

# Guidance on internal audits and self-assessments: support to external clinical audits

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**Abstract.** High quality and good safety culture in the use of radiation in health care are ensured by systematic assessments of the quality of the practices, both by internal and external assessments. Internal audits and self-assessments are the most efficient and quickest way to evaluate the practices and to identify the areas where there is a need for development. In planning of the internal audits and self-assessments, it is of high importance to ensure that these will support the external clinical audits and vice versa. Therefore, both in internal audits and self-assessments, it is useful to select for assessments also topics which are expected to be assessed in external clinical audits.

The Finnish National Advisory Committee for Clinical Audit (NACA) is responsible for the overall coordination of clinical audits in Finland and has published several recommendations for the implementation of clinical audits. The latest recommendation (February 2011) provides basic guidance for internal audits and self-assessments, as supplementary procedures to the external clinical audits. The basic principles and the essential contents of this recommendation are reviewed in this paper.

**KEYWORDS:** *Internal audit, self-assessment, clinical audit*

## INTRODUCTION

The measurement and assessment of a practice from several viewpoints are parts of the quality management and characteristic of successful organizations. These are the means for high quality management and development: before the quality can be improved, the status of practices has to be assessed. The central objectives of the assessment are to find out the strengths and weaknesses of the organization. The regular assessments are an essential element not only for quality assurance but also for a good safety culture.

The assessments of a practice can be implemented by self-assessments or by internal and external audits. The self-assessment is carried out by the own staff so that the persons or organizational units themselves assess their own practice. In internal audit, the assessment is carried out by persons or neighbor units of the organization which are independent of the unit to be audited. In external audit, the assessment is carried out by independent auditors coming from outside the organization. The added value of external audit is that the auditors can have a wider perspective and basis for comparisons, and can find out also weaknesses where the own staff might be "blind". A clinical audit, as defined for the assessment of medical radiological practices (European Commission 1994), is a good example of both internal and external audits.

The implementation of self-assessments must be considered together with internal and external audits, such as clinical audits, and with possible other quality assessments, such as the audits for accreditation. The different assessments must support each other and unnecessary multiplication or overlap of efforts must be avoided. The self-assessments and internal audits can be valuable in order to be prepared for external audits, whereby these assessments can have some desired overlap e.g. with external clinical audits.

The self-assessments and internal audits are among the cornerstones in quality management, because these will review of the needs and preparedness for development within the organization in a fast, systematic and participative manner. The assessments will improve the awareness of the staff of the strategy of the organization, as well as of the key factors for maintaining high quality. It will also improve the communication within the organization. The self-assessments and internal audits are very effective because these can be easily targeted on the practices or sub-practices where problems have been observed or anticipated and where the need for improvements is evident. The implementation of self-assessments and internal audits is somewhat easier than that of external audits, both on technical and administrative point of view.

The Finnish decree (Ministry of Health and Social Affairs 2000) requires that the practitioners must promote self-assessments of the radiological practices for the development of the practices. Further, it is stated that the self-assessment can be made with a support of an external advisor and that the same methods can be applied as used in external clinical audits. According to the decree, external clinical audits shall be organized to supplement self-assessments in an appropriate way. In a European guidance on clinical audit (European Commission 2009) it is stated that both external and internal audits are needed and these should supplement each other. Further, it is noted that in a small health care unit, internal audits can essentially be replaced by self-assessments.

This recommendation by the Finnish National Advisory Committee for Clinical Audit (NACA) deals with self-assessments and internal audits for the use of radiation in health care, as envisaged in the Finnish legislation (Ministry of Health and Social Affairs 2000). The purpose is to clarify the concepts and provide guidance for the implementation of self-assessments and internal audits in x-ray diagnostic radiology, interventional radiology, nuclear medicine and radiotherapy.

