INTERNATIONAL STANDARD

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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)<br>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.

## 4.7 Service to the customer

**4.7.1** The Authorized Laboratory shall be willing to cooperate with customers or their representatives in clarifying the customer's request and in monitoring the laboratory's performance in relation to the work performed, provided that the laboratory ensures confidentiality to other customers.

NOTE Such cooperation could include:

a) providing the customer or the customer's representative reasonable access to relevant areas of the laboratory for the witnessing of tests and/or calibrations performed for the customer;

b) preparation, packaging and dispatch of test and/or calibration items needed by the customer for verification purposes.

Customers value the maintenance of good communication, advice and guidance in technical matters, and opinions and interpretations based on results. Communication with the customer, especially in large assignments, shall be maintained throughout the work. The laboratory shall inform the customer of any delays or major deviations in the performance of the tests and/or calibrations.

**4.7.2** The Authorized Laboratory shall seek feedback, both positive and negative, from its customers. The feedback shall be used and analysed to improve the management system, testing and calibration activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys and reviews of test or calibration reports with customers.

## 4.8 Complaints

The Authorized Laboratory shall have a policy and procedures for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the Authorized Laboratory (see also 4.11).

## 4.9 Control of nonconforming testing and/or calibration work

**4.9.1** The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that:

a) the responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports and calibration certificates, as necessary) are defined and taken when nonconforming work is identified;

b) an evaluation of the significance of the nonconforming work is made;

c) correction is taken immediately, together with any decision about the acceptability of the nonconforming work;

d) where necessary, the customer is notified and work is recalled;

e) the responsibility for authorizing the resumption of work is defined.

NOTE Identification of nonconforming work or problems with the management system or with testing and/or calibration activities can occur at various places within the management system and technical operations. Examples are customer complaints, quality control, instrument calibration, checking of consumable materials, staff observations or supervision, test report and calibration certificate checking, management reviews and internal or external audits.

**4.9.2** Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the laboratory's operations with its own policies and procedures, the corrective action procedures given in 4.11 shall be promptly followed.



 

## 4.10 Improvement

The Authorized Laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review. The Authorized Laboratory shall actively contribute to the improvement of the quality of the optical calibration system.

## 4.11 Corrective action

### 4.11.1 General

The Authorized Laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

NOTE A problem with the management system or with the technical operations of the laboratory may be identified through a variety of activities, such as control of nonconforming work, internal or external audits, management reviews, feedback from customers and from staff observations.

### 4.11.2 Cause analysis

The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

NOTE Cause analysis is the key and sometimes the most difficult part in the corrective action procedure. Often the root cause is not obvious and thus a careful analysis of all potential causes of the problem is required. Potential causes could include customer requirements, the samples, sample specifications, methods and procedures, staff skills and training, consumables, or equipment and its calibration.

### 4.11.3 Selection and implementation of corrective actions

Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem.

The laboratory shall document and implement any required changes resulting from corrective action investigations.

### 4.11.4 Monitoring of corrective actions

The Authorized Laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

### 4.11.5 Additional audits

Where the identification of nonconformities or departures casts doubts on the Authorized Laboratory's compliance with its own policies and procedures, or on its compliance with this document, the laboratory shall ensure that the appropriate areas of activity are audited in accordance with 4.14 as soon as possible.

NOTE Such additional audits often follow the implementation of the corrective actions to confirm their effectiveness. An additional audit is necessary only when a serious issue or risk to the business is identified.

## 4.12 Preventive action

**4.12.1** Needed improvements and potential sources of nonconformities, either technical or concerning the management system, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce

the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

**4.12.2** Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

NOTE 1 Preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints.

NOTE 2 Apart from the review of the operational procedures, the preventive action might involve analysis of data, including trend and risk analyses and proficiency-testing results.

## 4.13 Control of records

### 4.13.1 General

**4.13.1.1** The Authorized Laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.

**4.13.1.2** All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established. Records may be in any media, such as hard copy or electronic media.

**4.13.1.3** All records shall be held securely and in confidence.

**4.13.1.4** The Authorized Laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

### 4.13.2 Technical records

**4.13.2.1** The Authorized Laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

NOTE 1 It may be impossible or impractical to retain records of all original observations.

