



ExTAG/617/CD  
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**INTERNATIONAL ELECTROTECHNICAL COMMISSION IEC SYSTEM FOR  
CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN  
EXPLOSIVE ATMOSPHERES (IECEX SYSTEM)**

**Title: Draft Revision of OD 207 Operational Document – Retention of Records**

**To: Members of the IECEx ExTAG and IECEx Management Committee, ExMC**

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**INTRODUCTION**

The following proposal for a revision of Edition 1.0 of IECEx OD 207, Guidance on the Retention of Records (to be published as Edition 2.0 of IECEx OD 207, Retention of Records) is presented to the 2020 ExTAG meeting as part of the ExTAG WG12 report.

ExTAG members are requested to review this proposal and if accepted, recommend to the 2020 ExMC meeting that it proceed to publication. The attached shows changes (green as additions or moves, ~~red struckthrough~~ as deletions) as compared to Edition and will be used to (1) prepare a clean version for publication and (2) prepare a Redline version for publication

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# IECEX OPERATIONAL DOCUMENT

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

~~Guidance on the~~ Retention of Records

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IECEX Certified Equipment Scheme

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

# INTERNATIONAL ELECTROTECHNICAL COMMISSION

## IECEX Operational Document OD 207

### IECEX Certified Equipment Scheme

#### ~~Guidance on the~~ Retention of records

#### Introduction

This document is supplementary to the IECEx rules, other IECEx operational documents and procedures operated by IECEx Certification Bodies (ExCBs), approved by the IECEx Management Committee to issue IECEx Certificates of Conformity (CoCs) for Equipment.

The purpose of IECEx Operational Documents (ODs) is to ensure that each ExCB, accepted by the ExMC for the purposes of issuing IECEx CoCs, does so in a consistent manner.

This Redline Version of Operational Document, OD 207 Edition 2.0 displays changes as compared to Edition 1.0 as green text for additions or moves and ~~red struckthrough~~ text for deletions.

This document, was initially prepared by ExTAG Working Group 12 with final consideration during the 2016 Umhlanga IECEx series of meetings. Document ExMC/418A/CD was submitted for consideration at the 2016 ExTAG meeting with an ExTAG recommendation made to ExMC to proceed to publish.

#### Document History

Date	Summary
September 2017	Original issue (Edition 1.0)
October 2020	Edition 2.0 published to clarify requirements

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## Guidance on records retention - records specification

### 0 Introduction

There are at least 2 reasons for retention of records. Those are:

- Proof of compliance of equipment (ensuring evidence of safety) and
- Source for investigation, if needed, e.g. if incident with equipment occur.

In general ~~it is noted that~~ there is a lack of understanding of the differences between electronic back-up and archiving. This is particularly noticeable during the assessment of ExCBs and ExTLs.

Typically, back-up is about retaining your current data and is application specific. The idea is to be able to recover your data if the computer systems fail. It is not unusual for records to be overwritten after a period of time. For tape records this can be as short a time as one week. For other media it may be longer but subject to deletion of records inadvertently. For example, if records are accidentally deleted in the workplace computer or server, they may then be deleted in the back-up records (e.g. if records are synchronized).

Archiving normally stores the data in a non-application specific form so it can still be retrieved many years later. Some indications of a proper electronic archival system are:

- a) Records that must be retained are protected and cannot be deleted in the current or archival version of the data storage for the specified period of time for retention.
- b) The type of media used must be capable of storing the data without corruption for the specified period of time for retention.
- c) The media must not be capable of being affected adversely by foreseeable problems in the manner they are stored, e.g. magnetic fields, fire, water (from fire protection system).
- d) The nature of storage of the medium must not be so application specific that it might not be possible to read some years hence while still within the specified period of time for retention.

It was agreed by the ExMC WG4 meeting in Paris (in 2008) that the following approach be taken by IECEX:

- Assessors should seek evidence of oldest records both in electronic and hard copy to test the retrieval and existence of records.
- Assessors should also find out the method of secure disposal of hard copy records when going electronic.

### 1. Scope

This IECEX Operational Document contains the requirements for retention of records by ExCBs and ExTLs in the IECEX Certified Equipment Scheme.

Note 1 Possible revision of this OD for application in other IECEX Schemes is under consideration.

Note 2 The ExTL referred to in this document includes additional testing facility (ATF).

### 2. Normative references

ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*

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

### 4.3. 2 Definitions

#### 4.1.3.1. Records

information created, received, and maintained as evidence and information by an organization or person, in pursuance of legal obligations or in the transaction of business.

#### 4.2.3.2. Records management

field of management responsible for the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records, including processes for capturing and maintaining evidence of and information about business activities and transactions in the form of records.

#### **1.1.3.3. Records system**

information system which captures, manages and provides access to records through time.

## **2.4. Policy, procedures and responsibilities**

### **1.1.4.1. General**

As required by ISO/IEC 17065 and ISO/IEC 17025 the ExCBs and ExTLs shall establish, document and maintain policies, procedures and practices for records management to ensure that their needs for evidence, accountability and information about operation of its Scheme are met.

