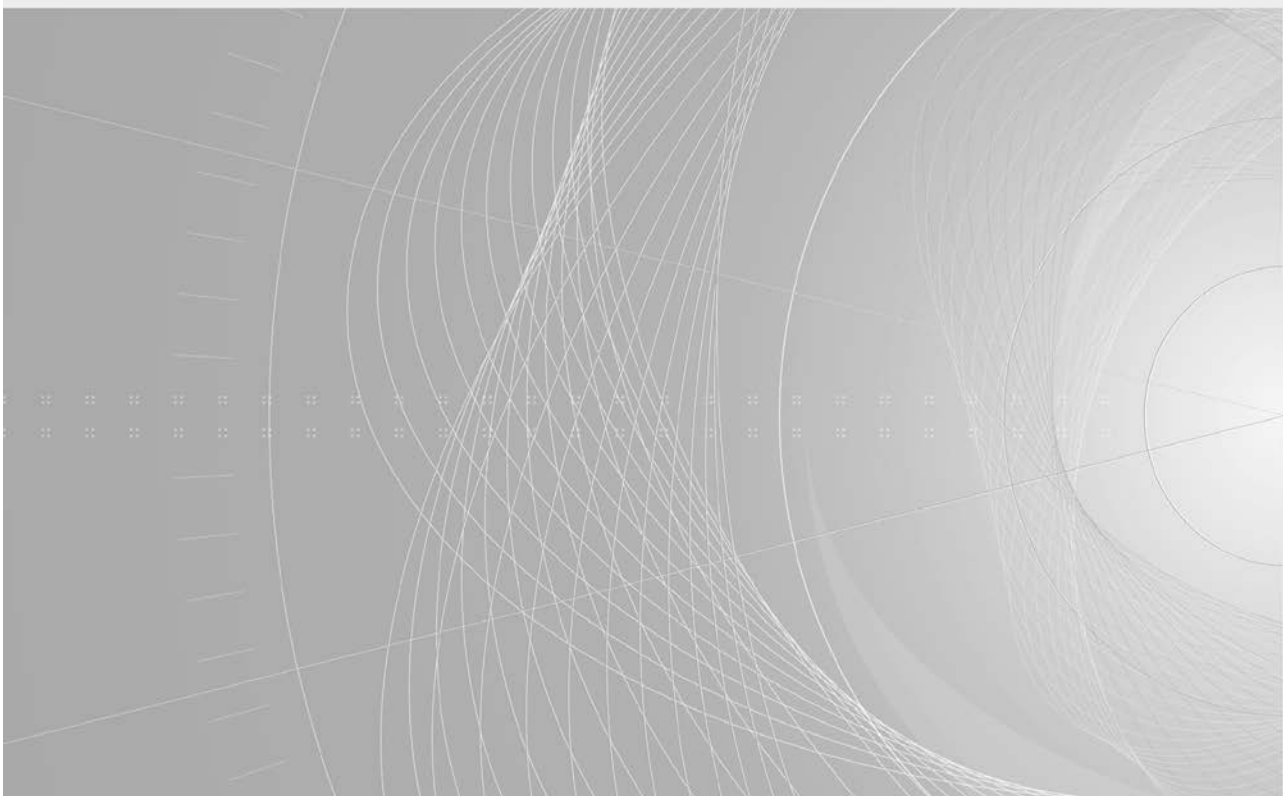# IECEx OD 026

Edition 3.0 2017-10

IECEx OPERATIONAL DOCUMENT

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

IECEx Certified Equipment Scheme –

Guidelines for qualifying Lead Auditors and Auditors, in accordance with the IECEx System.

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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 (QAR) in accordance with IS0/IEC 80079–34.

The purpose of this document is to provide guidance when qualifying Lead Auditors and Auditors to conduct assessments and audits of manufacturer's quality systems in a uniform manner. It is expected that ExCBs would use this document as guidance when developing their own specific requirements.

This document is based on work conducted by the European Notified Bodies Group for ATEX and in turn is based upon *ISO 19011:2011 Guidelines for auditing management systems.*

> NOTE ISO 19011: 2011 uses the term "audit" throughout but IECEx 02 uses the separate terms "assessment and surveillance". For the purpose of this document the term "audit" is applicable to both "assessment and surveillance".

This Edition 3.0 as circulated as ExMC/1252/DV and subsequently approved by the 2017 ExMC Meeting (via Decision 2017/43 replaces Edition 2.0 upon publication.