## **CONCEPTS**

### *Self-assessment*

Self-assessment is a systematic assessment of one's own practices, work methods and experiences against given assessment criteria

- The self assessment aims at settling out whether the objectives of the practices are met and whether this is achieved with the most sensible way
- The self assessment helps the organization to identify the present status of the practices, to set out new objectives and implement procedures for development in order to achieve these objectives

### *Audit*

Audit is a systematic, independent and documented process whereby

- the information gathered from the practices (audit observations) is assessed in an objective way in order to find out whether agreed principles and work methods are obeyed and whether the preset objectives and requirements for the practices are met
- the results of audit are used to identify the strengths and weaknesses of the practices and to develop the practices (ISO 2002)

*Internal audit* is an audit carried out or conducted by the organization itself. *External audit* is an audit carried out by another organization (customer, stakeholder group) or a third party (independent auditors from outside the organizations, e.g. certification or accreditation bodies).

#### *Clinical audit*

Clinical audit is a systematic examination or review of medical radiological procedures which seeks to improve the quality and the outcome of patient care through structured review whereby radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices where indicated and the application of new standards if necessary (European Commission 1997).

### **GENERAL PRINCIPLES**

Self-assessments and internal audits aim at systematic evaluation of one's own practices. The quality manual of the health care unit should include guidance for their implementation. For the evaluation of medical radiological practices, a list of appropriate questions, relevant to the topic of evaluation and with the criteria of good practices should be developed.

To be successful, the self-assessments and internal audits should comply with the following general principles:

- Self-assessments and internal audits are not separate procedures but a firm part of the regular planning and development of the practices

Self-assessments and internal audits and the subsequent, continuous development are part of the normal functioning of the organization. The timing of the assessments and audits should be appropriate so that the recommendations for development, based on the findings, can be successfully implemented in the work plans and budgeting. Along with the assessments, the objectives of the organization are clarified, mutual communication is improved, and the staff will experience a happy feeling of working together and gain new working power.

- The persons involved in self-assessments and internal audits must have time and knowledge for the evaluation procedures

Sufficient time for the self-assessments and internal audits must be provided in the work plan. This includes also the time needed for informing the staff about the evaluations and for the training of the evaluators for the methods of evaluations.

- The observations on the needs of development do lead to the implementation of the development procedures

The improvements and development completed based on the findings of self-assessments and internal audits encourage to implement new self-assessments and internal audits. However, too frequent self-assessments and internal audits may lead to a need of a large number of procedures for development without necessary resources for their implementation. Therefore it is important to set priorities for the development proposals and start the implementation from the most important ones.

The self-assessments and internal audits provide an opportunity to participate in the development of practices for all members of the staff. Motivation for work is improved when one can influence, participate in planning and give feedback, and see the progress of development. Open and cooperative atmosphere and the respect of the work of the others will ensure the success of self-assessments and internal audits.

The main steps of the self-assessments and internal audits can be distinguished as follows (Fig.1):

- planning, including setting of the objectives (general objectives and specific objectives relevant to the topic of evaluation), selection of the evaluation targets and topics, and deciding on the evaluation criteria
- preparation, including deciding on the methods of evaluations, on the persons to carry out the evaluations and their training, and informing the organizational unit to be assessed and all persons involved
- implementation
- compilation and analysis of the results of evaluations, identifying the strengths and weaknesses, drawing conclusions and giving recommendations for development
- reporting and informing on the results
- selection and planning of the development procedures and remedial actions
- implementation and follow-up of the development procedures and remedial actions
- assessment of the accountability of self-assessments and internal audits and their further development

Several models have been developed for the overall, very comprehensive self-assessments of the practices, such as the EFQM Excellence Model and Common Assessment Framework (CAF). These are also useful but relative heavy and time consuming for frequent self-assessments. For medical radiological practices, the above more "tailored" assessment is needed so that it can be easily and sufficiently often implemented at all levels of the organization, focused on the most critical areas of radiation practices.

## **SELF-ASSESSMENT**

Self-assessments with a limited scope are recommended at least annually, while more comprehensive overall evaluations can be less frequent.

