IAEA HUMAN HEALTH SERIES

No. 4

Comprehensive Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement

Quality Assurance Audit for Diagnostic Radiology Improvement and Learning (QUAADRIL)

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COMPREHENSIVE CLINICAL AUDITS OF DIAGNOSTIC RADIOLOGY PRACTICES: A TOOL FOR QUALITY IMPROVEMENT

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QUALITY ASSURANCE AUDIT
FOR DIAGNOSTIC RADIOLOGY IMPROVEMENT
AND LEARNING (QUAADRIL)

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

The application of radiation to human health, for both diagnosis and treatment of disease, is an important component of the work of the IAEA. While much of this work has typically centred on components of radiation medicine such as quality assurance (QA), dosimetry and calibration, more recently it has become apparent that a comprehensive review of all aspects of radiation medicine, or comprehensive clinical audits, will deliver many benefits to patients that cannot otherwise be realized. This publication is intended to cover the practice of diagnostic radiology.

Currently, there is much interest in QA processes and quality improvement in diagnostic radiology, which is driven by a number of factors. These include the high cost of radiological equipment, the ever increasing complexity of examination equipment and examination procedures due to technical advances, the acknowledgement of the possibility of increasing doses to patients, and the importance of radiological diagnosis to patient management within the health care environment. The importance of these matters has been acknowledged within Europe through a European Council directive (No. 97/43/Euratom), and is also under consideration in other regional areas. However, it has not been possible to find within the published literature any existing guidelines for comprehensive audit that could be adopted by Member States.

Development of this publication was started in 2007 with the appointment of a drafting committee of international experts. The committee was informed by an earlier IAEA book, Comprehensive Audits of Radiotherapy Practices: A Tool for Quality Improvement, which was published in 2007. Two pilot audits have been carried out using the current publication, one in Asia and one in Europe. The current publication has been endorsed by the European Federation of Organisations in Medical Physics and the Asia–Oceania Federation of Organizations for Medical Physics.

The IAEA acknowledges the special contribution of the drafting committee chaired by H. Järvinen (Finland), with B. Abdullah (Malaysia), P. Butler (United States of America), K. Faulkner (United Kingdom), M. Rickard (Australia). The American College of Radiology, which sponsored the participation of M. Pentecost, is also thanked. The IAEA officer responsible for this publication was I.D. McLean of the Division of Human Health.

EDITORIAL NOTE

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1. INTRODUCTION

1.1. CLINICAL AUDIT: A TOOL FOR QUALITY IMPROVEMENT

1.1.1. Basic objectives

For a variety of reasons — professional, public, financial and political — most countries seek to establish visible systems for managing quality in health care. One of the key elements in this development is the establishment of clinical audit. This may be defined as:

> "the systematic and critical analysis of the quality of clinical care. This includes the procedures used for diagnosis and treatment, the associated use of resources and the effect of care on the outcome and quality of life for the patient." (see Ref. [1]).

The primary goal of this form of quality assurance (QA) is to improve patient care with the intention of maximizing the effect of clinical care and minimizing its harm to the individual and to society as a whole. An alternative definition as given by the European Council directive [2], 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."

Clinical audit involves evaluation of data, documents and resources to check performance against standards. It is essentially a process of fact finding and interpretation and, as such, provides an efficient tool for improvement of quality. 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.

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.

1.1.2. Internal or external audits?

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. Clinical audit thus reflects the clinical directorate and health care team setting, as well as their relationship to the overall management structure.

The general principle of audit imposes the requirement that the auditor has to be independent of the service or process to be audited. Clinical audits are often *internal*, i.e. carried out within a certain health care institution, when the principle of independence is implemented by nominating auditors from subunits or departments of the institution different from the subunit to be audited. Internal audits should be routine activities within a good quality system.

Emphasis has recently been placed on *external* audits, in which the auditors are external to the institution to be audited and thus totally independent of this institution [3]. The value of external audits lies mainly in providing the audit with more universal and broader perspectives, removing the possible inability of internal auditors to recognize, in their own environment, the weaknesses and limitations which may involve long-standing or routine practices. The external auditors may be able to better judge the consistency of procedures from one health care service to another and from one user to another. Recognition of substantial variations of a medical procedure among health care services and among clinicians can encourage a more systematic approach to this procedure and lead to subsequent improvement of the agreed practices. The systematic undertaking of clinical audits in a local or national health care area, and the sharing of the knowledge of good practices with a wider audience, will also contribute to further quality improvement of the practices, for the benefit of the medical services, patients and staff.

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 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.

1.1.3. Confidentiality of audits

Confidentiality is a critical issue in relation to clinical audits. It is essential that all parties, those being audited and those carrying out an audit, respect the confidentiality of patient data, interviews/discussions with staff and audit checklist/performance data. Patient confidentiality should be respected, and, whenever possible, anonymized patient information should be provided to the audit team.