1 Competence of quality management system auditors to perform IECEx related audits

1.1 Introduction

In order to ensure that reliance can be placed on the audit process, it is essential that auditors be competent. To become an IECEx product certification auditor, a person needs to demonstrate the competence to conduct audits, i.e. the capability to apply knowledge and skills that are necessary to conduct audits. Personal attributes, education, audit training, work, and audit experience are the building blocks for the knowledge and skills needed to be a competent auditor.

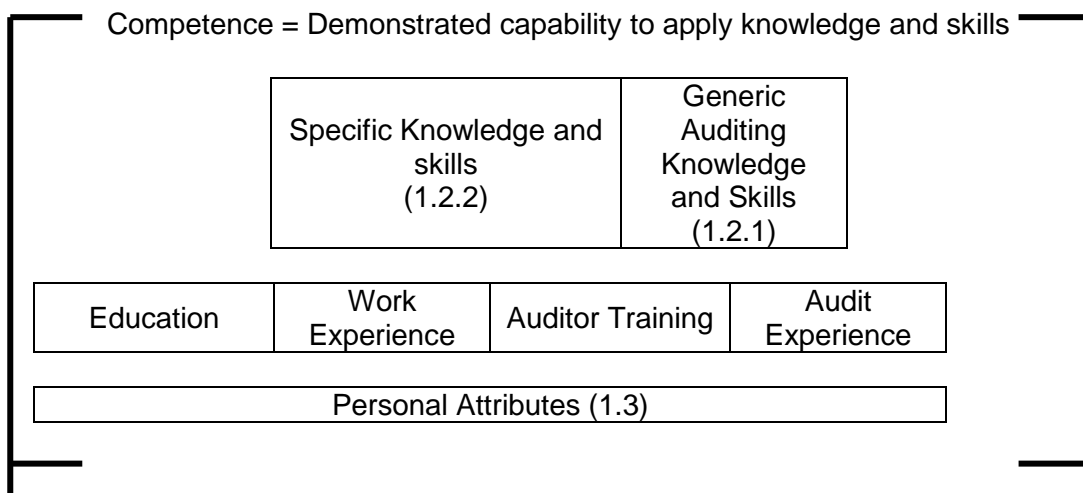These relationships are shown in Figure 1.

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┌─────────── Competence = Demonstrated capability to apply knowledge and skills ───────────┐

                    ┌─────────────────────┬─────────────────────┐
                    │                     │      Generic        │
                    │  Specific Knowledge │     Auditing        │
                    │      and skills     │    Knowledge        │
                    │       (1.2.2)       │    and Skills       │
                    │                     │      (1.2.1)        │
                    ├──────────┬──────────┴──────┬──────────────┤
                    │          │     Work        │    Audit     │
         Education  │          │  Experience     │  Auditor Training │  Experience │
                    ├──────────┴─────────────────┴──────────────┤
                    │        Personal Attributes (1.3)          │
                    └───────────────────────────────────────────┘
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Figure 1 - Relationship between the various elements of product certification auditor competence

In addition to describing the building blocks this clause outlines the knowledge and skills needed to become:
a) an IECEx product certification auditor with knowledge and experience in assessment and auditing of quality management systems;
b) an IECEx audit team leader.

This clause also describes a process for evaluating product certification auditors and audit team leaders.

The evaluation process described should first be used to conduct the initial evaluation of a person who wishes to become a product certification auditor.

Providing competent auditors is only the first step towards ensuring the reliability of the audit process. The second step is selecting the appropriate auditor(s) for the audit team to ensure audit team competence for a specific audit. The

evaluation criteria described in table 3 should be used for selecting auditors to a specific audit team.

