Asia Pacific Laboratory Accreditation Cooperation

GUIDANCE NOTES ON ISO/IEC 17020

PURPOSE

This document provides guidance notes additional to the ILAC/IAF guidance document on accreditation of inspection bodies. It is intended primarily to assist inspection bodies to understand issues that will be examined by accreditation bodies during assessments. It is to be used in conjunction with the ILAC/IAF document.

The commentary and interpretative material is numbered with the relevant clause number of the standard, e.g. 12.2(1) is commentary number 1 on the requirements of clause 12.2 of ISO/IEC 17020:1998.

AUTHORSHIP

This document was produced by the APLAC Technical Committee.

COPYRIGHT

FURTHER INFORMATION

For further information about this document, contact the APLAC Secretariat at:

NATA
Level 1
675 Victoria Street
Abbotsford VIC 3067
Australia
Tel: +61 3 9274 8200
Fax: +61 3 9421 0887
email: aplac@nata.com.au
Website: www.aplac.org

TABLE OF CONTENTS

1 SCOPE

1.4(1) In cases of ambiguity, final determination of whether a particular activity may be included in the scope of accreditation as an inspection activity should be made by the accreditation body, taking into account accepted international practice where relevant.

2 DEFINITIONS

2.1(1) For professional judgement to be exercised the staff member responsible for the inspection, referred to in clause 8.2 of ISO/IEC 17020, should personally perform the inspection or effectively supervise the inspection.

3 ADMINISTRATIVE REQUIREMENTS

3.5(1) The conditions referred to in this clause of ISO/IEC 17020 are contractual conditions not physical conditions at inspection sites. Items which are commonly included in conditions of contract include:

- access to documented inspection history
- responsibility for safe site access
- timely availability of key client personnel
- preparation of items for inspection
- response to adverse weather conditions
- level of reporting
- terms of payment
- level of liability insurance, etc.

3.5(2) In the case of Type C inspection bodies the conditions of contract should include a clear statement of the activities that prevent it being classified as a Type A inspection body.

4 INDEPENDENCE, IMPARTIALITY AND INTEGRITY

4.1(1) An effective procedure normally requires personnel to report and record any incidents of undue pressure they experience.

4.1(2) Undue pressure on personnel may be brought to bear through financial, marketing, customer relations and personal matters, as well as by other technical or non-technical considerations.

4.2.3(1) In the case of type C inspection bodies, contractual conditions should include a clear statement summarising the interests or activities of the inspection body or associated bodies that resulted in the type C classification. This statement should be sufficiently explicit to enable potential clients to make informed decisions on the adequacy of the level of independence offered.

6 ORGANIZATION AND MANAGEMENT

6.2(1) Details of personal or position responsibilities should be included in the quality system documentation. This may cover clerical staff as well as management, technical and inspection personnel.

6.3(1) Functions of the technical manager may include, but not be limited to, authorisation of inspection methods, and technical support for inspectors.

7 QUALITY SYSTEM

7.1(1) Policy statements are intended to demonstrate senior management commitment to the quality system. Objectives should include measurable targets, which are reviewed at least annually. Training records should include details of extent to which familiarity with the quality system that has been assessed.

7.5(1) In cases where an inspection body has a number of offices in different locations, responsibility for the practical maintenance of the quality system should be assigned to a named individual in each office.

7.6(1) The document control system shall be documented. A statement that documents will be controlled is not sufficient.

7.6a)(1) There must be a clear and authoritative means for all employees to identify the current authorised version of any controlled document.

7.6a)(2) Effective systems must be in place to ensure that each relevant employee has been made aware of and understands updates to any document which could affect the conduct, outcome, recording or reporting of an inspection.

7.6b)(1) It must always be possible to identify the individual who is responsible for the technical validity of any specific technical document.

7.7(1) Internal audits cannot be considered to meet the requirements of ISO/IEC 17020 unless there is evidence of effective corrective action following identification of any non-compliances.

7.8(1) Feedback includes internal feedback for the purposes of improvement, as well as complaints and preventive action.

7.8(2) Procedures for feedback and corrective action should normally include but not be limited to the following constituents:

- description of the issue
- investigation of the cause
- description of immediate action taken
- description of corrective action to be taken to prevent recurrence
- identification of the person responsible for corrective action
- target date for completion of corrective action
- monitoring of progress of corrective action
- sign off of completed corrective action.

Records of feedback and corrective action should be kept.

7.9(1) An important aspect of management review is the identification of trends in all forms of feedback that may indicate areas of the quality system that would benefit from review. This aspect of management review need not be carried out more than once a year unless there are large volumes of feedback suggesting an urgent need for review.

7.9(2) The outcome of a management review should include the setting of objectives for the coming period, proposed improvements to the quality system or an explicit statement that no improvements are required.

8 PERSONNEL

8.2(1) For professional judgement to be exercised the staff member responsible for inspection, referred to in clause 8.2 of ISO/IEC 17020, should personally perform the inspection or effectively supervise the inspection.

8.4(1) All stages of training, such as those detailed in clause 8.3 of ISO/IEC 17020, should be recorded.

Note: Training records do not establish competence. They are a statement that the management considers the individual to be competent to perform specific inspection tasks and, where relevant, to use specific equipment.

