EUROPEAN COMMISSION GUIDELINE ON CLINICAL AUDIT FOR MEDICAL RADIOLOGICAL PRACTICES (DIAGNOSTIC RADIOLOGY, NUCLEAR MEDICINE, AND RADIOTHERAPY)

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EXECUTIVE SUMMARY

The purpose of this EC guideline is to provide guidance on clinical audit in order to improve implementation of Article 6.4 of Council Directive 97/43/ EURATOM (European Commission, 1997). The guideline will provide comprehensive information on procedures and criteria for Clinical audit in RADIOLOGICAL[1] practices: diagnostic radiology, nuclear medicine and radiotherapy.

The main recommendations of this guideline are summarized in this executive summary as follows:

Purpose, scope and general principles of clinical audit for RADIOLOGICAL practices

- By definition, clinical audit is a systematic examination or review of medical RADIOLOGICAL procedures. It 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. Modifications of the practices are implemented where indicated and new standards applied if necessary.
- Clinical audit should
  - Be a multi-disciplinary, multi-professional activity.
  - Follow general accepted rules and standards which are based on international, national or local legal regulations, or on guidelines developed by international, national or local medical and clinical professional societies.
  - Be a systematic and continuing activity, whereby the recommendations given in audit reports are implemented.
  - Be carried out by auditors with extensive knowledge and experience of the RADIOLOGICAL practices to be audited.
  - Combine both *internal* and *external* assessments in order to achieve optimal outcomes. For small units the internal audit could take the form of a self-assessment rather than actual audit. In external audits, the results of internal audits or self-assessments should also be reviewed. The internal and external audits should supplement each other.
  - Aim at evaluating the current status of the RADIOLOGICAL unit with respect to its RADIOLOGICAL services and to identify areas for future improvement.
  - NOT be research, quality system audit, accreditation or regulatory activity.
- The general objectives of clinical audit should be to
  - Improve the quality of patient care
  - Promote the effective use of resources
  - Enhance the provision and organization of clinical services
  - Further professional education and training
- The detailed objectives of clinical audit should be defined related to the standards of good practices
  - For *internal audits* the objectives of audits should be set by the management of the department

[1] "RADIOLOGICAL", written in capital letters, is used throughout this document to denote all three fields of application: diagnostic radiology, nuclear medicine and radiotherapy. When only diagnostic radiology is concerned, the term is written in small letters ("radiological").

  - For *external audits*, the objectives should be agreed between the auditing organization and the health care unit to be audited. The objectives should be based on any legal requirements on the audit programmes, as well as on any recommendations on priority areas by national coordinating organisation or health professional and/or scientific societies when available.
  - In defining the aims and objectives it is important to ensure that clinical audits supplement rather than duplicate other activities of quality assessment such as accreditations or regulatory inspections
- Clinical audit should
  - Address the practical clinical work by different professionals
  - Assess the local practice against the defined good practice, taking into consideration the local facilities and resources when the ultimate good practice cannot be reached by one step
  - Have professional initiation and foster an environment which enhances professional relationships and the multidisciplinary approach required to optimise patient care
- All parties, those being audited and those carrying out the audit, should respect the confidentiality of patient data, the interviews and discussions with staff, audit reports and other performance data.

Priorities and coverage of RADIOLOGICAL practices

- Clinical audit can be partial but should eventually become comprehensive and cover the whole clinical pathway in RADIOLOGICAL practices, outlining a course of care provided to a patient. It should address the three main elements: *structure, process,* and *outcome*. These should be covered both in internal and external audits.
  - For instance the internal audit could address a range of individual topics on an ongoing basis and the external audit the full clinical pathway.
  - It is accepted that the outcome can only partly be assessed through external audits. As a minimum approach for auditing the outcome, there should be a clear indication as to how outcomes are measured within the RADIOLOGICAL unit.
  - At a hospital level, a broad focus on the departmental level is required.
- Clinical audits should assess the parts of practices which are generic to all RADIOLOGICAL practices, and also go deeper into a selected individual RADIOLOGICAL examination, procedure or treatment.
  - Clinical audits should address both the critical issues of the radiation protection for the patient as well as key components of the overall quality system. The priorities should be set as specified in Table 1, Section 4.3.3 of this Guideline.
  - *Patient dose and image quality in* diagnostic radiology and nuclear medicine procedures and the *procedure of dose delivery to the patient* in radiotherapy should be among the necessary physical parts of all clinical audits.

Standards of good practice

- Standards of good practice can be based on legal requirements, results of research, recommendations by learned societies, consensus statements or local agreement (if there is no other more universal reference). Evidence-based standards of good

practice should be disseminated in a timely fashion to the entire health care community. Clinical audit should promote the development and use of international standards of good practice.

- Both generic and specific criteria should be applied for the standards of good practice, as highlighted in sections 4.6 of this Guideline. The recommendation in this document (Sections 8 and 9) should be considered as the minimum criteria, while more specific criteria should be developed for specific examinations and treatments, for the advanced level of clinical audits. The list of publications given in Appendix 8 of this document can serve as a source of information for developing and adopting the criteria of good practices.
- Quality indicators should be developed when possible as a practical measure of performance. These are useful in particular in internal audits.
- The standards of good practices should be reconsidered from time to time with the development of evidence based medicine and RADIOLOGICAL equipment and techniques.
- The definition of clinical audit presumes that suitable written criteria for good practice are available for the assessments. In conditions when there are no written criteria available, as a preparatory approach to clinical audit, the assessment could be based on an expert opinion or preferably on a consensus opinion of a relevant expert group. However, this is not recommended as the permanent approach for clinical audits because it does not ensure the uniformity and impartiality of judgements.

Frequency of clinical audits

- The *internal* clinical audits should be a continuous activity with the aim of having significant parts of the overall audit programme covered *once a year*. The recommended frequency for *external* audits may depend on the local infrastructure and the intensity of other quality review activities, but a minimum frequency of *once in five years* seems to be a reasonable aim.
- Irrespective of these minimum frequencies, case-specifically higher frequencies (shorter intervals) can be justified and extra audits are recommended whenever there are major changes of the installation or operation.

Interrelation of clinical audit with other quality assessment activities and regulatory inspections

- It must be strongly emphasised and understood that clinical audit is different from other quality assessment systems and from regulatory inspections. There are clear differences in the purpose and focus of the evaluation, scope, and the methods employed as well as in the consequences of the results of the observations, their impact and use.
- Clinical audits should be established and developed in a way which minimizes unnecessary overlap, or duplication of efforts, with the other quality assessment systems and regulatory inspections.
- Regulatory bodies may give advice in the early developing phase of clinical audits but should neither carry out clinical audits directly nor exclusively set up the criteria for the audits. Often the desired optimal role of the authorities can only gradu-

ally be achieved in the course of development of the necessary national infrastructure.

Role of professional and scientific societies

- The role of the professional and/or scientific societies can be of great value in developing the criteria of good practice for the evolution of clinical audits and in providing practical advice, stimulus and support for the establishment of appropriate clinical audit organizations or practical solutions on carrying out clinical audits.

Practical organizing of clinical audits

- Internal audits and special projects to undertake external clinical audit in a well defined purpose, as well as mutual audits, can be a good start for clinical audit. However, the long term aim should be towards special organizations, in order to ensure the continuity and credibility of the audit system. Special organizations for clinical audits should preferably be non-profit organizations, when possible supported by the RADIOLOGICAL professional and/or scientific societies. To ensure the full competence of such organizations, they should be accredited by a national accreditation body. International audit services may be exploited (if available) where no national systems exist.
- The basic competence of the auditors for clinical audits should be based on their professional competence and long-term clinical experience. Besides this basic competence, the auditors should receive specific training on the general audit procedure and techniques, as well as the agreed audit programme and the criteria of good practices to be applied.
- Auditors should be as independent as possible of the responsibility for the process being audited. The requirements for the independence of the auditors from the audited unit should be defined.
- A team of auditors is usually needed, comprising different professionals (radiologist, radiation oncologist, nuclear medicine expert, medical physicist, radiographer, RTT etc), the optimal composition depending on the scope of the audit and on type of application to be audited.
- The undertaking of internal audit, as well as the request for external clinical audit, should be endorsed by the staff at higher management level of the unit. Thorough preparation by all partners of the audit process is important. Appropriate guidance for on-site procedures and reporting by the auditors need to be established in accordance with Sections 7.2.4 - 7.2.6 of this Guideline.
- The costs of external audits need to be considered in the annual budgeting of the RADIOLOGICAL unit, unless the organization of clinical audits through a government body is funded directly. The general tendency in health care systems seems to assume that the health care unit requesting the clinical audit and deriving the benefits of it should also cover the costs incurred.
- The unit to be audited has to allow sufficient time to create a motivating atmosphere and open attitude about the audit in the unit before an audit, in particular for the first external clinical audit of the unit. This is important in order to avoid misunderstandings or prejudices or confusing clinical audits with other quality assessment activities. The staff at higher management levels of the unit should

commit to audit and give sufficient working time and material resources as well as general support and encouragement to the staff for its proper preparing for and participation in the audit procedure. Due attention should be paid to considering and fulfilling the recommendations given in the audit report, in order to achieve subsequent follow-up success and maintain high motivation of the staff.

- A special *national or regional advisory group,* or *steering committee,* of clinical experts, independent of the auditing organizations, may prove useful in the overall coordination and development of the clinical audit implementation, criteria and procedures. The group should preferably be established by the Health Ministry or other government organization, in order to ensure appropriate authority and financing.

1. INTRODUCTION

It has been estimated (UNSCEAR, 2000) that worldwide there are about 2000 million x-ray studies, 32 million nuclear-medicine studies and over 6 million radiation therapy patients treated annually, and the numbers are constantly increasing.

The use of radiation for medical diagnostic examinations contributes over 95 % of the man-made radiation exposure and is only exceeded by natural background as a source of exposure (UNSCEAR, 2000). In the next few years, particularly with the rapidly increasing use of computed tomography (CT), the medical use of radiation may exceed natural background as a source of population exposure. In countries with advanced health care systems, the annual number of radiological diagnostic procedures approaches or exceeds one for every member of the population. Furthermore, the dose to patients for the same type of examination differs widely between centres, suggesting that there is considerable scope for management of patient dose. Since the excess radiation leads to increased risk of cancer, the general principle of radiation protection requires that the doses should be kept as low as reasonably achievable (ALARA). On the other hand, in spite of many technical improvements, there are still a great number of detection errors in diagnostic radiology (Revesz and Kundel, 1997; Birdwell et al. 2001).

About 40 to 60 % of all cancer patients are treated at least once during their disease with radiotherapy and more than half of these with curative intent. The difference between the dose that is required to achieve local control and the dose that can cause serious side effects is often quite small (WHO, 1988; ICRP 1985). There is ongoing research to improve the dose delivery in an attempt to achieve the optimum result of cure with minimal complications.

For the above reasons, improving and maintaining a high quality of medical RADIOLOGICAL procedures is of primary importance, and a lot of attention has been paid to the quality management in the medical use of radiation. Worldwide there has been a tendency to establish quality systems and introduce appropriate quality audits.

The concept of clinical audit has long been applied in other fields of health care (Williams 1996; Tabish, 2001; Shaw 2003). Through the Council Directive 97/43/EURATOM (the MED directive; Article 2 and Article 6(4); European Commission, 1997) it was introduced also for medical RADIOLOGICAL procedures. This directive not only concerns avoiding unnecessary or excessive exposure to radiation but also aims at improving the quality and effectiveness of the medical use of radiation (Sarro Vaquero, 2003). Besides clinical audit, it introduced several other new concepts and thus widened the scope of the legislation compared with the previous Directive 84/466/EURATOM. According to the MED directive, clinical audits shall be implemented in accordance with national procedures.

The review of the status of the implementation of clinical audits at the first International Symposium of Clinical Audit in Tampere 2003 (Soimakallio et al., 2003) revealed that there was a very high variation between the Member States in the ways clinical audit had been implemented. In a few Member States there was a systematic approach with regular external clinical audits while, in most of the others, external or internal clinical audits were only carried out occasionally, with minimal and rather

haphazard practical audit activity. This situation still largely prevails as can also be seen from the results of the present survey carried out by a questionnaire to all Member States (see Appendix 1).

The conclusions from the above symposium (Soimakallio et al., 2003), as well as the present questionnaire, also indicate that there are a lot of practical problems related to clinical audit. The major problems identified in the replies to the questionnaire were among other things (see more details in Appendix 2): lack of formal framework of auditing (whether external or internal audits), poor understanding of the purpose and scope of clinical audits, lack of criteria for the standards of good practices, difficulty in employing sufficient number of auditors, insufficient time available for auditors, lack of specific training of auditors, the need for technological modernization of radiology equipment to meet quality standards, incomplete national legislation for clinical audit and the methods of financing.

The results of the present questionnaire confirmed the earlier conclusions (Soimakallio et al. 2003) that there is a clear need to clarify the purpose of clinical audit and to provide further guidance on clinical auditing in order to improve its implementation and to harmonize the approaches to a reasonable extent. The guidance should enable the Member States to adopt the model of clinical audit with respect to their national legislation and administrative provisions. It is important to point out the need of having both internal audits, or self-assessments, and external audits, and to stress that these should supplement each other. It is also important to discuss the borderline between clinical audit, research and other quality assessments such as accreditation, certification of quality systems and peer review. Likewise, the difference between clinical audit and regulatory inspection needs to be clarified.

The present document aims at clarifying the basic concepts and general principles of clinical audit while also providing a general framework for their implementation in the field of RADIOLOGICAL practices. Within this framework, neither the practical procedures nor the criteria of good practice can be discussed in full detail. Useful detailed guidance for external clinical audit of radiotherapy and X-ray radiology has recently been prepared by the International Atomic Energy Agency (IAEA, 2007; 2009), and the IAEA is currently working on corresponding guidance for clinical audit of nuclear medicine procedures.

2. PURPOSE AND SCOPE

The purpose of this EC guideline is to provide guidance on clinical auditing including optimal standardization which could improve implementation of Article 6.4 of Council Directive 97/43/ EURATOM (European Commission, 1997).. The guideline will provide comprehensive information on procedures and criteria *for clinical audit in RADIOLOGICAL practices: diagnostic radiology, nuclear medicine and radiotherapy.* The guideline will clarify the terminology used, define the core elements of clinical audit and provide examples of the various approaches and good practice. The aims are to raise awareness and to educate about clinical audit, thereby promoting culture change and offering practical advice and guidance on implementation. It will enable the Member States to adopt the model of clinical audit with respect to their national legislation and administrative provisions.

As will be described later (Sections 4.3 and 4.4), clinical audits can be of various types and levels, more or less comprehensive relative to the coverage of activities or the depth of assessment, and either carried out internally (internal audit) or by auditors from outside the unit (external audit). This guideline deals with all types and levels of clinical audit, and is applicable to both internal and external audits.

It is important to recognize that this guideline is not a legal requirement. According to the MED directive, clinical audits shall be carried out in accordance with national procedures. The purpose of this guideline is to give recommendations and highlight some possible "national procedures".

In clinical audit aspects of local practice are compared with "good practice". An essential element for the implementation of clinical audit is therefore to define good practice. For this definition, three levels of specificity can be distinguished (Sections 4.3 and 4.6), whereby the availability of documented criteria or the difficulty of their establishment is increasing with the level. It is neither possible nor the purpose of the present guideline to describe all such criteria in detail. Instead, this guideline will define the list of topics which should be covered by clinical audits, and the actual criteria of good practice are discussed to some extent only on the upper two generic levels.

The guideline has been designed to be for appropriate RADIOLOGICAL staff (all professional groups), health care unit's management, auditing organizations and regulatory bodies, in order to improve their awareness of their responsibilities and duties. The guidance is addressed to RADIOLOGICAL practices of all types of health care units, whether public or private, large or small.

Improved clinical audit will then yield multiple benefits to the health care system:

- provision of a tool for quality improvement
- improvement of practice
- recognition for quality and awareness of good practices
- recognition of outdated practice
- motivation of staff to increase quality
- improvement of local standards and adherence to national standards
- prevention against litigation
- improvement of communication within the institution,
- revealing weak points and
- promoting development of quality systems.

Through addressing technical, financial and clinical provision for high quality RADIOLOGICAL procedures, the main beneficiary of enhanced clinical audit should eventually be the patient.

For diagnostic radiology services, the present guideline has been prepared for the various applications of ionizing radiation. However, the general audit structure and the principles, criteria and audit programme for the various components of the clinical service (Sections 4-8) can be either directly applied, or used as a basis for appropriate modification, for the evaluation of other diagnostic modalities (ultrasound, MRI etc).

3. DEFINITIONS

3.1 Clinical audit

By definition of the MED directive (97/43/EURATOM), 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 modifications of the practices where indicated and the application of new standards if necessary".

It is obvious from this definition of clinical audit that all grades of staff (all professionals) of medical care must be involved. In other words, it is a truly multi-disciplinary, multi-professional activity integrated in the operational management of the health care environment. The term "medical audit" is sometimes used when the activity is confined to the work and service that physicians, alone, provide.
It is also obvious from the definition that clinical audit must be carried out by auditors with extensive knowledge and experience of the RADIOLOGICAL practices to be audited, i.e., they must generally be professionals involved in clinical work within these practices (Section 7.1.2).

The definition of clinical audit does not specify the performer of the examination or review, thus making possible to introduce both internal audits or self-assessments and external audits (Section 4.4). It should be understood that both internal and external assessments are necessary and optimally these should supplement each other.

According to the definition, clinical audit deals with RADIOLOGICAL practices, procedures, and results which should be understood in a collective sense, i.e. the audit is not considered to focus on a single patient.

While the above definition is clear in principle, its implementation in practice is subject to varied interpretations and its detailed meaning can be understood at several levels. Therefore, without trying to modify the definition itself, its profound meaning and recommended application will be discussed and clarified through the following sections of this guideline.

As a source of clarification, it is also important to quote what clinical audit is NOT and to explain its difference to other activities which can be confused with clinical audit. Examples of what clinical audit is not include:

- research
- quality (system) audit to verify that the quality systems conform to a quality standard
- accreditation
- regulatory inspection nor any other regulatory activity

This can be briefly clarified as follows (for the last three items, see more details in Sections 5 and 6):

Research is a systematic investigation to increase the sum of our knowledge. For clinical audit, the aim of research is to determine what is a good practice, while audit itself should ask the question: "Are we actually following good practice?" or "Does the quality of our clinical care meet the agreed standard, and if not, why not?" In other words, audit is a review on whether current practice is in line with good practice.

Quality (system) audit is an audit to verify that the quality system (QS) of the organization, e.g., a radiological department, conforms to a given quality system standards, for example ISO 9001 (ISO, 2000). The assessment of the QS is usually carried out by an independent body (i.e., by external audit), called a certification body, which will then issue a certificate that the QS is in conformance with the selected quality standard. The certification body has high expertise in quality standards and in general auditing procedures, but it does not necessarily employ health care professionals as auditors. On the contrary, clinical audit addresses the practical clinical work by different professionals, and the auditors should have considerable professional expertise related to clinical work.

Accreditation. Accreditation is an external assessment of the competence of the organization to carry out defined tasks (e.g. patient examinations) in accordance with a given standard. Audits carried out for accreditation may in certain respects come closest to the objectives of clinical auditing, but they do not include all those items which are included in clinical audits and are focused on standard procedures where definite standards are available.

Regulatory inspection is an inspection by a regulatory body in order to verify that RADIOLOGICAL practices are carried out in conformance with legal requirements (laws, statutes, regulations). These are typically unambiguous with binding requirements. Non-compliance can lead to enforcement actions. By comparison, in clinical audit, the focus of a review is on the agreed standards for good practice (see also Sections 4.6 and 6.2). The results of clinical audit are summarized in an auditor's report with findings and recommendations. The auditors cannot enforce any actions but the subsequent actions are to be decided by the user.

3.2 Good practice

Good practice is the practice which can be recommended based on the most recent considerations of evidence based data, long term experience and knowledge gained on the necessary structure, process and outcome. It should be defined in accordance with the principles described in Section 4.6. Good practice is also that practice which is agreed to be the basis of the assessment in clinical audits (i.e. local practice is compared with good practice).

It should be understood that "good practice" is not a permanent concept but should evolve with the general development of evidence based medicine, medical RADIO-

LOGICAL equipment and techniques. Agreed good practices should be reconsidered from time to time and modified, when there are evidence based reasons for change. Such modifications can become necessary when new data or experience is gained through research, clinical trials or from the follow-up of results from long term application of various practices. Modifications can also be initiated due to development of the techniques or equipment which can provide better tools to achieve the desired objectives of certain procedures.

Sometimes good practice has to be adapted to the available local facilities and resources. Due to local situations, a universally agreed good practice (optimized practice) may be difficult to achieve initially but should be considered as an ultimate aim. In such a case, the audit should look at the best practice which, in the interim period, can be readily achievable with the local facilities and resources. In this sense, there may be more than one 'good practice' to be applied as the basis of assessment.

4. BASIC PRINCIPLES AND PREREQUISITES

4.1 The concept of audit

The general understanding of the concept "audit" implies that the review or assessment is carried out by auditors *independent of* the organizational unit or practice to be audited, i.e., the auditors should not be responsible for the procedures to be assessed. This understanding can be derived from the use of this term in the business world, wherein originates perhaps the most traditional application of the concept. The Collins Universal Dictionary[3] defines audit as

> "an examination, by qualified persons, of the books and accounts of a business, public office or undertaking to prevent or discover fraud on the part of a person keeping them", or "to test and vouch for the accuracy of accounts"

It is also part of the general understanding that the auditors have *no power to enforce any actions* or requirements on the basis of their findings. Their role is simply to produce an independent assessment, report the findings and recommendations to the audited unit, and leave it for the unit to decide on any actions necessary for the findings.

The findings of the auditors should generally be considered to be *confidential* information between the auditing and audited units (see Section 4.5).