Figure 2 illustrates the relationship between the initial evaluation of an auditor, audit team selection, continuing professional development, maintenance of auditing ability and the continual process of auditor evaluation.
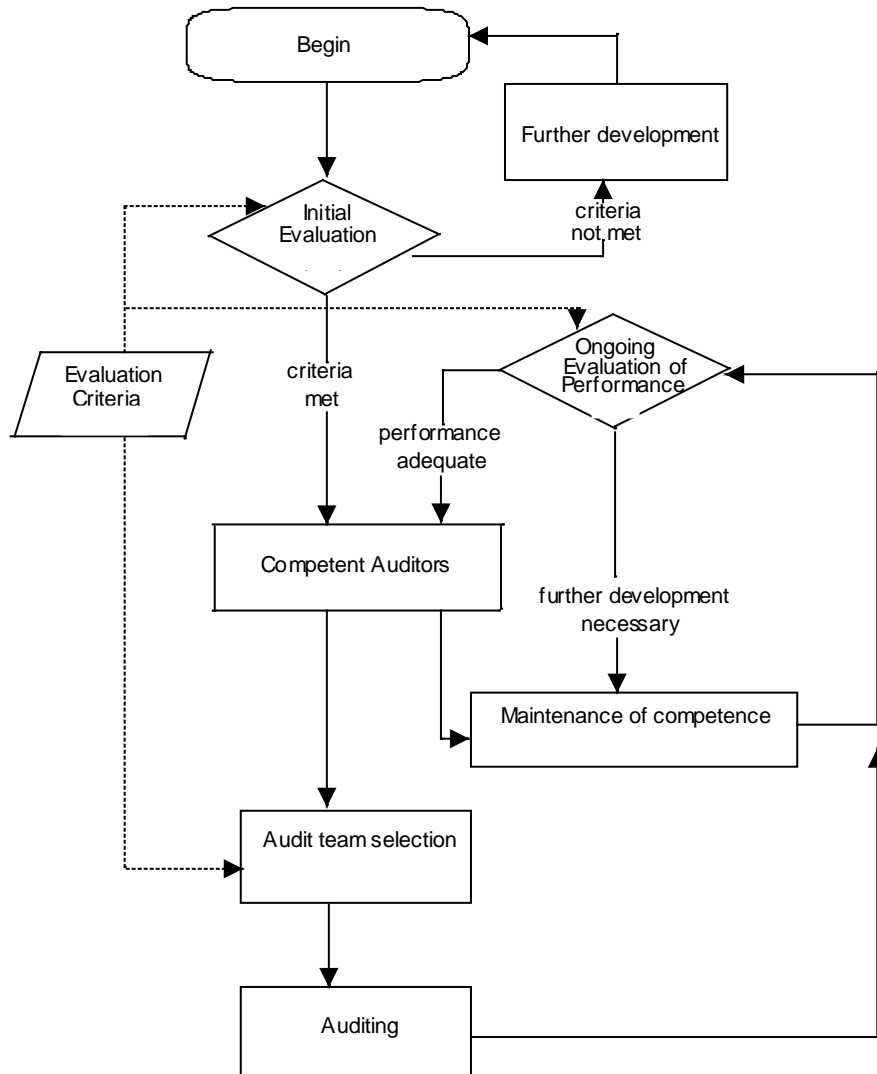

Figure 2 - Initial and on-going evaluation of auditors and audit team selection

1.2 Knowledge and skills

Sub-clauses 1.2.1 and 1.2.2 covers the knowledge and skills that apply to IECEx product certification auditors.

1.2.1 Generic Auditing knowledge and skills of quality management system auditors

Product certification auditors should have knowledge and skills in the following areas:

a) audit procedures, tools and methods - to enable the auditor to select and apply those appropriate to different audits and ensure that audits are conducted in a consistent and systematic manner. An auditor should be able to:

- apply audit procedures, tools and methods;

- plan and organise the work effectively;

- conduct the audit in a timely manner;

- prioritise and focus on matters of significance;

- collect information through effective interviewing, listening, observation, reviewing documents, including records;

- verify the accuracy of collected information;

- confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions;

- assess audit risk;

- understand the appropriateness and consequences of using sampling techniques;

- record audit activities through work documents;

- prepare audit reports that are clear and concise;

- hold information confidential;

- communicate effectively, either through personal linguistic skills or through the support of a competent interpreter.

b) management system and reference documents - to enable the auditor to comprehend the scope of the audit and apply audit criteria. Knowledge and skills in this area should cover:

- application of management systems to different organisations;

- interaction between the components of the management system;

- quality management system standards, applicable procedures or other management system documents used as audit criteria;

- differences between and priority among the reference documents;

- application of the reference documents to different audits;

- information systems and technology for the management, authorisation, distribution and control of documents, data and records.

c) organisational situations - to enable the auditor to comprehend the auditee's operational context. Knowledge and skills in this area should cover:
  - organisational size, structure, functions, and interrelationships;

  - general business processes and related terminology;

  - cultural and social customs of the auditee;

  - language of the auditee.

d) applicable laws, regulations and other requirements relevant to the discipline to enable the auditor to work within, and be aware of the requirements that apply to the organisation being audited. Knowledge and skills in this area should apply to:
  - contracts and agreements;

  - labour, workplace safety, and working conditions;

  - activities products and services;

  - international treaties and conventions:

  - production environment.

