**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/661A/CD, Information relevant to particular protection Ex 60079-46 into the quality management system* has been prepared by INERIS/LCIE and includes track changes. The original document, ExTAG/661/CD was listed for initial discussion during the 2021 ExTAG Remote Meeting to be followed by the usual process according to OD 035.

During 2021 ExTAG Remote Meeting it was agreed to reactivate ExTAG WG14, *Certification of Ex Equipment assemblies*, and to transfer this topic on the manufacturing control of assembly to this WG. However, the aim of this DS is to define what is required to check during manufacturing due to the fact that IEC TS 60079-46 allows the possibility to certify an assembly using a Certificate of Conformity which means using a manufacturing control.

Today, there is nothing in ISO/IEC 80079-34 nor in IEC TS 60079-46 regarding the manufacturing control of assembly.

Please submit comments on this new Draft DS using the comments table, a separate document, by –

**2021 10 27**

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COLLECTION OF IECEx / ExTAG DECISIONS

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| Standard:  IEC TS 60079-46:2017  ISO/IEC 80079-34:2018 | **Clauses:**  ISO/IEC 80079-34:2018  Annex 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: September 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).

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.

Today, more than 165 CoCs of assemblies were issued and 33 of them are linked to a QAR.

Both LCIE and INERIS who are the Originator of this proposal did not issue a CoC for assembly linked to a QAR. We remembered the discussion in the MT 60079-46 and in ExTAG WG14 which has defined that inspection was required but some ExCBs did use the possibility offered by IEC TS 60079-46 and certify assembly linked to a QAR. We understand the need since some assemblies are manufactured in series. It is important that all ExCB do the manufacturing control of assembly in the same way.

Therefore, this DS is to be an immediate solution for manufacturing control of assembly even if the ExTAG WG14 will define more clearly the rules for manufacturing control of assembly.

**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.*