Confidentiality will facilitate the discussion of important QA issues. The information obtained and evaluated as part of clinical audit should therefore be regarded as peer review information and hence not be discoverable by third parties. The clinical audit report is the formal public document describing the visit and its findings.

1.1.4. Borderline between clinical audit and other related activities

Owing to their wide general purpose and multidisciplinary nature (see Section 1.1.1), external clinical audits in diagnostic radiology bear a close relationship to other quality assessment systems, such as certification of quality assessment systems and accreditations, and also to regulatory inspections of radiation protection and safety. However, it is of high importance to understand that clinical audit is different from these other quality assessment systems. While the practical procedures can be partly similar, there are clear differences in the focus of the evaluation, as well as in the consequences of the results of the observations. While the exact borderline is dependent on the national infrastructure and provisions for quality assessments, clinical audit should be considered as supplementing and not duplicating the other efforts.

The focus in clinical audits is, as a peer review activity, always on the clinical issues of the service, where comparisons with clinical good practice are relevant, and the results are recommendations with no inherent obligation on their implementation. Regulatory inspections address the legal requirements and can lead to enforcement actions if practices do not comply with requirements. Quality audits for the certification of quality systems are directed towards checking the conformity of the local quality system to the given quality standard, and do not directly ensure the good quality of the practices in terms of clinical judgements. Audits carried out for accreditation may in certain respects come closest to the objectives of clinical auditing, but they are often limited to standard procedures where definite standards are available.

Legal requirements and international basic safety standards in relation to radiological procedures require QA programmes for medical exposure, which in turn impose requirements on audits of aspects of these programmes [4]. Such

audits are part of clinical audit but cover only a limited part of a comprehensive clinical audit. The results of these audits should be reviewed and utilized in carrying out a comprehensive clinical audit in the context of these IAEA guidelines.

Further information on the relationship of clinical audit with regulatory inspections and other quality assessment systems is given in the clinical audit guidelines published by the Commission of the European Communities (CEC) [5] for the improved implementation of the requirement on clinical audits given in CEC directive 97/43/Euratom [2]. The CEC guidelines also contain information on many practical aspects of establishing a sustainable system of clinical audits to cover all three disciplines of the medical uses of radiation (diagnostic radiology, nuclear medicine and radiotherapy), and can be used to supplement the guidance given in these IAEA guidelines.

1.2. PURPOSE AND SCOPE

Advice about quality practices has formed an integral part of the advice provided by the IAEA [6]. Such practices have a basis in statistical sampling [7] and have long been an integral part of industrial processes, and more recently also in the assessment of clinical practice [8]. Donabedian [8] has described three approaches to clinical practice assessment, which can be classified under three categories: *structure*, *process* and *outcome*:

(1) *Structure* denotes the attributes of the settings in which care occurs. This includes the attributes of material resources (such as facilities, equipment and finance), of human resources (such as the number and qualifications of personnel), and of organizational structures (such as organization of medical staff, methods of peer review and methods of reimbursement).
(2) *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.
(3) *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, as is the degree of the patient's satisfaction with care received.

Clinical audit should ideally cover the three categories above. In external clinical audits, structure and process can be well covered; however, assessment of outcome is more difficult in diagnostic imaging. For effective assessment of the outcome,

evidence based medical research is usually needed. Research is ongoing to develop appropriate indicators of clinical outcome. Any methods of outcome follow-up used by the diagnostic radiological facility[1] should be assessed during external audit.

A comprehensive clinical audit of diagnostic radiology practices consists of a review and evaluation of the quality of all elements involved in the practices, including staff, equipment and procedures, patient protection and safety, and overall performance of the diagnostic radiology facility, as well as its interaction with external service providers. Any gaps in technology, human resources and procedures should be identified so that the institution will be able to plan for improvement.

These IAEA guidelines have been prepared for the various applications of ionizing radiation in diagnostic radiology services, whether in public facilities or in private facilities. For the evaluation of other diagnostic modalities (e.g. ultrasound and magnetic resonance imaging (MRI)), the general audit structure (Section 2) and the principles, criteria and audit programmes for the various components of the clinical service (see Sections 3–6) can either be directly applied or be used as a basis for appropriate modification.

As is evident from Section 1.1, it is important to recognize that clinical audits are *not* designed for:

(a) Regulatory purposes. The audit teams are not convened as an enforcing tool but solely as an impartial source of advice on quality improvement.
(b) Investigation of accidents or reportable medical events. In the event of an investigation specifically into adverse events, a more focused audit is required.
(c) Assessment for entry into cooperative clinical research studies. These assessments are conducted by peers within the group involved in the study and are focused on the strict adherence of an institute to a single specified clinical protocol in a selected group of patients.

