Internal audits and management reviews - guidance for laboratories and inspection bodies
This document has been produced to provide laboratories and inspection bodies with guidelines on how to set up a programme for the internal audit of their management systems and their management reviews. This document replaces SWEDAC DOC 97:3 (EAL-G3) and SWEDAC DOC 96:11, and has been revised in line with SS-ENISO/IEC 17025 and SS-ENISO/IEC 17020.

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The word ‘must’ is used in this document to specify the requirements that are found in the SS-EN ISO/IEC 17025 and SS-EN ISO/IEC 17020 standards. The word ‘should’ is used in this document when giving advice on how to meet the requirements set out in these standards. There can be other ways of fulfilling the requirements than those set out in this guidance document.

This document uses the concept ‘internal audit of management systems’ to emphasise the fact that audits are carried out by the organisation itself. Internal audits are often called first party audits as they are carried out by the organisation itself or contracted by the organisation itself.
1 INTRODUCTION

1.1 SS-EN ISO/IEC 17025 [1] General requirements for the competence of testing and calibration laboratories, SS-EN ISO 15189 Medical laboratories – Particular requirements for quality and competence [3] and SS-EN ISO/IEC 17020 [2] General criteria for the operation of various types of body performing inspection specify that the laboratory or inspection body has to have a management system adapted to the type, area and scope of its activities.

Note: For medical laboratories, SS-EN ISO 15189 Medical laboratories – Particular requirements for quality and competence [3] can be used as an alternative to SS-EN ISO/IEC 17025. However, for practical reasons, only SS-EN ISO/IEC 17025 will be referred to as the standard for accredited laboratories.

1.2 SS-EN ISO/IEC 17025 [1] requires that “the laboratory shall periodically, and in accordance with a pre-determined 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 International Standard”.

1.3 SS-EN ISO/IEC 17020 [2] requires that “the inspection body shall carry out a system of planned and documented internal quality audits to verify compliance with the criteria of this standard and the effectiveness of the quality system”.

1.4 This document has been drawn up to provide laboratories and inspection bodies with instructions and advice on how to create programmes for internal audits of their management systems and management reviews. It has been produced with the understanding that the laboratory/inspection body has introduced a management system that meets the requirements set out in SS-EN ISO/IEC 17025 [1] and SS-EN ISO/IEC 17020 [2].

1.5 The guidelines set out in this document are general guidelines. How internal audits of management systems and management reviews are carried out depends on the size, application area and organisational structure of the laboratory or inspection body. Many of the measures described in this document can be simplified; also refer to section 7.
2 DEFINITIONS

2.1 Quality – The degree to which a set of inherent characteristics fulfils requirements. (SS-EN ISO 9000:2000) [4]

2.2 Quality management system – a management system to direct and control an organisation with regard to quality. (SS-EN ISO 9000:2000) [4]

2.3 Quality management – Coordinated activities to direct and control an organisation with regard to quality. (SS-EN ISO 9000:2000) [4]

2.4 Quality Manager/person responsible for quality – Person who is responsible for the management system of the laboratory or inspection body and its application, who reports direct to top management.

2.5 Audit – a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. (EN ISO 19011:2002) [5]

2.6 Audit evidence – records, statements of facts or other information which are relevant to the audit criteria and verifiable (EN ISO 19011:2002) [5]

2.7 Auditor – a person with demonstrated personal attributes and competence to conduct an audit (EN ISO 19011:2002 [5]. Audits (when there are enough resources in accordance with SS-EN ISO/IEC 17025) are carried out by staff who are independent/detached from the activities that are being audited. The auditor must have good knowledge of the current normative documents and be familiar with the activities that are going to be audited.

2.8 Management review (also called quality system review) – Formal evaluation of the management system and activities, carried out by the executive management of the laboratory/inspection body. This is done to ensure the continued suitability and effectiveness of this management system and to introduce important changes and improvements.

3 AIM OF INTERNAL AUDITS

3.1 An accredited laboratory/inspection body must regularly carry out internal audits of their activities to ensure that the entire management system is being applied in practice. Questions to be answered could be: How do we describe in our quality system how to do and have we done that? Does it fulfil the requirements for accreditation (review of policies and instructions)? Do we do as we say (review of practice and control of records)?

Any non-conformities that are identified during an internal audit should be used to make improvements to the management system and should form the basis for the management review.
ORGANISING INTERNAL AUDITS

4.1 Internal audits must be carried out in accordance with written instructions which describe the methodology for accomplishment.