4.2 Objectives of clinical audit

4.2.1 General purpose

Clinical audit involves evaluation of data, documents, and resources to check performance against standards of good practice. It is not a new concept but has long been applied to many branches of medicine. It is essentially a process of fact finding and interpretation and, as such, provides an efficient tool to monitor and improve the quality of medical practices. It usually has two functions, to evaluate the current status of the health care unit with respect to its health care services and to identify areas for future improvement.

The purpose of a multidisciplinary clinical audit can be generally summarized as:

- To improve the quality of patient care
- To promote the effective use of resources
- To enhance the provision and organization of clinical services
- To further professional education and training in a healthcare team environment

The last purpose highlights the fact that many clinicians accept clinical audit also as an educational activity, led by the profession but reported in general terms to managers. It is difficult to change practice and performance without first measuring it. Clinical audit should be seen as part of an ongoing learning curve to bring about personal and professional improvement rather than a sanction or pay related process. The results of audits should encourage *sharing good practice across different parts of the depart-*

ment, or health care unit, so that lessons learnt in one area might stimulate audit in another area of the department, or allow change to be implemented effectively.

Through the assessment against chosen standards of good practice, clinical audit should promote the development and use of international standards of good practice, be applicable in all areas of healthcare, reflect the available resources and foster exchange of knowledge and information. Clinical audit should have professional initiation and foster an environment which enhances professional relationships and the multidisciplinary approach required to optimise patient care.

4.2.2 Aims and objectives

In order to define the detailed objectives of clinical audit it is first necessary to define the *aims*, *standards, scope and expected outcomes*. Once the aim or aims have been defined a series of standards or criteria of good practice are developed (Section 4.6). The standards or criteria of good practice must reflect the aims and are a measurable statement about performance describing the quality of care to be achieved (Grimshaw and Russell, 1993).

The aims are a broad statement of intent and describe the rationale underlying the audit. Audit can be related to a specific area of practice or may encompass the activities of a department or health care unit covering the entire patient pathway (Section 4.3).

The objectives should be specific measurable parts of the aim and directly related to the standards of good practice. They should reflect the aims and how they will be achieved. The objectives should be realistic, unambiguous and achievable, focusing on quality improvement. To be effective they should be measurable within a defined and agreed time frame. Initially, in order to improve service, audits may start with simple objectives, the objectives may increase over time though, leading to a more comprehensive audit (Section 4.3). Considerations should also be given on how readily the practice can be improved based on available standards and research evidence.

The objectives should highlight the areas of practice most in need of development. They should be written in such a way that it is possible to measure the level of care delivered to patients in comparison to agreed evidence based good practice and to indicate where improvement can be made. Common terminology used in defining objectives includes *to improve, to ensure, to reduce or to confirm.*

The critical areas and priorities for audits should be identified and the objectives agreed before the clinical audit is carried out. For internal audits (Section 4.4), the objectives of audits are set by the management of the unit to be audited, as the management should be aware of the areas of practice most in need of development, often based on the observations and initiatives of the practitioners. For external audits, the detailed objectives should be agreed between the auditing organization and the health care unit to be audited. The objectives should be based on any legal requirements on the audit programmes, as well as on any recommendations by national coordinating organizations or health professional and/or scientific societies when available (see Sections 7.6 and 7.7). Such recommendations usually originate in expert considerations on the up-to-date priority areas for clinical audits, often based on regional or national surveys on the status of practices.

The aims and objectives determine the type of audit to be carried out and the personnel who should be involved. In general, clinical audits should be multidisciplinary including all professionals involved in the delivery of the service, but in certain instances a single discipline audit may be appropriate (Section 4.3).

Aims and objectives of clinical audit have a generic content but can vary in detail according to national policy and procedures and with the RADIOLOGICAL practice being audited. The aims and objectives of clinical audit for diagnostic radiology, nuclear medicine and radiotherapy can be rather different, highlighting the importance of the professional teams in each RADIOLOGICAL practice working together to define them.

In defining the aims and objectives for external clinical audit, it is important to ensure that they supplement rather than duplicate other activities of external quality assessment such as accreditation or regulatory inspection (Section 5 and 6). In particular, effective clinical audit, based on clear and well defined aims and objectives should support regulatory inspection as they should measure also the implementation of the provisions of the Council Directive 97/43/EURATOM.

4.2.3 Continuous improvement through an audit cycle

Clinical audit aims at continuous improvement of the medical practices. Therefore, clinical audits should be carried out *regularly* and it should be ensured that the *audit cycle* (Fig. 1) is completed by closing the loop and the proposed changes effected. The general audit cycle consists of selecting a standard of good practice, assessing the local practice, comparing it with the standard, implementing change when necessary, and re-auditing after a certain time. An important feature of the audit cycle is, therefore, that clinical audit generally results in the implementation of change which improves practice and ultimately benefits patients. Regular re-audits will thus improve the quality or give reassurance that a good quality is maintained. Re-audit is integral to the process to ensure improvement is maintained.

By comparing the practice of the service against the standards of good practice, clinical audits can inform the staff of the health care service as well as all other stakeholders about the essential elements of quality and the weak points of the overall clinical service. The audits will indicate the areas for improvement and provide reassurance on issues such as safety and efficacy, all of which are essential to creating an environment of continuous development.

It is important to realise that audit, a measurement of a parameter against a standard, is of little value on its own, as are quality indicators (section 4.7.1). To be of value they need to be incorporated within a feedback system, in which the outcome of the audit is assessed, and improvements made to the process audited. Further audit then assesses whether the improvements introduced have had the desired effect. The need for a re-audit can be dictated by how well the observed practice complies with the criteria of good practice. If major deviations from good practice are observed, a re-audit should be instituted earlier rather than later.

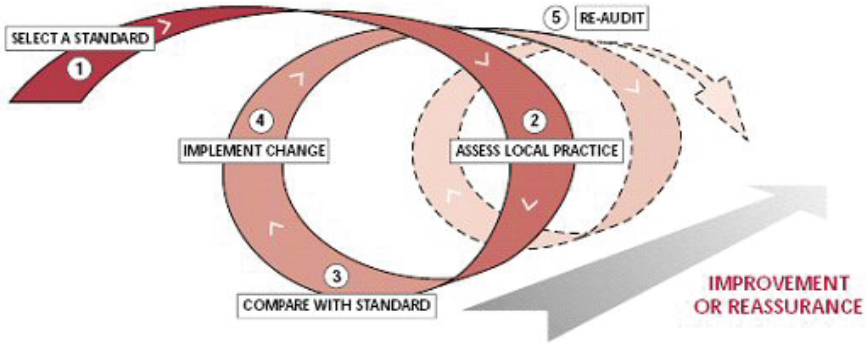

Fig.1 The audit cycle. Reprinted from Goodwin R, de Lacey G, Manhire A (eds). *Clinical Audit in Radiology: 100+ Recipes*, 1996 by permission of The Royal College of Radiologists.

4.3 Clinical audit coverage

4.3.1 General coverage

Clinical audit should be based on all or part of the clinical pathway defined as a' road map' outlining a course of care provided to a patient. It is a combination of clinical practices that result in the most effective, resource-efficient, appropriate treatment for a specific condition, procedure or symptom. Clinical pathways are a 'point of service' tool used to disseminate and implement clinical guidelines (Ministry of Health, New Zealand 2003). Therefore, it is justifiable that audit should cover all inter related stages of the clinical pathway as they contribute to overall quality of care.

To cover the whole clinical pathway, clinical audit should address the three main elements of the health care practices: *structure, process,* and *outcome* (Shaw 2003, Donabedian, 2005):

Structure - Structure denotes the attributes of the settings in which care occurs. This includes the attributes of material resources (such as facilities, equipment, and money), of human resources (such as the number and qualifications of personnel), and of organizational structure (such as staff organisation and methods of reimbursement).

Process - Process denotes what is actually done in giving and receiving care. It includes the patient's activities in seeking care and carrying it out as well as the practitioner's activities in making a diagnosis and recommending or implementing treatment.

Outcome - Outcome denotes the effects of care on the health status of patients and populations. Improvements in the patient's knowledge and salutary changes in the patient's behaviour are included under a broad definition of health status, and so is the degree of the patient's satisfaction with care.

Typically clinical audits focus on the assessment of structure and process, while it is mainly the role of evidenced based medical research to assess practice in terms of out-

come. This is true in particular for external audits, because it is difficult to implement the necessary long term assessment of outcome except in internal audits. External audit can usually assess only the quality of the follow-up procedures.

Clinical audit should focus on evaluation of the overall performance of the health care unit. For this purpose, clinical audit should review the level and quality of equipment in the unit and whether it is adequate for the expected function. It should include an evaluation of the role of each professional discipline in the delivery of service and care and how appropriate their educational background is in relation to their role and responsibilities. The processes and procedures in the department should be reviewed in conjunction with the protocols to assess the level of adherence and how effective they are in practice. Effective audit requires access to expertise in the specialist area and any patient related documentation considered necessary in order to review practice.

Clinical audit should cover all services, departments and professions and all professionals should be involved in the process, as appropriate. It should be seen as a tool to identify areas within the clinical pathway where change will bring about improved quality of care, more effective and efficient use of resources and the necessary support for personnel needed to bring about change. Multidisciplinary clinical audit concerns not only the clinical practice within individual professions but also demonstrates the contributions made by each and the organizational links between them. It focuses on the organization and its sub-units as a whole and not on the performance of individuals, however assessing that their competence to contribute to the necessary team work is appropriate. Clinical audit thus reflects the clinical directorate and health care team structure and the involvement of management.

4.3.2 Scope and depth, partial and comprehensive audits

Clinical audits in practice, whether they are internal or external, can be of various types and levels, either varying in their coverage of various activities *(scope)*, or in the thoroughness of the assessment *(depth)*.

The first variability (scope) means that a single clinical audit can assess either the whole clinical pathway of the RADIOLOGICAL process, from referral to follow up *(comprehensive audit),* or can be limited to specific critical parts of it *(partial audit)*. In the long run, the aim should be to audit of the whole clinical pathway, while partial audits can be used to focus in detail on the parts of the process of highest interest.

The second variability (depth) means that clinical audits can assess the generic parts of the practices, generic either to all RADIOLOGICAL procedures (level 1) or to a given speciality (level 2), or can go deeper to a selected individual examination or treatment (level 3). The specificity and *depth* of the audit can thus be characterized by three levels which can also be used when defining the criteria of good practices (Section 4.6).

When clinical audits, either internal or external (Section 4.4), are established for the first time in a given health care environment, the nature of the audit can be relatively superficial in depth, to obtain an indication of the *overall* quality of the radiological procedures and that the quality system is working well. In successive re-audits, the targets could go deeper in selected critical areas while the overall evaluation can be

somewhat simplified and focused on checking of the status of the problems found in the earlier audits.

4.3.3 Coverage of the radiological procedures

In RADIOLOGICAL practice, in terms of the Council Directive 97/43/EURATOM, clinical audits should address both the critical issues of the radiation protection for the patient as well as key components of the overall quality system. The priorities can then be distinguished as shown in Table 1; these will be further discussed and detailed in Sections 8 and 9.

Table 1. The priorities of clinical audit of RADIOLOGICAL practices

Structure	The mission of the unit for RADIOLOGICAL practices Lines of authorities and radiation safety responsibilities Staffing levels, competence and continuous professional development of staff, in particular for radiation protection Adequacy and quality of premises and equipment
Process	Justification and referral practices, including referral criteria Availability and quality of examination and treatment guidelines (protocols, procedures) Optimization procedures Patient dose and image quality in diagnostic radiology and nuclear medicine procedures, and comparison of patient dose with nationally accepted reference levels Procedures for dose delivery to the patient in radiotherapy (beam calibrations, accuracy of dosimetry and treatment planning) Quality assurance and quality control programmes Emergency procedures for incidents in use of radiation Reliability of information transfer systems
Outcome	Methods for the follow-up of outcome of examinations and treatment (short term and long term)

As for the depth of the audit of RADIOLOGICAL practices*, the audit should address the generic as well as the specific features of the practice, i.e. all the three levels of activities as defined above* (Section 4.3.2). For practical reasons, in the early development of clinical audits the main concern could be in the generic parts of the practice (levels 1 and 2), but it should be the aim to include also in-depth assessments of selected examinations or treatments (level 3). Furthermore, a broad focus on the departmental level of the health care unit is required, given the high integration level of several sets of specialties required for optimal patient care (administration, technical departments, imaging and pathology, nuclear medicine, surgery, medical oncology, etc).

The general practice of the complete radiological process highlights the elements of the quality system. The scope of this should comprise the three elements specified above: structure, process and outcome (Table 1). These start with the mission of the unit for RADIOLOGICAL practices and its quality system, including responsibilities and lines of authorities. As a part of the structure, the training of the staff should be

considered, for example the training programme and records, continuous professional development, access to meetings, conferences etc, along with access to libraries and the availability of professional literature. As a part of the process and outcome, all instructions and their practical implementation, from patient referral to diagnostic radiology examination or to radiotherapy, to the follow-up of the examination or treatment, should be audited.

In the assessment of the quality of the examination and treatment guidelines, special attention should be paid to the implementation of optimization procedures. This involves consideration of patient dose and image quality in X-ray radiology and nuclear medicine, and the accuracy of targeting dose distributions in radiotherapy.

Assured dosimetry is an essential component of assured clinical practice (IAEA, 2007). Therefore, the assessment of *patient dose* from X-ray radiology and nuclear medicine procedures and the *dose delivery to the patient* in radiotherapy should be among the necessary physical parts of all clinical audits.

In the audits of X-ray radiology and nuclear medicine, the patient dose or administered activity should be addressed in comparison with the given Diagnostic Reference Levels (DRL) or reference levels (in interventional radiology) (ICRP, 2007; IAEA, 1996). Furthermore, it is important to address image quality, because the optimization principle requires accurate radiological interpretation of the image by adequate image quality but with as low radiation dose as possible. In this context, also the image rejection rate and procedures to detect and recognize image artefacts should be considered.

In radiotherapy, at least the dose per monitor unit and associated parameters (also for IMRT fields) in external beam radiotherapy should be addressed, and at least reference air kerma rate and geometric reconstruction in brachytherapy. At an advanced level of clinical audit, the treatment planning process, the correctness of input data, treatment delivery etc, should also be addressed.

It is appreciated that auditing the clinical *outcome* may be very difficult, in particular for external audits, as described in Section 4.3.1. In radiological procedures, outcome refers to the results of the examination or treatment as they apply to the patient. The difficulty of auditing the outcome evidently varies between the three disciplines: radiology, nuclear medicine and radiotherapy. A few examples can demonstrate the outcome and the difficulties of its auditing:

- In diagnostic radiology, if a renal lesion is diagnosed by a radiologist as a simple benign cyst, it will not usually be operated upon; how can the accuracy of the report be confirmed? Similarly, if a pulmonary scintigram or pulmonary CT angiogram is reported as having a high probability of pulmonary embolism, the patient will be treated for pulmonary embolism, but it is impossible to know the accuracy of the diagnosis. In mammography, it is possible to make some estimate of the false positive rate, as all lesions reported as suspicious will usually be biopsied. However, it is almost impossible to know the false negative rate – those studies reported as normal where a cancer is truly present (although this will usually become apparent later).
- In radiotherapy, the outcome includes the results both in terms of cancer status and in terms of the side effects of the treatment. For the former, this may be ex-

pressed in terms of cure with figures such as five years survival, disease free survival or local control. It may also be expressed in terms of symptom palliation or quality of life. With regard to toxicity assessment, outcomes can be expressed in terms of quality of life, specific toxicity scores including mortality, complication rates and interventions necessary to overcome complications.

As a minimal approach for clinical audit of the outcome, how outcomes are measured within the health care unit should be checked, and how this information is recorded in the quality assurance and quality control manuals. In the long run, because of the importance to cover the whole clinical pathway also for RADIOLOGICAL practices, strategies should be developed so that the outcome could be covered more thoroughly.

Auditing *the examination or treatment specific practices* (level 3) can usually mean only a few selected examination or treatment processes per audit run. Full details of the procedures should be assessed at least for the items of the procedure where a reasonable consensus on a good practice can be achieved for application as the criteria of assessment (see Section 4.6). Such items for a given *radiological examination* (x-ray diagnostics, interventional radiology and nuclear medicine) could for example, include:

- Indications (based on studying a sample of referrals)
- Image criteria, reproduction of anatomical structures
- Patient position, radiographic technique, use of grid, tube voltage
- Protective shielding

For *radiotherapy*, such items for a given treatment could be for example

- Adequacy of the evidence-based data available in the literature and the patient/tumour features which justify the treatment plan. Depending on the tumour type and clinical setting, good practice could include genetic or family history, clinical and pathological stage of tumour, tumour size and grade and performance status of patient.
- Practices for dose prescription, specification of the target volume.
- Achievement of normal tissue tolerance in dose planning.
- Quality of the treatment delivery
- Follow-up practices (acute and late complications, recurrence): Adequacy of recorded data, follow-up model (frequency of examinations, clinical items, examination in a local health care unit or in a radiotherapy hospital, information flow etc), comparison of complication rates with expected.

4.4 Internal and external audits

Clinical audit should be a systematic and continuing activity, whereby internal audits or self-assessments and external audits are of equal importance and should supplement each other in order to achieve optimal outcomes. *Internal clinical audits* and self-assessments are carried out within the health care unit as part of its overall quality assurance procedures. The principle of independence (Section 4.1) is implemented whenever possible by nominating auditors from sub-units or departments of the health care unit different from the sub-unit to be audited. However, for small units this might

not be possible and internal audits can take more a form of a self-assessment rather than actual audit. *External clinical audits* are carried out by an external auditing body or auditors, independent from the health care unit to be audited. An external audit could help to assure good practice, as it might be difficult or inadequate to reveal problems only by internal efforts.

Internal audits or self-assessments should be the first priority when there has been no earlier experience on audit and when clinical audits are introduced for the first time. This could be an optimal approach in order to get properly started, to provide motivation for audits, to become oriented with the possible problem areas in need of most urgent improvement and to make the staff familiar with general audit technology. The internal audits could serve as a useful preparatory phase for introduction of external audits. In the long run, regular internal audits or self-assessments could build-up and maintain an open attitude also for external audits, and provide experience and background information in order to derive maximal benefit from the external audits.

The value of external audits lies mainly in providing the audit with more universal and broader perspectives, removing the possible inability of internal experts to recognize the weaknesses and items for improvement in their own long-standing and routine practices. The external auditors may be able to better judge the consistency of procedures from one health care unit to another and from one user to another. Recognition of substantial variations of a medical procedure between clinicians and between health care units can encourage a more systematic approach to this procedure and lead to subsequent improvement of the agreed practices. For increasing complexity of RADIOLOGICAL procedures, the added value of external audits becomes more prominent.

The development in the field of radiotherapy provides a good example for the value of external audits. Not all treatment protocols are equivalent and a significant variation between countries has been demonstrated regarding cancer survival. This "sub-optimality" went undetected for a long time, until comparison of treatment effectiveness was initiated at the national and international level. Reasons for this are insufficient diagnostic facilities, sub-optimal education of patients (as awareness of cancer screening programs), limited drug supply, a low density of radiotherapy facilities, and a shortage in nurses, RTTs, medical physicists and radiation oncologists. All of this has contributed to a delay in cancer diagnosis and a further delay in cancer treatment. The increase and distribution of the awareness of better practices through comparisons and external audits (for dosimetry and quality assurance) has initiated corrective actions in many places and at many different levels: European Union, governmental, regional, and local.

The external audits have also a better capability to detect how useful the procedure to be audited can be. For example, the frequency of abnormalities detected by radiological investigation, or other performance measures observed through clinical audits in a number of health care units, can form the basis of guidelines for more efficient use of the procedures. Through the systematic undertaking of external clinical audits in a local or national health care area, the audits will disseminate knowledge about good practice while also contributing to further improvement for the benefit of the medical services and patients.

A cycle of routine ongoing internal audits complemented by a five year external audit can be effective and not particularly onerous. For instance the internal audit could address a range of individual topics on an ongoing basis and the external audit the full clinical pathway. This type of approach is consistent with the analogy of a learning curve with continuous, rather than spasmodic improvement. In will also give an effective way to supplement internal audits by external ones and vice versa.

For very simple RADIOLOGICAL procedures, such as ordinary dental radiography (bitewing radiography), allowance with respect to external audits could be made and internal audits regarded as an acceptable clinical audit programme.

4.5 Confidentiality of audits

Confidentiality is a critical issue in relation to clinical audit. It is essential that all parties, those being audited and those carrying out the audit, respect the confidentiality of patient data, the interviews and discussions with staff, audit reports and other performance data. Auditors should sign a confidentiality statement.

Confidentiality will facilitate the discussion of important quality assurance issues. The information obtained and evaluated as part of clinical audit should therefore be regarded as confidential, analogous to peer review information, and hence not discoverable.

A critical point of the confidentiality arises when the audit reveals serious problems or non-conformities which may endanger the safety of patients or staff. In such cases, the auditors should immediately notify the health care unit management of the findings with a request that the notification of the authorities is not to be excluded. The auditors should ensure that the regulatory authorities will be informed according to the national law, and if necessary, make this notification. It would be a good practice if the auditing and audited organizations would agree in advance of the audit, e.g. in the formal tendering and ordering process of the audit, that any observations of serious problems will be informed to the regulatory body when considered necessary by the auditing organization.

4.6 Standards of good practice

To make clinical audit successful - that means that its outcome and advice will provide added value to the audited institution - clinical audit, whether internal or external, has to abide by general accepted rules and standards which are based on international, national or local legal regulations or guidelines developed from international, national or local professional and/or scientific medical societies. This applies particularly to the definition of good practice.

In general, the standard of good practice is a conceptual model against which the quality or excellence of a particular activity may be assessed. Standards of good practice can be based on:

- Legal requirements
- Results of research

- Recommendations by learned societies
- Consensus statements
- Local agreement (if there is no other more universal reference)

The first option on this list is an obvious necessity, because any RADIOLOGICAL procedure should be in accordance will all legal requirements. The second one is the most fundamental source of data for evidence-based standards of good practice. The results of research in advanced research-oriented health care units, yielding improvements in medical care, should be disseminated in a timely fashion to the entire health care community. Several approaches have been concurrently promoted over the past 15 years. The original publication in the JAMA, *Evidence-based medicine; a new approach to teaching the practice of medicine*, has been a benchmark in the way diagnostic and treatment protocols are analysed and eventually recommended as optimal practice (JAMA, 1992; Dixon 1997).

