



IECEX OPERATIONAL DOCUMENT

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

IECEX Certified Equipment Scheme

Guidance on the Retention of Records



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Equipment for use in Explosive Atmospheres (IECEX System)**

IECEX Certified Equipment Scheme

Guidance on the Retention of Records

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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 Operational Document, OD 207 provides guidance 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.

Document History

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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.

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:

1. 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.
2. The type of media used must be capable of storing the data without corruption for the specified period of time for retention.
3. 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).
4. 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.
5. 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 Policy and responsibilities

1.1 General

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 its Scheme are met.

Note: Throughout this document all references to Scheme refer to IECEx System Certified Equipment Scheme.

1.2 Policy

1.2.1 General

The ExCBs (and ExTLs) shall define and document a records management policy. 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. The ExCBs (and ExTLs) shall ensure that the policy is communicated and implemented at all levels in the organization. Responsibility for compliance should be assigned. Policies should be regularly reviewed to ensure that they reflect current business needs.

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).

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 should be clear who is responsible for taking the necessary action. 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.

2 Definitions

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.

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.

Records system

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

3 Records management

3.1 General principles of records management programmes

ExCBs (and ExTLs) should institute and carry out 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.

3.2 Characteristics of a record

3.2.1 General

A list of types of records (related to this Scheme) covered by this document that must be kept accordingly are included in Annex A to this document.

4 Design and implementation of a records system

4.1 Records systems characteristics

4.1.1 Reliability

A records system shall:

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

4.1.2 Systematic

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

4.2 Designing and implementing records systems

4.2.1 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 (incl. "in the cloud" storage), records contained on CD ROMs, magnetic tape, floppy discs and audio tapes.

4.2.2 Retention and disposition

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

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 decommission or discontinued use of a records system no additional records may be 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).

5 Records management processes and controls

5.1 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 4.2.1 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.

5.2 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 disposition action it has 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 disposition 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 7 Requirements when an ExCB or ExTL exits the Scheme).

5.3 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 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).

6 Monitoring and auditing

ExCBs (and ExTLs) shall undertake compliance monitoring on regular basis 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 from such monitoring shall be maintained.

7 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 need to 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.
- 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.

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
1. Publicly available documents – e. g. CoC and information associated with the CoC	Date of cancellation of CoC	10 years	IECEX System and ExCB: <ul style="list-style-type: none"> • ExCB must retain a copy of the certificate as issued including pre and post edited versions. • IECEX System responsible to maintain on-line version.
2. Issued ExTR	Date of cancellation of associated CoC	10 years	ExCB
3. Test records, especially original data	Date of cancellation of associated CoC	10 years	ExTL
4. Calibration records, including historical calibration records	Date of last calibration	10 years	ExTL
5. Historical competency records	Date when they were recorded	10 years	ExCB and ExTL
6. Historical records of procedures/work instructions	Issue date of the document	10 years	ExCB and ExTL
7. Drawings and documentation	Date of cancellation of CoC	10 years	ExCB
8. QAR	Date of expiry of QAR	10 years	ExCB
9. Auditing reporting information supporting the QAR	Date of expiry of QAR	10 years	ExCB

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