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IAS ACCREDITED LABORATORIES : GUIDELINES FOR CONDUCTING INTERNAL AUDITS AND MANAGEMENT REVIEWS

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IAS has found that laboratory personnel are often confused by requirements in ANS/ISO/IEC Standard 17025:2005 (*General requirements for the competence of testing and calibration laboratories*) that they conduct "audits" and "management reviews" of their operations and quality system. (See Sections 4.14 and 4.15 of Standard 17025.) Frequently, laboratory personnel assume that if someone in authority is checking regularly on the work the laboratory performs, then they are doing "audits"; and if someone in management is periodically reviewing the laboratory's overall performance, then they are doing "management review." Unfortunately, such informal checks on work and performance will not satisfy accreditation requirements of IAS or any other legitimate accreditation body. Presented below are guidelines to help you meet requirements for audits and management reviews.

AUDITS (OFTEN CALLED "INTERNAL AUDITS")

An "internal audit" is a formal laboratory activity that must be performed in accordance with a documented procedure and on a regular schedule. One laboratory may choose to conduct an audit of its entire quality system once a year, while a different laboratory may choose to conduct a complete audit every six months. Yet a third laboratory may choose to audit small parts of its system every month, with the intention that every part will be covered at least once a year. Generally, as a minimal requirement, you must audit every part of your quality system at least once every twelve months.

During a quality-system audit, you look at the way your laboratory actually operates, and you compare this to the laboratory operations as described in your quality manual or other quality-system documentation. The system described in the documents, and the system as it operates in the real world, must be in accordance. For example: Suppose your quality manual says the laboratory will maintain records on the qualifications, training, skills, and experience of technical personnel. (This is required by Section 5.2.5 of Standard 17025.) During the internal audit, you would check to see that such records are actually being maintained. If they are not, then the audit has detected a problem that must be remedied.

Let's take another example. Say that according to your quality manual, every piece of test equipment must, in some way, have its calibration status indicated. (This is required by Section 5.5.8 of Standard 17025.) During the audit, you might randomly check a half-dozen pieces of equipment to see if their calibration status is identified. If it is not, then your audit has detected another problem that requires correction.

It is possible you will need just one person to audit your laboratory, although it could take several people to audit a big laboratory. Whoever performs the audits, he or she must be fully qualified to do so, and it is preferable that the auditor receive some special training on how to conduct an audit. Also, if it is possible, each laboratory activity must be audited by a staff member who is not personally involved in carrying out that activity. (This is to prevent any conflict of interest. You would not want the person responsible for equipment maintenance to audit the maintenance of equipment.)

It is *absolutely essential* that your internal auditors keep written records of the audit. The laboratory must

also keep written records of any actions taken to remedy problems uncovered during the audit. (See Section 4.14.3 of Standard 17025: "The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded.") Follow up audits shall be conducted to verify the effectiveness of corrective actions. When IAS representatives come to your laboratory to conduct assessments, they will certainly make a point of reviewing the records of internal audits.

Finally, you might want to refer to Attachment A for a sample procedure on internal audits. Section 4.14.1 of Standard 17025 says that the laboratory "shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits." Attachment A may give you some ideas on what to include in your own procedure.

MANAGEMENT REVIEWS

Like internal audits, management reviews are regularly scheduled, formal activities that shall be conducted in accordance with a documented procedure. As a rule, a "management review" is a special meeting of the laboratory's top management, called to discuss the laboratory's quality system, its effectiveness, and any changes that may be needed. Usually, management reviews are timed to follow closely after each internal audit, so that the results of the audit may be discussed during the management meeting.

Attachment B presents a sample procedure for management reviews, and might give you some ideas on how your laboratory management should carry out reviews of the quality system. (You will need your own written procedure, since Section 4.15.1 of Standard 17025 says every accredited laboratory must have "a predetermined schedule and procedure" to conduct management reviews.)

Keep in mind that, to meet requirements for accreditation, you must have *written records* of management review meetings. The easiest way to document each meeting is to have someone keep minutes, which will be reviewed by IAS assessors when they visit your laboratory. The written records should also cover actions taken as a result of management meetings.

Attachment A
Sample Procedure for Internal Audits

Everybody's Laboratory, Inc.	**Procedure No.:** 12
Standard Operating Procedures	**Effective Date:** August 24, 2006
	Revision: 1
Approval: _____	**Page 1 of 1**

TITLE/SUBJECT: *Internal Audits*

Purpose: This procedure provides for regularly scheduled audits of the quality system, to confirm the system's implementation and check on its effectiveness.

Scope: This procedure applies to all internal audits.

Procedure:

1. Every activity comprising part of the quality system shall be audited at least once every twelve months.

2. The quality manager is chiefly responsible for planning internal audits and overseeing their execution.

3. Persons performing audits shall be adequately trained and qualified.

4. Persons performing audits must be independent of the functions they are auditing.

5. Auditors shall note problems on Corrective Action Request (CAR) forms, and send the forms to the most appropriate management person to have the problem corrected. Auditors shall then follow up to confirm that corrective actions have been carried out.

6. The quality manager shall retain records of internal audits for at least three years. Records shall include audit checklists, CARs, and related documentation.

7. Results of internal audits shall be a standing item on the agenda for management reviews of the quality system.

Attachment B
Sample Procedure for Management Reviews

Everybody's Laboratory, Inc.	**Procedure No.:** 13
Standard Operating Procedures	**Effective Date:** August 23, 2006
	Revision: 1
Approval: _____	**Page 1 of 1**

TITLE/SUBJECT: *Management Review of the Quality System*

Purpose: This procedure provides for regular management reviews of the entire quality system, to ensure its continuing suitability and effectiveness.

Scope: This procedure applies to all participants in the periodic management reviews.

Procedure:

1. Management review meetings take place at least every twelve months, and are scheduled by the quality manager.

2. Participants normally include the president, vice president, laboratory manager, senior engineer, quality manager, other personnel as appropriate.

3. The quality manager shall prepare the agenda and keep the minutes of the meeting. The agenda shall include discussion of the following:

- 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 interlaboratory comparisons or proficiency testing
- Changes in the volume and type of work
- Client feedback
- Complaints
- Other relevant factors (quality control activities, resources, staff training)

4. Action items will be assigned to specific personnel, and target dates will be set for completion.

5. After the meeting, the quality manager will distribute, to all participants, copies of the minutes and a memorandum on conclusions reached and actions planned or initiated. The quality manager will also follow up on action items, to ensure completion.

6. The quality manager shall retain records of each meeting for at least three years. Records shall include minutes of the meeting, memorandum on results.