NOTE Throughout this document all references to Scheme refer to the IECEx Certified Equipment Scheme.

## **4.2 Policy**

ExCBs ~~(and ExTLs)~~ shall define and document a ~~records~~ management policy for the retention of records. The objective is creation and management of authentic, reliable and useable records, capable of supporting functions and activities related to operation of Scheme related activities for as long as they are required by the Scheme (incl. ISO/IEC 17065 and ISO/IEC 17025, as applicable). ~~The~~ ExCBs ~~(and ExTLs)~~ shall ensure that the policy is communicated and implemented at all levels in the organization.

NOTE: Responsibility for compliance should be assigned. Policies should be regularly reviewed to ensure that they reflect current business needs.

## **4.3 1.2.2 Procedures**

Individual ExCBs' ~~(and ExTLs')~~ ~~policies~~, procedures, processes and practices shall comply with the requirements of this and other applicable documents (such as ISO/IEC 17065, ISO/IEC 17025).

## **4.4 1.3 Responsibilities**

Records management responsibilities and authorities shall be defined and assigned throughout the ExCBs ~~(and ExTLs)~~ so that, where a specific need to create and capture records is identified, ~~it is~~ ~~should be~~ clear who is responsible for taking the necessary action.

NOTE: These responsibilities should be assigned to appropriate employees of the organization, including records managers, allied information professionals, executives, business unit managers, systems administrators and/or others who create records as part of their work, and should be reflected in job descriptions and/or similar statements. Specific leadership responsibility and accountability for records management should be assigned to a person with appropriate authority within the ExCB's (or ExTL's) organization.

## **53 Records management**

### **53.1 General ~~principles of records management programmes~~**

ExCBs (and ExTLs) shall ~~should institute and carry out~~ implement a comprehensive records management programme which includes:

- complying with legal and regulatory requirements, applicable standards and organizational policy;
- ensuring that records are maintained in a safe and secure environment;
- ensuring that records are retained only for as long as needed or required.

Where a "cloud" system is used, ExCBs and ExTLs shall ensure that the requirements of this OD are met by that system.

## 53.2 ~~Types~~ **Characteristics of a-record and management responsibility**

### 3.2.1 ~~General~~

The ~~A list of~~ types of records (related to this Scheme) covered by this document that shall ~~must be~~ kept are listed as follows: ~~accordingly are included in Annex A to this document.~~

- IECEX CoC and Annexes, if any;
- issued ExTR and associated test records, especially original data;
- manufacturer's drawings and documentation;
- QAR incl. auditing information supporting the QAR;
- calibration records, including historical calibration records;
- historical competency records; and
- historical records of procedures/work instructions.

The detailed management responsibility for specific types of records are indicated in Annex A to this document.

## 64 **Design and implementation of a-records systems**

### 64.1 **Records systems characteristics**

#### 64.1.1 **Reliability**

~~A-R~~records system shall:

- protect the records from unauthorized alteration or disposition and
- provide ready access to all relevant records and related metadata.

#### 64.1.2 **Systematic**

Records shall be created, maintained and managed systematically. ~~For the management of~~ ~~R~~records system shall include documented policies, assigned responsibilities and formal methodologies. ~~shall exist.~~

### 64.2 **Basic requirements for ~~Designing and implementing~~ records systems**

#### 64.2.1 **Physical storage medium and protection**

This document applies to all records in any form or media including, without limitation, printed records, e-mails, electronic (digital) records of all types ~~(including "in the "cloud" storage)~~, ~~records contained on~~ CD ROMs, magnetic tape, floppy discs ~~and~~ audio tapes etcetra.

#### 64.2.2 **Retention and disposition**

Additional information regarding retention and disposition (minimum retention time) is provided in Annex A to this document.

#### 6.2.3 ~~4.3~~ **Conversion, migration and discontinuing records systems**

For the entire period of their retention all records shall remain authentic, reliable and useable. This includes any kind of system change, format conversion, hardware or software change.

After decommissioning or discontinued use of a records system there shall be procedures preventing ~~no~~ additional records ~~may~~ being added to the system. The records shall continue to be accessible. They can only be removed from the system in accordance with the current retention and disposition requirements and guidelines of the ExCB ~~(or ExTL)~~.

## 75 Records management processes and controls

### 75.1 Storage and handling

Usability, reliability, authenticity and preservation of records for as long as they are needed (as described in Annex A) shall be ensured. This applies for all types of media mentioned in 6.2.1 Physical storage medium and protection.

Storage conditions and handling processes shall take into account the specific physical and chemical properties of the media used.

Whenever any kind of system change occurs, systems for electronics records shall be designed so that records remain accessible, ~~reliable~~, authentic and useable for the entire period of their retention.

