

Notes regarding matters not applicable to testing activities

VLAC-VR102-4:2024

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Date of issue: April 12, 2024

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1. Scope

Our laboratory accreditation is based on ISO/IEC 17025 and the scope of accreditation is testing activities.

If the standards used in conformity testing include matters other than tests and testing activities[Note 1], the laboratory may, at the request of regulatory authorities and certification bodies, or at the request of the customer, include matters other than tests and testing activities and pass/fail Judgment may also written in the test report.

When matters other than testing activities that are included in the standards used in conformity test tests, and when the standards used in conformity tests cite standards that include matters other than testing activities. This document describes points to note regarding pass/fail judgments regarding matters other than testing activities in a report.

Note 1: For example, IEC 60601-1 and JIS T 0601-1 state “Compliance is checked by inspection of the xx FILE”

2. Definition of terms

2.1 Testing Activity

In this document, the conduct of a test and the inspection necessary for conducting a test are considered testing activities. For example, inspection of risk management files, inspection of instruction manuals, and visual inspection of test items shall be considered testing activities related to the conduct of the test if these are necessary to establish test conditions.

If the inspection is not related to the conduct of a test, it is not considered a testing activity. For example, activities such as only inspection of risk management files or only inspection of usability process execution files do not fall under testing activities.

3. Points to note when a testing laboratory issues a report that describes pass/fail judgments for matters that do not fall under testing activities

In addition to the requirements of ISO/IEC 17025, the laboratory must meet the following:

- (1) The laboratory has the competence to evaluate matters other than the relevant testing activities by itself, or has the competence to conduct file inspection, etc. concerning matters other than the relevant testing activities conducted by customers (conducted by other than the testing laboratory)
- (2) The testing laboratory shall have rules for writing pass/fail judgments in reports regarding matters other than the relevant testing activities.
- (3) When issuing a report with the VLAC accreditation symbol by writing pass/fail judgments on matters other than testing activities, take measures such as stating that only testing activities are within the scope of accreditation to avoid misunderstandings about the scope of accreditation.

Examples are shown in the Figure 1 below, but are not limited to these.

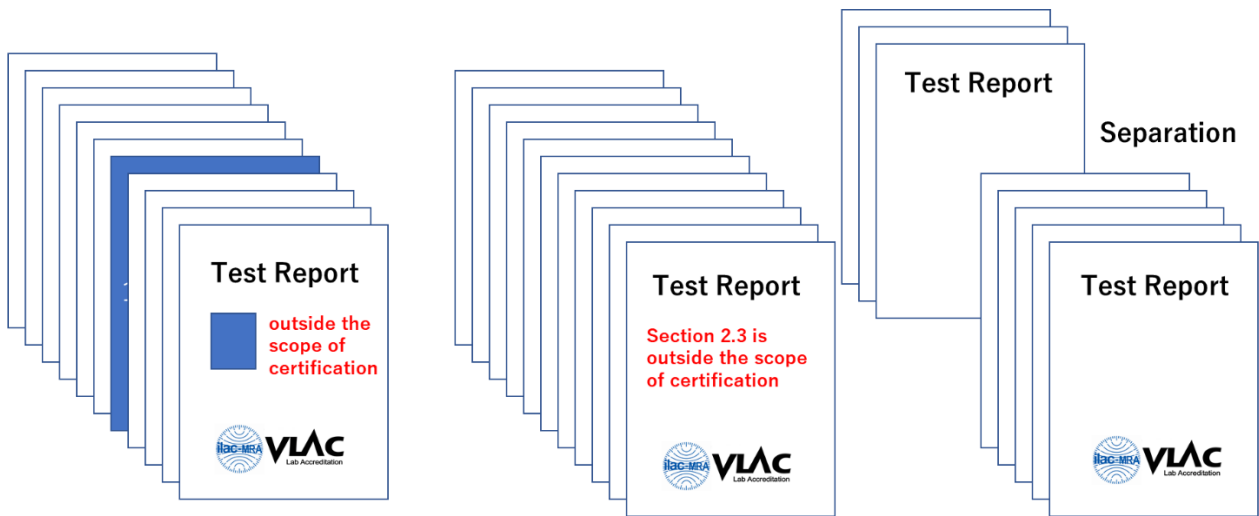


Fig.1 Example: Identification when the test report includes results other than the scope of certification

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Revision histories VR102-4:2024

April 12, 2024: First edition
