

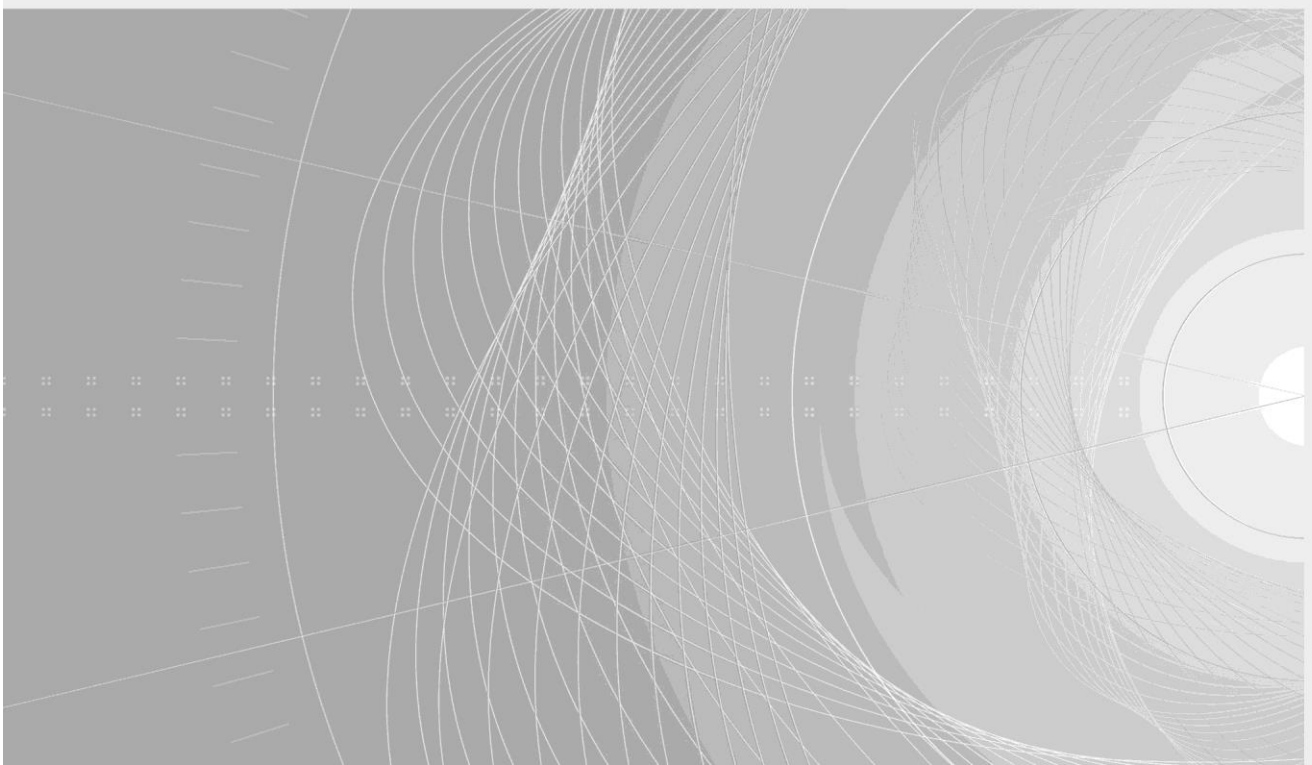


# IECEX OPERATIONAL DOCUMENT

**IEC System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres (IECEX System)**

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**IECEX Certified Equipment Scheme –  
Guidance on retention of records**





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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## IECEX Operational Document OD 207 –

IECEX Certified Equipment Scheme –  
Guidance on retention of records

## FOREWORD

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 Operational Document IECEx OD 207 provides ~~guidance~~ requirements on the matters relating to the retention of records.

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.

This redline version of IECEx OD 207 highlights the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

## Document History

Date	Summary
2017-09	Original issue (Edition 1.0)
<u>2020</u>	<u>Edition 2.0 published to clarify requirements</u>

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## INTRODUCTION

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

- Proof of compliance of equipment with applicable requirements (ensuring evidence of safety)
- 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 (where such media is utilized) 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 need to~~ 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~~ selected and managed in a way that ensures that the data ~~without corruption~~ is not corrupted 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 System:

- 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.

## Guidance on retention of records

### 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).

### 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

## 3 Definitions

### 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

### 3.2 records management

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

### 3.3 records system

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

## 4 Policy, procedures and responsibilities

### 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

#### ~~4.2.1 General~~

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 (including ISO/IEC 17065 and ISO/IEC 17025, as applicable). 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 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 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 ~~should be~~ is 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.

## 5 Records management

### 5.1 General principles ~~of records management programmes~~

ExCBs and ExTLs ~~should institute and carry out~~ shall 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; and
- 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.

### 5.2 ~~Characteristics of a record~~ Types of records and management responsibility

#### 5.2.1 ~~General~~

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

- IECEX CoC and Annexes, if any;
- issued ExTR and associated test records, especially original data;
- manufacturer's drawings and documentation;
- QAR, including 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 is indicated in Annex A.

## 6 Design and implementation of ~~a~~ records systems

### 6.1 Records systems characteristics

#### 6.1.1 Reliability



~~A~~ Records systems shall:

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

### 6.1.2 Systematic

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

## 6.2 ~~Designing and implementing~~ Basic requirements for records systems

### 6.2.1 Physical storage medium and protection

This OD applies to all records in any form or media including, without limitation, printed records, emails, electronic (digital) records of all types including “cloud” storage, ~~records contained on~~ CD-ROMs, magnetic tapes, floppy discs, audio tapes, etc.

### 6.2.2 Retention and disposal

Additional information regarding retention and ~~disposition~~ disposal, including minimum retention times, is provided in Annex A.

### 6.2.3 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 be 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~~ disposal requirements and guidelines of the ExCB or ExTL.

## 7 Records management processes and controls

### 7.1 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 Subclause 0.

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.

### 7.2 Implementing ~~disposition~~ disposal

Records shall be removed from operational systems on a systematic and routine basis in accordance with normal business activities and according to this OD. Before initiating the ~~disposition~~ disposal action, it ~~has to~~ shall 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 ~~disposition~~ 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 Clause 0).

### 7.3 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 ~~have to~~ shall 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.

## 8 Monitoring and auditing

ExCBs and ExTLs shall undertake compliance monitoring as a part of the internal auditing system 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. Records from such monitoring shall be maintained.

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

## 9 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 be undertaken:

- ~~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.~~
- 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 OD.
- In the event of the closure of an ExCB or ExTL the manufacturer/applicant ~~will~~ shall be given the option to decide to which existing IECEx accepted ExCB or ExTL they ~~want~~ require to transfer the file records ~~(including the one created after the acquisition).~~

**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.

## Annex A (normative)

### List of affected records

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