



Rules for recognition of Test Laboratories

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Technical Rules

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1 FIELD OF APPLICATION

These Rules provide the general criteria adopted by RINA for the evaluation and recognition of testing laboratories intending to carry out tests and measurements of materials and products subject to inspection by RINA.

Their enforcement is mandatory for laboratories operating for the purpose of EC certification of products in accordance with European Directives, when RINA acts as a Notified Body and when they are not already accredited, for the test methods under consideration, by an accreditation body full member of ILAC (International Laboratory Accreditation Cooperation).

2 APPLICATION

The laboratory is to submit to RINA an application for recognition, enclosing the following details:

- general information regarding the laboratory (designation, address, legal status, human and technical resources);
- list of tests for which recognition is requested;
- name and qualification of the persons responsible for the technical validity of the tests;
- description of the internal organisation and of the system adopted by the laboratory to ensure the quality of the testing services.

Having examined the application and verified that the information and documents are complete and comply with the provisions contained in these Rules, RINA will arrange with the laboratory the date for the performance of the assessment survey.

3 MANAGEMENT REQUIREMENTS

3.1 General

The laboratory is to comply with the requirements of UNI CEI EN ISO/IEC 17025: 2005 and subsequent amendments and additions.

3.2 Impartiality, independence and confidentiality

The testing laboratory and its personnel are to be free from any commercial, financial or other pressures which might affect their judgement.

The laboratory is not to be involved, either directly or through the employer, in the design and manufacture of the product tested as this could affect its impartiality. Should the laboratory be part of an organisation that conducts other activities in addition to testing, such as design, manufacturing, R&D, market research and financing (for example, testing rooms on production sites), responsibilities are to be defined in order to identify any potential conflict of interests and ensure that the applicable requirements are complied with.

The laboratory is to treat as confidential any information and documents obtained in the course of its activities and is not to divulge such information and documents to third parties, unless specifically authorised by the data subject or required by law.

3.3 Management and organisation

The laboratory or the organisation to which it belongs is to be a body with legal status and liability.

The laboratory is to be competent to perform the tests for which recognition is requested. It is responsible for carrying out testing activities so as to satisfy these Rules, the demands of the customer and the provisions issued by the competent authorities.

The laboratory is to:

- a) have management and technical personnel with the necessary authority and skills to carry out their tasks, identify any non-conformities in the quality system or the testing procedures, and implement preventive actions designed to eliminate or minimise such non-conformities,
- b) define its organisational and management structure, its position in the parent organisation and the relations between the quality department, the technical activities and the support services,
- c) specify the responsibilities, authority and interdependence of all personnel involved in the management, performance or supervision of work related to the quality of the testing services,
- d) appoint a staff member to the position of quality director; this person is to have the responsibility and authority necessary to ensure that the quality system is instituted and implemented at all times. The quality director is to have direct access to senior management responsible for decision-making in the field of quality policy and resources,
- e) adopt policies and procedures guaranteeing the protection of confidential information and safeguarding the property rights of customers, including procedures for the storage and electronic transmission of test results,
- f) provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test and with the assessment of test results,
- g) have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations,
- h) appoint deputies for key managerial personnel,
- i) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.

3.4 Quality system

The laboratory is to institute, implement and maintain a management system appropriate to the scope of its activities. The laboratory is to document the policies, systems, programs, procedures and instructions to the extent that these are needed to ensure the quality of the test results. The system documentation is to be made available so that it can be understood and applied by the laboratory personnel.

The laboratory's management system policies and objectives are to be defined in the quality manual. The general objectives are to be documented in a quality policy statement to be defined by the top management. This statement is to cover at least the following points:

- a) a commitment by the top management to good professional practice and to the quality of its testing in servicing its customers;
- b) a commitment by the top management about the laboratory's standard of service;
- c) the purpose of the management system related to quality;
- d) a requirement that all personnel involved in testing activities are familiar with the quality documentation and implement the relevant policies and procedures at work;
- e) the laboratory management's commitment to comply with the UNI CEI EN ISO/IEC 17025: 2005 standard

and to continually improve the effectiveness of the management system.

The quality manual is to contain or refer to associated procedures in support of quality policy; this includes technical procedures and the structure of management system documentation.

3.5 Document control

The laboratory is to set up and maintain procedures to control all management system documents (whether they are prepared internally or externally) such as regulations, rules and requirements, test methods as well as drawings, software, specifications, instructions and manuals.

All the laboratory's management system documents issued are to be reviewed and approved for use by authorised personnel in advance. A general checklist with indication of the current revision status and the distribution of quality system documents is to be prepared and made readily available in order to ensure that only the most recent editions of documents are circulated and used.

Unless otherwise stated, changes to documents are to be reviewed and approved by the same person (or by whoever is working in that position) that carried out the initial review. The staff members concerned are to have access to all relevant information on which to base their review and approval.

3.6 Personnel

Personnel conducting tests are to have the necessary qualifications, technical skills, experience and training to carry out their assigned tasks, in compliance with the requirements of ISO 17025 and subsequent amendments and additions.

3.7 Subcontracting

In general, the laboratory is not authorised to subcontract the testing for which it has obtained recognition from RINA.

4 TECHNICAL REQUIREMENTS

4.1 General

The laboratory is to comply with the requirements of ISO 17025 and subsequent amendments and additions.

4.2 Premises

The premises used for tests are to be such as not to have an adverse effect on the testing or results; to this end the environmental conditions concerning temperature, humidity, dust, vibrations, etc. are to be suitably controlled. Such conditions are to be specified in the test procedures. The premises are to be sufficiently spacious and suitably lit so as to enable operators to work adequately. Access to the testing laboratories is to be suitably controlled.