1.2.2 Specific knowledge and skills of product certification auditors

Product certification auditors should have knowledge and skills in the following:

a) product quality related methods and techniques - to enable the auditor to examine those aspects a quality management system relevant to the production of Ex products and to generate appropriate audit findings and conclusions. Knowledge and skills in this area should include:

  - quality terminology;

  - quality management principles and their application;

  - product quality plans and their application as part of an overall quality management system

  - quality tools and their application (for example statistical process control, failure mode and effect analysis, etc).

b) products, including services, and operational processes, to enable the auditor to comprehend the technological context in which the audit is being conducted. Knowledge and skills in this area should include:

  - Ex terminology;

  - critical characteristics of Ex related processes and products, including services;

  - Ex product assessment and testing processes and practices.

- Up to date knowledge of IEC standards relating to products covered by the IECEx System

Auditors should have:
- not less than 3 years recent experience working directly with or associated with certified products;
- an understanding of the IECEx System, associated terminology and relevant Standards;
- an understanding of critical characteristics of processes and products;
- an understanding of sector IECEx processes and practices.

1.3 Personal attributes
Personal attributes contribute to the successful performance of an auditor. An auditor should be:
a) open minded - willing to consider alternative ideas or points of view;
b) diplomatic - tactful in dealing with people;
c) observant - constantly and actively aware of physical surroundings and activities;
d) perceptive - instinctively aware and able to understand and adapt to situations;
e) tenacious - persistent, focused on achieving objectives;
f) decisive - reaching timely conclusions based on logical reasoning and analysis;
g) self-reliant - acts and functions independently while interacting effectively with others;
h) ethical - fair, truthful, sincere, honest and discreet.

1.4 Education, work experience, audit training and audit experience

1.4.1 Introduction
This sub-clause describes the building blocks needed to acquire the knowledge and skills described in sub-clause 1.2. Table 1 provides the recommended levels of education, work experience, auditor training and audit experience. Table 1 can be used to establish the evaluation criteria in Table 3. The appropriate levels can vary and will depend on:
- the overall competence of the individual;
- the objectives and scope of the audit programme;
- size, nature and complexity of the organisation to be audited;
- certification/registration requirements; and
- complexity of the management system.

1.4.2   Product Certification Auditor

To acquire the knowledge and skills necessary to become a product certification auditor a person should have:

a)   Education - completed an education sufficient to permit the acquisition of knowledge and skills defined in clause 1.2.

b)   Work experience - work experience in a technical, managerial or professional position involving the exercise of judgement, problem solving and communication with other managerial or professional personnel, peers, customers and/or other interested parties.

Part of the work experience should be in a position where the activities undertaken contribute to the development of knowledge and skills in the quality management field.

c)   Auditor training - undergone training that contributes to the development of the knowledge and skills described in sub-clause 1.2.1. Training may be provided by the person's own organisation or by an external organisation.

d)   Audit experience - gained experience in the audit activities described in clause 6. The overall audit experience should cover the complete audit process and the entire quality management system standard. This experience should have been gained under the supervision and guidance of an audit team leader in the same discipline. This on-the-job training should be current.

NOTE: In exceptional cases, e.g. where the audit programme or quality system Standard has been recently introduced, alternative methods may be considered to provide guidance and supervision to the auditor-in-training. However, in such cases care should be taken to ensure that the overall reliability of the audit process is not impaired.

1.4.3   Audit team leader

Prior to assuming responsibility for leading an audit team an auditor should:

a)   demonstrate the knowledge, skills and personal attributes necessary for effective leadership and efficient management of the audit. This includes planning, organising, directing, performing and reporting audits;

b)   have performed the additional audits recommended in Table 1 acting as an audit team leader under the supervision and guidance of another auditor who is competent as an audit team leader;

c)   be able to reach audit conclusions on the overall capability of the quality management system.

Table 1 - Recommended education, training and work and audit experience

	Product Certification Auditor (see Note 3)	**Additional audit experience for an audit team leader**
Education	Secondary education (see Note 1)	No additional recommendations
Total work experience	5 years (see Note 2)	No additional recommendations
Quality work experience	at least 2 years of the total 5 years	No additional recommendations
Auditor training	40 hours of audit Training	No additional recommendations
Audit experience	Four (4) complete audits in any field and not less than eight (8) days of audit experience as an auditor in training. These audits should have been completed within the last three consecutive years.	Three (3) complete audits and not less than six (6) days of audit experience acting in the role of an audit team leader. These audits should have been completed within the last three consecutive years.

NOTE 1:   Secondary education is that part of a national educational system that comes after the primary or elementary stage, but that is completed prior to entrance to a university or similar educational institution. Plus a recognised qualification in a relevant technical subject.