Clinical audits are intended as an independent assessment of how actual clinical practice compares with good practice, and of how well the systems in place are achieving the set quality standards, with the primary aim of improving patient care.

The primary purpose of these guidelines is to give advice on standards and processes used for comprehensive clinical audit of diagnostic radiology services, both to IAEA Member States requesting audits of diagnostic facilities and to the audit teams convened by the IAEA to carry out the requested audits. This

[1] Within this publication, a diagnostic radiological facility is taken to mean the department or clinic where radiological procedures are carried out.

publication can also be used for clinical audits with a limited scope, where only selected aspects of radiological practice are evaluated.

The guidelines given here outline the principles and criteria for good practice of the various components of the clinical service, followed by advice for the conduct of the audit programme, and provide corresponding audit checklists for items undergoing evaluation. More exactly, Sections 3.1, 4.1, 5.1 and 6.1 define the principles of good practice, while Sections 3.2, 4.2, 5.2 and 6.2 introduce the corresponding audit programmes, i.e. the practical methods of assessment. Appendices IV and V introduce the corresponding forms for recording of observations. Further information on the basis of setting the criteria for good practice can be found in Refs [9–24]. The guidelines also include guides to audit applications, preparations, site visits and audit reports.

It is the ultimate objective of the IAEA that Member States will establish their own appropriate sustainable systems for clinical auditing of diagnostic radiology practices, covering their own local or national needs. The principles, methods and procedures presented in these guidelines can serve as a model for developing such Member State systems.

2. AUDIT STRUCTURE FOR QUAADRIL MISSIONS

2.1. REQUEST FOR AN AUDIT

IAEA comprehensive clinical audits in diagnostic radiology are voluntary. The request for an audit normally originates from the diagnostic radiology facility to be audited. In some cases, the administration of the institution or another body may request an audit. In cases where radiological procedures are performed outside of the diagnostic radiology facility, in the cardiology department, for example, the request for the audit should include authorizations from all relevant facilities for participation in the audit. The head of the radiology facility is responsible for coordination of the audit process, in order to ensure optimum cooperation and adherence to time-frames, and to maximize the benefits of the audit.

It is expected that the responsible staff at any facility/institution participating in an audit should have read these audit guidelines before the request is made.

It is assumed that the requesting facility/institution will have at least the basic infrastructure and quality processes in place to deliver good quality diagnostic imaging or interventional procedures.

As a result of the comprehensive clinical audit, the facility/institution may expect:

—Assistance in improving clinical practice;
—Strengthening of their QA programme;
—Assistance towards ensuring that the requirements for patient protection are met;
—Assistance in the development of local clinical audit programmes;
—Guidance for further development of the facility/institution.

The vision and immediate objectives of the facility/institution should be clearly stated in the request. The audit process may assist in the achievement of goals such as:

—Becoming a training centre for a region;
—Soliciting funding from national authorities or other funding bodies including the IAEA.

The request should be prepared in accordance with given application instructions (the application form is given in Annex I).

The auditing body, the IAEA, will communicate the result of the audit request to the requesting facility/institution. If the request is approved, a proposed time-line for the audit process will be agreed upon between the facility/institution and the audit body, subject to the availability of the audit team.

2.2. COMPOSITION OF THE AUDIT TEAM

The audit team will consist of a multidisciplinary peer review panel with expertise in diagnostic radiology and familiarity with clinical audit methodology. At least one member of the audit team must be able to interview members of the audited department in a language they understand. One member of the audit team will act as the team leader.

The composition of the audit team will depend on the nature of the audit visit, but will usually include as a minimum:

—A radiologist[2];
—A diagnostic radiology medical physicist;
—A radiographer or diagnostic radiology facility manager.

[2] Also referred to as a radiological medical practitioner in the text.

As appropriate, a service engineer or other person with special competencies (e.g. radiation protection or medical specialization) may be included.

2.3. PREPARATION FOR THE AUDIT

The success of an audit depends strongly on thorough preparation by all the parties involved, including the auditing body, the audit team and the participating facility/institution.

2.3.1. Auditing body

The auditing body, the IAEA, is responsible for:

(a) Forming an appropriate audit team and appointing a team leader;
(b) Informing the facility/institution about the composition of the audit team;
(c) Agreeing, in conjunction with the facility/institution and the auditors, on suitable dates for the audit visit;
(d) Confirming the contact persons for radiology, medical physics and radiography at the facility/institution;
(e) Confirming the delivery address for equipment with the medical physics contact person at the facility/institution;
(f) Providing the audit team with the audit guidelines, copies of the application and responses to data requests and the proposed audit time-line;
(g) Providing the audit team with copies of any prior interactions between the facility/institution and the auditing body, for example, reports from earlier audits and subsequent correspondence;
(h) Briefing the audit team, outlining any issues specific to the facility/institution, and emphasizing the importance of the completeness and timeliness of their final report;
(i) Arranging for all necessary equipment to be delivered to the audit team on-site;
(j) Making arrangements for travel and accommodation for the audit team.