In the planning stage (Fig.1) it is important to define the general objectives of the self-assessment on point of view of the organization's policy statement. A preliminary review of problems, needs and status of the selected evaluation topic is needed because it is difficult to implement improvements unless the present status is known. Once the evaluation topic has been selected, the most important specific objectives on point of view of this topic have to be defined and ensured that these are really the objectives of interest. No doubt should appear later whether these objectives are met or not and

therefore, the objectives must be realistic and measurable. The measures can be quantitative or qualitative and they should evidence the changes in the target. The measures must be provided with criteria to enable conclusions to be made: the criteria should give the basis on assessing how perfectly the objectives are met.

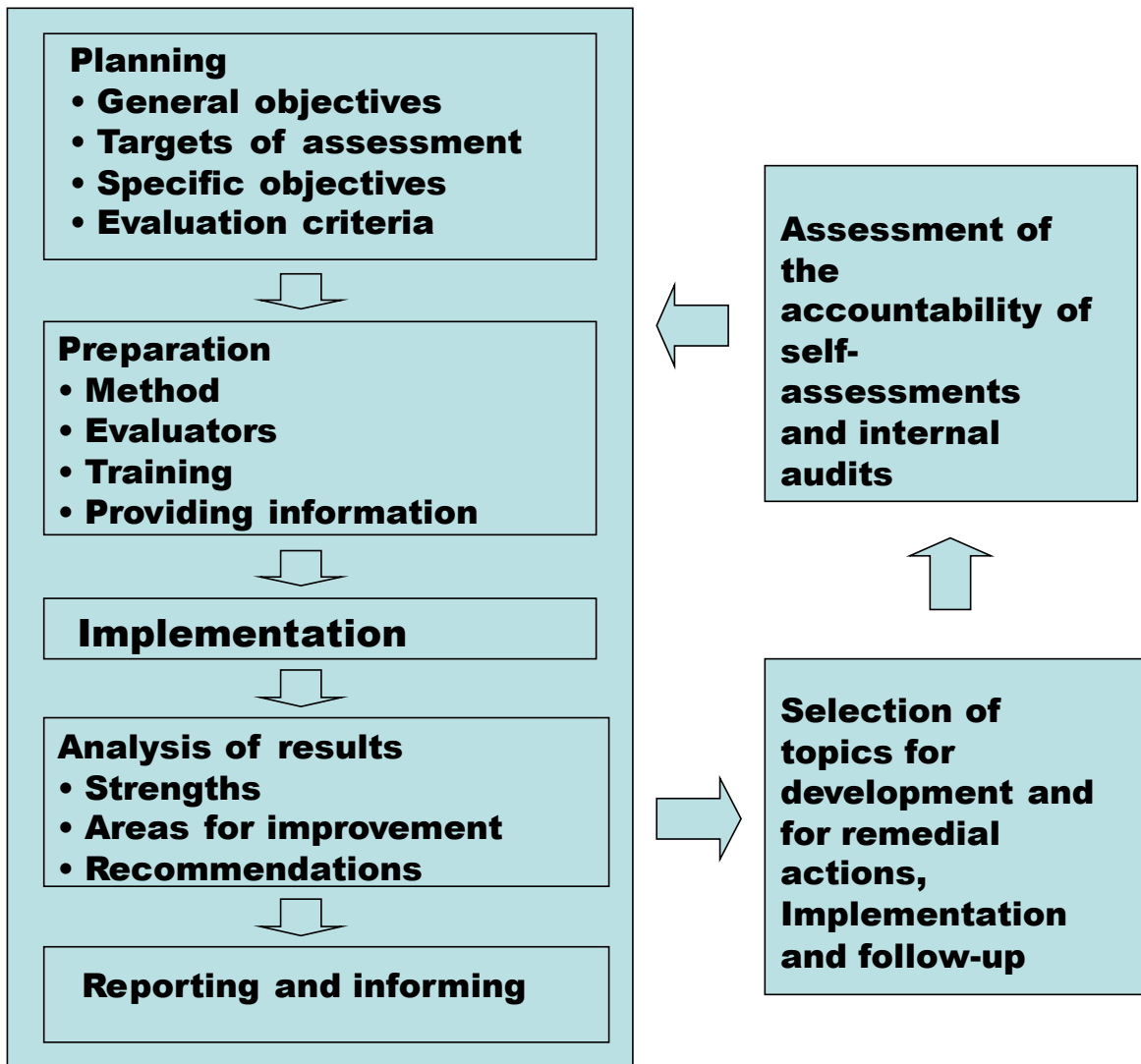


Fig. 1 The main steps of self-assessments and internal audits

Good preparation is essential for a successful self-assessment. The staff has to be informed about the objectives and methods to be used. The material needed must be easily accessible, preferably available in electronic form through the organization's information transfer systems. The preparation includes decisions on what will be done, how (methods, measures, criteria), who (evaluators) and when (timetable). The training of the staff must also be organized unless the methods of the self-assessment are well-known from earlier experiences.

The implementation of the self-assessment can include studying all documents relevant to the topic of evaluation, e.g. results of examinations and treatments or results of quality assurance, organizing group discussions, undertaking necessary measurements, or studying the referrals, radiological images, reports, and other output of the practices in accordance with the objectives of the self-assessment. During the implementation phase, the feasibility of the chosen methods needs to be considered and changes applied when necessary.

The results of self-assessment must be analysed with the staff carrying out the evaluations. Before wider discussion for example at the staff meetings, the results need to be compiled and pre-analysed for an easily usable form. To speed up the analysis, the compilation of the necessary material (measures, criteria) and the results should be completed using appropriate electronic forms and tables. The analysis of the results should result in a summary of the strengths and the items for improvement relevant to the topic of evaluation and the objectives. Sufficient time for discussions with the staff need to be reserved in order to ensure joint conclusions to be drawn and the subsequent commitment of the staff to the proposed development procedures.

The report of the self-assessment, with the results and the conclusions and proposals for the development procedures, is prepared and informed to all staff members.