Standards of good practice for radiological procedures can be the combination of three different levels, corresponding to the thoroughness or depth of the audits (Section 4.3.2):

Level 1, The most generic criteria. These standards or criteria relate to the general quality of the practices and can be applied to all type of practices, whether it is diagnostic radiology, nuclear medicine or radiotherapy. Typical examples are, e.g., quality system, the lines of authority and definition of radiation safety responsibilities, provisions for continuous professional education, and the waiting time of the patient to be examined or treated.

Level 2, The criteria generic to a given field of application (diagnostic radiology, nuclear medicine or radiotherapy). These criteria can be applied for example to any diagnostic radiology procedure, independent of the purpose of the examination or the chosen modality.

Level 3, Specific criteria. These criteria are specific to a given examination or treatment, and can be part of the clinical protocol. Consensus on this type of criteria might not be easily obtainable and can vary universally. It may also be dependent on the available techniques and facilities. Such criteria should usually be agreed on individually for each audit run e.g. through consensus meetings of professionals at the health care unit for internal audits, and through consensus meetings of professional and/or scientific societies for external audits.

The definition of clinical audit (Section 3.1) presumes that suitable written criteria for good practice are available for the assessments. In conditions when there are no written international, national and local criteria or accepted standards available (except for legal requirements), as a preparatory approach to clinical audit, the assessments could be based on an expert opinion, or preferably on a consensus opinion of a relevant expert group. However, this is not recommended as the permanent criteria because it does not ensure the uniformity and impartiality of judgements. For example, different experts might have different preferences related to good practice, and the good practice at the experts' own clinical environment might not be the most relevant in another clinical environment with different availability of resources. There might be variation

in the equipment level or training level, or different "schools", beliefs or habits which affect the understanding of a good practice.

Standards of good practices for level 1 and 2 clinical audits are reviewed in detail in Sections 8 and 9. Level 3 criteria is not further discussed in this Guideline but examples can be found from published audits (e.g. Van Houtte et al., 2007; BNMS, 2007).

4.7 Quality indicators and classification of audit findings

4.7.1 Quality indicators as a practical measure of performance

The most practical way of the assessment of quality or performance can be through introducing measurable variables or *quality indicators* and their relative thresholds for specified parts of the criteria of good practices. The quality indicators will make it easier to decide on the necessary changes of the practice, while it also helps in clarifying the objectives of the audit. The purpose of an indicator is to define if a problem exists, and if so, to what extent, and lastly, to allow the measurement of the success of interventions.

While the quality indicators can be of high value in internal audits and self-assessments, they are not always applicable to external audits, because their assessment may require a long term evaluation of data or results, or follow-up of the local procedures to the extent which is not possible at a single visit of external auditors. Instead, in external audits it would be worth-while to audit the procedures to set and monitor the quality indicators.

A quality indicator should be reliable, accurate, sensitive to changes, specific in terms of quality, pertinent, scientifically robust, able to influence decisions, easily understood and simple (Cionini et al., 2007). As far as data collection is concerned, a quality indicator should allow easy collection of complete data in a timely manner, and be of reasonable cost. Data bases for indicators can be obtained by statistical and demographic data collections, by systematic health data collections, from clinical documents or from ad hoc data collections.

Any new indicator should have an operational definition accompanied by a pilot study to test, at least, the reliability of the indicator and the real-life possibility for the indicator to be collected, including considerations of difficulties in data collection. To this purpose a grid of the type given in Table 2 could be of some help.

For the indicator to be effective, it is important that it is accompanied by a *threshold.* The threshold can be defined statistically with respect to the indicator values distribution and can be based on international literature but also on internal value (for example a value relative to the indicator distribution of the first year and then increased year by year). At its first definition, an indicator may also lack the threshold, but it should be given as soon as sufficient experience has been gained to propose a value.

Table 2. Grid used to define indicators (Cionini et al., 2007).

Items	*Definitions*
Topic	What is measured
Rationale	Why it is measured, which are the advantages and the relevance in terms of quality
Type of indicator	Structure, process or outcome
Numerator	Parameter value
Denominator	Reference population
Stratification	Recommended categories for the indicator application
Standard	Reference value
Data collection	Type (population or sample, time period for data collection, frequency, responsible of data collection, of data analysis and interpretation)

Quality indicators are most easily defined for levels 1 and 2 of the criteria (Section 4.6), or for a limited scope covering the structure or process only. An example of such indicators is a turn-around time, which is a typical process indicator. There is a high desire to develop indicators also for level 3 of the criteria and to cover also the outcome, e.g. to assess that at any diagnostic procedure the highest-quality diagnostic outcome is achieved for the lowest possible radiation dose to the patient.

By use of the quality indicators, separate parts of a complex process can be assessed. For example, due to the increasing complexity of radiotherapy procedures, process indicators can be useful to monitor different steps of the treatment from the initial clinical decisions through the treatment delivery to the subsequent follow-up. Participation of a radiotherapy centre to dose comparisons is of great importance and should be monitored through "ad hoc" indicators. The assessment of quality control programmes is an important part of the audit, where quality indicators can be very helpful. Many general issues such as patient satisfaction, or that of prescribers or other specialists requesting the RADIOLOGICAL procedure, can be also monitored through process indicators.

Examples of quality indicators as developed for radiotherapy are given in Appendix 4 (Cionini et al., 2007).

4.7.2 Classification of the deviations from good practice

For certain cases, in particular with the use of quality indicators, it may be helpful for the preparation of the recommendations of the auditors and for the further actions (e.g. re-audits), if the observed faults or deviations from the good practices are classified as for their severity. An example of the classification system applied in German system of clinical audits is given in Appendix 5 (ZAeS, 2007).

As a minimal approach, a simple system of three levels of severity can be established: (1) No significant deviations, (2) Significant deviations but resolvable with unit's internal resources, (3) Significant deviations which may require external input in order

to be resolved. This type of system has been applied by the IAEA for external audits (IAEA, 2007); see also Section 7.2.5.

5. INTERRELATION OF CLINICAL AUDIT WITH OTHER AUDIT SYSTEMS

5.1 External review systems for health care facilities

Between 1996 and 1999 the project team of ExPeRT (External Peer Review Techniques Project funded by the EC), catalogued the range of external review systems of health care facilities in the European Union and countries associated with EU (Shaw, 2000).

Four main categories of systems aiming at measuring the quality of service management and delivery were identified:
(1) professional peer review –based schemes,
(2) accreditation,
(3) award seeking such as European Quality Award and their national variants (i.e. European Foundation for Quality Management (EFQM) Excellence Model); and
(4) certification by International Standards Organization (ISO) (Bohigas and Heaton, 2000).

All of those systems are continuously implemented, adopted and improved by many organizations and governments around the world. Accreditation (originated in USA in 1917) and certification (originated in UK in 1947, popularized among health care organizations within last 10 years due to its international recognition, universality, applicability and suitability) are the most commonly used systems. The basic difference between accreditation and certification is that accreditation is assessment of competence while certification is assessment of fulfilment of standard requirements and does not refer to competence. Less popular are EFQM excellence model (introduced in Europe in 1988) and peer-review based scheme (*Visitatie* – implemented in the Netherlands by medical associations in 1992) (Heaton, 2000).

All of the above mentioned systems are based on PDCA cycle [2] (except for EFQM based on RADAR cycle[3]) and are characterized by three crucial activities:

- the development of standards,
- the selection, training and monitoring of evaluators (auditors, visitors), and
- the evaluation process with common features such as: process initiation by the institution, self-assessment, agenda or audit plan, evaluation visit, trained evaluation team, report and evaluation of findings.

The above systems have been compared in detail in Appendix 6. Though the methodology and terminology of the four main external review systems differ, a constant movement towards collaboration and convergence of those models has been observed, as the ISO model of certification can be easily embedded in an accreditation (also based on ISO standards) or EFQM approach. Peer review is the closest to accreditation, as they both refer to health care, whereas ISO model of certification and EFQM touch mainly upon the managerial and organizational conditions under which care processes are executed. Moreover ISO based certification, mostly due to its universal

[2] PDCA – plan, do, check, act cycle model proposed by W.E. Deming
[3] RADAR – results, approach, deploy, assess and review (modification of PDCA cycle model)

nature is most commonly absorbed and adapted, being a core or a framework of existing quality evaluation systems, programs or models (Bogusz-Osawa et al., 2006).

5.2 Clinical audit versus other review systems

Clinical audit, as defined in the EC directive 97/43/EURATOM and discussed in this EC guideline, has certain similarities with the above mentioned external evaluation systems (especially with the peer review model - *Visitatie*). However, it is of high importance to understand that clinical audit is different from these other systems: it differs in its purpose, scope, method, impact and use, as it was designed for different purpose. These points for clinical audit are compared in detail with the other review systems in Appendix 6.

Due to the many similarities with other review systems, clinical audits should be established and developed in a way which minimizes unnecessary overlap, or duplication of efforts, with the other systems. The key factors to avoid the overlap or duplication can be distinguished as follows:

General:

- Perform audit *both internally and externally* on regular basis.

Focus of assessment:

- Concentrate on organizational, physical, technical, clinical and safety aspects of the service delivery.
- Concentrate on *detailed* and not overall information/feedback on the performance of clinical procedures from the evidence-based point of view.
- Make use of the quality system documentation for the assessment of clinical audit items but do not focus on checking the conformance of the quality system to a quality standard.
- Put much emphasis on a dynamic *quality assurance and quality improvement*.
- Put more emphasis on goal setting, analysis of the process and planning the improvement.
- Focus on recording and *improvement of practice*.
- Measure changes in practice to effect change (Section 4.2.3).

Criteria for assessment

- Avoid limitation to minimal standards or norms.
- Assess the practice against sufficient criteria of good clinical practice given e.g. at national or international level
- Provide indicators and standards of good clinical practice which audited organization can refer to.
- Review and update standards systematically, according to the latest evidence based medicine, current results of research, bench-marking (Section 4.6).

Practical implementation

- Give aims and objectives, where an aim is a one-sentence description of what is to be achieved by the audit and an objective is a statement of how a particular factor is to be investigated to contribute to the overall aim of the audit.

- Provide auditors who have good knowledge and clinical experience in the field of application to be audited,
- Follow workflow and patient flow, conduct interviews with staff, review or perform measurements and control tests (physical, technical) when appropriate, review documentation and records,
- Assess the appropriateness of the selection of examinations or treatments for patients or the health outcomes,
- Involve anonymous patient data in the audit process (e.g. the quality of the referrals for a sample of patients).

5.3 Implementation of audit systems in Europe

Due to the social, political, and economical aspects of each European country, the different audit systems presented above have been implemented either on voluntary or mandatory basis. For instance, in radiotherapy (Bogusz-Osawa, 2007), some states such as Austria, Belgium, Finland, France, Italy, Germany, the Netherlands, UK and Poland have comprehensive legislation on the management of health care quality including the uptake of external audit system (either accreditation, ISO certification, peer review or clinical audit). For example, Belgium (since 1987), Italy and France have legislation (passed in 1997) for governmental accreditation schemes, Austria requires implementation of quality assurance system in health care organizations (law passed in 1993), Poland on the other hand has legislation (passed in 2001) for certification based on ISO norm and clinical audits (passed in 2005) in radiation oncology, radiology, nuclear medicine and laboratory medicine.

6. INTERRELATION WITH REGULATORY CONTROL

6.1 Regulatory control

A legal infrastructure in a country should ensure that a legislative and statutory framework is established to regulate the safety of facilities and activities, including medical use of radiation. A regulatory body shall be established and maintained, having the responsibility for authorization, regulatory review and assessment, inspection and enforcement, and for establishing safety principles, criteria, regulation and guides (IAEA, 2000).

The regulatory requirements for the use of sources or devices in diagnostic or therapeutic medical exposure will generally depend on the level of risk or complexity associated with the medical use, as determined by the regulatory body. In general, *authorization* is required for the use of ionizing radiation in medical practices. In most cases this is achieved through a *licensing* procedure, while in some cases (e.g. in dental radiography) this can be achieved through requirements on just *registration* of the practices. The regulatory body should develop special guides for each practice to assist the licence holders and registrants in meeting the regulations.

Compliance monitoring should be conducted by the regulatory body to determine whether radiation sources are being used in accordance with the requirements of the relevant regulations and any conditions of authorization. Key elements of compliance monitoring include on-site inspections, radiological safety appraisals, incident notifications and periodic feedback from users about key operational safety parameters.

On-site inspection is the most positive component of compliance monitoring. According to the MED directive (Article 13), Member States shall ensure that a *system of inspection* enforces the provisions introduced in compliance with the directive. The inspections are often the principal means for direct personal contact between the users and the staff of the regulatory body.

Regulatory inspection can be defined as:

> "An examination, observation, measurement or test undertaken by or on behalf of the regulatory body to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence." ,

or, as in the MED Directive (European Commission, 1997):

> “Inspection is an investigation by any competent authority to verify compliance with national provisions on radiological protection for medical radiological procedures, equipment in use or radiological installations”.

In brief, the purpose of the inspection is to *verify* that various detailed requirements for radiation protection are being met.

The methods of verification can include both *documentary* assessments and verification *measurements*. The former comprises inspection and checks of the existence and quality of required documents, such as operational guides, safety guides and quality assurance programmes, as well as inspection and checks of the results of quality assurance or quality control measurements, such as patient dose determinations (diagnostic radiology), calibration of isotope calibrators (nuclear medicine) and beam calibration (radiotherapy). The inspection and checks should include verification of key safety factors and the performance of the local quality assurance by appropriate measurements, e.g. leakage radiation of equipment, the adequacy of radiation shielding of the rooms etc.

The verification measurements are more typical of the inspections for the safety of personnel, and less typical of the inspections for the safety of the patient. This is mainly because the latter measurements require higher technical competence of the inspector, usually a good experience in similar measurements in medical practice, and this may be difficult to achieve and to maintain by the regulatory body.

The nature of the verification measurements should be the verification of the correctness and reliability of the local methods of measurements and procedures, rather than the performance of individual radiation equipment. It is important that the verification measurements by the regulatory body should never replace any quality control checks or measurements that are the prime responsibility of the user (licence holder or registrant).

Enforcement actions are designed to respond to non-compliance with specified conditions and requirements. The action is commensurate with the seriousness of the non-compliance. The enforcement actions thus range from written warnings, or requests for further investigations or remedial actions, to penalties and, ultimately, withdrawal of an authorization. The regulatory inspectors may be given the authority to take on the spot enforcement actions, or the information is transferred to the regulatory body so that necessary actions are taken in a timely manner.

6.2 Distinction between clinical audit and regulatory inspection

It is clear from the above that external clinical audit and regulatory control are two different concepts. In particular, external clinical audit is not a regulatory concept and should not be confused with regulatory inspection.

On one hand, strictly speaking, the authorities doing inspections should neither carry out clinical audits nor directly and exclusively set up the criteria for the audits. On the other hand, the focus in clinical audits should be on non-mandatory issues of good clinical practice and not on such legal requirements which are controlled through the inspections by the regulatory body (even though it is a necessity that the standards of good practice include all legal requirements, see Section 4.6). Thus, the focus of regulatory inspections and clinical audits are different as are also the use the results (Table 2), even though some review procedures for can be very similar. In the optimum situation, external clinical audits should supplement regulatory control, while the optimum relationship is dependent on the extensiveness of the regulatory control in the country.

Table 2. Main differences between clinical audit and regulatory inspection.

	Clinical audit	Regulatory inspection
Focus of review	"Agreed standards for good medical RADIOLOGICAL procedures". These are often not requirements but recommendations to the users. There may be more than just one agreed standard.	Legislative and statutory framework (laws, statutes and other regulations). These are unambiguous and usually binding requirements to the users.
Use of the results	Auditor's report, with the findings and recommendations, is given to the user. *The auditor cannot enforce any actions*, but the actions are solely decided by the user.	The non-compliance with specified conditions and requirements leads to *enforcement actions* by the regulatory body. The regulatory inspector may impose on the spot corrective requirements to the user.

7. PRACTICAL IMPLEMENTATION

The guidance of this section for the practical implementation of clinical audit relates mainly to organizing external clinical audits. However, many of the principles can also be applied to organizing internal audits. This section is based on the Guidance prepared by the IAEA (IAEA, 2007).

In this section, a traditional approach of carrying out external audits through a site visit is adopted. For limited parts of the process (partial audits) a useful alternative can be collection of data via mail or internet, with central assessment of the data, or by checking a process with a mailed system. An example of the former is the assessment of the quality of referrals by mailed questionnaire (W. Leitz, 2009). Examples of the latter are the postal thermoluminescent dosimetry services for checking the beam dosimetry in radiotherapy (see Section 7.1.1). A pre-requisite for these type of partial audits is that the assessment can be based on recordable or measurable data.

7.1 Clinical audit organization and auditors

7.1.1 Organization

For *internal* clinical audits, establishing the organization for audit within the health care unit is relatively straightforward, while the general guidance on audit principles and techniques should still be followed. The principle of independence can be met at least in larger health care units by using auditors from another department or sub-unit, which is not directly involved in the activities to be audited (cf. Section 4.4).

For *external* clinical audits, there are four main approaches for the practical organization of the audits:
(1) establishing a special national or regional organisation for clinical audits, or
(2) making individual "case by case" agreements between the auditors and the institution to be audited (similar to peer review activities), or
(3) establishing a special project to undertake clinical audit in a well defined purpose but for a limited scope and timescale, or
(4) making use of international audit services if available.

The first approach is the most effective in achieving a systematic regular system of audits, while the three others are typical solutions for occasional and less systematic efforts. The most suitable organization can also depend on the national health care culture and infrastructure. When planning the implementation, it might be useful to compare the planned approaches with the organization of other efforts of quality assessment such as peer reviews, quality (system) audits and accreditations. Further, a mechanism should be established to ensure the full competence and credibility of the auditing organization, e.g. through requiring its accreditation by a national accreditation body.

The special organization (within approach 1 above) can be a government body, in particular when the audits are financed through the government budget, or a private organization established and maintained e.g. by a professional societies or other entities. The audit organization is needed in order to embed a consistent audit programme and to develop the programme for continuing audits, and to manage the practical prepara-

tions, contacts, organisation of the audit visits, reporting and financial matters (see Section 7.2). The auditors are most typically employed for each individual audit from a pool of volunteered health care professionals based on special agreements.

The individual "case by case" type of audit (approach 2) is usually based on special agreement between two health care units. The audit programme and implementation can be agreed very freely between these units, although this method does not ensure continuity and wider uniformity of the audits in a region or country. Further, this method may lead to the consideration of the adequate independence of the procedures, in particular if the audits are based on mutual audits between the two units.

The third approach, through special projects, can be very comprehensive and effective in the short term, because it can be easily supported by sufficient authority and funding schemes, and important partners and expertise can be involved through the project structure. While such a project can provide a high impetus towards the creation of the future audit systems, the significant drawback is that the project itself is only a temporary activity and do not as such provide a continuous engine for on-going external clinical audits.

The last approach, making use of international audit services, can be an "easy" way of starting external audits and gaining experience on their implementation and impact. These could be very useful in providing some "model audits" in the process of developing a national organization for clinical audits. The drawback of this option is that international services for clinical audit are not widely and extensively available, or are available only under special conditions, or for very limited applications. For example, the clinical audit service provided by the IAEA (IAEA, 2007) is bound to the Technical Co-operation projects between the IAEA and the IAEA Member State. The postal dosimetry audits for radiotherapy, provided by the IAEA (Izewska et al., 2004) and the ESTRO (Ferreira et al., 2000; Roué et al. 2006; 2007), are also bound to certain conditions and represent only one component, although an important one, of a comprehensive clinical audit.

7.1.2 Auditors

The basic competence of the auditors for clinical audits should be based on their professional competence and long-term clinical experience. In practice this means that *in their permanent profession they have to be involved in clinical work at a speciality approximately similar to the one to be audited.* Besides this basic competence, the auditors should receive specific training on the general audit procedure and techniques, as well as the agreed audit programme and the criteria of good practices to be applied.

Due to the multidisciplinary nature of audit, a team of auditors is usually needed, comprising different professionals - radiologist, radiation oncologist, nuclear medicine expert, medical physicist (preferably a medical physics expert), radiographer etc - depending on the scope of the audit and on type of application to be audited. The team should have up-to-date experience in the practice to be audited. As a general guidance, the following minimum composition of the team is suggested:

- <u>for conventional radiology</u>: radiologist and radiographer

- for more sophisticated radiology: (CT, interventional radiology, etc): radiologist, medical physicist and radiographer
- for nuclear medicine: nuclear medicine specialist (physician), medical physicist and nuclear medicine technologist, and radiopharmacist for big NM units
- for radiotherapy: radiotherapy oncologist, medical physicist, RTT[4]

The audit programme may sometimes necessitate that the group of auditors includes also some other professionals (i.e. cardiologist, engineer, etc).

The principle of independence in external audits (Section 4.1) requires that the auditors are independent from the organization to be audited. For a given country or region, it is advisable to define this independence exactly. For example, in case of public health care, the auditors could be required to come from another health care district or from the private health care practice. Special considerations of the independence are needed in some countries where health care systems are a mix between private and public practice and the same health care professional can work in both systems at the same time. Further, it can be recommended that the auditors should not have been employed by the health care unit to be audited in the last few (e.g. five) years.

7.2 Audit process

7.2.1 Request for clinical audit

The request for a clinical audit normally originates from the administration department of the health care unit to be audited. It is essential that the management of the unit to be audited, both the clinical lead and the managerial administrator, will endorse it, in order to ensure optimum cooperation, and maximize the benefit of the audit.

For the audit to be planned and the audit team or auditors to be chosen appropriately, basic information on the status of the health care unit needs to be gathered prior to the site visit. This is generally requested by the auditing organization after the formal request of the audit has been received.