NOTE 2 Technical records are accumulations of data (see 5.4.7) and information which result from carrying out tests and/or calibrations and which indicate whether specified quality or process parameters are achieved. They may include forms, contracts, work sheets, work books, check sheets, work notes, control graphs, external and internal test reports and calibration certificates, customers' notes, papers and feedback.

**4.13.2.2** Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

**4.13.2.3** When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialled by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.



 

## 4.14 Internal audits

**4.14.1** The Authorized Laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this document. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

The cycle for internal auditing shall normally be completed in one year.

**4.14.2** When audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the Authorized Laboratory's test or calibration results, the Authorized Laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that the laboratory results may have been affected.

**4.14.3** The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.

**4.14.4** Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

## 4.15 Management reviews

**4.15.1** In accordance with a predetermined schedule and procedure, the Authorized Laboratory's top management shall periodically conduct a review of the Authorized Laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements. The review shall take account of:

— the suitability of policies and procedures;

— reports from managerial and supervisory personnel;

— the outcome of recent internal audits;

— corrective and preventive actions;

— assessments by external bodies;

— the results of inter-laboratory comparisons or proficiency tests;

— changes in the volume and type of the work;

— customer feedback;

— complaints;

— recommendations for improvement;

— other relevant factors, such as quality control activities, resources and staff training.

NOTE 1 A typical period for conducting a management review is once every 12 months.

Results shall feed into the Authorized Laboratory planning system and shall include the goals, objectives and action plans for the coming year.

NOTE 2 A management review includes consideration of related subjects at regular management meetings.

**4.15.2** Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are carried out within an appropriate and agreed timescale.

# 5 Technical requirements

## 5.1 General

**5.1.1** For a laboratory to function as an Authorized Laboratory, it shall comply with both the general and specific (Annex A) requirements of this document.

**5.1.2** Many factors determine the correctness and reliability of the tests and/or calibrations performed by an Authorized Laboratory. These include:

— human factors (personnel) (5.2);

— accommodation and environmental conditions (5.3);

— test and calibration methods and method validation (5.4);

— equipment (5.5);

— measurement traceability (5.6);

— proficiency testing and inter-laboratory comparisons (5.7);

— sampling (5.8);

— the handling of test and calibration items (5.9).

**5.1.3** The extent to which these factors contribute to the total uncertainty of measurement differs considerably between (types of) tests and between (types of) calibrations. The laboratory shall take account of these factors in developing test and calibration methods and procedures, in the training and qualification of personnel, and in the selection and calibration of the equipment it uses.

## 5.2 Personnel

**5.2.1** The Authorized Laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff who are undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills and knowledge, as required.

The personnel responsible for the opinions and interpretation included in test reports shall, in addition to the appropriate qualifications, training, experience and satisfactory knowledge of the testing carried out, also have:

— relevant knowledge of the technology used for the manufacturing of the items, materials, products, etc. tested, or the way they are used or intended to be used, and of the defects or degradations which may occur during or in service;

— knowledge of the general requirements expressed in the standards; and

— an understanding of the significance of deviations found with regard to the normal use of the items, materials, products, etc., concerned.

**5.2.2** The management of the Authorized Laboratory shall formulate the goals with respect to the education, training, knowledge and skills of the laboratory personnel. The Authorized Laboratory shall have a policy and procedures for identifying training needs and providing training of personnel.



 

The training programme shall be relevant to the present and anticipated tasks of the laboratory. The effectiveness of the training actions taken shall be evaluated.

**5.2.3** The Authorized Laboratory shall use personnel who are employed by, or under contract to, the laboratory. Where contracted and additional technical and key support personnel are used, the laboratory shall ensure that such personnel are supervised and competent and that they work in accordance with the laboratory's management system.

**5.2.4** The Authorized Laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

Job descriptions can be defined in many ways. As a minimum, the following shall be defined:

— the responsibilities with respect to performing tests and/or calibrations;

— the responsibilities with respect to the planning of tests and/or calibrations and evaluation of results;

— the responsibilities for reporting opinions and interpretations;

— the responsibilities with respect to method modification and development and validation of new methods;

— expertise and experience required;

— qualifications and training programmes;

— managerial duties.