### 75.2 Implementing disposition

Records shall be removed from operational systems on a systematic and routine basis in accordance with normal business activities and according to this document. Before initiating the ~~disposal~~ action it ~~shall have to~~ be assured that the record is no longer required, that no work is outstanding and that no investigation is current or pending which would involve relying on the records.

While ~~disposal~~ action may take different shapes it is of high importance to pay close attention to the confidentiality aspects in particular when the records are transferred to another organization (e.g. refer to 9 Requirements when an ExCB or ExTL exits the Scheme).

### 75.3 Documenting records management processes

In the ExCB's ~~(and ExTL's)~~ quality documentation describing records management processes and records systems technical, organizational and legal requirements ~~shall have to~~ be addressed. Authority for records management processes shall be clearly defined. Records associated with the outcome of these processes shall be kept in accordance with the requirements of the responsible ExCB ~~(and ExTL)~~.

## 86 Monitoring and auditing

ExCBs ~~(and ExTLs)~~ shall undertake compliance monitoring as ~~part of the internal auditing system~~ ~~on regular basis~~ to ensure that the records systems procedures and processes were implemented as required by the organizational requirements and that the records are accessible, authentic and usable ~~anticipated outcomes are met~~. Records from such monitoring shall be maintained.

## 97 Requirements when an ExCB or ExTL exits the Scheme

If an ExCB or ExTL exits the Scheme (e.g. voluntary exit, an organization is closed, acquired or merged with other organization) the following actions ~~shall need to~~ be undertaken:

- In the event of acquisition or merging the new ExCB or ExTL shall ensure that it has acquired all the records from the former body and put in place a system for retention of those records compliant with this Operational Document.
- In the event of the closure of an ExCB or ExTL the manufacturer / applicant shall be given the option to decide to which existing IECEx accepted ExCB or ExTL they require to transfer the records.

NOTE The IECEx Secretariat is responsible to monitor the process, and to ensure and report back to the ExMC once they have confirmed that the process of transferring the records is completed.

- ~~All customers (manufacturers) of the organization (to which they have issued an IECEx document of conformity) and IECEx Secretariat shall be informed that the organization will exit the Scheme at a certain date.~~
- ~~The manufacturer / applicant will be given the option to decide to which existing IECEx approved ExCB or ExTL they want to transfer the file (including the one created after the acquisition).~~

- ~~IECEX Secretariat is responsible to monitor the process and to ensure and report back to the ExMC once they have confirmed that the process of transferring the records was completed.~~

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## Annex A

### Normative

#### List of affected records:

Type of record	Point of reference for retention of record times	Actual minimum retention time	Responsibility for records
<p>IECEX CoC and Annexes, if any</p> <p>Summaries of ExTRs and QARs</p> <p>1. <del>Publicly available documents — e.g. CoC and information associated with the CoC</del></p>	<p>Not applicable</p> <p><del>Date of cancellation of CoC</del></p>	<p>These records are kept by the IECEX System indefinitely.</p> <p>There is no requirement for ExCBs to meet the requirements of this OD for CoCs and their associated supporting summary documents.</p> <p>NOTE In practice it would be expected that the ExCBs would still have copies of the CoCs in their records together with the associated ExTRs and QARs.</p> <p>This OD is not assigning minimum retention times for copies of these CoCs</p> <p><del>10 years</del></p>	<p>IECEX Secretariat</p> <p><del>IECEX System and ExCB:</del></p> <ul style="list-style-type: none"> <li><del>• ExCB must retain a copy of the certificate as issued including pre and post edited versions.</del></li> <li><del>• IECEX System responsible to maintain on-line version.</del></li> </ul>
<ul style="list-style-type: none"> <li>• Issued ExTR and associated test records, especially original data</li> <li>• Manufacturer's drawings and documentation that are referred to in the CoCs and/or ExTRs</li> </ul>	<p>Date of cancellation of associated CoC or if there is no CoC, date of issue of ExTR</p>	<p>10 years</p>	<p>ExCB and ExTL as appropriate</p>
<p>Issued QAR and associated auditing information supporting the QAR</p>	<p>Date of expiry of QAR</p>	<p>10 years</p>	<p>ExCB</p>
<p><del>Test records, especially original data</del></p>	<p><del>Date of cancellation of associated CoC</del></p>	<p><del>10 years</del></p>	<p><del>ExTL</del></p>
<p>Calibration records, including historical calibration records</p>	<p>Date of last calibration</p>	<p>10 years</p>	<p>ExTL</p>
<p>Historical competency records</p>	<p>Date when they were recorded</p>	<p>10 years</p>	<p>ExCB and ExTL</p>
<p>Historical records of procedures/work instructions</p>	<p>Issue date of the document</p>	<p>10 years</p>	<p>ExCB and ExTL</p>

Drawings and documentation	Date of cancellation of CoC	10 years	ExCB
2. QAR	Date of expiry of QAR	10 years	ExCB
3. Auditing reporting information supporting the QAR	Date of expiry of QAR	10 years	ExCB

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