7.2.2 Selection of auditors

The clinical audit methodology is usually designed for execution by a multidisciplinary panel or team, whose expertise is predominantly in the RADIOLOGICAL practice to be audited. As the clinical practices are typically team efforts, it is of a great advantage that team work can also be applied for the assessment of the practices. The composition of the on-site visit team will depend on the scope, level and expected content of the audit visit (see Section 7.1.2). It is important that the members of the audit team include experts in all aspects of the program to be audited. They must also be familiar with the audit methodology. It is a good practice also that the auditors have been agreed on with the health care unit to be audited.

[4] Abreviation RTT has been used in this Guideline to denote therapeutic radiographer, radiation therapy technologists etc. There is no consistent title for this professional group but by consensus of the working group and representatives of the National Societies in the development of European Core Curriculum the use of the term RTT (radiation therapist) was agreed to represent the wide range of titles used in the profession.

7.2.3 Preparation of the audit visit

The success of any clinical audit depends heavily on thorough preparation by all participants. The audit should not be started until each party involved (auditing organization, auditors and the health care unit to be audited) have confidence in the sufficient preparation by the other parties. The auditing organization and auditors have to be able to build the confidence of the health care unit in the capacity of the auditors to review its organisation fairly and thoroughly.

Auditing organization

The responsibilities of the auditing organization are to:

- Agree on the objectives of the audit with the health care unit.
- Select an appropriate audit team, nominate a coordinator (team leader) and make adequate briefings. The coordinator is necessary for facilitating the work of the audit team in the health care unit and also to coordinate the preparation of the final report. The coordinator is the main contact person for the health care unit on all audit activities.
- Plan the audit and the timetable together with the auditors and the health care unit.
- Request all necessary data from the health care unit (type of unit, size of unit, type of equipment, people in charge, staffing, patient load, etc.). This should conform to the checklist of audit, see Section 7.2.4.3.
- Inform the health care unit about the methodology (provide appropriate documents) and send them all relevant other information.
- Review previous audits (if any)

Health care unit to be audited

The responsibilities of the health care unit to be audited are to:

- Prepare data and relevant documentation according to the questionnaire sent by the auditing organization.
- Identify individuals responsible for interaction, although the audit team should be free to interview any staff member they deem appropriate.
- Inform the entire health care unit of the timing and nature of the audit.

Auditors

The responsibilities of the auditors are to:

- Communicate with the health care unit before departure (make yourself known) and confirm the detailed timetable of audit (entrance meeting, appointment with relevant people, check of equipment, exit meeting). This is usually the responsibility of the coordinator.
- Communicate with other team members beforehand and agree on the coordinator of the team, unless specified by the auditing organization.

- Ensure they are familiar with the objectives and methodology, discuss their approach and allocate their responsibilities prior to departure. Ensure that all needed equipment is available (if the audit includes measurements and/or tests).
- Review the background information available.
- Define areas where additional information is necessary.
- Ensure that terms commonly used are clearly specified in the department to be audited (examination, treatment, session, patient, etc).
- Ensure that the health care unit to be audited has received relevant information on the audit (plan, manual etc)

7.2.4 On-site audit procedures

7.2.4.1 General guidance

The clinical audit focuses on evaluating the overall performance of the health care unit to be audited, in accordance with the given aims and specific objectives. In the audit process, the team should obtain a comprehensive understanding of the total operation of the unit. The auditors need to consider the interaction of the unit with other health care departments or units. For example, in auditing a radiotherapy unit, other units to be considered are such as gynaecology, surgical specialties and medical oncology, and the hospital administration. The auditors must have *free access* to all staff members (physicians, physicists, radiographers, engineers, etc), to assess the free and efficient flow of information and co-operation between the different professionals.

The auditors must seek evidence for a *patient oriented* organisation, with a culture of improving through learning and openness to new technologies and practices, and a culture of strong cooperation between staff members. To ensure effective assessment of the practices, an appropriate quality assurance programme or system should be in place with the objectives of continuous quality improvement.

If research has been conducted, its integration into clinical practice must be judged, (e.g. the auditors need to assess whether the publication level matches the research efforts).

The auditors should be systematic, and should not be overly impressed by high-tech equipment, nice furniture or friendly staff, since such features have no direct relationship to the performance level which needs to be assessed.

The audit team should meet daily to review and crosscheck the information gathered during the day. It is wise to share the same hotel and to agree on a common timetable.

The final audit report is an important but heavy part of the audit. Therefore, the coordinator should work daily on it. Basic elements (conclusions and recommendations) should be ready for the exit briefing (Section 7.2.4.4), in order to discuss the preliminary findings with the health care unit's management and staff and to verify facts before leaving the place.

Adaptation of the timetable might prove appropriate, according to findings. Flexibility is needed, and therefore, good coordination. While the auditors must have the freedom to speak to every individual in the department, they have, however, no authority to overrule the local hierarchy and should comply with authorisations or refusals from

the people in charge. The head of department is the final referee in case of conflict. Should such difficulties arise, they must be presented as part of the final report.

7.2.4.2 Entrance briefing

The entrance briefing is required to introduce the auditors and to remind the various staff members of the objectives and the details of the audit (who requested, what is requested). The auditors should reassure the department that patient and staff confidentiality will be respected. Therefore, all auditors of the team should attend on the initial day, and be present at the introductory meeting.

The key staff members in a position of managerial responsibility must attend this entrance meeting, and introduce themselves at the start of the meeting.

The audit team should explain what it is going to do and that it will see persons *individually* while simultaneously stressing that the assessment concerns the organization as the whole and not the performance of individuals. This is the right time to insist on *confidentiality* during the visit, and afterwards with the report.

Building an atmosphere of confidence is very important, because people may feel intimidated by the site-visit. The auditors should act honestly and without prejudices. Even small details can matter, like dressing appropriately, showing respect but not submission, etc. The use of the *SGGT* (smile, good morning, good bye, thank you) communication toolkit is recommended.

7.2.4.3 Assessments

After the introductory meeting, the auditors are expected to understand the organizational chart and management of the unit.

In the process of assessments, auditors should aim at raising health care unit's confidence in the team. For this reason, only verifiable or measurable facts should be used as the basis of assessments.

The structure, process and outcome (Section 4.3.1) of the practices are audited according to the objectives and plan of the audit. Detailed written guidance is useful to help the auditors in organizing the audit programme and assuring coverage of the relevant topics (IAEA, 2007). This guidance should include detailed descriptions of the criteria of good practices to be applied or each item to be audited, and a series of procedures (checklists or audit programme) to assess the local practices against the criteria. An example of such detailed guidance is shown in Appendix 7 (IAEA, 2009). For practical recording of the findings, it is useful to design a series of specific forms based on the checklists. These forms can be part of the final report or serve as a firm basis for the preparation of the final report to be given to the audited health care unit (Section 7.2.6).

Clinical audit should be based on interviews of the staff and observations of practical work, reviews of local documents and data (quality manual, procedural guides and protocols, quality control test data etc), and sometimes also on physical measurements or tests. The whole team should audit aspects of the process that should have coordinated input from physicians, medical physicists and radiographers, RTTs (or equivalent). Individual team members should audit only specialised aspects.

It is understood that each professional of the team discusses and interviews with the staff members of the same profession. However, the audit team should overlap their efforts and are expected to have adequate conversations with each other during the site visit. Joint interviews and procedural reviews can be very beneficial as each professional member of the audit team brings a different knowledge and skill set giving a more complete perspective.

The audit process inevitably involves sampling but is not designed to be 'accurate' in the same way that a research protocol is designed. This is allowable in audit because it is has no regulatory function and the softer evidence is used to see if there is cause for concern and need for improvement, reassurance that all is well or validation of a high standard of care. It is also a continuous process and not a pass/fail judgement and therefore the evidence does not have to be absolutely robust.

Often the interviews, observations of work and documentary reviews give sufficient evidence of the local practice fulfilling the good practice. Sometimes, however, in particular for radiotherapy audits, it is desirable to support the observations by the results of suitable measurements or tests. These measurements and tests can be most comprehensively carried out during site visits, while parts of the targets of the audit can also be covered by postal methods in advance of the audit visit.

In detail, the approach taken for the assessments can include:

- Complete tour of the facility,
- Staff interviews,
- Review and evaluation of procedures and all relevant documentation, data and results
- Practical measurements and other tests of the performance of local systems and procedures, where appropriate and relevant,
- Observation of practical implementation of working procedures.[5]

Experienced auditors usually identify problem areas quickly. It is wise to concentrate on these (without forgetting about the other elements of process).

7.2.4.4 Exit briefing

It is essential that the evaluation of the auditors be presented to the health care unit audited. At the completion of the audit, the experts should convene the key persons of the health care unit's management and as many representatives as possible from the staff who were interviewed or participated in the audit procedures for an interactive exit briefing. This should include a detailed and open discussion of the findings of the experts, checking points for accuracy and the presentation of all recommendations.

Auditors are expected to be open and honest during the exit meeting. All encountered problems must be exposed and feedback from the staff must be obtained regarding the auditor's interpretation of existing problems (misunderstandings, suggestions etc). This is an appropriate time for discussing potential solutions to identified problems.

[5] Direct observation of patient examination or treatment is part of the review of records. This may require both patient and doctor's consent.

However, a good balance must exist during this meeting between positive comments regarding areas of quality and critical comments on more problematic domains. In any case, auditors are expected to stick to facts and measurements.

When measurements have been performed as part of the audit, completed forms and calculations should be left with the institution.

7.2.5 Conclusions from the audit

It is generally advisable to judge the overall conclusion of the audit team at the following levels:

- The health care unit conforms to the criteria of good practice to a high level and only minor deviations could be observed.
- Several areas for improvement have been identified: either minor changes that are easy to implement or major concerns requiring modification in infrastructure are recommended, all resolvable by the department. These will be included in the detailed recommendations of the audit team.
- There are underlying major problems that may not be resolvable by the health care unit without significant changes or support from outwith the unit (e.g. financial support from central administration).

Auditors are expected to form and express an opinion regarding the appropriateness of the staffing in terms of the patient workload.

If the health care unit wishes to expand to new areas of expertise, appropriate separate recommendations should be drawn up.

The auditors may recommend whether a follow-up visit or internal audit is required. If the follow-up visit reveals that the recipients of the audit report fail to implement recommendations and these are considered to be significant in terms of patient outcomes, the recipients should be informed that they have the responsibility of notifying the regulatory body.

7.2.6 The audit report

The draft of the report should be prepared during the visit. This helps to deliver a definitive report on time.

A useful audit report should contain the conclusions (Section 7.2.5) formulated in an unambiguous way, with clear and practical recommendations. To deliver valid conclusions, an audit team should address a series of key topics and measurements which will constitute the objective part of the report. These items will then be discussed in the report in the broader perspective of local health care organisation and culture, in order to produce a comprehensive document regarding the audited department.

The audit report should be concise. A suggested structure is:

- Objectives of the audit.
- A brief description of audit activities.
- Description of the facility (infrastructure, workload).
- Findings and results of the audit (can include completed specific forms).
- Benchmarking if appropriate.
- Conclusions.
- Recommendations.

- Annexes.

At all times, the confidentiality of the audit report should be considered. The final report should be addressed to the persons authorized by the health care unit to be the recipients, usually at least to the person who undersigned for the audit request. In any case, the reporting shall be in accordance with the national legal requirements on clinical audit reports (see also Section 4.5).

7.3 Frequency of audits

Clinical audits should be a systematic activity with regular re-auditing after a certain period or whenever there appears a specific need of extra audits (e.g. after significant changes of the installation or operation). The audit cycle (Section 4.2.3) should be completed, including the actions for improvement based on the audit recommendations.

The *internal* clinical audits should be a continuous activity with the aim of having significant parts of a comprehensive audit (Section 4.3.2) covered *once a year*. In practice, a comprehensive internal audit before a formal external audit often identifies minor problems which can be rectified in advance of the external audit. The minimum frequency of once a year for internal audits is a logical term, as the operation of the unit, including all quality management and financial procedures, are usually planned and implemented on an annual basis.

The overall audit programme should aim at covering all radiological procedures with the same frequency as the external clinical audits. The optimal frequency for *external* audits may depend on the local infrastructure and the intensity of other quality review activities, but a minimum frequency of *once in five years* seems to be a reasonable aim. However, for certain most critical parts of the practices, such as the accuracy of dose delivery in radiotherapy, a higher frequency (shorter interval) could be justified. Further, case-specific external re-audit sooner that the established frequency may be justified on the basis of the results of earlier audits.

7.4 Costs and financing

The costs of a clinical audit consist of labour cost, material cost and the costs for travel and accommodations (in external audits).

The *labour cost* is by far the greatest contribution to the overall costs of the audit. For internal audits, this is a calculable cost in the budget and does not form much extra expenditure funding. For external audits, it can be up to the expenditure of several man-days corresponding to the team of 2-3 auditors working for 1-5 days. The number of man-days is thus dependent on the length of the audit, the size of the audit team and also on the size of the audited unit. Therefore, it is essential that the costs of external audits are considered in the annual budgeting of the health care unit, unless the organization of clinical audits through a government body is funded directly.

The other costs of clinical audits come from the use of specific equipment or materials and the travel costs of the auditors (usually only for external audits). The material expenditure is generally not significant but difficult to estimate and depends greatly on the type of activities included in the audit. These are typically capital costs needed to maintain dosimetric or other technical equipment for the measurements or checks during audits. Some parts of external clinical audits (e.g. the checking of the accuracy of dose delivery in radiotherapy) can be also implemented by postal methods (Izewska et al., 2004; Ferreira et al. 2000; Roué et al. 2006; 2007), in particular if the frequency of such partial audits is higher than corresponding comprehensive audits (see Section 4.3). The travel costs are more straightforward to estimate and should include the travel and accommodation costs for the audit team.

For internal audits, the financing is straightforward as the audits are part of the normal operation of the unit with associated reservations in the budget. For external audits, the financing may become a crucial point because the costs can be a significant addition to the unit's normal expenditures. If clinical audits are organized as an activity of a governmental or government supported organization, it may be the possibility that the financing comes directly from the budget of this particular organization. However, the general tendency in the health care structures is to assume that the health care organization creating the cost should also be responsible for the costs. Therefore, the health care unit requesting the clinical audit and deriving the benefits of it should also cover the costs incurred. This tends to be the preferred scheme even if the health care unit is supported by the government (the public health care sector).

When clinical audits are carried out by special organizations, either private or "semi-private" ones (i.e. establishments supported by government, professional societies or other interested bodies; see Section 7.1), the operation has to be financed either totally or partly by introducing fees to the institutions audited. The fees should correspond, at least in the semi-private approach, to the real costs of the operation. In case of fully private companies, the possibility of over-charging due to aims of profit making is possible but not very likely because of the limited markets and the openness of clinical audit to competition. On the contrary, the possibility of undercharging with the aim of increasing share market, with the risk of not doing proper clinical audits, can be more likely; these could be avoided by appropriate national coordination of clinical audit activities (Section 7.6) and by the awareness of the health care units on the objectives of the audit and vigilant observation on the audit procedures and results.

When clinical audits are organized based on mutual agreements between the health care unit to be audited and that providing the auditors, or auditors serving as independent experts in their personal capacity, the labour costs might be agreed to a level which is lower than the real costs, or be managed by the principle of reciprocity (i.e. not charging each other for mutual audits). However, this approach is not generally recommended due to the problems of non-uniformity and lack of independence mentioned in Section 7.1.

7.5 Actions expected from the organizations requesting external audit

The health care unit requesting external clinical audit should complete all preparations described in Section 7.2.3. It is also of importance to recognize and to ensure that the

health care unit's quality system has been established and functioning to a sufficient extent, and that a responsible person such as the quality manager has been nominated.

Besides the general responsibility of informing the staff of the health care unit about the planned or forthcoming audit, it is necessary to devote a significant amount of time to creating a motivating atmosphere for an audit, in particular for the first clinical audit of the unit. The staff might have strong misunderstandings or prejudices about the purpose of the audit which has to be removed through clarification. The connection of the clinical audit to other quality assessments, whether internal or external, as well as to regulatory inspections should also be discussed with the staff.

Creating the motivating atmosphere before any external audit may comprise information letters and specific seminars or meetings to provide background information and clarifications of the concepts and purposes, and may also require personal discussions with some key persons. A good practice for improving the motivation of the staff for external audits could also be to start with an internal audit. It is very important for a successful audit if a positive and open attitude about the audit can be created in the unit. The staff at higher management levels of the unit should commit to audit and give sufficient working time and material resources as well as general encouraging support to the staff for the appropriate preparation for and participation in the audit procedure.

Once the clinical audit has been completed and the auditor's report with recommendations is available to all staff, the unit should pay due attention to considering and fulfilling the recommendations. This is of importance not only to achieve maximum benefit of the audit but also to retain the respect and motivation of the staff concerning subsequent re-audits.

7.6 National, regional and international coordination

A special *national or regional advisory group,* or *steering committee,* of clinical experts, independent of the auditing organizations, may prove useful in the overall coordination and development of the clinical audit implementation, criteria and procedures (for external as well as internal audits). The "independence" here means that the members of the committee shall not participate directly or indirectly in the organization of the auditing body (e.g., through a managerial or advisory committee of the auditing body itself) nor participate in any clinical audits as auditors. The group should also have a representative of general quality assessment bodies (like accreditation bodies) and that of the national radiation protection authority (regulatory body). This group can have an important role in ensuring the consistency and quality of the audits in the situations where more than one system of audits, or several auditing organizations for external audit have been established.

The group should preferably be established by the Health Ministry or other government organization, in order to ensure appropriate authority and financing. The group should give advice and recommendations on the overall implementation of clinical audits in the region or country. This should include competence and training of auditors, the priorities of the assessments, the criteria for good practice to be applied, and the procedures to avoid unnecessary overlap of clinical audit with other quality assess-

ments and regulatory inspections. The group should also provide regional or national surveys and summaries of the results or outcome of external clinical audits, follow-up international development of clinical audits and provide mutual exchange of information to other national and international organisations dealing with clinical audits or other types of quality assessments.

The International Atomic Energy Agency (IAEA) has developed a mechanism and guidance for clinical audit to provide comprehensive clinical audits, through Technical Cooperation programmes, to a number of health care units of the IAEA Member States (IAEA, 2007; 2009). In the long run, these activities can also serve as a model to initiate establishment of sustainable national systems of clinical auditing. The IAEA and the European Society for Therapeutic Radiology (ESTRO) have also run postal services to audit the dosimetry of radiotherapy (Izewska et al., 2004; Ferreira et al. 2000; Roué et al. 2006; 2007), which can be seen as a part of clinical auditing. As evident from these examples, international organizations can provide useful input for the development of clinical audit systems, thus also having a coordinating impact on such development.

7.7 The role of scientific and/or professional societies

Scientific and/or professional societies, both international and their national equivalents, can play an important role in the development of clinical audits to the maximum benefit of radiological health care units. In particular, societies including several professional groups can have an effective impact on this development. Co-operation between the societies is also of high importance.

There are two aspects, in particular, where the societies can be of great help:

(1) by developing the criteria of good practices for the evolution of clinical audits, in particular towards the most specific audits (level 3; see Section 4.6), and
(2) by providing practical advice, stimulus and support for the establishment of appropriate clinical audit organizations or practical solutions on carrying out clinical audits (the practical support could include e.g. providing advisors or experts to support some external and sometimes problematic clinical audits, or to develop automatic on-line systems for assessments of the results of audits).

The development of criteria for good practice is the area where many societies have traditionally had a good impact by providing suitable guidance and recommendations. The advantage of the societies' involvement lies also in the fact that a lot of active clinical experts can be approached who have a good and wide understanding of the weak points of the radiological services and the need to set priorities in planning the clinical audits. The support of the societies in the practical implementation, moreover, will improve the general credibility, acceptance and motivation of the clinical audits by different health care professionals at the units to be audited.

7.8 Role of regulatory body

As described in Section 6.2, it is important to recognize that clinical audit is not a regulatory activity. In the development of clinical audits, the optimal role of the regulatory body could be:

- To provide the legislative basis and control the implementation of clinical audits in accordance with the legislative requirements
- To participate in a national or regional coordination of the audit activities (Section 7.6)
- To establish the requirements for auditors or auditing organizations
- To promote international harmonization of the criteria and procedures

Despite the above general principles, in the early developing phase of clinical audits the role of the regulatory body may be wider, in particular, to advise the users and auditors on suitable methods and criteria. Often the desired optimal role of the regulatory body can only gradually be achieved in the course of development of the necessary national infrastructure.

8. GENERIC CRITERIA OF GOOD PRACTICE

8.1 General

As described in section 4.6, the legal requirements form an obvious and necessary part of the standards of good practice. In the following paragraphs and in Section 9, it is assumed that all legal requirements have to be fulfilled and these are not specifically indicated in various sections.

A quality system (see e.g. ISO 9001, ISO 17025 and ISO 15189; ISO 2000; 2005; 2007) is a base for quality and should generally be considered as one basic criterion of a good practice. Besides a quality system, there are a number of features of good practice which are common to all RADIOLOGICAL procedures: diagnostic radiology, nuclear medicine and radiotherapy. The criteria of good practice for these common features constitute the first level of criteria (level 1; Section 4.6) which can be agreed on to a great extent. These features can be addressed through a few key elements of the quality system as mentioned in Section 4.3. In terms of the desired coverage of structure, process and outcome these features can be grouped as follows:

Structure
- Mission and vision
- Organization and management structure
- Personnel and training
- Premises, equipment and materials

Process
- Justification and referral process
- Examination and treatment practices and guidelines
- Quality management
- Information flow and documentation control

Outcome

The most generic criteria of level 1 relates mainly to the *structure*, which can be easily summarized to cover all the three specialities. A major part of the *process,* and in particular that of the *outcome*, are dependent on the given speciality, and therefore the major parts of these criteria belong to levels 2 and 3. Level 2 criteria will be discussed further in Section 9.