Some of the proposed development procedures can be easily implemented in the context of daily practices, while some of them require specific planning and resources. For short term procedures, the definition of responsibilities may be adequate. The long term procedures must be arranged in the order of their importance, and the procedures accepted for implementation are provided with a detailed implementation plan and responsible persons.

Regular follow-up of the progress is necessary to control how the objectives of the development procedures are achieved. The follow-up is also crucial to maintain the motivation for the self-assessments. The follow-up period can also be exploited to develop the methods for the next self-assessment.

In the long term, the results of self-assessments must be evaluated to ensure that the benefit gained is sufficient compared with the resources used. The systematic evaluation of accountability of the self-assessments also helps to improve the methods of their implementation.

## **INTERNAL AUDIT**

### *Special features*

Internal audit is a commonly used effective tool to ensure that the daily routines are executed in accordance with the agreed methods, and also to look for the need of improvement. Thereby it provides an effective channel of communication within the organization, as the staff will audit different parts and practices of the organization. Internal audits are also helpful to get prepared to external audits.

The following general principles are characteristics of internal audits:

- Audit process is implemented independently (not auditing one's own work) and the results are based on objective findings
- Auditors give due considerations of ethical principles (trust, fairness, secrecy and delicacy), justice and appropriate professional actions

- Because audits will support the leadership, the objectives set by the management form the basis of the audits. The objectives of audit are based on the strategic and quantitative objectives of the organization.
- To ensure flexible and efficient implementation of audits, the responsibilities of the staff for the planning, implementation and follow-up of audits have to be defined. The management usually has the main responsibility, while the quality manager or quality responsible usually has the responsibility for the implementation.
- Audits are based on pre-defined criteria which is composed of agreed, documented functions of the organization and the internal or external requirements for these functions
- To achieve the pre-set objectives of audits, it is important to give sufficient training on the methods of audit to the auditors. The training should include the purpose and detailed objectives of the audit and the audit process: planning, preparation, audit techniques, acting as an auditor (ethical viewpoints), reporting and exploitation of the results. The training will ensure that the organization can use the audit tool with an efficient manner. The competence of auditors should be controlled and their professional skills developed.