4.2 Internal audits should be organised so that every stage in the management system (regarding requirements in standards and regulations) is audited at least once per year. The organisation shall have a plan that includes all stages of the management system and preferably covers several years. The plan shall take the following in account:
   a) the purpose of and the extent of the review, see 3.1
   b) the frequency of the reviews
   c) which areas the organisation has defined as critical, as for example areas of high complexity, volume areas e.g., that can need more frequently interval. Still all areas of methods/inspection areas shall be reviewed within one accreditation cycle (4 years).
   d) the premises of the activities that are going to be reviewed including field activities if any.
   e) standards, regulations, agreements and other requirements for review
   f) the scope of accreditation and needs for changing in the scope
   g) results and conclusions from earlier reviews together with known trouble areas
   h) risks and consequences with misapplication
   i) question regarding difficulties with implementation
   j) interested parties point of view
   k) essential changes in way of working or organisation

For large laboratories/inspection bodies, it can be better to audit different parts of the management system at different times of the year. The person in charge of the audit programme should set up, implement, monitor, review and improve the audit programme.

4.3 The top management in an organisation must hand over responsibility and authorisation to one person to manage the audit programme. This person could be responsible for quality (irrespective of their job title). The assigned person is responsible for planning the internal audits, but he/she can delegate its implementation.

4.4 In small organisations, the audit can be carried out by the person responsible for quality (irrespective of the job title) by themselves. However, the management of the laboratory/inspection body should assign someone to regularly evaluate the work of the quality manager to ensure that the quality manager is carrying out his/her work in a satisfactory way and that the internal audits of the management system are effective.

4.5 The person responsible for the audit programme can delegate audit tasks to people who are familiar with the management system of the laboratory/inspection body and who know what requirements apply for accreditation. All people who work with internal audits must receive the necessary training to carry out the audit, be familiar with the standard in question (incl. requirements in other regulations relevant for the accreditation) and have a general understanding of the audit principles.
For large laboratories/inspection bodies that carry out tests/inspections of a wide spectrum of test/inspection areas, the internal audits might have to be carried out by several people under the management of the person who is in charge of the audit programme. Auditors must not normally carry out audits of areas that they are responsible for.

Note: For close companies (one or two people) it may, of course, be difficult to find staff in the company who is independent of the functions/tasks that are being audited. SWEDAC has accepted that internal auditors may also audit their own areas of responsibility for these laboratories/inspection bodies.

4.7 If a laboratory/inspection body is accredited for field activities or sampling, these activities must be included in the audit programme.

4.8 Any audits that are carried out by, for example, customers or the accreditation body cannot be seen as replacing the laboratory’s/inspection body’s own internal audits.

5 PLANNING INTERNAL AUDITS

5.1 The audit programme must ensure that both horizontal and vertical audits are carried out. For inspection bodies could a vertical audit be substituted with the requirements of witnessing stated in SS-EN ISO/IEC 17020. You can with advantage let the witnessing be complemented with elements before and after the witnessing itself, e.g. reporting.

5.2 A horizontal audit is a detailed inspection to ensure that an element in the management system has been implemented in all activities in the accreditation of the laboratory or inspection body. These quality system elements can include staff training, the handling of standards, the maintenance and calibration of equipment, calibration/test/inspection methods and instructions.

5.3 A vertical audit is a detailed inspection to ensure that all elements in the management system have been introduced when carrying out a specific test/calibration/inspection. For a vertical audit, a representative selection of the work that has been carried out is chosen at random from the cases that have recently been dealt with by the laboratory/inspection body. Where possible, the vertical audit should include a repetition of the test/calibration/inspection that has been carried out. Every part of the laboratory’s/inspection body’s work linked with the testing/calibration/inspection that has been selected should be inspected, including the following points where appropriate:

a) quote, contract
b) sample handling
c) competence and authorisation of the people involved
d) calibration and maintenance of equipment
e) use of test/calibration/inspection methods and instructions
f) quality controls
g) environmental conditions (premises, etc.) when work is carried out
h) test/calibration reports, inspection reports and reports of the results
i) archiving of data and calculations that have been carried out.
5.4 As well as the regular (planned) internal audits of the management system, it might be necessary to carry out special, unplanned audits. These audits can be initiated:
   a) because of customer complaints which put into question whether the laboratory/inspection body has been following its own policies and instructions
   b) when an abnormal result is discovered (e.g. when unacceptable results are reported during proficiency testing and calibration comparisons)
   c) to confirm that corrective action or other changes to the quality system have been implemented and work effectively.

6 CARRYING OUT INTERNAL AUDITS

6.1 The person who is in charge of the audit programme can be responsible for making the final decision about the aims, scope and type of audits that must be carried out. These decisions can also be taken by the laboratory/inspection body’s management, e.g. in conjunction with the management review. The responsibility for the decision making shall be defined in the managing system.