2.3.2. Facilities/institutions

In this context, the term ‘facility’ includes the radiology service/department and any other relevant services/departments (e.g. the cardiology department) that have requested to be audited.

The facility/institution is responsible for:

(a) Agreeing to a schedule for the audit visit in consultation with the audit team leader. Such agreement is particularly important for large facilities and institutions with a number of participating facilities (Appendix IV provides a typical audit schedule).
(b) Informing all relevant facilities and institution managements of the audit time-frame and of the schedule for the visit.
(c) Distributing copies of the audit guidelines and a completed application to all relevant facilities and to institution management.
(d) Identifying the contact persons for radiology, medical physics and radiography at the facility/institution, for liaison with the audit team prior to and during the audit visit.
(e) Supplying in advance of the audit any supplementary requested information in addition to the complete and correct application information.
(f) Identifying and ensuring the participation of those individuals at facilities and institutions who are needed at the time of the audit visit. However, the audit team should be free to interview any staff member they deem appropriate. For example, the audit team should have access to a local radiation protection practice expert, nominated by the facility/institution.
(g) Arranging for a private room to be available for the auditors to discuss or work on audit matters during the site visit, along with access to a printer and paper for the draft report.
(h) Preparing data and relevant documentation and making these available on-site at the time of the audit visit (see Annex II).
(i) Providing the images and reports requested by the audit team and making these available on-site at the time of the audit visit.

2.3.3. Audit team

The team leader is required to:

(a) Be in contact with the other members of the team, discuss their approach to the audit and allocate the responsibilities to the various team members;
(b) Confirm the contact persons for radiology, medical physics, radiography and administration at the facility/institution;
(c) Develop a system to ensure coordination of requests from team members for additional information;
(d) Be aware of the audit report requirements and discuss these with other team members;

(e) Confirm with the facility/institution that all needed equipment is in place and that all required preparations have been made for the audit;
(f) Offer and coordinate educational lectures and tutorials by the audit team to the facility/institution.

Each member of the audit team is required to:

(a) Be familiar with the audit principles and procedures as outlined and referenced in this publication;
(b) Review the information provided by the facility/institution with the application and that by the auditing body;
(c) Identify if any additional information is required;
(d) Request additional information either from the corresponding contact person at the facility/institution or from the auditing body;
(e) Familiarize themselves with all the audit schedule report forms — the report format summary, checklists and worksheets (see Appendices II and III and Annexes III and IV);
(f) Prepare for educational lectures/tutorials as applicable.

2.4. AUDIT SITE VISIT

The clinical audit site visit will include an entrance briefing, a review and an exit briefing.

2.4.1. Entrance briefing

A meeting, the entrance briefing, will be held at the commencement of the audit site visit. The audit team members and all relevant institution and facility representatives should attend. The entrance briefing should encompass:

(a) An introduction of the auditors to the facility/institution officials and staff members;
(b) A presentation by the facility/institution of its organization, governance and mission, and other background information. This should include information about the vision of the facility/institution and the perceived benefits of clinical audit.
(c) A presentation by the audit team leader on the goals of the audit and on the audit methodology. The principle of respect for the facility/institution and patient confidentiality will be reinforced.
(d) Confirmation of the audit schedule.

2.4.2. Review

The review process will utilize interviews, observations, documentation review and measurements, and will be carried out in line with the audit schedule. Sometimes the interviews, observations of work and documentary reviews provide sufficient evidence of the local practice meeting 'good' practice standards. Often, however, it is desirable to support these observations with the results of suitable measurements or tests. These measurements and tests should be carried out using appropriate methods and equipment independent of the host facility/institution. The purpose of the tests and measurements is to verify the technique and accuracy of the local methods, as well as the competence of the local staff.

Some aspects of the audit process will be carried out by the whole audit team; others will be carried out by relevant members of the audit team. The audit report forms in Appendix IV, equipment-specific checklists in Annex III and worksheets for physics procedures in Annex IV should be used by the team members to guide and record their evaluations during the audit review. It should be expected that all aspects of the diagnostic service will be reviewed in some way.

The review will cover all of the elements outlined in Sections 3–5, under the following headings:

—Quality management procedures and infrastructure;
—Patient related procedures;
—Technical procedures.