NOTE 2:   The number of years of work experience may be reduced by one year if the person has completed appropriate post-secondary education.

NOTE 3:   Where an audit is conducted by a sole auditor, then that auditor should have all the competencies of an audit team leader.

1.5   Maintenance and improvement of knowledge and skills

1.5.1 Continuing professional development
Continuing professional development is concerned with maintenance and improvement of knowledge and skills. Auditors should demonstrate their continuing professional development.

The continuing professional development activities should take into account changes in the needs of the individual and the organisation, the practice of auditing, standards and other requirements.

This can be achieved through a number of means such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities.

1.5.2 Maintenance of auditing capability

Auditors should maintain and demonstrate their auditing capability through regular participation in quality related audits and utilising ISO/IEC Guide 62, ISO/IEC 17065, ISO/IEC 17025 and ISO 14000.

1.6 Auditor evaluation process

The initial and continual evaluation of product certification auditors and audit team leaders should be planned, implemented and recorded in accordance with audit programme procedures to provide an outcome that is objective, consistent, fair and reliable. The evaluation process should ensure auditing capability, Ex knowledge and identify training and other skill enhancement needs.

Evaluation can be undertaken by a person or a panel utilising methods listed in Table 2. Table 3 illustrates the application of these methods to the evaluation of auditor competence.

Evaluation criteria (see Table 3) appropriate to the situation should be developed for each evaluation.

The process begins with the identification and initial evaluation of persons who wish to become product certification auditors in the Ex field.

The on-going evaluation of auditor performance to identify opportunities for maintenance and improvement of knowledge and skills is also a part of the auditor evaluation process.

Where the evaluation criteria are not met, additional training, work and/or audit experience are required. Following this there should be confirmation that the evaluation criteria have been met.

The methods for obtaining the information to compare against the criteria should be identified, see Tables 2 and 3. In using Tables 2 and 3, the following should be noted:

- the methods outlined represent a range of options and may not apply in all situations;

- the reliability of the various methods outlined can differ;

- typically, a combination of methods should be used to ensure an outcome that is objective, consistent, fair and reliable.

Table 2 - Evaluation Methods

Evaluation Method	Objectives	Examples
Records review	Records are reviewed to verify the background of the auditor	Analysis of records of education, training, employment, Ex experience and audit experience
Interview	Interviews are used to evaluate personal attributes, communication skills, verify information, test knowledge of both Ex and auditing processes, acquire additional information	Face to face and telephone interviews
Observation	Observation is used to evaluate personal attribute and the application of skills and knowledge	Role playing, witnessed audits, on the job performance
Post audit review	Post audit review is used where direct observation may not be possible or appropriate	Review of audit reports, debriefing with colleagues and clients, debriefing with the auditor
Testing	Testing is used to evaluate personal attributes and knowledge and skills and their application	Oral and written exams, psychometric testing
Feedback	Feedback (positive and negative) is used to provide information about how the performance of the auditor is perceived.	Surveys, questionnaires, personal references, testimonials, complaints

Table 3 - Examples of methods for evaluating auditor competence

Evaluation Criteria	Evaluation Method	Audit procedures, tools and techniques	Management systems and reference documents	Organisational situations	Relevant laws, regulations and other requirements	Quality related methods and techniques	Ex Products, services, and operational processes	Technical aspects of operations
Relevant Education (including Ex training)	Review records of education Obtain feedback from instructors or educational institutions		■	■	■	■		■
Relevant work Experience (including Ex experience)	Review records of Employment Obtain feedback from employers and supervisors		■	■	■	■	■	■
Completion of relevant training course(s)	Review training records: course content and result Obtain feedback from the training course provider		■		■	■	■	■
Personal attributes	Psychometric testing Interview the auditor Obtain feedback from the audit team leader and other members of the audit team Obtain feedback from audit clients Witness the person perform an audit(s) Role playing	■		■				
Completion of an auditor training course	Review training records: course content and result Obtain feedback from the training course provider	■						
Examination(s) results	Review test results	■	■		■	■		■
Audit experience: number of audits and audit days, complexity and type of audits completed	Review records of participation such as audit logbooks, audit reports	■	■	■			■	■
Auditor performance	Observe the person conduct audit(s) Conduct post audit review(s) Obtain feedback from the audit team leader and other members of the audit team Obtain feedback from audit clients	■	■	■			■	■

NOTE: In this table the dark shaded areas indicate the evaluation method and evaluation criteria that should apply to evaluate the knowledge and skills