ExNB	Co-ordination of Notified Bodies Directive 2014/34/EU of the European Parliament and of the Council (ATEX) *Equipment and protective systems intended for use in potentially explosive atmosphere*	**Clarification Sheet N° ExNB/CS/024**

Status:	**Step*5.2.2**	**Initial proposal by**	WG 04/13	**Date:**	2016-03-23
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Step refers to ExNB Rules

Management of assessment and surveillance programs for products covered by Annexes IV and VII of the ATEX Directive 2014/34/EU

Authorised by Chairman:	**Mr. Omerovic**	**Date:**	**2021-03-11**
Date of application:	**2021-03-11**	**Signature:**	

0 Introduction

The ATEX Directive (2014/34/EU) places responsibilities upon Notified Bodies for conducting assessment and surveillance activities and the issue of a Quality Assurance Notification (QAN) but it does not provide guidance upon the methodology of these activities.

Therefore, the purpose of this document is to provide guidance upon the methodology, so providing the opportunity for Notified Bodies to operate in a uniform manner.

This document expands upon the principles documented within ISO 19011:2018 and internationally recognised guidelines on this subject. As an ISO document, it is in the public domain and it also permits adaptation for other types of audits. Therefore, this document provides guidance for audits conducted by Notified Bodies with respect to Annex IV and VII of the ATEX Directive (2014/34/EU).

NOTE 1:

ISO 19011 uses the term “audit” throughout but the ATEX Directive uses the separate terms “assessment and surveillance” e.g. for legal, regulatory and similar purposes. For certification (see also the requirements in ISO/IEC 17021-1:2015). For the purpose of this document, the term “audit” is applicable to both “assessment and surveillance”.

NOTE 2:

The assessment of the QM system of the Ex-manufacturer should be focused on the fulfilment of the Health and Safety Requirements of the directive. If a manufacturer´s QM system is accordant to ISO 9001: 2008, then EN ISO/IEC 80079-34: 2011 should be applied. In case of a QM system of the manufacturer according to the ISO 9001:2015, the Notified Body, after consultation with the manufacturer, can follow the latest draft of the 2nd edition of the ISO/IEC 80079-34.

NOTE 3:

Subject:	**Directive, 2014/34/EU Article No.**	**Annex IV and VII**
	Directive, ESR No.	
	Directive, Module Annex No.	
	Standard, No.	ISO/IEC 80079-34:2018

In case of application EN ISO/IEC 17065:2012 for auditing activities according to module/s D, E (further module C1, but not in scope of this document) the relevant clauses of EN ISO/IEC 17021-1, chapter 9, shall be applied.

1 Scope

This document provides guidance on the principles of conducting assessment and surveillance visits, the management and planning of these activities and the qualification of auditors.

2 Normative references

ISO 9001:2015 Quality management systems – Requirements

ISO 9000:2015 Quality Management Systems - Fundamentals and Vocabulary.

ISO 19011:2018 Guidelines on quality and/or environmental management systems auditing.

EN ISO/IEC 80079-34:2011 Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture

EN ISO/IEC 80079-34:2020 Explosive atmospheres – Part 34: Application of quality systems for equipment manufacture

ISO/IEC 80079-34:2018 - Application of quality management systems for Ex Product manufacture

EN ISO/IEC 17065:2012 Conformity assessment — Requirements for bodies certifying products, processes and services

IAF GD 2:2005: Guidance on the Application of Guide 62:1996

ISO/IEC 17000:2020 - Conformity assessment - Vocabulary and general principles

EN ISO/IEC 17021-1: 2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems

3 Terms and Definitions

NOTE For the purpose of this document, the terms and definitions given in ISO 9000, ISO 19011 and ISO/IEC 17000 apply in addition.

3.1 Audit

Systematic, independent and documented process for obtaining audit evidence (3.3) and evaluating it objectively to determine the extent to which the audit criteria (3.2) are fulfilled

Additional in the guideline and related to EU Type Examinations:

Ex Product Audit

An **audit** (3.1) to determine whether the product complies with the type described in the EU Type Examination Certificate

3.2 Audit Criteria

Set of policies, procedures or requirements used as a reference against which audit evidence (3.3) is compared

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

3.3 Audit Evidence

Records, statements of fact or other information, relevant to the **audit criteria** (3.2) and which are verifiable.

NOTE: Audit evidence can be qualitative or quantitative.

3.4 Audit Finding(s)

Results of the evaluation of the collected **audit evidence** (3.3) against **audit criteria** (3.2)

NOTE 1: Audit findings indicate conformity or nonconformity.