In the following, more detailed outlines of the above topics will be given. This is partly a list of items to be covered while the actual criteria of good practice can only briefly be described or exemplified. For some of the items, also the review process has been described.

8.2 Structure

The health care unit for RADIOLOGICAL procedures should operate in accordance with the demands and health care level of hospitals, primary healthcare or private sector. The organization and practice should be based on national laws and regulations,

endorsed by the EC directives, and on the guidelines developed by international and national officials and societies. According to these regulations, RADIOLOGICAL departments must have proper organization, suitable space, enough competent professional staff, sufficient equipment and materials, financing and follow-up system.

8.2.1 Mission and vision

The role of the health care unit within its parent institution and the role of the institution within the national health care system, or its mission to provide RADIOLOGICAL services should be described in the institution's manual. It is important that the unit's relationship with associated services and other specialties within the institution are recognized and taken into consideration in the planning and organizing of its practices. The commitment of senior management to good practice and quality improvement should be documented in the unit's quality manual (Section 8.3.3).

The mission statement of the unit should describe the nature and extent of its services and also specify its objectives for teaching and research activities. The financial structure of the operation to meet the specified objectives should also be described.

8.2.2 Organization and management structure

Appropriate organisational structures and management systems should be in place in order to meet the specified objectives of the health care unit for RADIOLOGICAL services, to maximize the quality of service delivery and make efficient use of all resources. This should be achievable for the typical number of examinations, procedures or treatments encountered, and also when working under pressure with maximum patient throughput.

The demand for RADIOLOGICAL services, as indicated by the number and range of procedures performed annually, and the departmental staffing levels should be clearly documented. Patient demographic and annual workload data trends should be monitored to permit informed planning of facilities and personnel levels. Ideally there should be no socio-economic confounding factors which might have adverse impact on providing the specified RADIOLOGICAL services.

The lines of authority should be well specified and reflected in the health care unit's and departmental organizational charts. As appropriate, the organizational chart should identify sub-specialty services (CT, emergency radiological services, etc).

The assessment of the management structure should include a review of the following responsibilities and lines of authorities:

- Clinical responsibilities
- Radiation safety responsibilities
- Assignment and transfer of the responsibilities
- Share of responsibilities between different professions; practical functioning in borderline cases (cases where responsibilities may overlap)
- Responsibilities at various stages of education and training
- Responsibilities of visiting workers (visitors or fellows from other countries etc)
- Responsibilities for research and development
- Nomination of own radiologist, radiation oncologist or nuclear medicine expert and/or RTT for a patient

8.2.3 Personnel and training

The *staffing levels* and the professional competence of the staff should be sufficient to provide safe and efficient imaging examinations, or safe treatment of good quality, and to meet the specified objectives of the health care unit for RADIOLOGICAL services.

It is assumed that the *minimum qualifications* (including specialized and sub-specialized training) and *continuing education* of all staff involved in delivery, supervision, support and management of RADIOLOGICAL services are consistent with clinical requirements, and meet appropriate national or local regulatory requirements. In particular, the requirements for Radiation Safety Officer and Medical Physics Expert should be fulfilled. All staff should have adequate training for their tasks, and written training records for all staff should be dynamic and available for inspection. The introduction of any new techniques should be accompanied by information and training for the users of the new techniques. Training should include and emphasize the need of general good service when meeting the patients in daily practice. Training for emergencies and major disasters should also be available. Where tasks are delegated, professional supervision should be clearly defined and readily available.

Processes should be documented, preferably in the unit's quality manual, and followed with regard to all aspects of staff management including:

- Recruitment
- Orientation programmes for new staff (also visiting workers)
- Individual job descriptions
- Requirements for substitutes/locums
- Appropriate supervision and training by senior staff (mentoring)
- Staff performance evaluation
- Continuing professional development, in particular for radiation protection, training records
- Participation in departmental, institutional or external professional meetings and teaching or training programmes (such as internal seminars and external conferences); these should be scheduled as regular activity within staff job descriptions
- Access to library materials, including computer resources, internet
- Participation in internal and external audits
- Other matters (e.g. awareness of RADIOLOGICAL emergency procedures)

These activities should be encouraged and supported. Individual personnel records should be maintained.

If the mission of the health care unit includes teaching and research activities, there should be documented policy and programs which identify the staff allocated for these activities, the professional supervision and patient protection requirements that are in place, and research activities and publications.

8.2.4 Premises

The premises of the RADIOLOGICAL department should be adequate to safely meet the health care unit's specified objectives and operations. Radiation protection of the

patient, staff and general public should be addressed and follow the national legislation (appropriate shielding, warning signs, delineation of controlled areas etc). The premises should be clean and designed to optimize patient access, comfort, privacy and special needs. The location of the facilities should take into consideration the other services necessary for a good patient care and effective patient movement and access.

Appropriate space should be available for:

- imaging examination and treatment rooms, control rooms
- processing rooms, image interpretation rooms
- mould rooms, treatment planning rooms
- waiting rooms, patient changing rooms
- recovery/post-procedural/follow up areas
- patient movement within the department
- laboratories, dosimetry rooms
- administration
- storage, record filing
- engineering services
- staff accommodation.
- teaching rooms, research rooms (where relevant)

When the specified objectives include teaching and research activities, the proximity of the department facilities to other necessary facilities (such as libraries or laboratories) should be considered.

8.2.5 Equipment and materials

The types and number of machines should correspond to the objectives and scope of the health care unit's operations as specified in the units's quality manual. The health care unit should have policies and procedures in place in regard to equipment purchase and financing, commissioning, usage (instructions, training) and replacement[6], checking of proper functioning before usage, quality control and calibrations (Section 8.3.3), maintenance and repair, data protection and back-up. Policies and procedures should also be defined for the management of fault conditions, including recording, repair, permission to continue using the equipment, patient transfers to other equipment or change of modality, compensation for lost treatment time (radiotherapy). All policies and procedures should be documented and monitored. Equipment should only be used by authorized trained personnel.

All types of equipment should be recorded in a comprehensive equipment inventory. Inventories for materials like contrast agents, drugs and gases (for resuscitation, anaesthesia etc) should also be maintained. The types of equipment to be documented include:

- Imaging equipment/modalities
- Treatment equipment
- Auxiliary equipment like immobilization devices, patient alignment equipment, lasers, viewing devices, contrast pumps, cassettes, films, CD, catheters, power fluctuation control devices etc

[6] The replacement of equipment shall be consistent with appropriate regulatory requirements for radiation safety

- Phantoms, dosimetry equipment and other measuring and quality control instrumentation
- Staff and patient radiation protection devices
- Medical support equipment such as wheelchairs and trolleys
- Medical equipment for resuscitation, anaesthesia and sedation and monitoring
- Administrative equipment such as computers, printers, software, back-up facilities

Recorded information for each piece of equipment should include (as applicable):

- Name, manufacturer and serial number or other identifier
- Dates of acquisition and installation
- Instruction manual
- Acceptance performance or validation documentation
- Maintenance contract and maintenance and safety testing records
- Quality control, calibration and corrective action records
- Service records
- Manufacturer's specification and any modifications

8.3 Process

8.3.1 Justification

All RADIOLOGICAL procedures have to be justified on the grounds that they will confer a net benefit for the patient. Before completely new methods of examinations or treatments are taken into use, a generic justification has to be achieved through risk/benefit assessment. Participation in clinical trials should be documented and supported by permission from ethical committees and institutional review boards.

8.3.2 Examination and treatment practices and guidelines

The operating hours of the health care unit's RADIOLOGICAL services and the working hours and rosters of different professionals should meet patient and professional requirements. The opening hours and the costs of the services should be readily available to the patients (when required). The organization of the department's work processes should be consistent with the demand for services, based on the specified objectives of the institution and patient demographics. The unit should have an annual plan of activities and this should include vision statements and long term objectives.

Appropriate up-to-date guidance should be available for all RADIOLOGICAL procedures (diagnostic examinations and radiotherapy treatments). This guidance should include due considerations also for RADIOLOGICAL emergency procedures. The assessment of the guidance should include

- Coverage of existing practices
- Availability of guidance to staff
- Contents and quality of the guidance, taking into account of published good practices
- Implementation of optimization procedures

- Preparation and up-dating procedures, responsibilities
- Familiarizing for guidance and training for use
- Feedback procedures for guidance
- Observance of guidance in practical work

8.3.3 Quality management

The health care unit should have a quality system in accordance with international or national guidelines. The quality system is a framework to support the operation of a health care unit, with the objective of continuous quality improvement. It should be documented, preferably in a 'Quality Manual' (electronic or paper version). The manual should be regularly up-dated and reviewed at least annually, and older versions should be discarded. The commitment of senior management to good practice and quality improvement should be documented in the quality manual. A quality manager should be nominated in the quality manual.

A quality system includes

- The organisation's objectives and policies
- Documented procedures consistent with these objectives and policies
- Written practice instructions for staff
- Monitoring, recording and auditing of practice

The review of the quality system in the context of clinical audit is not aimed at checking its conformance with quality standards (such as ISO 9001 (ISO, 2000), ISO 17025 (ISO, 2005) and ISO 15189 (ISO, 2007)) but should concentrate on the assessment of:

- Updating and evaluation procedures for the quality manual
- Provision of adequate resources for quality assurance procedures (i.e. workload)
- The adequacy and appropriateness of technical quality control procedures (documented programmes and guidance, implementation, results; performance of equipment, compliance with acceptability criteria)
- The adequacy and appropriateness of clinical quality control procedures (for examination or treatment) (procedures, documentation and exploitation of results, responsibilities of various professionals)
- Implementation of regular internal and external quality assessments and comparisons (documented procedures, results; interrelations of assessments; implementation of the recommendations, learning from the results; management reviews, self-assessments, audits, certifications, accreditations, regulatory inspections etc)
- Records relating to incidents and other quality deviations (guidance for actions, recording, reporting, prevention and remedial actions, lessons learnt from incidents)
- Feedback collection mechanisms, recording and actions (feedback from referring physicians, other staff, patients, other customers)

For each item of the above list, detailed criteria of good practice should be agreed. As an example, the technical quality control program should specify for each test (IAEA, 2009):

- Purpose of the test

- Persons responsible for performing and evaluating the test
- Required test equipment
- Minimum frequency (how often carried out)
- Test procedures
- Test forms or charts for recording of results
- Performance criteria (reference values and action levels; remedial and suspension levels)
- Corrective action necessary when the performance criteria is not met
  - Type of corrective action
  - Time frame for corrective action
  - Verification that corrective action has been effective

8.3.4 Information flow and documentation control

All information must be in written form either on paper or electronically. There should be a computerized system of information management (e.g. HIS, RIS and PACS). There normally exists both an internal (within the health care unit) and external (hospital, national, patients) repository of information and most of this is confidential. Part of patient information is open (instructions, advice, scheduling) while all personal data is confidential. The management of confidential information or data requires legal permission (consent of patient) and a follow-up log system to record all access by personnel. The regulations also specify what information is available in abnormal situations such as a major disaster.

All health care unit's documentation, such as policy and procedure manuals and inventories, should be regularly updated. A master list of controlled documents should be maintained separately. Document control should include unique identification (for example: date, version number, page numbering, total pages, renewal date) and issuing authority. Only current documents should be available to staff and obsolete documents should be removed from circulation.

The assessment of the information flow should include the following:

- Information transfer and management system (HIS, RIS, PACS etc)
  - paper and electronic forms
  - identification of the responsible persons
  - verification of correctness, reliability and confidentiality of information
  - storage of information, availability and actions in abnormal situations
- Information and data transfer: instructions, orders, personnel data, patient data, patient consent, log information, scheduling, requests, reports, consultations, emergency, images, meetings, administration, education, research etc.
- Information exchange with officials (ministry, regulatory authority, fire brigade, police, etc.)
- Permission for the use of data
- Control of safety (records, log system)
- Alternative emergency procedures when the data handling systems (RIS/PACS) are down

8.4 Outcome

There should be a system in place to monitor the outcome of all RADIOLOGICAL procedures. This should include observations and recording of *short term* results (e.g. success of diagnosis, acute side effects) as well as *long term* results. The former can be assessed by follow-up of patients, while research is usually needed for the assessment of the latter.

The implementation of the optimization procedure is crucial for optimal outcome, both in diagnostic radiology (dose as low as reasonable achievable but high enough for obtaining image quality with required diagnostic information) and in radiotherapy (dose optimized to provide good tumour control with the minimum of side effects). Therefore, it is an important part of the review for the outcome to assess the accuracy and reliability of patient dose measurements (see Section 9).

9. SPECIFIC AUDIT CRITERIA

9.1 Introduction

In the previous section the most generic criteria of good practice were discussed, applicable to diagnostic radiology, nuclear medicine as well as to radiotherapy. In the following, examples of specific criteria for each RADIOLOGICAL specialty will be given. This will mainly deal with level 2 criteria (see Section 4.6), which means for example that the criteria are specific to diagnostic radiology but still generic to all imaging procedures. The most detailed criteria (level 3), which is specific for example to a given diagnostic procedure (e.g. X-ray examination of lung for pulmonary disease or scintigraphy) or to a given nuclear medicine therapy (e.g. radioiodine treatment for hyperthyroidism)) or to a given radiotherapy procedure (e.g. post-operative treatment of breast cancer), cannot be discussed here but examples can be found from literature (see Section 4.6).

The order of presentation follows the same sequences as for the most generic criteria of level 1, i.e. structure, process and outcome. For some of the items, also the review process has been described.

9.2 Diagnostic and interventional radiology and diagnostic nuclear medicine

Over the years numerous guidelines have been developed in diagnostic and interventional radiology and in diagnostic nuclear medicine, dealing with a variety of subjects, which can be used as the basis of the criteria of good practice. A list of relevant references is given in Appendix 8.

9.2.1 Structure

The criteria of good practice and the assessments for the structure of the diagnostic or interventional radiology department, or diagnostic nuclear medicine department, should meet with the principles given in Section 8.2, as relevant.

9.2.2 Process

9.2.2.1 Justification and referral process

All diagnostic examinations must be justified and should provide a net benefit for the patient. This requires a valid clinical indication with consideration of potential alternative diagnostic modalities. Justification of a radiological examination then implies that the necessary result cannot be achieved with other accessible methods. The specialist - radiologist, nuclear physician or other health care professional - having the legal responsibility for the procedure must be in close contact with the referring physician or other health care professional having the legal responsibility to refer for radiological examination.

Referring physicians must have access to all records of the patient, including the results of patient's previous examinations, knowledge about the radiation dose caused by the examination, and all other things influencing on the decision (allergy, previous reactions to contrast medium, safety, time and limits of examination, etc.). An adequate assessment of the patient's symptoms, complaints and physical condition has to be performed with the collaboration of the patient. The patient should receive proper advice on the purpose and risks of the examinations (including radiation risk) and how to prepare for it. Scheduling of the examination and waiting time must be appropriate.

The referral process should include appropriate transfer of information from the referee to radiologist, nuclear physician or other health care professional having the legal responsibility for the procedure, taking into the consideration also legal aspects (time, place, clinical information, referring physician, etc.). If necessary, the responsible specialist should contact the referee and/or patient's relatives or other involved persons. The pathways and the kind of information which has to be transmitted - in both directions - should be well structured and documented in working instructions.

There are many international and national guidelines on referral criteria for imaging adult and paediatric patients. Some references are given in Appendix 8. The review of the referral process in clinical audits should include:

- Implementation of justification: guidelines, principles
- Actions of the referring physician or other health care professional having the legal responsibility of referring to radiological examination
  - guidelines, patients records, earlier examinations
  - information on typical radiation dose to patient
  - contraindications and limitation (pacemaker, allergy)
  - local advice
  - information and advice to patient (preparing etc.)
- Request
  - contents, transfer of information
  - paper form, electronic form
- Scheduling of the process

9.2.2.2 Examination practices and guidelines

Regularly performed examinations and treatments should be as far as possible standardized by operation instructions, and they should meet internationally, nationally or locally agreed requirements. This will enable comparable outcomes and minimize possible failures. All necessary deviations from these standards, e. g. due to patient or disease specific demands, should be documented in the patient's record.

There are numerous guidelines (published by the EC and international and national radiological and nuclear medicine societies) concerning different examinations. These guidelines give examples of good practice including the procedure, radiation dose, Diagnostic Reference Levels, criteria for good image, results of treatments, therapy of complications, etc. Most of these guidelines are based on the evidence based medicine

and are commonly accepted in congress presentations, textbooks, research projects and daily routines. A list of relevant references is given in Appendix 8.

Radiological examinations are performed by multi-disciplinary teams including radiologist, radiographers, medical physicist, cardiologists, orthopaedic surgeons etc. Nuclear medicine imaging is performed by multidisciplinary teams which can include not only nuclear physicians, technologists, medical physicists, nurses but also, depending on the complexity of the department, radiochemists/radiopharmacists, engineers and other professionals. The duties and responsibility of each professional group and how the interaction is performed should be documented by working instructions.

The first task before the examination can start is to identify the patient in a reliable way. Before starting, depending on the anatomical region to be examined, consideration should be taken about the possibility of pregnancy in female patients. The imaging procedure itself should be safe, pleasant and as fast and painless as possible for the patient. The results of the process should be documented in a timely fashion in reports that also help to answer the medical problems for the referee. Reports should be standardized in respect of the structure and points to be mentioned. Relevant facts have to be made accurately, explicitly and understandably so it will provide clear information to the referee. The report should describe the presence of any artifact, if any, which could interfere with the diagnostic accuracy of the examination. The likely diagnosis and preferred supplementary investigations as well as follow-up management should be outlined. Every radiology department should have a feedback system about the results of examinations.

The confidentiality of patient information is important and archiving the data (biographical, clinical, images), permission and log system must meet the legal requirements.

The review of the examination guidelines in clinical audits should include, in particular the perspective of radiation protection:

- Guidelines for the process with different modalities
  - identification of patient
  - checking of pregnancy
  - imaging procedure
  - waiting time and place, changing clothes, examination, post process observation and advice
- Imaging
  - different methods (particular attention should be paid to the implementation of digital techniques (ICRP, 2004))
  - protocols (demography, radiography, parameters, clinical notes)
  - image quality and patient dose, optimization procedures
  - emergency situation
  - infection control
- Radiopharmacy procedures (for diagnostic nuclear medicine)
  - structures and instruments (dose calibrator, hot lab, etc.)
  - protocols (radiolabelling, fractioning, …)
  - quality control
- Reports

  - content (documentation of process)
  - legal aspects
  - findings (conclusion, follow-up advice)
- Feed-back system
  - from referee to radiologist, nuclear physician, or other health care professional having the legal responsibility for the procedure, and vice versa
  - statistics (mortality, morbidity, PAD)
  - compliance between clinical findings and acquired examinations
- Confidentiality
  - achieved data
  - permissions
  - log system

9.2.2.3 Quality management

The quality management in diagnostic and interventional radiology department and in diagnostic nuclear medicine department should be organized and assessed in clinical audits according to the generic guidelines presented in Section 8.3.3.

For the assessment of clinical image quality, a method of auditing could be a form of consensus reading, where a sample of examinations are reviewed by one or more external reviewers and assessed for a) image quality b) the quality of the report and c) the clinical opinion provided in the report. This kind of assessments can be applied more easily in internal than in external audits.

9.2.2.4 Information flow and documentation control

The information flow and documentation control in diagnostic and interventional radiology department and in diagnostic nuclear medicine department should be organized and assessed in clinical audits according to the generic guidelines presented in 8.3.4.

9.2.3 Outcome

When a medical examination using ionizing radiation has been justified and decided, the procedure must be optimized: the radiation dose which is delivered to the patient must be as low as reasonable achievable (ALARA) but high enough for obtaining the required diagnostic information taking into account economic and social factors. The written protocols (guidelines) for every type of standard practice should be optimized, and special attention has to be paid to the paediatric examinations. Patient doses have to be determined and compared with national or local Diagnostic Reference Levels (DRL) and corrective actions undertaken when the levels are exceeded. Patient doses should also be considered against the assessment of the achieved clinical image quality. All results of internal or external audits and assessments should be used to assess the adequacy and quality of the provisions for follow-up of patients and outcome analysis. Reporting of incidents is mandatory.

Not only do patients benefit from such follow-up, but it also helps to educate the staff and improve practice. Certainly it will not be possible to follow up every examination, but examinations with high frequency or high dose and risk to the patient should be considered a priority.

9.3 Nuclear medicine therapy

Nuclear medicine therapy is a specialised area of practice, and adequate clinical audit will take elements from both the diagnostic ant radiotherapy areas (Sections 9.2 and 9.4). Particular attention needs to be paid to facilities and dosimetry.

Nuclear medicine therapy (NMT) includes radiometabolic (e.g. radioiodine therapy for hyperthyroidism) and intracavitary treatments (e.g. radiosinovectomy). This requires a multidisciplinary approach with different branches of medicine. Several guidelines are available in literature and on the web (e.g.: www.eanm.org). A list of relevant references for the standards of good practice in nuclear medicine is given in Appendix 8.

Clinical audit can be partial or comprehensive also for NMT. In NMT the comprehensive clinical audit includes the full patient pathway from referral to follow up. All steps within this pathway are interlinked and interdependent. This includes: diagnosis, treatment decision, scintigraphic or tomographic evaluation, radiolabelling, dose administration with dosimetric evaluation, follow up.

The aims of the department must be clearly defined and the infrastructure, human resources and practice consistent with achieving and sustaining these aims. Staff numbers and their education level should be consistent with the aims and activity of the department. Primary qualifications, continuing education and formal training on new equipments and techniques for all staff should be documented.

Policies relating to patient referral for specialist procedures should be clearly defined and adhered to. The focus of the clinical audit should be on how the criteria for referral, patient access and waiting lists are defined and how closely these are adhered to.

Primary treatment decisions should be made by the nuclear physician, possibly involving a multidisciplinary team. This ensures that all treatment options and their timing are considered (surgery, chemotherapy, hormone therapy, etc). Full patient information must be available to ensure the best decision for the patient. Written guidelines should be followed and any deviation should be clearly documented and signed.

