present any corrective action plan.

The meeting should be formal and records of attendance should be kept. The meeting chaired by the audit team leader should be held with the auditee's management and those responsible for the functions audited.

Any unresolved diverging opinions relating to audit findings and/or conclusions between the audit team and the auditee should be discussed and, if possible, resolved. If not resolved, both opinions should be recorded.

6.6 Reporting on the audit

6.6.1 Audit report preparation and content

The audit team leader should be responsible for the preparation and contents of the audit report.

The audit report should provide a complete, accurate, concise and clear record of the audit and should contain audit conclusions on issues such as the following, if within the audit objectives and scope:

- extent of conformance of the quality management system to the requirements of ISO/IEC 80079-34
- the effective implementation and maintenance of the quality management system, relevant to the requirements of ISO/IEC 80079-34
- the ability of management review process to ensure the continuing suitability, adequacy, and effectiveness of the quality management system, relevant to the requirements of ISO/IEC 80079-34

The audit report should also include, or make reference to the following:

a) the identification of the organisational and function units or processes audited
b) the identification of the manufacturer and audit client
c) the identification of audit team members
d) the date(s) and place(s) the on-site audit activities were conducted
e) the audit criteria, and, if applicable, a list of reference documents, against which the audit was conducted, for example, ISO/IEC 80079-34
f) the audit findings.

The audit report can also include or reference, as appropriate:

g) the agreed audit objectives, scope and plan
h) the time period covered by the audit
i) the identification of the auditee's key representatives participating in the audit
j) a summary of the audit process including any obstacles encountered
k) a statement of the confidential nature of the contents
l) a distribution list for the audit report
m) confirmation that the audit objectives have been accomplished within the audit scope in accordance with the audit plan
n) any agreed follow-up action plans
o) any unresolved diverging opinions between the audit team and the auditee
p) areas not covered, although within the scope.

6.6.2 Report approval and distribution

Every attempt shall be made for the audit report to be submitted to the audit client within one month from the date of the audit. The audit team leader should be responsible for monitoring this. If this is not possible, the audit team leader shall inform the audit client of the reasons for the delay and a revised issue date then agreed.

The audit report shall be dated and reviewed by the relevant ExCB Manager and approved by a nominated representative within the ExCB.

The audit report should then be distributed as follows:

- Original to the audit client
- A copy to be retained by the IECEx Certification Body

When the audit report has been issued to the audit client, the ExCB conducting the audit shall register the QAR on the official IECEx On-Line System, www.iecex.com

Note: Refer to Operational Document OD 011-2 for guidance regarding On-Line issue of QARs.

The confidentiality of the audit report should be respected and appropriately safeguarded by the audit team members and all report recipients.

6.6.3 Retention of documents

The audit report should be retained for a period not less than 10 years by the IECEx Certification Body, or longer at their own discretion.

Unless required to do so by law, the IECEx Certification Body, audit team and those responsible for managing the audit programme should not disclose the contents of documents, any other information obtained during the audit, or the audit report, to any other party without the explicit approval of the audit client and, where appropriate, the approval of the auditee. If disclosure of the contents of any audit document is required, the audit client and auditee should be informed as soon as possible.

6.7 Audit completion

The audit is completed when all activities in the audit plan have been finalised and the approved audit report has been distributed to the manufacturer with a copy retained by the IECEx Certification Body.

6.8 Audit Follow-up

6.8.1 Review

The IECEx Certification Body should review the lead auditors audit report, any non conformities raised and the manufacturer's responses, and then the IECEx Certification Body should approve the report.

The IECEx Certification Body should have a unified method of addressing the actions required following an audit.

The following rating system is provided for guidance.

RATING	DEFINITION	ACTION FOLLOWING AN INITIAL ASSESSMENT OR RE-ASSESSMENT	ACTION FOLLOWING A SURVEILLANCE VISIT
A	Where a quality management system fully meets the requirements or where there are only very few minor nonconformities. Also where compliance of the product is observed during a product audit.	Issue new or updated IECEx QAR	Issue updated IECEx QAR
B	Where the quality management system has a series of minor nonconformities Also where compliance of the product is observed during a product audit.	Issue new or updated IECEx QAR upon receipt of satisfactory documentary evidence supporting effective corrective action which is then subject to verification at the next surveillance visit	Issue updated IECEx QAR upon receipt of an acceptable corrective action plan, which is subject to verification at the next visit.