Internal audits should cover the following points: management of practices, organization, staff and its competence, operating guides, storing the documents resulting from the practices, management of abnormal incidents, customer services (patients, referring physicians), carrying out of examinations and treatments, quality assurance procedures, equipment, rooms and facilities, environmental conditions and patient and staff safety. It is good to plan the audit program for a longer period (e.g. 4-5 years ahead) to ensure auditing of the whole operation at regular intervals. Audits are recommended at least annually in accordance with an agreed annual plan. Annual focusing of the audit should be planned so that the whole operation would be covered within a defined time period, e.g. five years. Critical functions should be audited annually to ensure their high quality. It is important to consider also the interfaces of the functions in order to ensure good overall quality of the practices.

#### *Audit process*

Audit process is very similar to that of the self-assessment (Fig.1.). Planning stage includes the definition of the objectives and preparation of the audit program. Responsibilities and resources should be defined in the audit program. The quality manual and other guidance for the work, or specially agreed criteria for a particular target of the audit, should be used as the audit criteria. Possible external requirements (regulatory requirements, expectations of the customers) should also be taken into consideration in the audits. Besides the local documentation also published other documents can be applied, such as relevant standards (e.g. ISO 2002).

Preparation of audits includes selection of the methods. Audit can concern the whole operation or focus to particular parts of it. Preparation includes also the selection of the group of auditors and providing training to them. It is recommended that the group has a leader who is responsible for the implementation of the audit in an agreed way and who can guide the other auditors when needed. The size of the group varies with the object of the audit and can be from one to several auditors.

Before actual audit visit, the auditors should agree with the unit to be audited on the practical arrangements (timetable, local staff involved) and on the documents to be delivered to the auditors in advance so that the auditors can get familiar with the practice and work rules of the unit. It is recommended that the auditors use the received documentation to prepare a check list of items to be considered at the audit.

The actual audit on the site is started with an entrance meeting where the audit process is introduced. Audit is then implemented by collecting information through the local documentation, by interviewing staff members, and by witnessing patient examinations and treatments. If needed also comparative measurements related to the use of radiation can be carried out. The audit visit is interactive and to be successful, requires good cooperation between the auditors and the staff. At the end of the audit the auditors will meet to combine their findings and to draw conclusions. The conclusions are presented to the unit being audited before the departure from the site.

The observations on shortcomings and on the needs of improvement are recorded as audit findings. The auditors also prepare a special report where these findings are described in detail with the conclusions on the strengths and weaknesses of the unit. In the audit report, due consideration should be given to the objectives of the audit.

The audit findings should be analysed and the strengths and weaknesses recognized by the unit which has been audited. The results should be discussed together with the staff to ensure their proper acknowledgement. Further, the results should be discussed by the management to ensure that appropriate actions of improvement can be undertaken. The management also verifies that the objectives of the audit have been met. Based on the results, priorities for the improvement actions are set and an action plan prepared, with the nomination of responsible persons and setting of deadlines. The completion of actions and their effectiveness must be ensured and also agreed on the responsibilities for their follow-up. The results must be considered also in the long term audit planning.

Like in self-assessments, the results of internal audits should be studied in long term in order to ensure that the benefit gained is sufficient compared with the resources used. The systematic consideration of the accountability of internal audits also helps to develop and improve the audit methods.

## **TOPICS FOR SELF-ASSESSMENTS AND INTERNAL AUDITS**

In the self-assessments and internal audits it is advisable to select for evaluation also the topics which will be considered in external clinical audits. This will ensure that these internal and external evaluations support and supplement each other.

The topic of evaluation can be the *structure* of the practices (e.g., the resources: facilities, means, staff), *processes* (e.g., referral practice, implementation of justification, use of radiation shielding devices, examination protocols) or the *outcome* (e.g., reliability of reports, frequency of complications). Self-assessments and internal audits can concern the same topics, whereby the essential differences are the evaluators (evaluation by own staff or by using an independent auditor) and the methods used (as described in the above sections).

The self-assessment can result in observations where the subsequent implementation of remedial actions would benefit from a more detailed evaluation through internal audit. Also the opposite is possible: the internal audit can raise findings which should be further evaluated by self-assessments before making final decisions on the improvement actions.

On the website of the NACA ([www.clinicalaudit.net](http://www.clinicalaudit.net)) examples of self-assessments and internal audits are published (in Finnish).

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