The treatment preparation procedures should start with the treatment prescription. Radiolabelling of the radiopharmaceutical and its fractioning should follow the EC and national laws in order to ensure a correct preparation in safe conditions. All radiotherapy treatments should be protocol based and reflect evidence based good practice. If possible, a dosimetric evaluation should be done in order to evaluate the optimal activity to be administered to the patient. The treatment plan must be signed by the physicist involved and approved and signed by the nuclear medicine physicist.

Outcomes including inefficacy, side effects, morbidity and survival should be routinely recorded. There should be evidence of documented procedures in place to follow up patients, monitor and manage side effects and measure the effectiveness of treatment regimes. Action statements for management of significant deviations should be available.

9.4 Radiotherapy

Radiotherapy is a complex procedure requiring a multidisciplinary approach from clinical and radiation oncologists, radiotherapy medical physicists, diagnostic radiologists and RTTs with interaction with other disciplines as appropriate. Current developments are adding significantly to the complexity and increase the need for ongoing comprehensive clinical audit.

Clinical audits can be of various types and levels, either reviewing specific critical parts of the radiotherapy process (partial audit) or assessing the whole process (comprehensive audit) (IAEA, 2007); also the depth of the assessment can vary (see Section 4.3.2). Dosimetry audit is included within the scope of a comprehensive clinical audit, as assured dosimetry is a vital component of accurate clinical practice.

In radiotherapy the comprehensive clinical audit must include the full patient pathway from referral to follow up. All steps within this pathway are interlinked and interdependent. This includes: diagnosis, treatment decision, simulation, treatment planning, verification, treatment delivery, patient review during and at the end of treatment, follow up.

The two functions of clinical audit described in Section 4.2.1 are also relevant for radiotherapy, i.e. to evaluate the current status of the department with respect to delivery of radiotherapy to patients and to identify areas for future improvement.

The main focus of the clinical audit in radiotherapy should be an assessment of the overall performance of the radiotherapy department and how staff, equipment, procedures, outcomes, patient safety and comfort correspond to the aims and objectives of the department. Responsibilities and reporting structures within the department must be clearly defined. Clinical audit should also evaluate how the department interacts with external service providers. This will include relationships with referring clinics and clinicians, equipment providers, etc.

The following sections give recommendations on the aspects of practice which should be reviewed as part of a comprehensive clinical audit. These should be considered additional to the generic points and criteria discussed in Section 8. A list of relevant references for the standards of good practice in radiotherapy is given in Appendix 8.

9.4.1 Structure

9.4.1.1 Mission and vision

The aims of the department must be clearly defined and the infrastructure, resources and practice consistent with achieving and sustaining these aims. There should be a clear statement of the position of the department both within the hospital and the national programme for cancer care.

9.4.1.2 Organization and management structure

The organization and management structure should be consistent with practice in the department and should be used in an optimal way. It is important in a department for

all collaborators to understand the management and reporting lines of their organisation. Therefore, auditors should verify the existence of a formal organizational chart.

There should be sufficient resources available to sustain and further develop the activities of the department. This should include service contracts, funding for accessory equipment, staff development etc.

9.4.1.3 Personnel and training

Staff numbers and their education level should be consistent with the aims and activity of the department. Primary qualifications, continuing education and formal training on new equipment and techniques for all staff should be documented and readily available. Appropriate staff training required for the effective and safe use of the equipment is mandatory. Departmental staffing policy should ensure the necessary expertise to deliver the full spectrum of activities carried out within the department.

9.4.1.4 Premises, equipment and materials

There should be a clearly documented policy for maintenance, replacement and/or upgrading of equipment, including accessory equipment such as laser lights, treatment couches and immobilisation systems. The introduction of any new equipment, procedure or technique should be preceded by discussion with all involved staff and defined clearly by protocol. New sophisticated techniques should not be applied without due considerations and balancing against the overall resources of the unit.

The accessory equipment should be consistent throughout the department to ensure accurate delivery of the prescribed treatment. Within the confines of the available resources equipment should ensure optimum delivery of treatments also in the event of machine breakdown, when transfer of patients to other machines may be necessary.

9.4.2 Process

9.4.2.1 Justification and referral process

Access to radiotherapy

The referral criteria and pattern to the radiotherapy department should be clearly articulated and details should be included on regional or national referral for routine or specialist treatment. In this context there should be clear policies on access to the radiotherapy services, including waiting times where applicable. Taking into account workload and resources a review of waiting times should be regularly carried out. This should include an analysis of the underlying reasons for any delays falling outside the defined departmental norm or national guideline targets.

Policies relating to patient referral for specialist procedures should be clearly defined and adhered to. In many instances a specialist team external to the radiotherapy department is required, including external clinicians. Where specialist procedures are required, departments should have sufficient patient numbers and resources to develop the level of expertise necessary to implement and carry out these procedures.

The focus of the clinical audit should be on how the criteria for referral, patient access and waiting lists are defined and how closely these are adhered to.

Treatment decision

Primary treatment decisions should be made by a multidisciplinary team. This ensures that all treatment options and their timing are considered, (surgery, chemotherapy, hormone therapy, adjuvant, etc). Full patient information must be available for the basis of treatment decisions. This will include histopathology, stage, grade, diagnostic information, previous treatment, clinical status and performance status. Written guidelines or standards in accordance with evidence based good practice should be followed and any deviation should be clearly documented and signed.

9.4.2.2 Treatment practices (preparation and delivery) and guidelines (protocols)

The treatment preparation procedures should start with the radiotherapy treatment prescription. This should include radical or palliative intent, total dose and fractionation, target volume, organs at risk, patient position and immobilisation, timing of on treatment reviews and tests required, verification and follow up.

All radiotherapy treatments should be protocol based and reflect evidence based good practice. Where there is clinical freedom in relation to the patient's treatment any deviation from the standard agreed therapeutic protocol must be documented and justified.

Patient position and immobilisation

The patient position and immobilisation system most appropriate for the accurate delivery of the treatment should be defined, together with all accessory equipment necessary to reproduce this position accurately throughout the entire process, and the details recorded.

Imaging

Imaging for treatment planning should be in accordance with the treatment prescription, and the imaging modality used should be appropriate for the site and technique to be used. For image acquisition for treatment planning, it is essential that the patient treatment position is accurately replicated and consistent with the position in which the patient is to be treated. Where two or more modalities are used for image fusion, consistency of positioning is crucial.

Treatment dose planning

Evidence based good practice guidelines should be used to optimise the beam composition, type and energy and field position. Protocols for delineation of target volumes and organs at risk should be in place. Doses should be specified in accordance with ICRU Reports 50 or 62 (ICRU 1993; 1999) or other acceptable protocols. Treatment plans should be optimised, not overly complicated and consistent with the treatment intent. There should be a balance between the complexity and the practical implementation of the prescribed treatment. The final treatment plan must be signed by the RTT

and/or physicist involved and approved and signed by the responsible radiation oncologist.

Dose delivery times for each beam should be double-checked by independent personnel and signed by a responsible and authorised person. There should be a protocol for data transfer from the treatment planning system to the next stage in the process. This can be manual or directly to the Record and Verify system connected with the treatment unit.

Treatment charts

The treatment charts can be manual or electronic, but they form the permanent record of the treatment delivered to the patient. The treatment chart must therefore record all the information that pertains to the prescription. The treatment chart should enable the auditor to accurately check and recalculate the treatment delivered to the patient. There should be a policy within the department for regular checks of the treatment charts.

The auditor should be able to find the following information from the treatment chart: patient identification, dose prescription (total dose, fractionation, overall time), detailed description of the technique (field definition, patient position, accessory devices), definition of organs at risk and critical dose levels, monitoring of side effects, total time over which the treatment was given where this differs from the prescription. Signatures of staff involved in all aspects of the treatment delivery should be clear and should include the following: daily delivery of the treatment, routine review the patient, verification and approval of verification images.

Treatment verification

Protocols must be in place for daily verification of the treatment parameters either using the written treatment chart or an electronic system. A system of double-checking the parameters before exposure should be in place.

Treatment field position and dose verification must be carried out according to defined protocols with responsibility for correction of deviation clearly noted. Any actions taken must be recorded and signed.

Brachytherapy

For a brachytherapy service, all of the activities described in the other sections will apply but additional factors must be considered.

Protocols for the storage, maintenance, preparation and use of radioactive sources must be in place. A detailed inventory for all sources must be maintained and regularly checked and updated. A source replacement programme must be in place with details on the disposal method for the old sources.

Treatment planning must be in accordance with one of the internationally accepted systems and should include protocols on combining with external beam treatment.

The treatment record must document details of time of insertion and removal, distribution of sources, activity of sources, verification of source position and dose delivered to the tumour and organs at risk.

For this application, the radiotherapy team will be extended to include anaesthesiologists and specialist nurses. Workflow must include management within the operating theatre and post insertion care. Where radioactive sources are in situ for an extended period of time, methods to ensure radiation protection of staff and visitors must be clearly documented and adhered to. Patients must be closely monitored throughout the treatment period and patient safety should include reduction of risk of infection and psychological distress.

9.4.2.3 Quality management

Quality assurance programme

A quality assurance programme must be in place for all treatment units, simulators and imaging modalities, accessory equipment, treatment planning systems and networking systems, and must include policies and procedures for commissioning of new equipment, acceptance testing and routine quality control procedures. Written or electronic records of the maintenance procedures, findings and actions taken must be maintained and be readily available. There should be a system of regular backup of patient and treatment data.

All instruction manuals should be easily accessible, clear and understandable to all personnel using them.

The department should have defined quality performance indicators that relate to structures, processes and outcomes and will allow the staff to evaluate in a measurable and objective way how they are maintaining and improving the quality of the radiotherapy service.

Dosimetry

Beam output should be regularly checked with a calibrated reference dosimeter. The department must have sufficient functioning dosimetry equipment and staff to allow regular checks of all therapeutic equipment and for measuring dose during treatment delivery. All dosimetry equipment should have valid calibration certificates. The department should participate in external dosimetry audits.

The department must have systems in place that check the dose in conventional and technologically advanced techniques such as IMRT, IGRT etc.

Reporting incidents / near incidents

There should be a system for reporting of incidents and near incidents. Protocols must be in place for the actions to be taken in the event of an incident. A record of the incident, action taken and feedback must be kept. Regular review and analysis of incidents should be conducted by the clinical management to prevent repetition of the incidents in the future.

9.4.2.4 Information flow and documentation control

The information flow and documentation control should be organized and assessed in clinical audits according to guidelines presented in Section 8.3.4, as relevant.

9.4.3 Outcome

Outcomes including morbidity and survival should be routinely recorded. There should be evidence of documented procedures in place to follow up patients, monitor and manage side effects and measure the effectiveness of treatment regimes. Action statements for management of significant deviations should be available.

REFERENCES

Birdwell R.L., Ikeda D.M., O'Shaughnessy K.F. and SicklesE.A., Mammographic Characteristics of 115 Missed Cancers Later Detected with Screening Mammography and the Potential Utility of Computeraided Detection, Radiology 2001; 219; 192-202.

British Nuclear Medicine Society (BNMS). The BNMS guidelines for static renal scintigraphy using Tc-99m-DMSA. Available at : http://www.bnmsonline.co.uk/index.php?option=com_content&task=view&id=42&Itemid=151

Bogusz-Osawa M. Results of an ESTRO working group survey on clinical audit conducted among 67 representatives of European scientific societies (Radiation Oncology, Radiotherpay, Medical physics and other). Published in Polish only (Wielkopolskiego Centrum Onkologii, No 4, Tom 4, 2007, Zeszyty Naukowe Wielkopolskiego Centrum Onkologii).

Bogusz – Osawa M, Malicki J, Osawa T; Present status of the implementation of MED Directive 97/43 at the national level of EU countries; Radiother. Oncol. 2006;81(S1):S382-3, ESTRO 25, Leipzig, Germany, 8-12.10.2006.

Bohigas L and Heaton C. Methods for external evaluation of health care institutions, Int. J. Qual. Health Care, 2000;12(3):231-38.

Cionini L., Gardani G., Gabriele P., Magri S., Morosini P.L., Rosi A., Viti V., Italian Working Group General Indicators. Quality indicators in radiotherapy, Radiotherapy and Oncology 82 (2007), 191-200.

Dixon A.K. Evidence-based diagnostic radiology. Lancet 1997 Aug 16; 350(9076); 509-12.

Donabedian, A. The Milbank Quarterly Vol. 83, Issue 4, p. 691-729 (December 2005)

Dutreix, A., Derreumaux, S., Chavaudra, J. and van der Schueren, E. (1994). Quality control of radiotherapy centres in Europe: beam calibration. Radiother. Oncol. **32**, 256-264.

European Commission (1997). Council Directive 97/43/Euratom of 30 June 1997, on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom. Official Journal of the European Communities No L 180/22-27, 9.7.1997.

Ferreira I.H., Dutreix A., Bridier A., Chavaudra J., Svensson H.. The ESTRO-Quality assurance network (EQUAL). Radiother. Oncol. 2000; 55; 273-284.

Grimshaw J and Russell I. 1993. Achieving health gain through guidelines. 1: Developing scientifically valid guidelines. Quality in Health Care 2: 243-8.

Heaton C, External peer review in Europe: an overview from the ExPeRT Project, Int. J. Qual. Health Care, 2000;12(3):177-82.

International Atomic Energy Agency (IAEA), International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety Series No. 115, Rep. No. 115, IAEA, Vienna (1996).

International Atomic Energy Agency (IAEA). Legal and Governmental Infrastructure for Nuclear, Radiation, Radioactive Waste and Transport Safety. Safety Standards Series No. GS-R-1. IAEA, Vienna (2000).

International Atomic Energy Agency (IAEA). Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Quality Assurance Team for Radiation Oncology (QUATRO). IAEA, Vienna 2007.

International Atomic Energy Agency (IAEA). Guidelines for Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement. IAEA, Vienna 2009.

International Comision on Radiation Protection (ICRP). Protection of the patient in radiation therapy. Ann ICRP. 15, 1985.

International Comision on Radiation Protection (ICRP). Managing patient dose in digital radiology. ICRP Publication 93, Ann ICRP. 2004;34(1):1-73.

International Comision on Radiation Protection (ICRP). Radiological Protection in Medicine. ICRP Publication 105, Ann ICRP. 2007;37(6).

International Comision on Radiation Units and Measurements (ICRU). Prescribing, Recording and Reporting Photon Beam Therapy, ICRU Report 50, 1993.

International Comision on Radiation Units and Measurements (ICRU). Prescribing, Recording and Reporting Photon Beam Therapy (Supplement to ICRU Report 50), ICRU Report 62, 1999.

International Standards Organisation (ISO). Quality systems - Model for quality assurance in design, development, production, installation and servicing, ISO 9001:2000.

International Standards Organisation (ISO). General requirements for the competence of testing and calibration laboratories, ISO/IEC 17025:2005.

International Standards Organisation (ISO). Medical laboratories - Particular requirements for quality and competence, ISO 15189:2007.

Izewska J., Svensson H., Ibbott G. Worldwide quality assurance network for radiotherapy dosimetry, Standards and Codes of Practice in Medical Radiation Dosimetry (Proc. Int. Symp. Vienna, 2002), Vol. 2, IAEA, Vienna (2004), 139-155.

JAMA. Evidence-Based Medicine Working Group. Evidence-based medicine. A new approach to teaching the practice of medicine. 1992 Nov.4; 268 (17); 2420-2425.

Leiz, Wolfram. Private communication (2008).

Ministry of Health, New Zealand. Towards clinical excellence: An introduction to Clinical Audit, Peer Review and other Clinical Practice Improvement Activities, April 2003, page ix.

Revesz G. and Kundel H.L. Psychophysical studies of detection errors in chest radiology, Radiology 1997; 123; 559-562.

Roué A., Ferreira I.H., Van Dam J., Svensson H., Venselaar J.L.M. The EQUAL-ESTRO audit on geometric reconstruction techniques in brachytherapy. Radiother. Oncol. 2006; 78; 78-83.

Roué A., Venselaar J.L.M., Ferreira I.H., Bridier A., Van Dam J. Development of a TLD mailed system for remote dosimetry audit for ^{192}Ir HDR and PDR sources. Radiother. Oncol. 2007; 83; 86-93.

Royal College of Radiologists, Clinical Audit in Radiology: 100+ Recipes, Goodwin R., de Lacey G., Manhire A. (eds), The Royal College of Radiologists, 1996.

Sarro Vaquero, Mercedes. Introduction to Clinical Audit, Proceedings of the International Symposium on Practical Implementation of Clinical audit for Exposure to Radiation in Medical Practices, Tampere 24-27 May, 2003, see www.clinicalaudit.net

Shaw CD. External quality mechanisms for health care: summary of ExPeRT Project on visitatie, accreditation, EFQM and ISO assessment In European Union countries, Int. J. Qual. Health Care, 2000; 12(3):169-75.

Shaw C.D. Measuring against clinical standards, Clinica Chimica Acta 333 (2003), 115-124.

Soimakallio S., Järvinen H, Kortelainen K. Proceedings of the International Symposium on Practical Implementation of Clinical audit for Exposure to Radiation in Medical Practices, Tampere 24-27 May, 2003; see www.clinicalaudit.net

Tabish S.A. Clinical audit, JK-Practitioner 2001; 8(4); 270-275.

United Nations Scientific Committee on the Effects of Atomic Radiation (UNCCEAR). Sources and Effects of Ionizing Radiation. UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes. Volume I: Sources. United Nations, New York, (2000).

Van Houtte, P., Bourgois, N., Renard, F., Huget, P., D'hoore, W., Scalliet, P., The Belgian Federal College of Radiotherapy, A federal audit of the Belgian radiotherapy departments in breast cancer treatment, Radiother. Oncol. 83 (2007), 178-186.

ZAeS: Federal Conference of German Department Clinical Audit in Radiation Protection - x-ray-diagnostic, radiation therapy, nuclear medicine. Einheitliches Bewertungssystem der Ärztlichen Stellen (ÄSt.en) nach §17a RÖV und §83 StrlSchV (ZAeS 14.11.2007).

Williams O. (1996). What is clinical audit? J R Coll Surg Eng 78; 406-411.

World Health Organization (WHO). Quality assurance in radiotherapy. WHO publications, Geneva 1988.

APPENDIX 1: SUMMARY OF REGULATORY FRAMEWORKS IN THE EU MEMBER STATES

Introduction

National regulatory frameworks in the EU Member States, i.e. the national provisions for the implementation of the requirements of Article 6.4 of Council Directive 97/43/Euratom on Clinical Audit, and the existing audit programmes, inspection and accreditation systems were surveyed through a specially designed questionnaire. Relevant information about organizational, technical and administrative provisions for clinical auditing were surveyed, in particular relevant criteria, standards and procedures, documentation and reporting requirements, monitoring and control systems. The survey was addressed to the national societies (for diagnostic radiology, radiotherapy and nuclear medicine) and the competent or radiation protection authorities. For the questions of legislative requirements, the instructions of the questionnaire gave advice to the societies to consult appropriate ministries and/or radiation protection authorities.

The response to the questionnaire was approximately 80 %. Only a few countries did not supply any reply in spite of repeated enquiries to several recipients. In the following, a brief summary of both the legislative requirements and the practical implementation of the requirements will be reviewed.

Status of legislation

The results indicate that the basic requirements of the Council Directive 97/43/Euratom for clinical audit (Article 6.4) have generally been implemented in the national legislations.

The conditions (technical, infrastructural) in which RADIOLOGICAL practices should be performed have been regulated in most countries by law, decree or other regulation. The regulations are usually given by the Health Ministry or a special radiation protection authority. In many countries, there are also recommendations on these conditions, usually given by the radiation protection authority or the national scientific societies.

The practical implementation of clinical audits has been regulated in most countries. In most cases, this concerns both external audits and internal audits, or self-assessments. In several countries, also recommendations on the implementation have been given, and these are usually given by the radiation protection authority or the national scientific societies.

In about half of the countries, the legal requirements give some specification of the practices to be audited and on the part of practices to be covered. E.g., in Finland, conventional dental practices have been excluded from the requirement of external audits. In a few countries, there are also recommendations on the practices to be audited and the coverage of audits.

For Quality Systems, about half of the countries have regulations while some countries have also recommendations, or only recommendations. Certification of the quality system was reported as a requirement in three countries only, while in a few countries there are recommendations for it. Regulations or recommendations on accreditation were reported in about 25 %

of the countries. In a few countries, there are regulations or recommendations also on other types of quality assessments. Relation of clinical audit with other quality assessment systems has been regulated or recommended only in a few countries, while the relation of clinical audit with regulatory inspection has been regulated or recommended in about one third of the countries.

The performer of clinical audits and requirements on auditor's competence and experience, auditor's training and independence have been regulated in about one third of the countries. Some countries have also, or only, recommendations which are usually given by authorities. The methods of audit have been regulated in about 25 % of the countries, while recommendations are given in about 33 %. The agreed standards of good practice have been regulated or recommended in about every third country; these are usually national or international standards, or recommendations by national professional societies or special committees.

The frequency of clinical audits has been regulated in about one third of the countries and seems to be 1-3 years when specified. The reports and follow-up of audits have been regulated also in about one third of the countries, and in a few countries there are also, or only, recommendation on them.

Practical implementation of clinical audits

In spite of the legislative requirements, the practical implementation of clinical audits in many countries is still not completed or in a very early development stage. The approaches in the practical implementation also vary considerably between the Member States.

The following conclusions can be drawn from the results:

- Clinical audits are mainly *occasional*. Clinical audits are carried out more regularly in Finland, France, Germany, Lithuania, Poland, Slovakia, Slovenia, UK and Switzerland. In some cases regular clinical audits are only internal (Spain, UK).
- Specific organizations for external clinical audits have been established in several countries, often by the Ministry of Health.
- Individual peer reviews are carried out independently to the clinical audits by specific organizations.
- Financing of clinical audits is implemented either by charging the recipients (fees) or by government support; in some cases the financing is based on "mutual agreements".
- Professional experience and independence are generally required from the auditors, and they usually work as a team. Independence is usually interpreted so that the auditors have to be from different health care unit. Training of the auditors is not adequate and usually covers only audit techniques, not the applied criteria. There are various approaches with training institutes (ministries, universities, private institutes, accreditation authorities, auditing organizations etc)
- National *coordination* of clinical audits has been established in most cases, either by Ministry or an organization established by the Ministry; in one case this is by a scientific society. There is a high variation of tasks of these coordinating organizations. Local coordination has been established only in a few cases.
- A *checklist* for carrying out clinical audits usually exists. Criteria for good practices have been defined in most cases and are based on national or international standards or

guidelines or recommendations by professional societies. In some cases the criteria have been prepared by the auditing organization.