The review process and schedule of the audit visit are outlined in Appendix II.

At the end of the review, the audit team will prepare a draft report to be presented at the exit briefing, using the supplied format (see Appendix III).

The auditors are expected to comment on the extent to which the facility/institution has met the criteria for good practice as outlined in the guidelines. Any significant issues should be verified prior to documentation in the draft report. It is also appropriate to document positive findings regarding areas of good practice.

The draft report should also include recommendations at two levels:

(1) Recommendations in regard to minor or major problems potentially resolvable by the facility/institution;
(2) Recommendations in regard to major problems that may require intervention from outside the facility/institution for resolution.

The report should summarize the auditors' assessment of the overall quality of patient care at the facility/institution and their vision for the future.

2.4.3. Exit briefing

At the completion of the audit visit, a meeting will be convened of facility/institution officials, appropriate members from all relevant facilities and the audit team, to conduct an interactive exit briefing. It is the prerogative of the facility/institution to determine which staff members attend the meeting. This meeting should allow enough time for the following activities:

(a) Presentation by the auditors of the draft audit report, including the preliminary findings and recommendations.
(b) Discussion of the report. The institution and facility members should be strongly encouraged to clarify any issues they consider may have been misunderstood by the auditors.
(c) Discussion by the audit team of the action plans for any recommendations, particularly those that may be urgent in nature.
(d) Confirmation by the audit team of the time-frame for receiving the final report.

A written summary of the draft report may be left with the facility/institution. Copies of completed forms, calculations performed and the results of essential measurements carried out as part of the audit should be left with the facility/institution.

2.5. THE AUDIT REPORT

The audit team will prepare the finalized draft report discussed during the exit briefing with the facility/institution. At all times the audit report will be confidential and available only to clearly designated recipients and the auditing body.

The report will be reviewed by the auditing body, which will discuss the contents of the report with the auditors and, if required, with the facility/institution. Once the report has been completed and approved by the audit team and auditing body, it will be disseminated. The document template for the audit report should follow the headings of Sections 2.5.1–2.5.6.

2.5.1. Title page and contents page

The title page should include the name and address of the facility/institution audited, the names of the members of the audit team (including identification of the leader), the date of the audit and any identification required by the auditing facility/institution. A contents page is essential, and this is generated automatically by the document template.

2.5.2. Executive summary

The summary should describe the reasons for a comprehensive clinical audit, and comment on the extent to which the facility/institution has met the criteria for good practice as outlined in these guidelines, along with the vision of the facility/institution for the future, concluding with a summary of recommendations to the clinical facility and the external organizations. This section should not exceed two pages in length.

2.5.3. Recommendations

Recommendations will be prepared for two recipients:

(1) The audited facility/institution. These recommendations should address minor or major issues potentially resolvable by the facility/institution. They should be grouped using the sections in this guide to allow the audited institution to rapidly reference the appropriate sections. A summary of these recommendations is included in the executive summary as mentioned above.
(2) External organizations (e.g. government agencies). These recommendations should address major issues that may require intervention from outside the facility/institution for resolution, and other recommendations that should be brought to the attention of the government. These recommendations are usually included in the executive summary; however, if they are detailed and lengthy they could form a distinct section.

All recommendations should be reviewed, with those of major importance as determined by the audit team being highlighted. A short summary of such a recommendation should appear in the executive summary. Any issues involving serious safety concerns should be appropriately indicated.

Recommendations that deal with issues within the authority of the auditing body, for example, the need for additional training of auditors, will not be part of

the audit report but will be made separately to the auditing body and will not be distributed outside of the auditing body.

While it is the role of the audit team to identify areas for quality improvement of the services provided by the facility/institution, it is not the responsibility of the auditing body to rectify any deficiencies identified. Instead, the role of the auditing body is to identify the need for improvements and thus to initiate their implementation and to facilitate learning.

2.5.4. Report on findings

This section of the report will include detailed data and observations as follows:

(a) The names of key individuals involved with the audit:
  (i) Those requesting the audit;
  (ii) Heads of audited facilities;
  (iii) Contact persons for the audit.
(b) A vision of the facility/institution for future development.
(c) A description of audit activities and findings as recorded on the audit report forms (see Appendix IV), and will cover the following areas:
  (i) Quality management procedures and infrastructure;
  (ii) Patient related procedures;
  (iii) Technical procedures;
  (iv) Education, training and research programmes.

2.5.5. Conclusions

The conclusions should include some mention of an agreed action plan with the audited facility in response to the audit recommendations (see Section 2.7), and may also include a statement from each individual audit team member (guideline length for each member: one page).

2.5.6. Annexes

Annexes should include:

— A full list of the individuals interviewed during the audit;
— The application form completed by the facility/institution;
— Any other documents relevant to the audit.

