



THOMAS LOMMATZSCH - CECIP WEBINAR 'CERTIFICATION IN ONE DAY'
EXPERIENCES AS NOTIFIED BODY IN REDUCING TIME FOR
CERTIFICATION PROCEDURES

September 2021

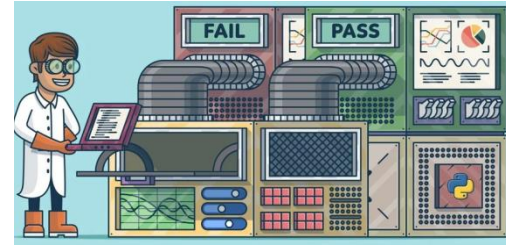


What contributes to the extension of the processing time of a certification file ?



1. Tests and examination
2. Incomplete application file
3. Planning and conducting audits

TYPE APPROVAL EXAMINATIONS AND TESTS

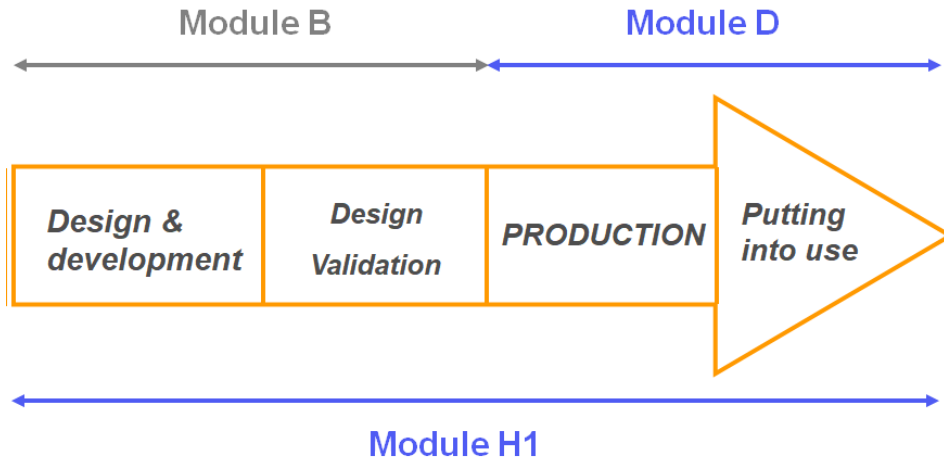


- Some tests take a long time to complete (ex : durability)
- Within the type examination process, the notified body is responsible for the examination and testing process and the timeframe may vary depending on the workload of the NB

 ***Possible solutions***

TYPE APPROVAL EXAMINATIONS AND TESTS: MODULE H1

→ Conformity assessment procedure H1



B+D≠H1

The difference between these two conformity assessment procedures is mainly at the level of the validation of the design of the measuring instruments.

TYPE APPROVAL EXAMINATIONS AND TESTS: MODULE H1

H1: the validation of the design is carried out according to the manufacturer procedures :



Thus the manufacturer remains in control of the timing of the tests and the whole process of validation



The implementation of these procedures requires however an important work

The notified body :

✓ *H1: carries out the examination of the documentation and the evidence*

✓ *B : examines the technical documentation & carries out the examinations and tests or have them carried out*



H1: During design validation, the work of the NB is more limited and therefore often completed in a shorter time frame



The audit within the framework of the H1 module is more substantial

TYPE APPROVAL EXAMINATIONS AND TESTS: THE OIML CS



- The OIML-CS allows you to have the tests performed during the type examination recognized by the OIML CS utilizers
- The tests must have been carried out in an OIML-approved laboratory, with a certificate issued by an OIML issuing authority
- Some utilizers have additional national requirements

COMPLETENESS OF THE APPLICATION FOR CERTIFICATION

The application files sent to NBs are sometimes not complete, as elements required by the directives are missing.



How to avoid it ?

COMPLETENESS OF THE APPLICATION FOR CERTIFICATION

→ Ensure that the documentation accompanying the application complies with the requirements of the Directives (MID: article 18, NAWID: Annex II 1.3).

→ Some NBs propose standard application frame

The image shows a screenshot of a web-based application form for certification. At the top right, the logo for LNE (Laboratoire National de Métrologie et d'Essais) is visible, along with the text 'Instrumentation and Information Technology Certification Department' and 'Legal metrology'. Below this, there is a section for 'Measuring instrument according to European directives 2014/52/EU (MID) or 2014/51/EU (NAWI)'. The form contains several input fields for 'Applicant' and 'Manufacturer' information, including 'Company name', 'Address', 'Postal code', 'City', 'Country', 'Contact', and 'Email'. There is also a checkbox for 'Identical address to the applicant'. At the bottom, there is a footer with the text 'Laboratoire national de métrologie et d'essais - Institut public à caractère industriel et commercial' and contact information for the laboratory.

PLANNING AND CONDUCTING AUDITS



- Planning an audit requires coordinating the agendas of multiple people
- Travel to sites can add time and difficulty



What to do about it?

PLANNING AND CONDUCTING AUDITS

- Part of the audits can be carried out remotely
- Inform the NB of your time constraints as soon as possible
- Some regulatory and voluntary audits can be conducted jointly (ex: MID / ISO 9001)
- The digitalization of processes in notified bodies will help to facilitate the exchange of information and the organization of audits

Thank you for your attention !