INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)

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| Standard:  IEC TS 60079-46:2017  ISO/IEC 80079-34:2018 | **Clauses:**  ISO/IEC 80079-34:2018  Annex A | **Draft Decision Sheet:**  ExTAG/661B/CD |
| **Subject:**  Information relevant to particular protection Ex TS 60079-46 into the quality management system  **Status of document: Approved** | **Key words:**   * Assemblies * Quality management system | Date: September 2022 **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 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 originators of this proposal have not issued a CoC for an assembly linked to a QAR. Discussion in MT 60079-46 and in ExTAG WG14 has defined that inspection is required but some ExCBs have used the possibility offered by IEC TS 60079-46 and certified assemblies linked to a QAR. Since some assemblies are manufactured following the same type of assembly, it is important that all ExCBs approach manufacturing control of assemblies in the same way.

Therefore, this DS is proposed as an interim solution for manufacturing control of assemblies until ExTAG WG14 defines more clearly the rules for manufacturing control of assemblies.

**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 shall address all the items (refer to clause 5 of the IEC TS 60079-46) defined into the documentation as part of the certification file.An inspection of the assembly shall be performed before the release from the manufacturing location and after site re-assembly if applicable. Documented inspection procedures shall 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.*

While ‘60079-46’ is a Type of Protection in accordance with IEC 60079-46, it is not to be indicated on its own as a Protection Concept on a QAR. If a QAR is to support an   
IEC 60079-46 assembly certification, the Protection Concept(s) field on the QAR shall read, '60079-46' followed by a parenthetical statement that itemizes the specific Types of Protection that support the assembly certification. For example, '60079-46 (d, e, m)'