- The practical methods in the existing systems of clinical audits tend to follow common principles of auditing (entrance and exit meetings, reviews and interviews, reporting, follow-up etc). The clinical audits include measurements (quality control, performance, radiation safety) in about half of the countries.
- The certifications of the quality systems or accreditations of the health care units for radiological practices are not very common, only from 0 to 20 % of the units.
- Regulatory inspections are carried out in most countries, with measurements mainly for occupational protection. The overlap of clinical audits with regulatory inspections was reported only in a few cases (Finland, UK, Switzerland). Regular meetings of authorities and auditing organizations are not very common.
- The need for harmonization of clinical audits has been recognized by all countries from which replies were received. For the items to be harmonized, most of the replies quote audit program, standards of good practice, training of auditors and practical methods of auditing. However, all possible items have been quoted at least once when summing up all the replies. Also the borderline between clinical audit and certification, accreditation and regulatory inspections has been stated as an important point of consideration.
- The major *problems* identified in the replies were among other things: incomplete national legislation for clinical audit and the methods of financing, lack of formal framework of auditing, poor understanding of the purpose and contents of clinical audits, lack of criteria for the standards of good practices, difficulty to employ sufficient number of auditors, insufficient time available for auditors, lack of specific training of auditors, need of technological modernization of radiology equipment to meet quality standards (see more details in Appendix 2)
- The major *benefits* reported include: a tool for quality improvement, recognition for quality, prevention against litigation, improvement of practice, motivation of staff to increase quality, benefit to patients, improvement of local standards and adherence to national standards, recognition of malpractices, improvement of communication within the institution, increased communication and awareness of good practices, revealing weak points and promoting development of quality systems (see more details in Appendix 3).
- Some *specific proposals* presented in the replies include: organization of European team to perform "model" audit in a reference centre in the country, assessment outcome system which allows comparing the outcome of clinical audit European wide, more attention should be paid to the resources of the health care unit for audits, more unifying feedback from the results should be given to audited units, and ”Guidance is needed but should be simple and friendly”.

APPENDIX 2: SUMMARY OF PROBLEMS IN THE IMPLEMENTATION OF CLINICAL AUDITS

Conclusions from the Symposium 2003 (Soimakallio et al., 2003)

- Lack of the fundamental understanding of the objectives, contents and the expected benefits of Clinical Audits for the medical RADIOLOGICAL procedures.
- Lack of qualified personnel resources (number of staff and dedicated work time) at the clinics for QA work (development of Quality Manual documentation needed for audits etc).
- Lack of trained and competent auditors.
- How to finance the necessary human resources.
- Lack of recommended or acceptable radiological procedures and criteria, validated at the EU level.
- The development culture and readiness for audits is varying from country to country. In some countries, a lot of work is needed to change the mentality of the radiation users towards recognizing the importance of audits.
- There is also a concern that Clinical Audits would be requested mainly by those who already have good practices and would not be in the highest need of audits. There is a need to look more at those who are not reporting routine Clinical Audits.

Extracts from the Questionnaire 2007

The recipients were asked to give three major problems encountered in the implementation of clinical audit in the Member State. The following is a list of problems mentioned, with the number of replies indicating how many of the replies specified the given problem.

Major problem	*No of replies*
Lack of well trained, independent auditors, who are well-known experts on their field of application (diagnostic radiology, nuclear medicine or radiotherapy) and in radiation protection, still actively working in a health care unit, but have time to travel and perform audits and report on it. - Small country, small units, only few specialists available - Lack of auditor training possibilities - Special difficulty in getting nuclear medicine experts as auditors - Lack of sufficient time for auditors to carry out effective audits	16
Problems of financing - No special financial support for performing clinical audits - Majority of units can not afford clinical audits	6
The purpose and scope of clinical audit is not clear to most stakeholders. - Not clearly stated procedures and outcomes / benefits. - Most consider it as an inspection with unknown consequences. - The involved authorities and medical environment are not ready to organize it.	6

Lack of appropriate standards of good practices - Lack of European standards, requirements acceptable for all parties. - There is no agreement on quality criteria for diagnostic performance (specificity and sensitivity) or for the therapy outcome (cure, side effects)	5
Lack of knowledge and guidance on audit methodology - Requirements for clinical audits - Checklist for clinical audit	5
Lack of motivation - Medical environment not feeling comfortable to be audited. - Auditing the Health System is not part of the training and education of the health professionals.	4
Bureaucratic and ineffective procedures and cooperation between ministries and organizations. - Clinical audit is a low priority – if any.	2
Incomplete national legislation with regard to clinical audit	2
Lack of a formal framework for clinical audits. - Establishment of competent auditing organization.	2
Problems appearing only in one reply	
- Difficulties to harmonise the different national approaches, regulations in order to establish the European auditing system. - Not enough radiation protection equipment and technical accessories for audits. - Audits should contain broader review and not just technical part. - No benefits or extra support from government after successful audit. - No coordinating organization. - Audits are not regularly performed. - Need of technological modernization of radiology equipment in order to meet quality standards. - Communication problems. - Assurance of use of data. - Lack of medical physicists	1

APPENDIX 3: SUMMARY OF MAJOR BENEFITS IN THE IMPLEMENTATION OF CLINICAL AUDITS

Extracts from the Questionnaire 2007

The recipients were asked to give three major benefits expected in the implementation of clinical audit in the Member State. The following is a list of benefits mentioned, with the number of replies indicating how many of the replies specified the given benefit.

Major benefit	*No of replies*
Improvement of medical RADIOLOGICAL services, the quality of care and the radiation protection of patients (in a broad view). - Improved quality assurance - Achievement of required quality and acceptable tolerances in accordance with standards - Improved patient satisfaction - Benefit to patients - A tool for quality improvement - Improved capacity and efficacy	23
Improved standardization of procedures and practices. - More frequent application of evidence based guidelines and protocols - Development of internal and national standards - Adherence to national standards	8
Financial benefits. - Less expenditures on radiation related service - Special applications on a European basis	5
Decrease of dose - Lowering patient and staff exposure to ionising radiation - Optimization of the patient exposures	5
Revealing the weak points of the practices and malpractices - Recognition for quality - Demonstration of need for resources	5
Avoidance of incidents and accidents - Reduction of errors	3
Increased communication and awareness of good practices within the health care unit	2
New ideas, new thinking, new procedures - Reducing blinkers view - New and modern procedures for optimization of radiation protection of patients	2
Promoting the development of quality systems	2
Benefits appearing only in one reply	
- Confidence in the procedures, practices and services. - Improvement of the expertise of professionals. - Advancements of the technical level of the institution. - Team building effect. - Improvements are made in a positive approach from the owner of the process (no pressure from a legal authority). - Transparency of procedures.	1

- High level of satisfaction for the residents. - Stimulation to professional continuing education, professional growth of young specialists. - Possibility to control the use of the written procedures and regulations in the institution. - Good management tool for institution, gives better overview about the workers responsibilities and their self-regulation. - Motivation of the staff to increase quality. - Staff of health care institutions would become more familiar with factors upon which patients' care depend. - Prevention against litigation. - Benchmarking. - Confirming good practice.	

APPENDIX 4. EXAMPLES OF QUALITY INDICATORS

The few examples shown below relate to radiotherapy and are taken from Cionini et al. (2007).

P1 - High Energy Unit (HEU) downtime for non planned maintenance

	HEU downtime for not-planned maintenance
Topic	Reliability of maintenance procedures of HEU
Indicator dimension	Process
Numerator	Number of days of machine downtime for not-planned maintenance NPM
Denominator	Number of days of machine downtime for planned maintenance PM
Recommended stratification	For each HEU
Standard	NPM/PM ≤ 1
Definitions and specifications	A day is defined as a day of down time of the machinery when the number of treated patients is reduced to a third or less of the planned ones
Time period for data collection, frequency of analysis	At least 1 year retrospectively, to be repeated every 3 years.

P2 - Instrumentation for dosimetry and quality control (QC)

INDICATOR P2	**Instrumentation for dosimetry and QC**
Topic	Instrumentation adequacy for dosimetry and QC
Indicator dimension	Structure and process
Numerator	Achieved score (see the following box)
Denominator	Maximum score, i.e. 22
Definitions and specifications	Instruments that should be present in a Radiotherapy Centre are reported in the following box. The check should be carried out by an external expert
Standard	≥ 0.90
Time period for data collection, frequency of analysis	To be checked at least once a year without previous notice

Box for indicator P2. List of instrumentation for dosimetry and QC	
Instruments	**Check and score**
Precision electrometers Ionization chambers	• if present, score 3 • if the local reference chamber has had the certificate of calibration in the latest 24 months, score 3
Water phantom	• if present and of 3-axis movement type, score 3 • if it meets the original specifications from the mechanical, geometric and dosimetric points of view, score 3
Dosimetric systems to control the *in vivo* dose: area and/or volume dosimetry	• if present, score 1 • if system calibration procedures are present, score 1 • if adequate documentation about the routine practice is present, score 1
Different kinds of phantoms (anthropomorphic, water equivalent, etc.)	• if present for each used treatment techniques, score 1
Instrumentation and systems for the QC of the treatment equipment	• if present, score 3 • if the procedures for instrumentation QC are present, score 3

AC1 - Treatment planning with CT

INDICATOR AC1	Treatment plans with CT scan
Topic	Frequency of treatment plans with CT scan and contouring of volumes of interest (VOI) on multiple slices
Indicator dimension	Structure and Process
Numerator	Number of treatment plans processed through CT scan and contouring on multiple slices.
Denominator	Total number of treatment plans processed by the TPS
Definitions and specifications	"Contouring on multiple scans" here is defined as including the whole clinical tumour volume (CTV) and organs at risk (OAR) with a maximum interslice distance $\leq$ 1.5 cm (excluding head and neck area)
Recommended stratification	For cancer sites to be identified by the Centre
Standard	$\geq$ 0.75
Time period for data collection, frequency of analysis	6 months every two years

APPENDIX 5. EXAMPLE ON CLASSIFICATION OF AUDIT FINDINGS

Example of the classification system applied in the German system of clinical audits (ZAes, 2007).

(1) Periodic quality control tests. The quality control testing of an x-ray-machine include amongst other things the measurement of the patient dose related quantity under defined conditions, and the comparison of the result with the initial and threshold values. The following two observations in an audit constitute a detection of a fault which is categorized as "immediate actions have to be considered":

- initial and/or threshold values have not been established, but measurements had been performed on a regular basis
- initial and threshold values have been established, measurements have been performed on a regular basis, but the measurement values are over a longer period of time outside the thresholds with no adequate reactions

(2) Justification of a radiological procedure. A child may have injured his skull with or without any visible skin laceration. The child is referred to the diagnostic radiology for an x-ray-examination of the skull in two projections.

- The examination is refused by the radiologist and the parents are informed why this examination was not indicated. The child is sent back to the referring physician, after he has been informed. This is considered as a correct decision (good practice).
- The examination is performed and the deviation from existing guideline and the specific medical reasons are well documented in the patient's record. This will be accepted as a good practice provided the medical reasons are comprehensible.
- The examination was effectively performed for "legal" reasons only. This is considered as an important fault, which should lead to reduced interval before the next audit.

(3) Appropriate equipment. National requirements oblige to use of an x-ray system with the speed class SC=400 for all diagnostic images of the body trunk. During the audit it is recognized, that

- There is no speed class system SC=400 and all x-rays are performed with a system SC=100 (approximately four times the dose as needed usually). This is considered as absolute fault, immediately actions have to be considered.
- There is no speed class system SC=400 and all x-rays are performed with a system SC=200 (approximately double the dose as needed usually). This is considered as an important fault, which might lead to reduced interval before the next audit.
- Once in a while, a speed class system lower than SC=400 was used accidentally. This is considered as a minor fault. The audited institution will be advised to take care of this problem, e. g. by color marking the film cassettes according to different speed classes, changing place of storage etc.
- The speed class system SC=200 was used in this particular examination on purpose and the medical reasons are well documented in the specific patient's record. This is considered acceptable within the standards of good practice, provided the medical reasons are comprehensible.

APPENDIX 6. COMPARISON OF EXTERNAL AUDIT SYSTEMS

	External audit system					
	Peer review	**Hospital accreditation**	**Accreditation in terms of ISO standards**	**Award seeking (EFQM)**	**ISO certification**	**Clinical audit (in terms of EC directive 97/43/EURATOM)**
Purpose	Systematic review, visitation, *Visitatie in Dutch*. Standard based on *on-site* surveys conducted by health care professionals in order to assess the clinical practice and performance, professional development organization of the care process, and its results aimed at improving the quality of patients care and exchanging ideas. It directs its attention to appropriateness of service delivery provided by medical practitioners. Does not award a certificate.	Systematic assessment of a whole organization (hospital) or specialty-specific areas (in UK), against explicit standards for the purpose of recognition of service delivery. Performed by a profit or non-profit, national or regional accreditation body. Accreditation is valid for 1-3 years: 1 year conditional (provisory) accreditation or 3 year full accreditation of organization and health service delivery confirming compliance with accreditation standards. Awards a certificate.	Systematic assessment of an organization against international ISO standards for the purpose of recognition of competence of an organization. In medical field accreditation is based on laboratory quality standards and will assess the competence of medical laboratories/units to run clinical examinations. Performed by a national accreditation body. Accreditation is valid for 2-5 years including annual surveillance visits to ensure that organization constantly conforms to the accreditation requirements. Awards a certificate.	Also called management excellence model. Assessment of organization's management against performance standards for service industries in specific areas (in health care: such as clinical results, patients satisfaction, administration and staff management). It provides conceptual framework, which is used both as a self-assessment tool and an external review to achieve the quality award. Award of excellence to the organization and its management or self - assessment of the organization.	Assessment of specific aspects of services incl. health services in the context of quality of system, processes and administrative procedures, rather than clinical results or outcomes. Addresses mainly the managerial processes surrounding clinical decision making. Mostly used in more technical/industrial departments. Performed by accredited certification body. Examines designated quality, focusing on how the institution objectives are achieved rather than the institution as a whole meets the needs of its patients. However it verifies if the organization stays in compliance with existing laws and regulations. 3 year certification of processes or management system of the whole organization confirming compliance with ISO standards	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 modifications of the practices where indicated and the application of new standards if necessary. The purpose of a multidisciplinary clinical audit can generally be summarized as: • To improve the quality of patient care • To promote the effective use of resources • To enhance the provision and organization of clinical services To further professional education and training in a healthcare team environment

	External audit system					
	Peer review	**Hospital accreditation**	**Accreditation in terms of ISO standards**	**Award seeking (EFQM)**	**ISO certification**	**Clinical audit (in terms of EC directive 97/43/EURATOM)**
Scope	Care process and its organizational aspects: care delivered, staffing levels, education, facilities, procedures [7]	1/access to care 2/ continuity of care 3/ patient and family rights 4/ assessment of patients 5/ care of patients 6/ patients and family education 7/ quality management and improvement 8/ governance, leadership and improvement 9/ facility management and safety 10/staff education and management 11/management of information 12/prevention and infection control	Management requirements 1) organization, management and quality management system 3) document and record control 4) review of contracts 5) subcontracting, external services and supplies 6) advisory services 7) resolution of complaints, identification and control of non-conformities, corrective and preventative actions, continual improvement 9) internal audits and management review Technical requirements 1) personnel 2) accommondation 3) equipment 4) pre-examination, examination and post-	The management of the organization and its: 1/ leadership 2/policy and strategy 3/people 4/partnership and resources 5/processes 6/customer results 7/people results 8/society results 9/key performance results[8,9]	Quality management system: 1/ aim of the organization 2/ structure of the organization a)responsibility b)organizational relationship c)departmental infrastructure d) qualification of staff 3/obtaining and maintaining means and materials for service delivery a/ purchasing b/ demonstrating its ability to consistently provide product that meets customer and applicable regulatory requirements c/safety and fitness for clinical use d/documentation and	Can be of various types and levels, either reviewing specific critical parts of RADIOLOGICAL process (partial audit) or assessing the whole process (comprehensive audit). Comprehensive clinical audit covers structure, process and outcome. It addresses organizational, physical-technical and clinical aspects of practices.

[7] Van Weert C, Developments In Professional quality assurances towards quality improvement: some examples of peer review In the Netherlands and the United Kingdom, Int. J. Qual. Health Care, 2000; 12(3):239-42
[8] Nabitz U, Klazinga N, Walburg J, The EFQM excellence model: European and Dutch experience with the EFQM approach in health care, Int. J. Qual. Health Care, 2000; 12(3):191-201
[9] Nabitz U, Schramade M, Schippers G, Evaluating treatment process redesign by applying the EFQM Excellence Model, Int. J. Qual. Health Care, 2006;18(5):336-45
[10] Thwaites DI, Scalliet P, Leer JW, and Overgaard J, Quality assurance in radiotherapy, Radioth. Oncol. 1995;35:61-73
[11] Klazinga N, Re-engineering trust: the adoption and adaption of four models for external quality assurances of health care services In western European health care systems, Int. J. Qual. Health Care, 2000; 12(3):183-89

	External audit system					
	Peer review	**Hospital accreditation**	**Accreditation in terms of ISO standards**	**Award seeking (EFQM)**	**ISO certification**	**Clinical audit (in terms of EC directive 97/43/EURATOM)**
			examination procedures, reporting results 5) assuring quality of examinations		records e/equipment replacement f/inspection and testing g/control of inspection, measuring and test equipment h/control of non-conformities i/corrective and preventive actions j/handling, storage, packaging, preservation and delivery 4/ process control 5/quality audits 6/training – knowledge and skills[10,11]	
Auditors	Visitors: clinical and interdisciplinary team of registered specialists for at least 5 yrs, independent of the clinical staff being surveyed. Addtionally in the Netherlands with the completion of 1 day training conducted by CBO – National Organization for Quality Assurance in Hospitals	Surveyors: multidisciplinary team of health professionals experienced in health care sector (doctors, nurses, administrators) with minimum 2-5 years experience in senior managerial position, practicing in a health care facility, after initial and ongoing update training in the field of accreditation	Assessors: multidisciplinary team of health professionals experienced in health care sector (doctors, nurses, physicists), with good experience in discipline, practicing in a health care facility, and quality professionals (lead assessors), after initial and ongoing update training in the field of accreditation.	Assessors: academics and quality professionals or experienced and currently practicing managers.	Auditors: experts in the ISO norm (not in a particular field or type of organization), professionals with necessary education, training, knowledge and experience for performing certification (minimum 20 days auditing experience, analytical skills, language fluency, management capabilities, at least 4 years full time appropriate practical work place experience, 2 years in QA activities, 4	Auditors: The basic competence of the auditors should be based on their professional competence and long-term clinical experience. Besides this, the auditors should receive specific training on the general audit procedure and techniques, as well as the agreed audit programme and the criteria of good practices to be applied. Due to the multidisciplinary nature of audit, a

	External audit system					
	Peer review	**Hospital accreditation**	**Accreditation in terms of ISO standards**	**Award seeking (EFQM)**	**ISO certification**	**Clinical audit (in terms of EC directive 97/43/EURATOM)**
					audits as a trainee auditor, trained, assessed and certified by externally recognized training bodies i.e. IRCA – International Register of Certificated Auditors). Experience in health care sector is not required as they are supported by experts with sufficient experience and knowledge in the field.	team of auditors is usually needed, comprising different professionals - radiologist, radiation oncologist, nuclear medicine expert, medical physicist (preferably a medical physics expert), radiographer etc - depending on the scope of the audit and on type of application to be audited.
Methodology of evaluation process	1/ request an evaluation 2/ questionnaire to identify the institution's aspects of professional performance, giving the visitation committee an opportunity to select and discuss key quality issues with the staff members before the evaluation visit 3/ agenda of visit composed by the practitioner being visited 4/ review – duration 1-2 days depending on the number of practitioners being visited or the number of locations. Peers evaluate circumstances under which	1/ request an evaluation 2/ questionnaire to identify the institution eligibility, its structure, size, nature, number of employees, demographic, biographic data etc. to plan the size and composition of the evaluation team, fee for accreditation based on number of days for visit. 3/ self assessment by the institution under evaluation to state/grade its compliance with standards. 4/ timetable and agenda of visit agreed by the organization	1/ request an evaluation 2/ questionnaire to identify the institution eligibility, its structure, size, nature, number of employees, demographic, biographic data etc. to plan the size and composition of the evaluation team, fee for accreditation based on number of days for visit. 3/ self assessment by the institution under evaluation to state/grade its compliance with standards. 4/ timetable and agenda of visit agreed by the organization	1/ request an evaluation 2/self-assessment as a comprehensive, systematic and regular review of structure, processes and outcome, which allows the organization to identify its strengths and weaknesses determining whether the institution may be eligible to compete for an award. 3/ feedback information to EFQM, on activities resulting from self assessment, which must be closely aligned with EFQM award assessment criteria. 4/ visit	1/ request and evaluation 2/ questionnaire to identify the institution eligibility its structure, number of employees, processes under evaluation, to plan the size of the auditing team, fee for audit based on number of days for audit 3/ presentation of evidences of self preparation documentation (i.e. quality manual, internal audits reports) 4/ audit plan agreed by the organization 5/pre-audit (on request) to determine the scope of the audit, make initial review	Organized in a cycle consists of the following stages: 1/ setting the objectives and identifying the issues to be audited, 2/setting the criteria of good practice, 3/assessing the practice, comparing with criteria 4/ giving recommendations for improvement 5/implementing the improvements 7/ re-audit. Includes both internal and external audits which supplement each other. Comprehensive external

	External audit system					
	Peer review	**Hospital accreditation**	**Accreditation in terms of ISO standards**	**Award seeking (EFQM)**	**ISO certification**	**Clinical audit (in terms of EC directive 97/43/EURATOM)**
	clinical practice take place by: a/ documentation: availability of guidelines, patients medical records etc. b/observation c/structured interviews: treatment outcomes, evaluation of patients' satisfaction, staff collaboration d/feedback session – suggestions for improvement 5/ written report – (confidential) consists of a description of the clinical department, positive and negative findings and recommendations for improvement 6/ evaluation of findings 7/ the return-visit mostly every 5 years, the facility is reviewed by another team of visitors to establish degree to which recommendation and suggestions have been followed and implemented.	5/ visit prior the formal evaluation (on request) – completed with rather verbal recommendations and guidance 6/ formal evaluation visit – duration depending on the size, complexity or nature of the organization: a/ review of documentation b/interviews c/sample of medical and other records d/visit-observations e/feedback 7/written report – with compliance and non-compliance with explicit standards including is numerical or descriptive grading against the standards. 8/ evaluation by the accreditation committee (visitors may take part) which makes the decision to accredit the organization, based on the report with graded compliance 9/ accreditation – valid for 1-3 years or non-accreditation 10/appeal procedure 11/ publication of a list of	5/ preliminary visit prior the initial assessment visit to assess the readiness of organization for initial assessment 6/ initial assessment visit – duration depending on the size, complexity or nature of the organization: a/ review of documentation b/interviews c/sample of medical and other records d/visit-observations e/feedback 7/written report – with compliance and non-compliance with international accreditation standards including numerical or descriptive grading against the standards. 8/ evaluation of assessment results by the independent accreditation committee or management of accreditation body which/who makes the decision to accredit the organization 9/ accreditation – valid for 2-5 years (depending on the procedures of national accreditation body) or	5/feedback written report – provides a list of strengths and areas for improvement under each criterion addressed in the application. The assessor's scoring profile is given together with comparative scoring of other applicants for the award. 6/ evaluation – by the evaluation committee based on the report with graded compliance 7/ Institution awarding	6/ audit – duration depending on the size, complexity or nature of the organization a/ opening meeting – introduction, review of the scope and objectives of the audit, summary of procedures used in audit. b/documentation review and examination c/interviews d/observations e/records review f/closing meeting – to present conclusions prior the report 7/ written report – contains details included in the audit plan, documentation against which the assessment was made, observations of major/minor non-conformities or areas which did not comply with the agreed standards, protocols, procedures and the auditors' judgment of the level of compliance. 8/ evaluation by the certification body (auditors do not take part)	audit organized as a site visit. Limited parts of the process can also be audited through collection of data by mail with central assessment of the data. Site visits include interviews of the staff and observations of practical work, reviews of local documents and data (quality manual, procedural guides and protocols, quality control test data etc), and sometimes also on physical measurements or tests.