Audit findings can indicate either conformity or nonconformity with **audit criteria** (3.3).

The audit findings can be identified with two levels:

- Minor nonconformity: nonconformity without any proven risk on the product(s)
- Major nonconformity: nonconformity with proven risk on the product(s)

NOTE 2: Audit findings can lead to the identification of opportunities for improvement or recording good practices.

NOTE 3: If the audit criteria are selected from legal or other requirements, the audit finding is termed compliance or non-compliance.

3.5 Audit Conclusion(s)

Outcome of an audit (3.1), after consideration of the audit objectives and all audit findings (3.4)

Outcome of an **audit** (3.1), provided by the **audit team** (3.10) after consideration of the audit objectives and all **audit findings** (3.5).

3.6 Audit Client

Organization or person requesting an **audit** (3.1)

NOTE: In the case of internal audit, the audit client can also be the auditee (3.7) or the person managing the audit program. Requests for external audit can come from sources such as regulators, contracting parties or potential clients.

3.7 Auditee

Organization being audited

3.8 Auditor

Person who conducts an **audit** (3.1)

3.9 Audit Team

One or more **auditors** (3.8) conducting an **audit** (3.1), supported if needed by **technical experts** (3.10)

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

NOTE 2: The audit team may include auditors-in-training.

3.10 Technical Expert

Person who provides specific knowledge or expertise to the **audit team** (3.9)

NOTE 1: Specific knowledge or expertise is that which relates to the organization, the process or activity to be audited, or language or culture.

NOTE 2: A technical expert does not act as an auditor (3.8) in the audit team.

3.11 Observer

Person who accompanies the audit team (3.9) but does not audit

NOTE 1: An observer is not a part of the audit team (3.9) and does not influence or interfere with the conduct of the audit (3.1).

NOTE 2: An observer can be from the auditee (3.7), a regulator or other interested party who witnesses the audit (3.1).

3.12 Guide

Person appointed by the auditee (3.7) to assist the audit team (3.9)

3.13 Audit Programme

Arrangements for a set of one or more **audits** (3.1) planned for a specific time frame and directed towards a specific purpose

3.14 Audit scope

Extent and boundaries of an **audit** (3.1)

NOTE: The audit scope generally includes a description of the physical locations, organizational units, activities and processes, as well as the time period covered.

3.15 Audit Plan

Description of the activities and arrangements for an **audit** (3.1)

3.16 Risk

Effect of uncertainty on objectives

NOTE: Adapted from ISO Guide 73:2009, definition 1.1.

3.17 Competence

Ability to apply knowledge and skills to achieve intended results

NOTE: Ability implies the appropriate application of personal behaviour during the audit process.

3.18 Conformity

Fulfilment of a requirement

3.19 Nonconformity

Non-fulfilment of a requirement

3.20 Management system

System to establish policy and objectives and to achieve those objectives

3.21 Initial Assessment

Audit (3.1) activities necessary to determine whether the manufacturer meets all the requirements of the relevant clauses of the **audit criteria** (3.2) (e.g. EN ISO/IEC 80079-34:2011) necessary for granting a Quality Assurance **Notification** QAN (3.24) and whether they are effectively implemented. These activities include a documentation review, an on-site audit at the manufacturer's premises, 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 a **Notification** (3.24) shall be granted.

3.22 Surveillance

Audit (3.1) activities necessary to verify that the approved quality system, upon which the **Notification** (3.24) is based, continues to be implemented, to consider the implications of changes to that system as a result of changes in the manufacturers operation and also to confirm continued compliance with any **QAN** (3.24) requirements. Surveillance of a manufacturers quality system shall take place on a regular basis as defined within this document.

The purpose of surveillance programmes is to:

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

3.23 Re-Assessment

Audit (3.1) activities necessary to verify overall continuing effectiveness of the manufacturer's quality system, upon which the **Notification** (3.24) is based, in its entirety

In most cases it is unlikely that a period greater than three years for periodic re-assessment would be acceptable. The re-assessment should provide for a review of past performance of the system over the period of the **QAN** (3.24). The re-assessment program should take into consideration the results of the above review and should at least include a review of the quality system documents and an on-site audit (which may replace or extend a regular surveillance audit) at the manufacturer's premises. 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;
- that a further period of Notification (3.24) is justified.

3.24 Quality Assurance Notification (QAN)

The approval given by an ATEX Notified Body to a manufacturer that has demonstrated conformity with the appropriate **audit criteria** (3.2) via implementation of a suitable quality system

4 Principles of auditing

Clause 4 of ISO 19011 applies.

5 Managing an audit programme

5.1 General

Clause 5.1 of ISO 19011 applies.