6.2 The following activities should be included in the audit:
   a) producing a programme for the current audit
   b) reviewing documents (including method descriptions and records)
   c) preparing the audit of practical activities
   d) carrying out the audit of practical activities
   e) producing and distributing the audit report
   f) reviewing corrective action
   g) carrying out any audit follow-ups.

6.3 The reporting method should be formalised where necessary to make the audit easier. It might, for example, be practical to use standardised forms for:
   a) the sections of the management system that must be audited
   b) notes of non-conformities and any corrective action that has been agreed, including follow-up activities (also specify who will carry out the action and the time frame)
   c) summary of the results of the audit.

6.4 The result of an internal audit must be based on objective facts.

6.5 The entire management system must be reviewed within the framework of the audit programme. Special attention should also be paid to ensure that:

6.5.1 Organisation
   a) the responsibilities and authorisations of the management and staff are specified and documented
b) the organisation and management structure of the laboratory/inspection body and its place in the main organisation are defined

c) the management and staff are free from conflicts of interests that could affect testing/calibration/inspection activities

6.5.2 Management system

a) the quality manual and underlying documents are kept up-to-date

b) the quality manual and underlying documents are known and understood by the staff

c) the quality policy is known and understood by the staff

6.5.3 Document management

a) there are procedures for managing all documentation in the system and that these procedures are followed.

b) only applicable documents are used at the laboratory/inspection body and are available to all staff

c) applicable documents are approved by an authorised person

d) any changes in the documents are traceable

6.5.4 Review of enquiries, tenders and contracts

a) there are procedures for reviews with customers and these procedures are followed

b) these reviews are documented

6.5.5 Subcontractors

a) if a laboratory/inspection body transfers part of a testing/calibration/inspection to another laboratory or inspection body, there must be information that shows that the subcontractors are competent to carry out the work and meet the requirements set out in SS-EN ISO/IEC 17025 [1] or SS-EN ISO/IEC 17020 [2] (also compare what is set out in SWEDAC’s applicable regulations for accredited laboratories and for accredited inspection bodies)

b) there is detailed documentation for any work that has been given to another laboratory/inspection body and the subcontractors that have been hired

c) there is documentation that shows that the customer has received relevant information that subcontractors have been hired

d) there is documentation showing which subcontractors have been hired

6.5.6 Purchase of services and goods

a) there are purchase documents for goods that affect the quality of the testing/calibrations/inspections of the laboratory/inspection body and that the quality requirements are met

b) there are checks when products are received that can affect the quality of activities

6.5.7 Complaints

a) procedures for how complaints that have been received are handled
b) action taken by the laboratory/inspection body as a result of a formal complaint follows the stipulated complaints procedure

c) documentation of complaints is easily accessible, contains all important information and is kept up-to-date

d) complaints and other non-conformities are handled during the management review

6.5.8 Personnel
a) all personnel have relevant training and this training is documented
b) tests/calibrations/inspections are only carried out by authorised staff
c) information about relevant qualifications, training and experience of the personnel are documented and kept up-to-date
d) there are relevant training programmes and these are followed
e) documentation is available that reports the tasks that each person carries out

6.5.9 Premises and environmental conditions
a) there are suitable conditions for environments where testing/calibrations/inspections are carried out
b) environmental conditions are documented when these are important (this documentation should be studied to find out whether any measurements are carried out during conditions that do not meet environmental requirements)
c) measurement equipment that is used to register environmental conditions is suitably calibrated
d) the accessibility and use of all spaces are inspected in a suitable way

6.5.10 Testing/calibration/inspection methods and method validation
a) calibration/testing/inspection methods are uniform and sufficiently detailed for what they are used for
b) calibration/testing/inspection methods and instructions are up-to-date
c) calibration/testing/inspection methods and instructions are available for the personnel and used
d) own methods and any modified standard methods are validated and this validation data is available
e) all calculations and data transfers have been correctly inspected
f) there are instructions for calculating/estimating measurement uncertainty and any extended measurement uncertainty is calculated where relevant
g) instructions for producing own reference material is documented
h) reference material and other measurement standards are stored and labelled correctly
i) the laboratory/inspection body takes part, where necessary, in relevant proficiency testing and inter laboratory comparisons
j) testing/calibration/inspection is carried out in accordance with the correct method and, if there are no special conditions, in accordance with the latest version
k) any new versions of standard methods have been reviewed, and, if these are introduced, confirmation has been given that work is being carried out in accordance with this latest version
6.5.11 **Equipment**