4.3 Equipment

The laboratory is to be provided with all the equipment necessary for sampling, measurement and testing as well as processing and analysis of test results. Where the laboratory needs to use equipment that is outside its permanent control, it is to ensure that the following provisions are complied with.

The equipment and software used for testing, calibration and sampling are to guarantee the degree of accuracy required and be in compliance with the relevant test specifications.

The laboratory is to:

- prepare and apply written procedures for the identification and calibration of the equipment;
- specify for each piece of equipment its type, identification, frequency of calibrations and limit of acceptance, as well as the system used to show the calibration status;
- carry out calibrations periodically, or prior to use, by means of certified instruments that can be compared against nationally recognised samples, or on the basis of documented criteria; a copy of the calibration documentation is to be retained;
- ensure that the use, handling and storage of equipment are such as not to impair its calibration, accuracy or suitability for the purpose.

RINA reserves the right to verify compliance with these requirements also during testing of products.

Equipment is only to be used by authorised personnel. Up to date instructions on use and maintenance (including any manual supplied by the equipment Manufacturer) are to be made readily available to the relevant laboratory staff.

A record card is to be kept for each piece of testing equipment with the following information:

- the name of the Manufacturer, the type and the serial number of the equipment;
- the frequency of calibration;
- the date of calibration checks performed;
- details of maintenance carried out.

4.4 Test methods and procedures

The laboratory is to prepare documented instructions on the use and operation of all equipment, on the standard testing techniques and, as far as possible, on the handling and preparation of materials subjected to tests.

The instructions, standards, manuals and reference data used in laboratory activities are to be kept up to date and made readily accessible to personnel.

The laboratory is to use the methods and procedures required by the standard or by the technical specification according to which the product is tested. Where it is necessary to employ non-standard test methods or procedures, these are to be comprehensively documented. All the calculations and data transfer are to be subjected to suitable monitoring. When numerical analysis is obtained by means of electronic and data elaboration techniques, the system is to be sufficiently reliable and stable (hardware and software) so as not to affect the accuracy of the results.

4.5 Test reports

The results of each test or series of tests carried out by the laboratory are to be recorded accurately, clearly, objectively, unambiguously and in conformity with the instructions specific to the particular test method.

The results are to be recorded in a test report and are to include all the information requested by the customer and needed for their interpretation as well as full details of the method used.

Each test report is to contain at least the following details:

- a) title of the document (e.g. "Test Report");
- b) name and address of the laboratory, and the place where the tests were conducted, if different from the above;
- c) unique identification of the report and of each page so that it is recognisable as part of the parent document, as well as clear identification of the end of the report;
- d) name and address of the customer;

- e) identification of the method used;
- f) description, including the condition, and unambiguous identification of the item(s) tested;
- g) date of receipt of the item(s) tested when this is a critical factor for the validity and application of the results, and the date(s) of testing;
- h) reference to sampling plans and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;
- i) test results, with the units of measurement when appropriate;
- j) the name(s), position(s) and signature(s) or equivalent identification of the person(s) authorising the issue of the test report;
- k) indication, if necessary, of the uncertainty of the measurements;
- l) if relevant, a declaration stating that the results refer only to the items tested.

4.6 Identification of samples and items for testing

A system of identification of the samples or items to be tested is to be implemented, by means of documents and marking, in order to avoid confusion over the identity of samples or items and over the results of measurements performed.

5 ASSESSMENT SURVEY

The laboratory requesting recognition will be subjected to an assessment survey by RINA in order to ascertain whether the requirements specified in items 3 and 4 are complied with.

The survey will be conducted using the questionnaire attached in annex C.

6 DOCUMENT OF RECOGNITION

6.1 Independent laboratories

Subject to the satisfactory outcome of the survey carried out, RINA will issue a "Certificate of Assessment of the Laboratory" listing the tests for which the laboratory is recognised suitable as well as any specific conditions for performing such tests.

6.2 Other laboratories

For laboratories other than those in 6.1, located in test rooms and/or production facilities belonging to the Manufacturer or designated by the latter as a test location, RINA will issue a "Statement of Assessment of the Laboratory" listing the tests for which the laboratory is recognised suitable and specifying that testing is to be carried out with RINA personnel in attendance.

7 VALIDITY OF THE RECOGNITION

The duration of the validity of the recognition of the laboratory is 3 years, effective from the date of issue of the document.

At the expiry of the period of validity, the recognition may be renewed subject to the satisfactory outcome of a survey of the laboratory carried out according to similar criteria as for the initial survey. The validity may be renewed without a new survey if the laboratory has performed tests during the period of validity of the recognition, under the supervision of RINA Surveyors and fully complying with the relevant requirements.

8 CONDITIONS FOR THE MAINTENANCE OF THE RECOGNITION

During the period of validity of the recognition the laboratory is to ensure ongoing compliance with the initial conditions surveyed by RINA.

The laboratory is to notify RINA of any change to the internal organisation and/or to the system used to ensure the quality of the testing services.

The laboratory is to take the necessary measures so that RINA Surveyors can carry out surveys and tests in complete safety. In this regard it assumes with respect to Surveyors all the responsibility of employers for their workforce such as to meet the provisions of applicable legislation.

As a rule, when in attendance the RINA Surveyor is to be accompanied by laboratory personnel and is to have free access to all areas where it is necessary to carry out inspections required to verify compliance with the Rules.

Free access is also to be given to auditors and/or inspectors from authorities or external bodies within the scope of vertical audits of RINA's own performance.

RINA may suspend or withdraw the recognition in the event of failure to comply with the conditions laid down in these Rules.