2.6. DISSEMINATION OF THE REPORT

The entire final audit report (not including the recommendations to the auditing body) will be sent to the requestor of the application and the designated contact persons on the initial application.

In most circumstances, an abbreviated report will be sent to the government body of the facility/institution. This report would typically consist of the summary and recommendations to the government.

2.7. EVALUATION AND FOLLOW-UP OF THE AUDIT PROCESS

As the purpose of clinical audit is quality improvement, the facility/institution should develop an action plan in response to the audit recommendations. Ideally, this action plan would be required by the auditing body and be used to monitor the response of the facility/institution and might include provision for a follow-up review or partial audit.

Any issues of serious safety concern should be addressed by the facility/institution as soon as possible. If, after an agreed time interval, the auditing body is aware that the facility/institution has failed to address significant recommendations relating to serious safety concerns, the facility/institution will be informed that they have the responsibility of notifying the appropriate regulatory authorities.

3. QUALITY MANAGEMENT PROCEDURES AND INFRASTRUCTURE

3.1. PRINCIPLES AND CRITERIA FOR GOOD PRACTICE

3.1.1. Mission and vision of the diagnostic radiology facility

3.1.1.1. Objectives of the facility

The role of the diagnostic radiology facility 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 quality manual (see Section 3.1.2). It is the responsibility of the head of the diagnostic

radiology facility to provide an environment to foster safe and good quality imaging services. It is important that the facility'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 mission statement of the facility should describe the nature and extent of its services and also specify its objectives for teaching and research activities. This should include the utilization of available resources, for example, to act as a national or local training centre. The financial structure of the organization to meet the specified objectives should also be described.

The facility should have an annual plan of activities, and this should include vision statements and long term objectives.

3.1.1.2. Patient demographic data and workload

The existing infrastructure and resources should be sufficient to meet the specified objectives of the institution for radiological services, for the typical number of examinations or procedures encountered, and also when working under pressure with maximum patient throughput.

The demand for imaging services, as indicated by the number and range of examinations performed annually, and the facility 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 socioeconomic confounding factors that might have an adverse impact on providing the specified radiological services.

3.1.2. Quality management system

A quality management system is a framework to support the operation of a facility/service, with the objective of continuous quality improvement.

A quality management system involves:

—The objectives and policies of the organization;
—Documented procedures consistent with these objectives and policies;
—Written practice instructions for staff;
—Monitoring, recording and auditing of practice.

A diagnostic imaging service should have a person or persons in the role of quality manager with the responsibility of implementing and maintaining the quality management system. This should be a facility-wide QA programme, covering all activities not only at the permanent site but also elsewhere (e.g., mobile services).

A QA committee should be established to provide periodic review and evaluation of the facility's QA programme. The committee should consist of physicians, radiographers, medical physicists, nurses, and administrative and other staff, as appropriate. Quality assurance of technical procedures is described in Section 5.1.

The quality management system should be documented, preferably in a quality manual.

The scope of responsibilities of the quality manager(s) should be defined and should include maintenance of the quality manual and associated documentation, and identification of persons responsible for practical implementation of QA and quality control (QC).

The quality manual and the policy and procedure manuals should be realistic and they should be regularly reviewed for relevance to existing practices. Records should be kept of the results of the reviews.

The results of QA activities should be assessed. Results that do not meet tolerance levels should lead to appropriate and timely remedial actions, and all such actions should be recorded. A QA committee should review the QA results, as appropriate.

Internal and external audits to assess the quality of practices should be regularly organized, and quality improvement activities implemented in response. A planned audit programme should be in place.

3.1.3. Structure of the diagnostic radiology facility

3.1.3.1. Personnel

The personnel of a radiology facility form a multidisciplinary team that typically includes: radiological medical practitioners[3], radiographers, technical assistants, sonographers, nurses, medical physicists, service engineers, information technology (IT) specialists and administrative staff. The facility staffing levels and the professional competence of the staff should be sufficient to provide safe imaging examinations of good quality, and to meet the specified objectives of the institution for radiological services. Facilities should implement

[3] A radiological medical practitioner is an individual who: (a) has been accredited through appropriate national procedures as a health professional; (b) fulfils the national requirements on training and experience for performing or overseeing procedures involving medical exposure; (c) is entitled in accordance with the relevant authorization to perform or oversee procedures involving medical exposures.

processes to ensure that all members of staff work in a collaborative relationship as part of a team.

It is assumed that the minimum qualifications and continuing education of all staff involved in delivery, supervision, support and management of diagnostic imaging services are consistent with clinical requirements, and meet appropriate national and local regulatory requirements.

