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Paper, board and pulps — General requirements for the competence of laboratories authorized for the issue of optical reference transfer standards of level 3

Papiers, cartons et pâtes — Exigences générales concernant la compétence des laboratoires autorisés pour la délivrance des étalons de référence de transfert optique de niveau 3

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 6, *Paper, board and pulps*.

This third edition cancels and replaces the second edition (ISO 4094:2005). This version underwent major changes and now follows the requirements and adopts the format of ISO/IEC 17025.

Introduction

The main objectives of standardization of testing methods are to create the means by which comparable results can be obtained on different occasions, with different instruments and in different laboratories, and to control the processes that determine the acceptability of a product. Most testing methods for paper, board and pulps are linked by some type of reference standards to which the numerical results are to be related. In many cases, the comparison is made by means of readily available instruments of appropriate accuracy: for example, a balance with certified weights, a chronometer, a calibrated length-measuring device such as a micrometer, etc. However, in certain instances, the relation to the reference standard may not be obvious, or there may be practical problems in measuring particular properties; the test method should therefore include additional instructions for ensuring reasonable accuracy of the results. This may be accomplished with the aid of transfer standards, when the results are related either to certain properties of a unique reference standard, or to results obtained at specified laboratories entrusted with the performance of certain delicate measurements. Standardizing Laboratories and Authorized Laboratories act as links in supplying the transfer standards required.

The acceptance of testing and calibration results between countries will be facilitated if specified laboratories authorized to issue optical reference transfer standards comply with this document or if they obtain accreditation from bodies which have entered into mutual recognition agreements with equivalent bodies in other countries using this document.

The use of this document will facilitate cooperation between specified laboratories authorized to issue optical reference transfer standards and other bodies, and assist in the exchange of information and experience, and in the harmonization of calibration standards and procedures.

A laboratory's fulfilment of the requirements of this document means the laboratory meets both the general and specific technical competence requirements, and the management system requirements that are necessary for it to consistently deliver technically valid results.

Paper, board and pulps — General requirements for the competence of laboratories authorized for the issue of optical reference transfer standards of level 3

1 Scope

This document provides both general requirements and specific requirements (Annex A) for laboratories seeking to become "Authorized Laboratories (ALs)" and to maintain their Authorized Laboratory status for the issue of optical reference transfer standards of level 3. This document follows the requirements and adopts the format of ISO/IEC 17025, with the aims of:

a) establishing and maintaining international optical reference transfer standards of level 2 (IR2) traceable to an international optical reference primary standard of level 1 (IR1) maintained by a standardizing laboratory;

b) distributing traceability required to achieve inter-laboratory agreement in the results of test methods specified in International Standards for optical properties of paper, board or pulp;

c) participating in the design and development of new methods and international harmonization of procedures.

When a laboratory does not undertake one or more of the activities covered by this document, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

This document is for use by specified laboratories authorized to issue optical reference transfer standards in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies can also use it in confirming or recognizing the competence of laboratories.

NOTE It might be necessary to explain or interpret certain requirements in this document to ensure that the requirements are applied in a consistent manner. Guidance for consistent application can be obtained from Technical Committee ISO/TC 6.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO 2469, *Paper, board and pulps — Measurement of diffuse radiance factor (diffuse reflectance factor)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000 and ISO 2469 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
Standardizing Laboratory
laboratory of a national metrology institute (NMI) or designated institute (DI) that complies with the requirements of the International Committee of Weights and Measures (CIPM) Mutual Recognition Arrangement (MRA) for international recognition of its capabilities to maintain in safe custody, or otherwise realize the international reference standard of level 1 (notation *IR1*) (3.4), to transfer the traceability of *IR1* (3.4) to level 2 (notation *IR2*) (3.5)

Note 1 to entry: These internationally recognized calibration and measurement capabilities (CMCs) of NMIs and DIs that are signatories to the CIPM MRA are published in the key comparison database, maintained by the Bureau International des Poids et Mesures (BIPM).

3.2
Authorized Laboratory
AL
laboratory complying with the general requirements of this document and other specific requirements (Annex A) that transfers the traceability of international reference standards of level 2 (notation *IR2*) (3.5) to level 3 (notation *IR3*) (3.6)

3.3
Authorized Laboratory requirements
set of specified requirements to be fulfilled in order to establish or maintain authorized status

3.4
international reference standard level 1
IR1
primary optical reference standard, the perfect reflecting diffuser, the ideal diffuser exhibiting isotropic diffuse reflection with a reflectance equal to 1, used for calibration of optical transfer standards

Note 1 to entry: Reflectance is defined as the ratio of the reflected to the incident radiation.