**5.2.5** The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The Authorized Laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

## 5.3 Accommodation and environmental conditions

**5.3.1** Authorized Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

The Authorized Laboratory shall ensure that the environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. The technical requirements for accommodation and environmental conditions that can affect the results of tests and calibrations shall be documented.

**5.3.2** The Authorized Laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid to, for example, dust, electromagnetic disturbances, radiation, humidity, electrical supply and temperature, as appropriate to the technical activities concerned. Tests and calibrations shall be stopped when the environmental conditions jeopardize the results of the tests and/or calibrations.

**5.3.3** There shall be effective separation between neighbouring areas in which there are incompatible activities.

**5.3.4** Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The Authorized Laboratory shall determine the extent of control based on its particular circumstances.

**5.3.5** Measures shall be taken to ensure good housekeeping in the laboratory. Special procedures shall be prepared where necessary.

## 5.4 Test and calibration methods and method validation

### 5.4.1 General

The Authorized Laboratory shall provide instruction documents describing, in detail, the procedures to be followed in the measurement and checking of assigned values for ISO reference standards of either levels 2 or 3, as applicable.

The Authorized Laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope. These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.

The Authorized Laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both, where the absence of such instructions could jeopardize the results of tests and/or calibrations. All instructions, standards, manuals and reference data relevant to the work of the laboratory shall be kept up to date and shall be made readily available to personnel (see 4.3).

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform the tests and/or calibrations do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used as published by the operating staff in a laboratory. It may be necessary to provide additional documentation for optional steps in the method or additional details.

### 5.4.2 Selection of methods

The Authorized Laboratory shall use test and/or calibration methods, including methods for sampling, which meet the needs of issuing international reference standards of level 3 and which are appropriate for the tests and/or calibrations it undertakes. The laboratory shall select appropriate methods that have been published in international, regional or national standards, or by reputable technical organizations, or in relevant scientific texts or journals, or as specified by the manufacturer of the equipment. Methods published in international, regional or national standards shall preferably be used. The laboratory shall ensure that it uses the latest valid edition of a standard unless it is not appropriate or possible to do so. When necessary, the standard shall be supplemented with additional details to ensure consistent application.

Laboratory-developed methods or methods adopted by the laboratory may also be used if they are appropriate for the intended use and if they are validated. The customer shall be informed as to the method chosen. The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.

### 5.4.3 Laboratory-developed methods

The introduction of test and calibration methods developed by the Authorized Laboratory for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources.

Plans shall be updated as development proceeds and effective communication among all personnel involved shall be ensured.



 

### 5.4.4 Non-standard methods

When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the customer and shall include a clear specification of the customer's requirements and the purpose of the test and/or calibration. The method developed shall have been validated appropriately before use.

For new test and/or calibration methods, procedures shall be developed prior to the tests and/or calibrations being performed and shall contain at least the following information:

a) appropriate identification;

b) scope;

c) description of the type of item to be tested or calibrated;

d) parameters or quantities and ranges to be determined;

e) apparatus and equipment, including technical performance requirements;

f) reference standards and reference materials required;

g) environmental conditions required and any stabilization period needed;

h) description of the procedure;

i) affixing of identification marks, handling, transporting, storing and preparation of items;

j) checks to be made before the work is started;

k) checks that the equipment is working properly and, where required, calibration and adjustment of the equipment before each use;

l) the method of recording the observations and results;

m) any safety measures to be observed;

n) criteria and/or requirements for approval/rejection;

o) data to be recorded and method of analysis and presentation;

p) the uncertainty or the procedure for estimating uncertainty.

### 5.4.5 Validation of methods

**5.4.5.1** Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Routine inter-laboratory comparisons for Authorized Laboratories, along with calibration with IR2 standards issued by a Standardizing Laboratory and the use of working standards (see ISO 2469), each help to validate laboratory methods.

**5.4.5.2** The Authorized Laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. The laboratory shall record the results obtained, the procedure used for the validation and a statement as to whether the method is fit for the intended use.