All staff should have adequate training for their roles, and the introduction of any new techniques should be accompanied by information and training for the users of the new techniques. Where tasks are delegated, professional supervision should be readily available.

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

—Recruitment;
—Individual job descriptions;
—Orientation programmes for new staff;
—Appropriate supervision and training by senior staff;
—Evaluation of staff performance;
—Continuing professional development (CPD).

The institution should provide an opportunity for staff development by participation in:

(a) Regular facility, institutional or professional meetings and audits. These should be scheduled as regular activities within staff job descriptions.
(b) Access to library materials, including computer resources.
(c) Internal teaching programmes (such as facility seminars).
(d) External educational programmes (such as conferences).

These activities should be encouraged and supported.

Individual personnel training records should be maintained.

If teaching, training and/or research are undertaken within the facility, the roles and responsibilities of staff involved in these activities need to be documented.

3.1.3.2. Facility organization and management

Appropriate organizational structures and management systems should be in place so as to maximize the quality of service delivery and make efficient use of all resources. The commitment of senior management to good practice and quality improvement should be documented in the quality manual.

Lines of authority should be reflected in the institution's and facility's organizational charts. The share of responsibilities among different professionals should be clearly and unambiguously defined through the job descriptions. The responsibilities and authorities of visiting workers should also be clearly defined. As appropriate, the organizational chart should identify subspecialty services (e.g., computed tomography (CT) and emergency radiological services).

The organization of the facility's work processes should be consistent with the demand for services based on the specified objectives of the institution and on the patient demographic data. The operating hours of the institution's radiological services and the working hours and rosters of different professionals should meet patient requirements. The staffing level should be sufficient to allow the equipment to be operated efficiently.

If teaching, training and/or research are undertaken within the facility, the organization of these activities should be documented (see Section 6.1).

3.1.3.3. Premises

The premises of the radiological facility should be adequate to safely meet the specified objectives and operations of the institution. The premises should be clean and designed to optimize patient access, comfort, privacy and special needs.

Radiation protection of the patient, staff and general public should be addressed. For a detailed review of the processes in radiation protection see Section 5.1. Note that this audit process is intended to avoid overlap with regulatory requirements (see Section 1.1.4).

The location of the facilities should take into consideration the other services necessary for good patient care, as well as effective patient movement and access.

Appropriate space should be available for:

—Imaging examination rooms;
—Control rooms;
—Processing rooms;
—Image interpretation rooms;
—Patient changing rooms;
—Recovery/post-procedural areas;
—Waiting areas;
—Patient movement within the facility;
—Administration;
—Storage;
—Record filing;

—Engineering services;
—Staff accommodation.

Equipment needed to ensure that environmental conditions are appropriate should be maintained, for example, heating and air-conditioning equipment.

The need for access to clinical services and physician admitting privileges must be available if interventional procedures are carried out.

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

3.1.4. Equipment

3.1.4.1. Equipment policy

The types and numbers of items of equipment should correspond to the objectives and scope of the facility's operations as specified in the institution's quality manual. Policies and procedures should be documented and monitored with regard to equipment, as follows:

—Purchase, usage and replacement[4];
—An inventory;
—Appropriate checks before use;
—Quality control;
—Maintenance, particularly with respect to safety and infection control;
—Data protection and backup.

The protection and maintenance of data and equipment should be ensured by measures such as power fluctuation control devices, computer network maintenance and use of backup facilities.

Equipment should only be used by authorized trained personnel. The types of equipment to be documented include:

—Imaging equipment and modalities;
—Software and hardware for digital imaging and teleradiology;
—Auxiliary imaging equipment such as viewing devices and contrast pumps;
—Quality assurance phantoms and dosimetry equipment;

[4] The replacement of imaging equipment shall be consistent with the appropriate regulatory requirements for radiation safety (see Section 5.1).

—Medical support equipment such as wheelchairs and trolleys;
—Medical equipment for resuscitation, anaesthesia and sedation, and monitoring;
—Administrative equipment such as computers, printers and software.

3.1.4.2. Equipment inventory

All types of facility equipment should be recorded in a comprehensive equipment inventory. 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.

Inventories for contrast agents, drugs and gases (for resuscitation, anaesthesia, etc.) should be maintained. Procedures for tracking implanted medical devices (e.g. stents and coils) should be documented.

3.1.5. Documentation control

All facility documentation, such as policy and procedure manuals and inventories, requires proper control to ensure that it is current, regularly updated and distributed. A master list of controlled documents should be maintained.

Document control should include unique identification (e.g., date, version number, page numbering and total number of pages) and issuing authority.

Only current documents should be available to staff, and obsolete documents should be removed from circulation.

Documents (in printed or computer form) should be regularly reviewed and amended as appropriate.