3.5
international reference standard level 2
IR2
secondary optical reference transfer standard for the certification of level 3 (*IR3*) (3.6) standards or for the calibration of instruments, consisting of a material certified against an *international reference standard of level 1* (3.4) by a *Standardizing Laboratory* (3.1), as specified in the relevant International Standard

Note 1 to entry: This document refers to two types of IR2: a non-fluorescent IR2, whose spectral reflectance factors have been determined by a Standardizing Laboratory in relation to the IR1; and a fluorescent IR2, whose total spectral radiance factors corresponding to a specified CIE illuminant have been determined by a Standardizing Laboratory. A non-fluorescent IR2 is used to calibrate the photometric scale of an Authorized Laboratory's reference instrument, and a fluorescent IR2 standard is used to adjust the UV level of an Authorized Laboratory's reference instrument.

3.6
international reference standard level 3
IR3
tertiary optical reference transfer standard consisting of a material certified against an *international reference standard of level 2* (3.5) by an *Authorized Laboratory* (3.2), as specified in the relevant International Standard, and used by a testing laboratory for the calibration of instruments

Note 1 to entry: This document refers to two types of IR3: a non-fluorescent IR3, whose spectral reflectance factors have been determined by an Authorized Laboratory in relation to the non-fluorescent IR2; and a fluorescent IR3, whose calibration values have been determined by an Authorized Laboratory in relation to the fluorescent IR2. A non-fluorescent IR3 is used to calibrate the photometric scale of a testing laboratory's instrument. A testing laboratory uses a fluorescent IR3 to adjust the UV level of the testing laboratory's instrument.

3.7
peer review
name given to judgement of scientific merit by other scientists working in, or close to, the field in question

Note 1 to entry: For a laboratory to be formally authorized for the dissemination of international reference standards of level 3 (*IR3*) (3.6), the assessment of its compliance with the requirements of this document and other relevant ISO TC6 standards is carried out by peer review by one or more technical managers of the existing Authorized Laboratories or their designates.

3.8
testing laboratory
laboratory that calibrates testing instrumentation with an IR3

Note 1 to entry: A testing laboratory cannot issue international reference standards.

Table 1 — Organization of laboratories

Laboratory	Activity	Standard issued
Standardizing Laboratory	Maintains IR1 (level 1 standard) Evaluates IR2 against IR1	Level 2 standard (IR2)
Authorized Laboratory	Evaluates IR3 against IR2	Level 3 standard (IR3)
Testing Laboratory	Calibrates test instrumentation with IR3	No international reference standard issued

4 Management requirements for Authorized Laboratories

4.1 Organization

4.1.1 It is the responsibility of the Authorized Laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this document and to satisfy the needs of the customer to continue to maintain its status as an “Authorized Laboratory”.

4.1.2 The management system shall cover work carried out in the laboratory’s facilities.

4.1.3 If the Authorized Laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration activities of the Authorized Laboratory shall be defined in order to identify potential conflicts of interest.

4.1.3.1 Where an Authorized Laboratory is part of a larger organization, the organizational arrangements shall be such that departments having conflicting interests, such as production, commercial marketing or financing, do not adversely influence the laboratory's compliance with the requirements of this document.

4.1.3.2 If the Authorized Laboratory wishes to be recognized as a third-party laboratory, it shall be able to demonstrate that it is impartial and that it and its personnel are free from any undue commercial, financial and other pressures which might influence their technical judgement. The third-party testing or calibration laboratory shall not engage in any activities that may endanger the trust in its independence of judgement and integrity in relation to its testing or calibration activities.

4.1.4 The Authorized Laboratory shall

a) have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the management system, and to identify the occurrence of

departures from the management system or from the procedures for performing tests and/or calibrations, and to initiate actions to prevent or minimize such departures (see also 5.2);

b) have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;

c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

d) have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgement or operational integrity;

e) define the organization and management structure of the Authorized Laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;

f) specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;

g) provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, the purpose of each test and/or calibration, and with the assessment of the test or calibration results;

h) 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;

i) appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;

j) appoint deputies for key managerial personnel (see NOTE);

k) 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.

NOTE Individuals may have more than one function and it may be impractical to appoint deputies for every function.

4.1.5 Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management system.

4.2 Management system

4.2.1 The Authorized Laboratory shall establish, implement and maintain a management system appropriate to the scope of its activities. The Authorized Laboratory shall document its policies, systems, programmes, procedures and instructions to the extent necessary to ensure the quality of the test and/or calibration results. The system's documentation shall be communicated to, understood by, available to, and implemented by the appropriate personnel.

4.2.2 The Authorized Laboratory's management system policies, including a quality policy statement, shall be defined in a manual. The overall objectives shall be established, and reviewed during management review. The quality policy statement shall be issued under the authority of the organization's top management. It shall include at least the following:

a) the Authorized Laboratory management's commitment to good professional practice and to the quality of its testing and calibration in servicing its customers;

b) the management's statement of the Authorized Laboratory's standard of service;

c) the purpose of the management system related to quality;

d) a requirement that all personnel concerned with testing and calibration activities within the Authorized Laboratory familiarize themselves with the quality documentation and implement the policies and procedures in their work; and

e) the Authorized Laboratory management's commitment to comply with this document and to continually improve the effectiveness of the management system.