Validation may include procedures for sampling, handling and transportation.

Additional techniques used for the determination of the performance of a method shall be one of, or a combination of, the following:

— inter-laboratory (round-robin) comparisons;

— calibration using reference standards or reference materials;

— comparison of results achieved with other methods;

— systematic assessment of the factors influencing the result;

— assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.

When some changes are made in the validated non-standard methods, the influence of such changes shall be documented and, if appropriate, a new validation shall be carried out.

**5.4.5.3** The range and accuracy of the values obtainable from validated methods (e.g. the uncertainty of the results, detection limit, selectivity of the method, linearity, limit of repeatability and/or reproducibility, robustness against external influences and/or cross-sensitivity against interference from the matrix of the sample/test object), as assessed for the intended use, shall be relevant to the customers' needs.

Validation shall include specification of the requirements, determination of the characteristics of the methods, a check that the requirements can be fulfilled by using the method, and a statement on the validity.

As method development proceeds, regular review shall be carried out to verify that the needs of the customer are still being fulfilled. Any change in requirements requiring modifications to the development plan shall be approved and authorized.

### 5.4.6 Estimation of uncertainty of measurement

**5.4.6.1** An Authorized Laboratory, in performing the calibration of IR3s, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations.

**5.4.6.2** When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.

NOTE 1 Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.

NOTE 2 The predicted long-term behaviour of the tested and/or calibrated item is not normally taken into account when estimating the measurement uncertainty.

NOTE 3 For further information, see ISO 5725-1 and the Guide to the Expression of Uncertainty in Measurement (see Bibliography).

### 5.4.7 Control of data

**5.4.7.1** Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

**5.4.7.2** When computers or automated equipment are used for the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use;



 

b) procedures are established and implemented for protecting the data; such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage, data transmission and data processing;

c) computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.

Commercial off-the-shelf software (e.g. word-processing, database and statistical programmes) in general use within their designed application range may be considered to be sufficiently validated. However, laboratory software configuration/modifications shall be validated as in 5.4.7.2 a).

## 5.5 Equipment

**5.5.1** The Authorized Laboratory shall have instructions on the use and operation of all relevant equipment, including that described in ISO 2469.

**5.5.2** The Authorized Laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data). In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the requirements of this document are met.

**5.5.3** Equipment and its software used for testing and calibration shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned. Calibration programmes shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications. It shall be checked and/or calibrated before use (see 5.6).

**5.5.4** Equipment shall be operated by authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.

**5.5.5** Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

**5.5.6** Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following:

a) the identity of the item of equipment and its software;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) checks that equipment complies with the specification (see 5.5.3);

d) the current location, where appropriate;

e) the manufacturer's instructions, if available, or reference to their location;

f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria and the due date of next calibration;

g) the maintenance plan, where appropriate, and maintenance carried out to date;

h) any damage, malfunction, modification or repair to the equipment.

**5.5.7** The Authorized Laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

**5.5.8** Equipment that gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming testing and/or calibration work" procedure (see 4.9).

**5.5.9** Whenever practicable, all equipment under the control of the Authorized Laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

**5.5.10** When, for whatever reason, equipment goes outside the direct control of the Authorized Laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.

**5.5.11** When intermediate checks are needed to maintain confidence in the calibration status of the equipment, these checks shall be carried out according to a defined procedure.

**5.5.12** Where calibrations give rise to a set of correction factors, the Authorized Laboratory shall have procedures to ensure that copies (e.g. in computer software) are correctly updated.

**5.5.13** Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.

## 5.6 Measurement traceability

### 5.6.1 General

For Authorized Laboratories, the programme for calibration of equipment shall be designed and operated so as to ensure that calibrations and measurements made by the laboratory are traceable to the IR1.

An Authorized Laboratory establishes traceability of its own measurement standards and measuring instruments to the IR1 standards by means of an unbroken chain of measurements.

### 5.6.2 Specific requirements – calibration

All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling, shall be calibrated before being put into service. The laboratory shall have an established programme and procedure for the calibration of its equipment.