Note: Training records should detail competence levels assessed in all relevant technical and administrative areas and should be reviewed regularly (normally annually).

8.6(1) In cases where it is impossible to separate remuneration from the number of inspections done, eg. in very small inspection bodies, other means, such as recording the duration of inspections, should be established to ensure that the quality of inspections is not compromised by financial considerations.

9 FACILITIES AND EQUIPMENT

9.7(1) The definition of measurement traceability given in ILAC P10:2002 should be applied in understanding this clause.

9.7(2) Where accuracy requirements permit calibrations of working instruments to be performed in-house, traceability to national standards should be assured by the use of reference standards of measurement for which the inspection body holds current traceable calibration certificates. The calibration certificate should detail an uncertainty of measurement that is appropriate for the equipment that is to be calibrated from the reference standard. For further information on uncertainty of measurement see ISO/IEC 17025, clause 5.4.6, and EA-4/02, *"Expressions of the Uncertainty of Measurements in Calibration".*

9.9(1) Records of in-service checks on equipment should be maintained.

9.10(1) In situations where non-certified reference materials are used, inspection reports should clearly state that the stated conclusion on conformity was based on uncertified reference materials.

9.13a)(1) In-house developed software such as spreadsheet programs shall be validated before use. Validation may be accomplished by processing a known data set and performing equivalent processing manually or by other means. The extent of the known data set should be such that all possible

outcomes of the software manipulation can be adequately checked. Software should be protected from unauthorised alteration. Unauthorised alteration may be detected by processing the known data set periodically. Records of software validations and any necessary periodic checks should be maintained.

9.13a)(2) All software, including proprietary products, should be controlled in an equivalent way to hard-copy documents. Records of version numbers and dates when each version was brought into or taken out of service should be maintained.

9.13d)(1) Where electronic records are the primary storage medium, appropriate methods such as regular backups and offsite safekeeping of backups should be implemented. The frequency of backups should be set to reduce the risk of loss to an acceptable level.

10 INSPECTION METHODS AND PROCEDURES

10.3(1) All non-standard methods should be authorised by the technical manager or another technically qualified person. Non-standard methods should be documented, retained and referenced in relevant reports.

10.7(1) Checking points should be identified in operating procedures. The extent of checking should also be defined, e.g. checks for completeness, for technical consistency or typographical errors.

10.7(2) There should be documentary evidence that checks have been done. This evidence should include the identity of the checker and the date of the check.

10.7(3) An inspection body that performs large numbers of routine inspections may perform less than 100% checking. In such cases justification of the sampling method and sample size should be documented.

12 RECORDS

12.2(1) Inspection records should be detailed and comprehensive. Satisfactory evaluation of the inspection may require more than the following types of information to be recorded:

- client instructions
- details of job review
- details of the items inspected
- inspection conditions
- information provided by the client
- identity of the person who performed the inspection
- equipment used
- equipment verification records
- the inspection procedures used
- inspection observations
- conformity decisions (with supporting justification)
- aspects not inspected, with reasons given, e.g. lack of safe access.

Additional information requirements should be considered at the times of the inspection and subsequent reporting.

13 INSPECTION REPORTS AND INSPECTION CERTIFICATES

13.2(1) Accreditation cannot normally be claimed for an inspection report that relies upon material provided by a subcontractor that does not have demonstrated competence as required by clause 14.2 of ISO/IEC 17020. Where regulations or other authoritative requirements stipulate that a report must include a claim of accreditation, all information, critical to the inspection decision, provided by a body that does not have demonstrated competence, should be clearly identified as such.

14 SUBCONTRACTING

14.2(1) To maintain consistent standards of assessment of competence (as required by international MRAs among accreditation bodies), where the assessment of a subcontractor is carried out by an inspection body, it should be able to be demonstrated that the assessment team is technically competent and knowledgeable in the application of ISO/IEC 17020 or ISO/IEC 17025, as appropriate, and that the assessing body complies with the requirements of ISO/IEC 17011.

14.4(1) Clause 14.4 refers to work outside the accredited scope of the inspection body, the results of which have a critical influence on conformity decisions in the inspection body's reports or certificates.

14.4(2) Inspection reports that rely on data or services not covered by a scope of accreditation for their conclusions cannot include any reference to accreditation except under the circumstances outlined in clause 14.4c of the ILAC/IAF guidance document on ISO/IEC 17020.

14.4(3) When an endorsed inspection report or certificate is required by regulations and no providers of demonstrated competence are available for a particular supporting service, the report or certificate shall state prominently that the conformity decision is made in good faith, based on information of unknown reliability, and that the conformity decision is not covered by an accreditation. The report or certificate should clearly identify which information is of unproven reliability. The inspection body shall take full responsibility for the conformity decision irrespective of the source of any information required to support the decision.

15 COMPLAINTS AND APPEALS

15.1(1) Complaints should include all feedback from dissatisfied clients, regulators or other stakeholders, however received.

REFERENCES

1. ILAC P10:2002 ILAC Policy on Traceability of Measurement Results

2. ISO/IEC 17025:1999 General requirements for the competence of testing and

calibration laboratories

3. EA-4/02:1999 Expressions of the Uncertainty of Measurements in Calibration

4. ISO/IEC 17011:2004 General requirements for accreditation bodies accrediting conformity assessment bodies