5.2 Establishing the audit programme objectives

Clause *5.2* of ISO 19011 applies with the following addition.

In addition to the above requirements, the audit programme should ensure that conformity with Annex IV or VII is maintained.

The audit should be conducted against the requirements of the applicable version or draft of EN ISO/IEC 80079-34 respectively (see clause 0 Introduction).

A manufacturer with a current ISO 9001 certificate does not automatically comply with all requirements of Annex IV or VII. The assessment programme should ensure all requirements of Annex IV or VII are addressed.

The initial audit programme should be of sufficient duration to ensure all audit programme objectives have been met. Where there is no current ISO 9001 certification in place, IAF GD 2:2005 should be used for determining the duration of the audit programme. (In most cases it is unlikely that a period less than two days would be acceptable). Where a manufacturer has a current ISO 9001 certificate, the duration of the assessment can be adjusted, but must ensure all appropriate requirements of Annex IV or VII are satisfied and recognised the number of different processes involved and/or products being manufactured. (In most cases it is unlikely that a period less than one day would be acceptable)

The durations in above paragraph may be extended where there is not a common language, or reduced (but not below the minimums) if processes are similar for several different products.

Surveillance visits will normally be conducted within before 18 months from the date of initial or recertification assessments. There may be circumstances that require a visit after a shorter period. (In most cases it is unlikely that a period less than one day would be acceptable). However, where there is no current ISO 9001 certification with an appropriate scope, this period should be reduced to 12 months (see EN 17021-1 clause 9.1.3.4 and EA 2/17 Tables 3 and 4). Additional surveillance visits may be conducted at the discretion of the Notified Body.

5.3 Audit programme responsibilities, resources and procedures and extent and identifying and evaluating audit programme risks

Clause 5.*3.* of ISO 19011 applies.

5.4 Audit programme implementation (objectives, scope and criteria for an individual audit, selecting the audit methods, selecting the audit team members and responsibility for the audit team leader, managing the audit programme outcome and managing and maintaining audit programme records)

Clause 5.4 of ISO 19011 applies.

5.5 Monitoring the audit programme

Clause 5.5 of ISO 19011 applies.

5.6 Reviewing and improving the audit programme

Clause 5.*6* of ISO 19011 applies.

6 Performing an audit

6.1 General

Clause *6.1* of ISO 19011 applies.

6.2 Initiating the audit

6.2.1 General

Clause *6.2.1* of ISO 19011 applies.

6.2.2 Establishing initial contact with the auditee and defining audit objectives, scope and criteria

Clause *6.2.2* of ISO 19011 applies with the following addition.

The objectives for the audit should include, but not be limited to:

a) conformity of the product with the type described in the EU Type Examination Certificate and with the requirements of Directive 2014/34/EU which apply to it;
b) management system requirements supporting conformity of the product;
c) customer feedback; and
d) the appropriate use of marks.

EN ISO/IEC 80079-34, in conjunction with Annex IV or VII, can be utilised as audit criteria for demonstrating conformity with the ATEX Directive (see also clause 0 Introduction).

An individual audit that is part of a surveillance programme may address only part of a quality management system.

6.2.3 Determining the feasibility of the audit

Clause *6.2.3* of ISO 19011 applies with the following addition.

Upon receipt of an application from a manufacturer for a QAN, the Notified Body should

- ensure the documentation as required by Clause 3.1 of Annex IV or VII, as appropriate, is available; and

- ascertain that sufficient and appropriate information regarding the manufacturer, and their key sub-contractors, are available e.g. size, location, status of quality system.

6.3 Preparing audit activities (performing document review in preparation for the audit, Preparing the audit plan, assigning work to the audit team, preparing work documents)

Clause 6.3. of ISO 19011 applies.

6.4 Conducting the audit activities

Clause 6.4. of ISO 19011 applies.

6.5 Preparing and distributing the audit report

Clause 6.5. of ISO 19011 applies with the following addition.

An example audit report can be found in ExNB19-QAR-Form[1]. Whilst its use is not mandatory, its content should be considered minimum information.

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

Unless required to do so by law, the Notified 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.

6.6 Completing the audit

Clause 6.6. of ISO 19011 applies.

A Notified Body should not to issue a QAN until all audit objectives have been satisfactorily completed and found to be compliant.

A Notified Body can amend the scope of an existing QAN (without a document review or site assessment visit) where the technology/processes are declared similar to those already covered.

6.7 Conducting audit follow-up

Clause 6.7. of ISO 19011 applies with the following addition:

The following table is provided for guidance.