	External audit system					
	Peer review	**Hospital accreditation**	**Accreditation in terms of ISO standards**	**Award seeking (EFQM)**	**ISO certification**	**Clinical audit (in terms of EC directive 97/43/EURATOM)**
		accredited institutions 12/ interim visits – to review progress in the implementation of the quality action plan and recommendations	non-accreditation 10/appeal procedure 11/ publication of a list of accredited institutions 12/ surveillance visits – to assess the constant fulfilment of accreditation requirements and effectiveness of corrective action of earlier visit's non-compliances		which makes the decision to certify the audited party based on the report with graded compliance 9/ certification – valid for 3 years in case of positive decision 10/ re-audit – in case of negative decision 11/ publication of a list of certified institutions 12/ interim audits – biannual or annual on agreed aspects of quality system.	
Occurrence in Europe	The Netherlands, Finland, Sweden, United Kingdom, Belgium	France, Italy, Germany, Poland, UK, Portugal, Spain, The Netherlands, Switzerland, Sweden	According to new EU legislation all EU countries shall arrange national accreditation system, in most of the European countries there is an accreditation body who accredits medical laboratories/organisations	The Netherlands, Denmark, Finland, Norway, Sweden, United Kingdom	Poland, Germany, Switzerland, Austria, Denmark, Finland, France, Italy, Luxembourg, The Netherlands, Norway, Sweden, United Kingdom, Spain	Poland, Finland, Italy, United Kingdom, The Netherlands, Czech Republic,

APPENDIX 7: EXAMPLE OF LEVEL 2 DETAILED CRITERIA OF GOOD PRACTICES AND AUDIT PROGRAMME

Based on IAEA Guidelines (IAEA, 2009)

Referral of the patient for examination

1. Principles and criteria for good practice

Appropriateness of examination

The radiology consultation begins with the critical task of exam selection.

Except for screening programmes, all patients must be referred for an examination by a physician or their designate. Indications and choice of examination are based on clinical assessment, existing guidelines and examination availability.

Fundamental to optimal patient care is selection of the appropriate exam, based on knowledge of

- Indications for available exams
- Advantages / limitations of exam options
- Complementary nature of other exams
- Risk / benefit considerations include adverse effects
- Contraindications.

Appropriate and informative clinical information is essential for quality radiology practice. While it is the responsibility of the referring physician to ensure that the request contains the necessary information, the department requires a written policy and procedure on the verification of request data and justification of exam selection.

A radiologist/physician (or delegate) should review the request and determine if the examination requested is appropriate given the clinical information provided, and, as appropriate, contact the referring physician for further discussion of the clinical findings and imaging exam options.

Quality of the referral

There should be a mechanism in place to confirm given information prior to the commencement of the exam.

Department processes should include review of referrals for accuracy and completeness, with a mechanism to correct errors as required.

Minimal information required is:

- Patient name, date of birth, address, contact details such as hospital ward or phone number
- Study requested
- Clinical indication for exam
- Date of request
- Referring physician's signature, printed name and contact details
- Pregnancy status

Referrer education

There should be a process in place to ensure information regarding exams – indications, advantages/benefits, limitations/risks – is readily available to the referring physicians to allow appropriate exam selection. The process should also include regular updating of available information. In particular information in regard to radiation exposure and associated risks is essential, particularly in infants, children and pregnant patients.

Patient education

Information regarding the relevant examination/s should be made available to the patient. The patient should be given the opportunity and adequate time to ask questions about the exam, its risks, including radiation exposure in pregnancy, and other options.

Patient consent to undergo examination should be obtained, in writing as appropriate.

Pre-procedure screening and preparation

Policies and procedures should be in place to identify clinical conditions relevant to the hazards of specific radiologic studies, such as;

- Contrast, latex and food allergies
- Renal impairment
- Pacemakers, aneurysmal clips
- Anti-coagulant therapy
- Pregnancy

Policies and procedures should also be in place to identify patient conditions that may affect safe conduct of the examination, such as

- Age
- Infection, particularly with regard to cross patient contamination e.g. with .Methicillin-Resistant Staphylococcus Aureus bacterium, MRSA
- Mobility/transport issues
- Sedation/anaesthesia support

Scheduling and patient preparation should be modified in response to these clinical conditions.

There should also be processes in place to ensure that exam-specific preparation processes (e.g. fasting) are communicated accurately to patients and/or their carers, and that the department have procedures for managing patients who are inappropriately prepared.

Scheduling

Timely scheduling is the next step. Staff with appropriate clinical training should be responsible for prioritizing exams.

Once exam scheduling is confirmed, there should a mechanism to ensure recall of prior imaging exams and reports with opportune availability to the reporting radiologist.

The monitoring of scheduling efficiency permits optimising of access, through-put and resource allocation.

2. Audit programme

Appropriateness of examination

The audit team should

- Review a sample of requests for appropriateness of authorisation
- Check for documented guidelines in regard to exam selection
- Check department processes to change orders as required
- Review policies and procedure documentation in regard to specific exam contra-indications

Quality of the referral

The audit team should

- Review a sample of requests for completeness of general and clinical information
- Review a sample of requests for completeness of order accuracy e.g. body part, sidedness
- Check that the department has a policy and procedure in regard to confirming accuracy of request information prior to exam commencement

Referrer education

The audit team should

- Review information - depth and extent of content - prepared for referrers
- Review information on radiation risks
- Check processes for information update and distribution

Patient education

The audit team should

- Check for provision of patient education information regarding examinations
- Check for patient consent forms
- Observe the consent process
- Check for compliance with patient consent policies

Pre-procedure screening and preparation

The audit team should

- Check for policies and procedures documentation in regard to identifying clinical conditions relevant to the hazards of specific radiologic studies
- Interview staff to assess compliance with “hazards” policies and procedures documentation
- Check for policies and procedures documentation to identify conditions that may affect safe conduct of the examination
- Interview staff to assess compliance with safe conduct policies and procedures docu-

mentation

- Check policies and procedures for exam-specific preparation requirements
- Interview staff to assess compliance with exam-specific preparation policies and procedures documentation

Scheduling

The audit team should

- Assess clinical training of scheduling staff
- Evaluate the timing of response to request for emergent and urgent exams
- Review film / file storage facilities and assess capacity and efficiency
- Request retrieval of a random sample of filed images and reports
- Establish that previous imaging exams and reports are routinely made available to the radiography and radiology staff prior to commencement of exams
- Check for processes for monitoring scheduling efficiency

APPENDIX 8: AVAILABLE LITERATURE FOR SETTING THE STANDARDS OF GOOD PRACTICE

The list of literature below is not considered to be exhaustive but gives a number of publications which can be helpful for setting the standards of good practice. Some of the publications apply only to a limited part of the complete RADIOLOGICAL process (e.g. dosimetry and quality assurance). The list deals with documents providing recommendations only, while documents of legal character, such as the EC Directive 97/43/Euratom (European Commission 1997) or the Basic Safety Standards of the IAEA (IAEA 1996) have not been included.

The websites of the scientific and professional societies can also be a valuable source of information and recommendations for this purpose (see for example the EFOMP policy statements: http://www.efomp.org/policyst.html)

Diagnostic radiology

1. American College of Radiology (ACR): Practice Guidelines for Performing and Interpreting Diagnostic Computed Tomography (CT) (2006)
2. American College of Radiology (ACR): Appropriateness Criteria (2000)
3. ENPR: European Guidelines for the Optimization of Fluoroscopic Imaging in Paediatrics
4. ENPR: Quality Criteria Guidelines for CT Examination
5. European Guidelines on Quality Criteria for Diagnostic Radiographic Images, EUR 16260 EN (1996) (http://europa.eu.int)
6. European Guidelines on Quality Criteria for Computed Tomography, EUR 19262
7. European Guidelines on Quality Criteria for Diagnostic radiographic Images in Paediatrics, EUR 16261
8. European Commission. Radiation Protection 109, EC (2001).
9. European Commission. Radiation Protection 118: Referral Guidelines for Imaging, EC (2001).
10. European Society of Radiology (ESR): Good Practice Guide for European Radiologist (2004)
11. International Atomic Energy Agency (IAEA). Dosimetry in Diagnostic Radiology: An International Code of Practice (Technical Reports Series No. 457) (STI/DOC/010/457). IAEA, 2007
12. International Atomic Energy Agency (IAEA). Applying Radiation Safety Standards in Diagnostic Radiology and Interventional Procedures using X Rays (Safety Reports Series No. 39) (STI/PUB/1206), IAEA 2006
13. International Atomic Energy Agency (IAEA). Guidelines for Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement. IAEA, Vienna 2009.
14. International Comision on Radiation Protection (ICRP). Managing patient dose in digital radiology. ICRP Publication 93, Ann ICRP. 2004;34(1):1-73.
15. International Comision on Radiation Protection (ICRP). Radiological Protection in Medicine. ICRP Publication 105, Ann ICRP. 2007;37(6).
16. The Royal College of Radiologists. BFCR(07)9: Standards for Self-assessment of Performance
17. The Royal College of Radiologists. BFCR(07)6: Advice on exposure to ionizing radiation during pregnancy in children.
18. The Royal College of Radiologists. BFCR(06): Guidelines for Nursing Care in Interventional Radiology

19. The Royal College of Radiologists. RCR(06)1: Recommendations for Cross-sectional Imaging in Cancer Management
20. The Royal College of Radiologists. BFCR(06)1: Standards for Reporting and Interpretation of Imaging Investigations
21. The Royal College of Radiologists. BFCR(05)8: Standards for Patient Consent Particular to Radiology
22. The Royal College of Radiologists: Making the best use of the department of clinical radiology (118)
23. The Royal College of Radiologists, Clinical Audit in Radiology: 100+ Recipes, Goodwin R., de Lacey G., Manhire A. (eds), The Royal College of Radiologists, 1996.
24. The Royal College of Radiologists, AuditLive http://www.rcr.ac.uk/audittemplate.aspx?PageID=1016

Nuclear medicine

1. BNMS Nuclear Medicine Generic Quality Guidelines for the Provision of Radionuclide Diagnostic Services (http://www.bnmsonline.co.uk/index.php?option=com_content&task=view&id=207&Itemid=155)
2. Other guidelines on BNMS website (Clinical, generic, other). (http://www.bnmsonline.co.uk/index.php?option=com_content&task=blogcategory&id=103&Itemid=151)
3. EANM Dosimetry Committee series on standard operational procedures for pre-therapeutic dosimetry I: blood and bone marrow dosimetry in differentiated thyroid cancer therapy. Lassmann M., Hänscheid H., Chiesa C., Hindorf C., Flux G. and Luster M.. Eur J Nucl Med Mol Imaging (2008) 35:1405–1412.
4. Other guidelines on EANM website (https://www.eanm.org/scientific_info/guidelines/guidelines_intro.php?navId=54)
5. International Atomic Energy Agency (IAEA). Quality Assurance for Radioactivity Measurement in Nuclear Medicine (Technical Reports Series No. 454) (STI/DOC/010/454), IAEA, 2006.
6. International Atomic Energy Agency (IAEA). Applying Radiation Safety Standards in Nuclear Medicine (Safety Reports Series No. 40) (STI/PUB/1207). IAEA, 2005.
7. International Comision on Radiation Protection (ICRP). Radiological Protection in Medicine. ICRP Publication 105, Ann ICRP. 2007;37(6).

Radiotherapy

1. Aletti P, Bey P : Recommendations for a quality assurance programme in external radiotherapy. ESTRO Booklet No. 2, Publ. 1 Leuven: Apeldoorn Garant, 1995
2. American Association of Physics in Medicine (AAPM). Report no 13. Physical aspects of quality assurance in radiation therapy. New York, American Institute of Physics, 1984, [63 web pages].accessible at: *http://www.aapm.org/pubs/reports/rpt_13.pdf*
3. American Association of Physicists in Medicine (AAPM): High-dose rate brachytherapy treatment delivery: Report of the AAPM Radiation Therapy Committee Task Group No.59. Med. Phys.25 (April 1998), 375-403.
4. American Collage of Radiation Oncology (ACRO). Standards for Radiation Oncology. [11 web pages]. accessible at:

http://www.acro.org/content/internet_resources/acro_practice_accreditation/radiation_standards.cfm

5. Asch DV: Waiting times for cancer treatment. Clin Oncol, 2000;12:140
6. Belletti S, Dutreix A, Garavaglia G et al: Quality assurance in radiotherapy: importance of medical physics staffing levels. Recommendations from an ESTRO/EFOMP join task group. Radiother Oncol, 1996;41:89-94
7. Bentzen SM, Heeren G, Cottier B et al: Towards evidence-based guidelines for radiotherapy infrastructure and staffing needs in Europe: the ESTRO QUARTS Project. Radiother Oncol, 2005;75:355-65
8. Bernier J, Horiot JC, Poortmans P: Quality Assurance in radiotherapy: form radiation physics to patient-and trial-oriented control procedures. Eur J Cancer 2002;38:S155-8
9. European Commission. Criteria for acceptability of radiological (including radiotherapy) and nuclear medicine installations. Radiation Protection 91. Luxembourg: Office for Official Publications of the European Communities, 1997. Dostępne na: *http//europa.eu.int/comm./environment/radprot/91/91.htm*
10. European Commission. Radiation Protection 116, Guidelines on Education and Training in Radiation Protection for Medical Exposures (2000). Brussels, European Commission, 2000
11. Fraass B, Doppke K, Hunt M, et al: AAPM Radiation Therapy Committee Task Group 53; quality assurance for clinical radiotherapy treatment planning. Med Phys, 1998;27:1773-818
12. Gerbaulet A.et al; The GEC ESTRO Handbook of Brachytherapy, ESTRO 2002
13. International Atomic Energy Agency (IAEA). Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement. Quality Assurance Team for Radiation Oncology (QUATRO). IAEA, Vienna 2007.
14. International Atomic Energy Agency (IAEA). International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, Safety series No. 115. Vienna, IAEA, 1996.
15. International Atomic Energy Agency (IAEA). On-site Visits to Radiotherapy Centres: Medical Physics Procedures (TECDOC-1543). IAEA, 2007.
16. International Atomic Energy Agency (IAEA). Specification and Acceptance Testing of Radiotherapy Treatment Planning Systems (TECDOC-1540), IAEA 2007.
17. International Atomic Energy Agency (IAEA), Setting Up a Radiotherapy Programme: Clinical, Medical Physics, Radiation Protection and Safety Aspects, (STI/PUB/1296), IAEA, Vienna, 2008.
18. International Atomic Energy Agency (IAEA). Applying Radiation Safety Standards in Radiotherapy (Safety Reports Series No. 38) (STI/PUB/1205). IAEA, 2006.
19. International Atomic Energy Agency (IAEA), Transition from 2-D Radiotherapy to 3-D Conformal and Intensity Modulated Radiotherapy, IAEA TECDOC Series No. 1588, IAEA, Vienna, 2008.
20. International Atomic Energy Agency (IAEA), Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer (Technical Reports Series No. 430) (STI/DOC/010/430). IAEA, 2005.
21. International Atomic Energy Agency (IAEA), Absorbed Dose Determination in External Beam Radiotherapy. An International Code of Practice for Dosimetry Based on Standards of Absorbed Dose to Water, IAEA TRS-398, 2004.
22. International Comision on Radiation Protection (ICRP). Protection of the patient in radiation therapy. Ann ICRP. 15, 1985.
23. International Comision on Radiation Protection (ICRP). Radiological Protection in Medicine. ICRP Publication 105, Ann ICRP. 2007;37(6).

24. International Commission on Radiation Units and Measurements (ICRU), Prescribing Recording, and Reporting Photon Beam Therapy, ICRU Report 50, ICRU 1993.
25. International Commission on Radiation Units and Measurements (ICRU), Prescribing Recording, and Reporting Photon Beam Therapy, ICRU Report 62, ICRU 1999.
26. International Commission on Radiation Units and Measurements (ICRU), Prescribing Recording, and Reporting Electron Beam Therapy, ICRU Report 71, ICRU 2004.
27. International Commission on Radiation Units and Measurements (ICRU), Dose and Volume Specification for Reporting Interstitial Therapy, ICRU Report 58, ICRU 1997.
28. International Commission on Radiation Units and Measurements (ICRU), Dose and Volume Specification for Reporting Intracavitary Therapy in Gynecology, ICRU Report 38, 1985.
29. Kolitsi Z, Dahl O, Van Loon R et al: Quality assurance in conformal radiotherapy: DYNARD consensus report on practice guidelines. Radiother Oncol, 1997;45:217-23
30. Kutcher GJ, Coia L, Gillin M et al: AAPM, American Association of Physicists in Medicine. Comprehensive QA for radiation oncology. Report of AAPM Radiation Therapy Committee Task Group 40. Med. Phys, 1994;21:581-618
31. Leer JWH, Corver R, Kraus JJAM et al: A quality assurance system based on ISO Standards: experience in a radiotherapy Department. Radiother Oncol, 1995;35:75-81
32. Leer J.W.H., McKenzie A., Scalliet P., Thwaites D.I: Practical guidelines for the Implementation of Quality System in Radiotherapy ; Booklet 4, ESTRO 1998
33. Martin CJ, Sutton DG: Practical radiation protection in health care. New York: Oxford University Press Inc., 2002
34. Organization of European Cancer Institutes (OECI). Clinical Assessment Guide, Preliminary document, Version 0. OECI, 2004
35. Slotman BJ, Cottier B, Bentzen S et al: Guidelines for infrastructure and staffing of radiotherapy, ESTRO-QUARTS: Work package 1, 27-06-2004, BSL. Brussels, ESTRO, 2004
36. Slotman BJ, Cottier B, Bentzen SM et al: Overview of national guidelines for infrastructure and staffing of radiotherapy. ESTRO-QUARTS: Work package 1. Radiother Oncol, 2005;75:349-54
37. Thwaites D, Scalliet P, Leer JW et al: Quality Assurance in Radiotherapy (European Society for Therapeutic Radiology and Oncology advisory report to the Commission of the European Union for the Europe Against Cancer Programme). Radiother Oncol, 1995; 35:61-73
38. Valli MC, Prina M, Bossi A et al: Evaluation of most frequent errors in daily compilation and use of a radiation treatment chart. Radiother Oncol, 1994;32:87-9
39. Van Esch A, Bogaerts R, Kutcher GJ et al: Quality assurance in radiotherapy by identifying standards and monitoring treatment preparations. Radiother Oncol, 2000;56:109-15
40. Van Weert C: Developments in professional quality assurance towards quality improvement: some examples of peer review in the Netherlands and the United Kingdom. Int J Qual Health Care, 2000;12:239-42
41. Venselaar J., Pérez-Calatayud J., A Practical Guide to Quality Control of Brachytherapy, Booklet 8 , ESTRO, 2004.
42. World Health Organization (WHO). Quality Assurance in Radiotherapy. Geneva, WHO, 1988

43. World Health Organization (WHO). Continuous Quality Development: a Proposed National Policy. Copenhagen, WHO, 1993
44. Yeung T K, Bartolotto K, Cosby S et al: Quality assurance in radiotherapy: evaluation of errors and incidents over a 10 year period. Radiother Oncol, 2005;74:283-91

EDITORIAL NOTE

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