Such a programme shall include a system for selecting, using, calibrating, checking, controlling and maintaining measurement standards, reference materials used as measurement standards, and measuring and test equipment used to perform tests and calibrations.

### 5.6.3 Reference standards and reference materials

#### 5.6.3.1 Reference standards

The Authorized Laboratory shall have a programme and procedure for the calibration of its IR2 reference standards. Reference standards shall be calibrated by a Standardizing Laboratory that



 

can provide traceability to an IR1. Such reference standards of measurement held by the Authorized Laboratory shall be used for calibration only and for no other purpose, unless it can be shown that their performance as reference standards would not be invalidated.

#### 5.6.3.2 Intermediate checks

Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards shall be carried out according to defined procedures and schedules (see ISO 2469).

#### 5.6.3.3 Transport and storage

The Authorized Laboratory shall have procedures for safe handling, transport, storage and use of reference standards in order to prevent contamination or deterioration and in order to protect their integrity.

NOTE Additional procedures may be necessary when reference standards are used outside the permanent laboratory for tests, calibrations or sampling.

### 5.7 Proficiency testing and inter-laboratory comparisons

Inter-laboratory comparisons provide routine feedback on the performance of, and the comparative differences between, each Authorized Laboratory.

On a routine basis as described in the specific requirements (Annex A), each Authorized Laboratory shall provide reference or calibration standards to each of the other Authorized Laboratories. The Authorized Laboratories shall evaluate, on an ongoing basis, the agreement with each other.

NOTE This "comparative benchmarking" allows the Authorized Laboratories to identify and evaluate any trends.

### 5.8 Sampling

The Authorized Laboratory shall record relevant data and operations relating to sampling, if applicable, that forms part of the testing or calibration that is undertaken.

### 5.9 Handling of test and calibration items

**5.9.1** The Authorized Laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer.

**5.9.2** The Authorized Laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a subdivision of groups of items and the transfer of items within and from the laboratory.

**5.9.3** Upon receipt of the test or calibration item, abnormalities or departures from normal or specified conditions, as described in the test or calibration method, shall be recorded. When there is doubt as to the suitability of an item for test or calibration, or when an item does not conform to the description provided, or the test or calibration required is not specified in sufficient detail, the Authorized Laboratory shall consult the customer for further instructions before proceeding and shall record the discussion.

**5.9.4** The Authorized Laboratory shall have procedures and appropriate facilities for avoiding deterioration, loss or damage to the test or calibration item during storage, handling and preparation. Handling instructions provided with the item shall be followed. When items have to be stored or

conditioned under specified environmental conditions, these conditions shall be maintained, monitored and recorded. Where a test or calibration item or a portion of an item is to be held securely, the laboratory shall have arrangements for storage and security that protect the condition and integrity of the secured items or portions concerned.

NOTE 1 Where test items are to be returned into service after testing, special care is required to ensure that they are not damaged or injured during the handling, testing or storing/waiting processes.

A sampling procedure and information on storage and transport of samples, including information on sampling factors influencing the test or calibration result, shall be provided to those responsible for taking and transporting the samples.

NOTE 2 Keeping a test or calibration item secure can be done for reasons of record, safety or value, or to enable complementary tests and/or calibrations to be performed later.

## 5.10 Assuring the quality of test and calibration results

**5.10.1** The Authorized Laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

a) regular use of certified reference materials and/or internal quality control using secondary reference materials;

b) participation in inter-laboratory comparison or proficiency testing programmes including round-robins, evaluations of materials, development of new procedures, etc.;

c) replication of tests or calibrations using the same or different methods;

d) retesting or recalibration of retained items;

e) correlation of results for different characteristics of an item.

The selected methods shall be appropriate for the type and volume of the work undertaken.

**5.10.2** Quality control data shall be analysed and, where they are found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results from being reported.

## 5.11 Reporting the results

### 5.11.1 General

The results of each test, calibration, or series of tests or calibrations carried out by the Authorized Laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.

The results shall be reported, usually in a test report or a calibration certificate (see NOTE), and shall include all the information requested by the customer and necessary for the interpretation of the test or calibration results and all information required by the method used. This information is normally that required by 5.11.2, and 5.11.3 or 5.11.4.