[1] This form is in preparation and will be available soon.

Table 1: Cases of follow-up in dependence of the level of compliance with the requirements of EN ISO/IEC 80079-34

	DEFINITION Compliance with EN ISO/IEC 80079-34 (see 0 Introduction)…	ACTION FOLLOWING AN INITIAL ASSESSMENT	ACTION FOLLOWING A SURVEILLANCE VISIT	ACTION FOLLOWING A RE-ASSESSMENT
A	has been demonstrated, no non-conformities have been found	Issue the Notification No corrective actions required.	Notification to be maintained No corrective actions required.	Re-issue the Notification No corrective actions required.
B	has been generally demonstrated, with the exception of observed minor non-conformities	Issue the Notification upon receipt and satisfactory NB review of documentary evidence supporting effective corrective action submitted within an appropriate and agreed period. Corrective actions to be examined and verified at next surveillance visit.	Notification is to be maintained upon receipt of an acceptable corrective action plan, Corrective actions to be examined and verified at next surveillance visit.	Re-issue the notification upon receipt of an acceptable corrective action plan, Corrective actions to be examined and verified at next surveillance visit.
C	has NOT been demonstrated, due to major non-conformities being raised	Issue the Notification only after a satisfactory additional assessment (that may include a follow-up visit) has verified that the corrective actions have been effectively documented and implemented. A satisfactory follow up visit may be conducted within an appropriate and agreed period. Where the follow-up is not conducted within an appropriate and agreed period then a complete assessment is required.	Notification is to be maintained only after a satisfactory additional assessment (that may include a follow-up visit) has verified that the corrective actions have been effectively documented and implemented. A satisfactory follow up visit may be conducted within an appropriate and agreed period. Should the manufacturer fail to take timely and effective corrective action, then the Notified Body reserves the right to suspend or withdraw the Notification.(*)	Re-issue the Notification only after a satisfactory additional assessment (that may include a follow-up visit) has verified that the corrective actions have been effectively documented and implemented. A satisfactory follow up may be conducted within an appropriate and agreed period. Should the manufacturer fail to take timely and effective corrective action, then the Notified Body reserves the right to suspend or withdraw the current Notification (*)
D	Where there is no quality system or a system that has serious deficiencies rendering it ineffective	Close the application, no Notification to be issued	Withdraw (*) the Notification and inform other Notified Bodies	Close the application, no Notification to be re-issued

* Where the nonconformities only affect a particular EU Type Examination Certificate(s) which are listed on the Notification, then as an alternative to suspension or withdrawal of the whole Notification the particular certificate(s) in question, may be removed from the Notification. In this case, all other Notified Bodies shall be informed.

7 Competence and evaluation of auditors

7.1 General

Clause 7.1 of ISO 19011 applies

7.2 Determining auditor competence to fulfil the needs of the audit programme

7.2.1 General

Clause 7.2.1 of EN ISO 19011 applies

7.2.2 Personal behaviour

Clause 7.2.2 of EN ISO 19011 applies

7.2.3 Knowledge and skills

7.2.3.1 General

Clause 7.2.3.1 of EN ISO 19011 applies

7.2.3.2 Generic knowledge and skills of management system auditors

Clause 7.2.3.2 of EN ISO 19011 applies

7.2.3.3 Discipline and sector-specific knowledge and skills of management system auditors

Clause 7.2.3.3 of EN ISO 19011 applies

7.2.3.4 Generic knowledge and skills of an audit team leader

Clause 7.2.3.1 of EN ISO 19011 applies

7.2.3.5 Knowledge and skills for auditing management systems addressing multiple disciplines

7.2.4 Achieving auditor competence

7.2.5 Achieving auditor team leaders competence

Clause 7.2 of ISO 19011 applies completely- including the sub clauses, with the following addition:

Auditors should have:

- not less than 3 years recent experience working directly with or associated with certified products;
- an understanding of the Directive 2014/34/EU, associated terminology and relevant Standards;
- an understanding of critical characteristics of processes and products;
- an understanding of sector accepted processes and practices,
- appropriate evidence of completing a training course for audit skills and methods

7.3 Establishing the auditor evaluation criteria

Clause 7.3 of ISO 19011 applies.

7.4 Selecting the appropriate auditor evaluation method

Clause 7.4 of ISO 19011 applies.

7.5 Conducting auditor evaluation

Clause 7.5 of ISO 19011 applies, with the following addition:

It is the responsibility of the Notified Body to ensure that auditors maintain their technical knowledge with respect to standards development and state of the art.

7.6 Maintaining and improving auditor competence

Clause 7.6 of ISO 19011 applies.