

Guideline

F-01

CLAP

FORM N°X123

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Directive References: Annex I § 3.1.2

Subject: ESR on manufacturing – Third party witness for the whole permanent joining and testing process

Question:

According to section 3.1.2 (permanent joining) of Annex I, the third party must perform examinations and tests in order to carry out the approvals of operating procedures and personnel. Must the representative of the third party witness the whole permanent joining and testing process?

Answer:

No.

In accordance with and under the responsibility of the notified body or of a third party organisation recognised by a Member State, some practical tasks concerning the approval of joining operating procedures and personnel may be accomplished by a competent person of a manufacturer according to a quality system.

NOTE 1: The Notified Body or Recognised Third Party Organisation must attend part of the different steps in the process for each procedure and for each person.

NOTE 2: See also section 5.2.5 of the “Blue Guide”