In the case of tests or calibrations performed for internal customers, or in the case of a written agreement with the customer, the results may be reported in a simplified way. Any information listed in 5.11.2 to 5.11.4 which is not reported to the customer shall be readily available in the laboratory which carried out the tests and/or calibrations.

NOTE Test reports and calibration certificates are sometimes called test certificates and calibration reports, respectively.



 

The test reports or calibration certificates may be issued as hard copy or by electronic data transfer, provided that the requirements of this document are met.

### 5.11.2 Test reports and calibration certificates

Each test report or calibration certificate shall include at least the following information, unless the authorized laboratory has valid reasons for not doing so:

a) a title (e.g. “Test Report” or “Calibration Certificate”);

b) the name and address of the Authorized Laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;

c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;

d) the name and address of the customer;

e) identification of the method used;

f) a description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;

g) the date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;

h) the test or calibration results with, where appropriate, the units of measurement;

i) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate;

j) where relevant, a statement to the effect that the results relate only to the items tested or calibrated.

Hard copies of test reports and calibration certificates shall also include the page number and total number of pages.

It is recommended that Authorized Laboratories include a statement specifying that the test report or calibration certificate shall not be reproduced except in full without written approval of the laboratory.

### 5.11.3 Test reports

In addition to the requirements listed in 5.11.2, test reports shall, where necessary for the interpretation of the test results, include the following:

a) deviations from, additions to, or exclusions from the test method, and information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of compliance/non-compliance with requirements and/or specifications;

c) where applicable, a statement on the estimated uncertainty of measurement; information on uncertainty is needed in test reports when it is relevant to the validity or application of the test results, when a customer's instruction so requires, or when the uncertainty affects compliance to a specification limit;

d) where appropriate and needed, opinions and interpretations (see 5.11.5);

e) additional information which may be required by specific methods, customers or groups of customers.

### 5.11.4 Calibration certificates

**5.11.4.1** In addition to the requirements listed in 5.11.2, calibration certificates shall include the following, where necessary for the interpretation of calibration results:

a) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;

b) the uncertainty of measurement and/or a statement of compliance with an identified metrological specification or clauses thereof;

c) evidence that the measurements are traceable.

**5.11.4.2** The calibration certificate shall relate only to quantities and the results of functional tests. If a statement of compliance with a specification is made, this shall identify which clauses of the specification are met or not met.

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference.

When statements of compliance are made, the uncertainty of measurement shall be taken into account.

**5.11.4.3** When an instrument for calibration has been adjusted or repaired, the calibration results before and after adjustment or repair, if available, shall be reported.

**5.11.4.4** A calibration certificate (or calibration label) shall not contain any recommendation on the calibration interval except where this has been agreed with the customer.

### 5.11.5 Opinions and interpretations

When opinions and interpretations are included, the laboratory shall document the basis upon which the opinions and interpretations have been made. Opinions and interpretations shall be clearly marked as such in a test report.

Opinions and interpretations included in a test report may comprise, but not be limited to, the following:

— an opinion on the statement of compliance/non-compliance of the results with requirements;

— fulfilment of contractual requirements;

— recommendations on how to use the results;

— guidance to be used for improvements.

In many cases it might be appropriate to communicate the opinions and interpretations by direct dialogue with the customer. Such dialogue shall be written down.

### 5.11.6 Electronic transmission of results

In the case of transmission of test or calibration results by telephone, email, telex, facsimile or other electronic or electromagnetic means, the requirements of this document shall be met (also see 5.4.7 control of data).

### 5.11.7 Format of reports and certificates

The format shall be designed to accommodate each type of test or calibration carried out and to minimize the possibility of misunderstanding or misuse.

Attention shall be given to the layout of the test report or calibration certificate, especially with regard to the presentation of the test or calibration data and ease of assimilation by the reader.

The headings shall be standardized as far as possible.

### 5.11.8 Amendments to test reports and calibration certificates

Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document or data transfer which includes the statement:

"Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]",

or an equivalent form of wording.

