**INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC) SYSTEM FOR CERTIFICATION TO STANDARDS RELATING TO EQUIPMENT FOR USE IN EXPLOSIVE ATMOSPHERES (IECEx SYSTEM)**

**Title: ExTAG/661/CD** – **Draft ExTAG Decision Sheet – Information relevant to particular protection Ex 60079-46 into the quality management system.**

**Circulated to: ExTAG – IECEx Testing and Assessment Group**

**INTRODUCTION**

This document, *ExTAG//CD, Information relevant to particular protection Ex 60079-46 into the quality management system has been prepared by INERIS/LCIE* including track changes, is now listed for initial discussion during the 2021 ExTAG Remote Meeting to followed by the usual process according to OD 035.

**ExTAG Secretariat**

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COLLECTION OF IECEx / ExTAG DECISIONS

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| Standard: IEC TS 60079-46:2017ISO/IEC 80079-34:2018 | **Clauses:** ISO/IEC 80079-34:2018Annex A |  |
| **Subject:** Information relevant to particular protection Ex 60079-46 into the quality management system**Status of document: Draft** | **Key words:** * Assemblies
* Quality management system
 | Date: July 2021**Originator of proposal:** INERIS / LCIE |

BACKGROUND:

According to IEC TS 60079-46, equipment assemblies can either be subjected to Unit Verification certificate or to Certificate of Conformity (type verification + manufacturing control).

Therefore, clause 4.4 of IEC TS 60079-46 requires the manufacturing process and the competency of the related personnel to be conform to ISO/IEC 80079-34.

However, the requirements for manufacturers, when doing the verifications based on the IECEx certification of conformity covering the type of the equipment assembly, are not clear.

**QUESTION:**

For equipment assemblies subjected to type verification, which aspects referring to the quality management system in accordance with ISO/IEC 80079-34 shall be addressed by the manufacturer?

**ANSWER:**

In addition to the information given by ISO/IEC 80079-34:2018 and especially in the Annex A, the following aspects shall be used to meet the requirements of the standard.

The following aspects for assembly are relevant:

* Production documentation should address all the items (refer to clause 5 of the IEC TS 60079-46) defined into the documentation of certification file.
* An inspection of the assembly shall be performed before the release. Inspection documented procedures should address the level and the content of the inspection, as defined into the Certificate of Conformity.
* Competence. It is stated in the IEC TS 60079-46 (4.4 Competencies ) that “*For equipment assemblies subjected to type verification, the manufacturing process and the competency of the related personnel shall conform to ISO/IEC 80079-34.*”
Then, the competency of the person involved in the inspection shall be checked during the audit performed by the ExCB in accordance with ISO/IEC 80079-34.

*Additionally the manufacturer shall ensure the persons who perform electrical tests or installation according to IEC 60079-14:2014 have the competencies requested by IEC 60079-14:2014 annex A (Knowledge, skills and competencies of responsible persons, operatives/technicians and designers). The evidence of these competences shall be documented.*