The quality policy statement shall be concise and may include the requirement that tests and/or calibrations shall always be carried out in accordance with stated methods and customers' requirements. When the calibration laboratory is part of a larger organization, some quality policy elements may be in other documents.

4.2.3 Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

4.2.4 Top management shall communicate to the organization the importance of meeting customer requirements as well as statutory and regulatory requirements.

4.2.5 The manual shall include or make reference to the supporting procedures, including technical procedures. It shall outline the structure of the documentation used in the management system.

4.2.6 The roles and responsibilities of technical management and the quality manager, including their responsibility for ensuring compliance with this document, shall be defined in the manual.

4.2.7 Top management shall ensure that the integrity of the management system is maintained when changes to the management system are planned and implemented.

4.3 Document control

4.3.1 General

The Authorized Laboratory shall establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

NOTE 1 In this context, "document" could refer to policy statements, procedures, specifications, calibration tables, charts, text books, posters, notices, memoranda, software, drawings, plans, etc. These may be on various media, whether hard copy or electronic, and they may be digital, analogue, photographic or written.

NOTE 2 The control of data related to testing and calibration is covered in 5.4.7. The control of records is covered in 4.13.

4.3.2 Document approval and issue

4.3.2.1 All documents issued to personnel in the Authorized Laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.

4.3.2.2 The procedure(s) adopted shall ensure that:

a) currently approved editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise ensured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3 Document changes

4.3.3.1 Changes to documents shall be reviewed and approved by the same function that performed the original review unless specifically designated otherwise. The designated personnel shall have access to pertinent background information upon which to base their review and approval.

4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

4.3.3.3 If the Authorized Laboratory's document control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialled and dated. A revised document shall be formally reissued as soon as practicable.

4.3.3.4 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

4.4 Review of requests, tenders and contracts

4.4.1 The Authorized Laboratory shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract for testing and/or calibration shall ensure that:

a) the requirements, including the methods to be used, are adequately defined, documented and understood (see 5.4.2);

b) the Authorized Laboratory has the capability and resources to meet the requirements;

c) the appropriate test and/or calibration method is selected and is capable of meeting the customers' requirements (see 5.4.2).

Any differences between the request or tender and the contract shall be resolved before any work commences. Each contract shall be acceptable both to the laboratory and the customer.

The request, tender and contract review shall be conducted in a practical and efficient manner, and the effect of financial, legal and time schedule aspects shall be taken into account. For internal customers, reviews of requests, tenders and contracts can be performed in a simplified way.

The review of capability shall establish that the laboratory possesses the necessary physical, personnel and information resources, and that the laboratory's personnel have the skills and expertise necessary

for the performance of the tests and/or calibrations in question. The review shall also encompass results of earlier participation in inter-laboratory comparisons or proficiency testing and/or the running of trial test or calibration programmes using samples or items of known value in order to determine uncertainties of measurement, limits of detection, confidence limits, etc.

4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

For review of routine and other simple tasks, the date and the identification (e.g. the initials) of the person in the laboratory responsible for carrying out the contracted work are considered adequate. For repetitive routine tasks, the review need be made only at the initial enquiry stage or on granting of the contract for ongoing routine work performed under a general agreement with the customer, provided that the customer's requirements remain unchanged. For new, complex or advanced testing and/or calibration tasks, a more comprehensive record shall be maintained.

4.4.3 The review shall also cover any work that is subcontracted by the laboratory.

4.4.4 The customer shall be informed of any deviation from the contract.

4.4.5 If a contract needs to be amended after work has commenced, the same contract review process shall be repeated and any amendments shall be communicated to all affected personnel.

4.5 Subcontracting of calibrations

Authorized Laboratories are not permitted to subcontract calibrations.

NOTE The Authorized Laboratory can refer the customer to one of the other Authorized Laboratories.

4.6 Purchasing services and supplies

4.6.1 The Authorized Laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures shall exist for the purchase, reception and storage of laboratory consumable materials relevant for the tests and calibrations. The Authorized Laboratory shall use harmonized procedures for selection and purchasing of IR3 papers as defined in Annex A.

4.6.2 The Authorized Laboratory shall ensure that purchased supplies and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

4.6.3 Purchasing documents for items affecting the quality of Authorized Laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

The description may include type, class, grade, precise identification, specifications, drawings, inspection instructions, other technical data, including approval of test results, the quality required and the management system standard under which they were made.

4.6.4 The Authorized Laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.