Such amendments shall meet all the requirements of this document.

When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.

# Annex A
(normative)

# Specific requirements for laboratories authorized to issue optical property reference transfer standards of level 3

## A.1 Introduction

This document is in two parts: part one concerns compliance with the general technical competence and management system requirements of this document and part two (Annex A) concerns the specific technical requirements for the laboratory to be authorized for issuing optical reference transfer standards of level 3.

Participating laboratories that are recognized as Authorized Laboratories (ALs) recognize the degree of equivalence of the optical reference transfer standards of level 2 (IR2) that are developed and maintained in accordance with the requirements of this document, as evidenced by the results of proficiency testing for the ISO/TC 6 standards and quantities that are listed in Annex B.

Participating laboratories that are issued certificates of compliance (Annex C) as ALs recognize the validity of each other's calibration and testing certificates for the issue of optical reference transfer standards of level 3 (IR3), from the results of bilateral comparisons of each other's IR3s for the ISO TC6 standards and quantities that are listed in Annex B.

## A.2 Technical basis of specific requirements for the competence of Authorized Laboratories

a) The technical basis of providing confidence in the calibration system established by this document for laboratories authorized to issue IR3 calibration and testing certificates is the set of results obtained in the course of time through proficiency testing, round-robin comparisons and bilateral comparisons carried out by the ALs and reported at meetings of ISO/TC 6/WG 3 Optical Properties.

b) The monthly bilateral comparisons carried out by the ALs according to this standard are referred to as OPAL group bilateral comparisons. The OPAL group is the name given to the collective group of technical representatives from the ALs for optical property measurements.

c) One of the key technical requirements for qualifying new applicant ALs is the set of results obtained when they participate in the OPAL group bilateral comparisons for a minimum period of 6 months, to ensure that acceptable inter-laboratory agreement is achieved and maintained for a minimum period of 6 months. Further technical requirements for new ALs are detailed in A.6.2.

## A.3 Responsibilities of the Authorized Laboratories

**A.3.1** The hierarchy of the calibration system showing the relationship between the use of a standard and the type of laboratory that is responsible for maintaining and issuing these different levels of standard is summarized in Table 1 (3.8).

The ALs (3.2) have the responsibility of selecting suitable materials for use as optical reference transfer standards of level 3 (IR3) (3.6), having their optical reference standards of level 2 (IR2) (3.5) calibrated by a Standardizing Laboratory (3.1), choosing methods and frequency of proficiency testing, and affirming and documenting the validity of the results are within the reported inter-AL precision statement. The specific responsibilities of the ALs are detailed in A.3.2 to A.3.5:

**A.3.2** The ALs shall be prepared to support their representative to the OPAL group to fulfil the responsibilities, which include:

**A.3.2.1** Attendance and active participation at OPAL group meetings and teleconferences.

NOTE Currently face-to-face meetings are held approximately every 18 months, in conjunction with the ISO/TC 6 meetings.

**A.3.2.2** Active participation in the work of the OPAL group within the scope of this standard.

**A.3.3** ALs shall coordinate the selection, evaluation and purchase of the papers that constitute the IR3 so that all IR3s issued come from the same production lot. ALs shall develop and carry out common procedures for the validation of non-fluorescent and fluorescent paper to be used as IR3s.

**A.3.4** ALs shall send IR2s to the Standardizing Laboratory for calibration at least every two years.

**A.3.5** ALs shall implement harmonized procedures, for example, the geometric correction for the calibration transfer from the Standardizing Laboratory's instrument to the ALs' instruments. Any technical changes in the harmonized procedures are based on consensus obtained during the OPAL group meetings. These decisions are recorded and reported in the written minutes of the meeting.

## A.4 Participation in bilateral comparisons

ALs shall engage in monthly bilateral comparisons and arrange for the results of these comparisons to be compiled, analysed and reported to all of the AL members on an annual basis. These inter-AL comparison results over a period of several years serve as the basis for the precision statement issued by the ALs, which is also made available on the ISO/TC 6 public site.

## A.5 Participation in continuous improvement

ALs shall actively contribute to the continuous improvement of the quality of the optical calibration system for IR3s.