RATING	DEFINITION	ACTION FOLLOWING AN INITIAL ASSESSMENT OR RE-ASSESSMENT	ACTION FOLLOWING A SURVEILLANCE VISIT
C	Where the quality management system has major nonconformities and, or there is a non-compliant product observed during the product audit.	Issue new or updated IECEx QAR only after a satisfactory follow-up visit has verified that the corrective actions have been effectively documented and implemented.	Issue updated IECEx QAR only after a satisfactory follow-up visit has verified that the corrective actions have been effectively documented and implemented. Should the manufacturer fail to take timely and effective corrective action, then the IECEx Certification Body reserves the right to suspend or cancel the IECEx Certificate of Conformity.
D	Where the quality management system has many major nonconformities which may include non-compliant product observed during the product audit	Issue new or updated IECEx QAR only after a further complete assessment of the quality management system has been satisfactorily completed.	Suspend the IECEx Certificate of Conformity pending a further complete assessment to re-establish the effectiveness of the quality management system. This is to be followed by surveillance visits at a frequency which maintains confidence in the effectiveness of the quality management system.
E	Where there is no quality management system or a system that has serious deficiencies rendering it ineffective	Close the application, no IECEx QAR to be issued or re-issued	Cancel the IECEx Certificate of Conformity and inform other IECEx Certification Bodies

6.8.2 Issue of QAR

A Quality Assessment Report (QAR) shall be valid for a period not exceeding 3 years.

IECEx Certification Bodies shall register the QAR on the IECEx Website in accordance with Operational Document OD 011 Part 2. This On-line registration provides the following summary information, which is publicly available.

- QAR reference number
- ExCB conducting the audit
- Manufacturer and audit location(s)
- IECEx Certificates of Conformity linked to the QAR
- Comments of the ExCB if any

In accordance with OD 011-2, the online QAR summary should include the Manufacturer's name in the "Manufacturer" field, and the location(s) audited in the "Site(s) Audited" field. The ExCB shall consider whether a separate QAR is needed for each site audited.

The "Comments" field or Annex C of a completed IECEx Form F-001 may be attached to the QAR summary to explain the relationships between sites audited, in cases when different critical operations take place at different locations. One exception to this is for Case 2 or Case 3 Trade Agents per OD 203, when the relationship between the trade agent and OEM is to be kept confidential. In these cases, the details are to appear in the QAR but not in the online QAR summary.

In addition, IECEx Certification Bodies shall inform the IECEx Secretary of any IECEx Certificates of Conformity that are to be suspended or cancelled. This will ensure that other IECEx Certification Bodies are informed of all Certificates that are issued, suspended or cancelled.

7 Application of remote auditing methods

7.1 Introduction

Manufacturer audits shall be conducted on-site and in-person unless otherwise provided for in this section. Remote audits that are required due to extraordinary circumstances or events are handled in accordance with IECEx OD 060.

ExCBs conducting remote audits shall be compliant with IAF MD 4 requirements. Demonstration of this can be provided by national accreditation to conduct remote audits OR by verification via assessments conducted in accordance with IECEx OD 003-2 and IECEx OD 032.

7.2 Allowances for utilization of remote auditing methods

Utilization of remote auditing methods is permitted when the location being audited has a limited scope that does not include production or final release of the product and the ExCB determines that a complete assessment of the responsibilities of that location can be conducted effectively without being on-site. This shall be carried out by identifying and documenting the risks and opportunities that may impact audit/assessment effectiveness. The decision-making process should follow the activities and practices outlined in ISO/IEC TS 17012. Records supporting the decision-making process shall be maintained and be available for review during peer assessments of the ExCB and upon request from the IECEx Secretariat.

NOTE: Typically, such situations involve a manufacturer that controls the design of a product and its certification, but contracts others to act as manufacturing locations, production sites, etc. Furthermore, utilization of remote auditing methods may be suitable for manufacturers with multiple sites where particular sites perform limited ancillary functions, such as the management of training records, oversight of the recall of nonconforming product process, internal auditing, management review, or customer-related processes (for example, order entry and contract review). Remote audits shall not be used as the regular or preferred method of auditing sites that perform critical functions such as production and final release.

Care must be taken to ensure that all critical activities that could affect the compliance of the product are audited effectively and in cases of doubt, an on-site audit is required.

An audit utilising remote auditing methods may only proceed once a fully documented plan is established and sufficient documentation and client personnel are available to ensure an acceptable outcome of a full and complete audit.

7.3 Preparing for a remote audit

Utilization of remoting auditing methods shall be conducted using the same principles and requirements detailed in this Operational Document unless otherwise identified in this section.

7.4 Remote Audit Steps

7.4.1 Pre-remote Audit document review

Utilization of remote auditing methods should include a pre-audit document review whereby the manufacturer provides sufficient documents to allow a review by the auditor prior to conducting the remote auditing activities. If required, upon successful completion of the pre-audit document review, the results of the document review may be provided to the manufacturer to assist with the remote auditing activities.

7.4.2 Remote auditing activities

It is expected that the activities involved in utilization of remote auditing methods (by use of, for example, Zoom, MS Teams etcetera) should include at least the following:

- opening meeting
- completion of the document and records review
- video tour of the facility, witnessing of measuring equipment and applicable routine testing, if applicable
- closing meeting to discuss the audit findings.