a) all equipment, including equipment that has been taken out of use, is numbered, labelled or identified in another way

b) where the traceability concept can be applied, reference standards and reference materials have to be traceable to national or international standards (proof of this is valid calibration certificates or other documents that can prove the calibration status)

c) reproducibility for results, which is dependent on standards where the traceability concept is not applied, is shown through documented results from proficiency testing

d) reference standards are only used for calibration

e) where relevant, the long-term stability of reference standards is investigated

f) the internal calibration programme gives reassurance that all measurement/testing/inspection equipment and their working standards that could affect the validity of calibrations/tests/inspections are correctly calibrated or verified, and that these activities are sufficiently well documented

g) equipment and their working standards, where relevant, are inspected internally with regular calibrations

h) the correct function of equipment that has been moved and its working standards are inspected before being used again for its intended purpose

i) the programme for the maintenance of equipment and its working standards is correctly applied to ensure that any object that is exposed to overloading or neglect, or that produces suspicious results or is shown to be faulty in another way, is taken out of use, repaired and only used again once calibration or verification has produced satisfactory results

j) maintenance of the equipment and its working standards are documented in a sufficiently detailed manner

k) written instructions for the use of the equipment are suitable and are followed by the staff that use the equipment.

l) computer programs are validated, have working procedures for back up and that instructions are used and are understood by the operators.

6.5.12 **Sampling** (relates to laboratories) (if the laboratory staff take samples for subsequent testing, sampling must be included in the accreditation)

a) there are instructions for sampling and these instructions are followed

b) tests during the time between sampling and testing are carried out correctly.

6.5.13 **Handling test, calibration and inspection objects**

a) there are instructions for identifying test/calibration/inspection objects and these instructions are followed

b) there are instructions for storing and preparing test/calibration/inspection objects and these instructions are made available to the staff and are followed

c) the instructions for receiving, storing and discarding test/calibration objects are followed

6.5.14 **Quality assurance of test/calibration/inspection results**

a) there is a system for discovering any trends in frequent measurements of the same tests using the same methods

b) results from the comparison measurements or comparison tests that have been
carried out have been evaluated and any corrective action that is necessary has been taken.
c) if there are no proficiency testing or certified reference materials, the laboratory/inspection bodies must find another way to show that the work that is being carried out is correct.

6.5.15 Reporting results

a) test reports/calibration certificates/inspection reports are signed by the authorised person.
b) reports/calibration certificates contain all the necessary information.
c) original data and copies of the reports/calibration certificates are stored correctly for the set period of time.
d) amendments and additions to the reports/calibration certificates are identified in a uniform work in a new document, which contains references to the original reports/certificates that they replace.
e) any opinions and interpretations that are in reports/calibration certificates must be clearly marked in the reports/calibration certificates, and the basis for these opinions and interpretations must be documented.
f) results from any tests carried out by subcontractors and any non-accredited measurements/testing/inspections must be clearly marked.
g) electronic reporting system are safe, that system for control exist and are followed to ensure that data are not corrupt/lost.

6.6 In addition to the points set out in sections 6.5.1 to 6.5.15, the audit must include all other parts of the laboratory’s/inspection body’s management system, including those that are subject to any additional requirements that are specified by the accreditation body or another regulatory authority.

6.7 Non-conformities identified through an audit must be documented, and suitable corrective action, the person responsible for corrective action and time limits for when this action should be completed must be set out.

6.8 Whenever a non-conformity has been discovered that could risk the results of a calibration/testing/inspection, activities should be discontinued until suitable corrective action is taken and this has been shown to produce satisfactory results. In addition, any results that could have been affected as a result of this non-conformity should be investigated and customers should be informed that the validity of any calibration certificates or reports may be called into question.

6.9 The application and effectiveness of the corrective action should be inspected as soon as possible after the time limit has passed.

7 AUDITS OF SMALL LABORATORIES/INSPECTION BODIES

The extent of the internal audit must be assessed on a case by case basis, for example, the size of the laboratory/inspection body, as well as the scope and complexity of their activities.
8 DOCUMENTATION FOR INTERNAL AUDITS

8.1 Audits that are carried out must be documented in a suitable way.

8.2 The audit should be documented in a report that contains the following information:

   a) name of auditors
   b) date of the audit
   c) audited part of the system
   d) specification of the parts/areas that have been inspected
   e) all non-conformities that have been observed

8.3 The report and other documents linked to the audit should include the following information:

   a) any corrective action that has been agreed, the agreed time limits for this corrective action and the person responsible for ensuring that that action is carried out
   b) date for confirming that that action has been carried out
   c) the signature of the auditor or quality manager, approving the action carried out.