NOTE Contributions can include leading and participating in round-robins organized by the OPAL group to evaluate new materials as candidate IR3s, or proposals for new or modified calibration procedures for IR3s, etc.

## A.6 Registration of a laboratory as an Authorized Laboratory

### A.6.1 Existing Authorized Laboratory

The period of validity for an AL is two years, with this statement of compliance being issued in April of every even-numbered year.

For a laboratory to retain its status as an AL, it shall provide for peer review a biennial report whose content is specified in Annex D by March 1st of every even-numbered year. It shall also provide documentation, such as a letter, stating the following:

— that the AL can, and shall continue to, meet the requirements for an AL as specified in this document, including the specific requirements described in Annex A;

— that in all activities concerning the preparation of ISO reference or transfer standards, the laboratory shall follow the standards and instructions in the relevant International Standard;

— that the AL shall continue to calibrate against standards of level 2 (IR2) issued by a Standardizing Laboratory;

— that the AL shall issue international reference standards of level 3 (IR3) to any laboratory in any country requesting them;

— that the AL shall continue to participate in comparative measurements (bilateral comparisons, see Clauses A.4 and A.5);

— that the AL shall annually upload results of their bilateral comparisons for evaluation and comparison to the common server space dedicated to that purpose;

— that the AL representative is willing to serve as a peer reviewer for a new applicant AL, to confirm that it meets the general competence and management system requirements of this standard;

— that the AL is willing to receive the visit of representatives of the other ALs for an on-site peer review of compliance to this document.

NOTE The on-site peer review could be in conjunction with ISO TC6 meetings in the city of the existing AL or, upon special request, by the convenor of the OPAL group.

### A.6.2 New Authorized Laboratory

A new calibration laboratory that wants to become an AL shall carry out the following steps:

— Submit a formal application letter to any one of the existing ALs with supporting documentation to demonstrate compliance to this document, including calibration details for IR2 transfer standards acquired from a Standardizing Laboratory. The other information that shall be contained in this supporting document is the same as the biennial report whose table of contents is given in Annex D.

— The applicant laboratory shall also demonstrate equivalence of their measurements with the existing ALs. This is carried out by the applicant laboratory participating in the regularly scheduled ALs' bilateral monthly comparisons for the requested measurement quantities in accordance with the relevant ISO/TC 6 standards. This is to ensure that acceptable inter-laboratory agreement is achieved and maintained for a minimum period of 6 months. During this probationary period, the laboratory cannot issue optical reference standards of level 3.

— During this probationary period, at every stage, the matter shall be held in strict confidence by the members of the OPAL group. The OPAL group shall respect and protect any and all proprietary technical information acquired during the qualification procedure. If any member of the OPAL group cannot be neutral in these matters, then he or she shall not participate directly in the procedure.

— Upon successful demonstration of inter-laboratory agreement, the applicant laboratory shall undergo an on-site peer review by one of the members of the existing ALs or a designate (the deputy). Any person acting as a technical assessor for this peer review shall be appointed only if he or she is acceptable to the applicant laboratory. The technical assessor(s) shall report their overall conclusions to the members of the OPAL group, respecting and protecting any and all proprietary and technical information acquired during the assessment.

— The peer review shall include the review of supporting documents, including calibration detail for an IR2 transfer standard, and at least 6 months of acceptable bilateral inter-laboratory comparison results. At the next meeting of the OPAL group, the OPAL group convenor or deputy shall present the evidence supporting the acceptance of the laboratory and the laboratory's results in the bilateral (international laboratory) comparisons, and request confirmation of the laboratory's appointment by a vote of the OPAL group members present at this meeting. For this purpose, only one designated OPAL group member from each AL shall have the right to vote.

  — If the applicant laboratory is successful in receiving > 60 % consensus acceptance by the voting OPAL group members, then the convenor of the OPAL group shall inform the ISO/TC 6 Secretariat, who in turn may post this information on the new AL on their public site. This information would generally include the name and address of the AL, and its acceptance by the members of the OPAL group as an AL for the designated TC 6 International Standards.



 