8.4 The quality manager should give reassurance that the audit report, and where appropriate, any non-conformities are communicated to the management.

8.5 Action must be taken on non-conformities and this action should be followed up to ensure that it has been suitable. Non-conformities can then be ‘removed’.

8.6 Reports and records from internal audits must be archived for the stipulated amount of time.

9 AIM OF MANAGEMENT REVIEW

9.1 The management review should be carried out in accordance with the schedule that has been drawn up in advance.

9.2 The management review is carried out in order to:

   a) establish whether the management system is suitable and effective
   b) establish whether the laboratory’s/inspection body’s testing/calibration/inspection activities are suitable and effective
   c) introduce any necessary changes and improvements.

Questions to be asked could be: Is the management system as we want it and the accreditation require? How have we managed to live up to it? If there are some deficiencies, what shall we do about it? What are the plans for the future and do they influence the management system and the activities?
9.3 The management system may need to be modified because of changes that have taken place (or are planned to take place) in the organisation or to the premises, equipment, personnel, procedures, application area or work load.

9.4 Changes in the organisation or to the premises, equipment and/or procedures may be necessary to ensure that the testing/calibration/inspection activities of the laboratory or inspection body are suitable and effective.

9.5 The need for changes to the management system or activities can be necessary as a result of:
   a) what has come to light during internal or external audit
   b) any changes to requirements from the surrounding world
   c) complaints from customers
   d) surveillance or re-assessment that has been carried out by the accreditation body.

10 ORGANISING MANAGEMENT REVIEW

10.1 The laboratory’s/inspection body’s management must be responsible for ensuring that the management review is carried out.

10.2 People from management who have overall responsibility for designing and applying the laboratory’s/inspection body’s management system and who make decisions based on internal audits should take part in the management review.

10.3 People from management who have overall responsibility for the laboratory’s/inspection body’s test/calibration/inspection activities and who make decisions based on internal audits should take part in the management review.

10.4 The management is responsible for ensuring that all reviews are carried out systematically in accordance with set procedures and that the results of the reviews are minuted. The procedure should describe how the agenda for the management review shall look like, which shall participate, which input necessary to prepare before the meeting and by whom it shall be done together with what shall be recorded from the meeting, (see paragraph 11 and 12).

10.5 The management is responsible for ensuring that all action that needs to be taken as a result of the review is carried out within the agreed amount of time.

11 PLANNING AND CARRYING OUT MANAGEMENT REVIEW

11.1 A management review should be carried out at least every 12 months. The review must be planned and the executive management of the laboratory/inspection body must be involved, including the person who was responsible for the introduction and authorisation of the quality manual. It is important that the head of the laboratory/inspection body, the technical manager, the quality manager and any section heads are also involved. For smaller laboratories/inspection bodies, one person could hold more than one of these functions.
11.2 The review should be carried out in a systematic way by using a formal agenda. This should include at least the following points:

a) suitability of policies and procedures
b) reports from the management and surveillance personnel
c) reports on surveillance and re-assessment carried out by the accreditation body
d) reports from audits carried out by customers and other bodies (if any)
e) results of internal audits carried out since the previous review
f) results from inter laboratory comparisons and proficiency testing
   that the laboratory/inspection body has taken part in
f) planned and/or ongoing corrective and preventative action
h) changes in work volume and the kind of work
i) feedback from customers
h) complaints
i) recommendations for improvements
j) need for quality management activities
k) need for resources
l) need for staff development
m) aims for the coming year
n) action plan for the coming year

Specific points that are required by ISO 15189 [3]:
o) quality indicators for the monitoring of the laboratory’s contribution to patient care
p) monitoring of turn-around time (TAT).

11.3 It is the responsibility of the management to ensure that all action taken as a result of the audits is carried out in the intended manner.

12 DOCUMENTATION OF MANAGEMENT REVIEW

12.1 The management review must be documented. This documentation may consist of minutes from meetings with the management along with clear indications of what action should be taken, by whom and within what time limit. The documentation shall also include a statement about the suitability and effectiveness of the management system.

12.2 The documentation must be easily available and archived for the stipulated amount of time.

13 MANAGEMENT REVIEW FOR SMALL LABORATORIES/INSPECTION BODIES

Often one person is in possession of several positions. The extent of the management review must be assessed on a case by case basis, for example, the size of the laboratory/inspection body, as well as the scope and complexity of their activities.
14 REFERENCES

[1] SS -EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories

[2] SS-EN ISO/IEC 17020 General criteria for the operation of various types of body performing inspection

[3] SS-EN ISO 15189 Medical laboratories – Particular requirements for quality and competence