3.1.6. Patient confidentiality, feedback and complaints

To ensure that patient personal information is protected, the confidentiality policies and procedures should be documented, and each staff member in contact

with patient data should have agreed to abide by the facility and institution rules in regard to confidentiality (see Section 4.1.3.1).

As a measure of how well the service provided meets the expectations and needs of patients, the facility should actively seek patient feedback. There should be policies and procedures in place to address complaints from patients. Records should be maintained of patient complaints, the results of their investigation, and actions taken to rectify problems identified.

3.1.7. Communication

Good communication is essential for the effective conduct of a diagnostic radiology service. Communication systems throughout the diagnostic radiology facility and with related facilities should ensure reliable, unambiguous, confidential and timely transfer and recording of information.

There should be no gaps in the flow of information among staff members, regardless of job responsibilities or working hours.

The facility should have its policies and procedures documented, and these should be communicated to, and be available to, personnel. Personnel should be aware of the requirement to know and implement these policies and procedures.

3.2. THE AUDIT PROGRAMME

3.2.1. Mission and vision of the diagnostic radiology facility

3.2.1.1. Objectives of the facility

The audit team should:

(a) Review the mission statement of the facility in the quality manual;
(b) Check the statement in regard to the nature and range of the service objectives;
(c) Check the facility's relationship with other specialties and related services;
(d) Discuss with senior management the role of the facility in teaching and research;
(e) Discuss with senior management the financial structure in place to support these objectives;
(f) Discuss with senior management the extent to which objectives are being met, and any impediments to achieving them;

(g) Make an assessment of the role of the facility and the adequacy of its objectives in the context of the national health care system;
(h) Discuss the facility's annual plan of activities;
(i) Review the vision statement and the long term objectives of the facility.

3.2.1.2. Patient demographic data and facility workload

The audit team should:

(a) Review the current demand for imaging services, the number and range of examinations performed annually, and the trend data;
(b) Examine the age range of patients examined;
(c) Examine the routine hours of operation and the emergency/after-hour services provided;
(d) Review the facility staffing levels (current and planned);
(e) Review the funding mechanism for the facility and patient payments;
(f) Discuss with management future plans for development of the facility, including socioeconomic concerns.

3.2.2. Quality management system

The audit team should:

(a) Identify the person(s) who has the role of quality manager and discuss with them their roles and responsibilities;
(b) Review the membership, role and records of the QA committee;
(c) Check that all aspects of the facility's activities are subject to quality management, including those at other sites;
(d) Identify staff responsible for various QA and QC activities across the facility;
(e) Review the quality manual, and the policy and procedure manuals;
(f) Check the dates and records of reviews of the quality manual;
(g) Assess the audit programme of the facility and review the documentation of past internal and external audits, and the responses to those audit reports.

3.2.3. Structure of the diagnostic radiology facility

3.2.3.1. Personnel

The audit team should:

(a) Review the range of staff employed or contracted by the facility, for example, radiological medical practitioners, radiographers, technical assistants, sonographers, medical physicists, nurses, administrators, clerks, engineers, computer technicians and IT support staff;
(b) Review the number of trainee and supervisory staff if applicable;
(c) Discuss with management the local/national qualification requirements for staff positions, and how these are met and documented;
(d) Review evidence of training policies, and discuss with staff their experience with training for the use of routine and new equipment/technology;
(e) Discuss with staff the supervision that they receive;
(f) Review documentation with regard to staff management, including recruitment, individual job descriptions and orientation programmes for new staff;
(g) Review evidence of staff performance appraisals;
(h) Confirm documented CPD for all staff members;
(i) Examine records of the contents of, and attendance at, facility/institutional meetings and audits;
(j) Confirm with staff their access to a library and other teaching materials;
(k) Confirm with staff their participation in CPD, through internal or external programmes;
(l) Confirm that individual personnel records are kept;
(m) If applicable, discuss with staff involved in teaching and/or research their roles and responsibilities, and the mechanisms used to meet professional supervision.

3.2.3.2. Facility organization and management

The audit team should:

(a) Discuss with senior management their commitment to QA and quality improvement for the facility, and their planning for use of resources;
(b) Review the quality manual for documentation of commitment to quality management;

(c) Examine the facility's organizational chart and lines of authority, including those for subspecialty services (e.g. CT and emergency radiological services);
(d) Examine the share of responsibilities through job descriptions and the rules for visiting workers;
(e) Discuss with management the relationship of the facility with services in other parts of the institution or other institutions (if any);
(f) Discuss with management the demand for services, operating hours for radiological services, and staff working hours and rosters.

3.2.3.3. Premises

The audit team should:

(a) Check the cleanliness of the premises;
(b) Review the design of the premises with respect to patient comfort, privacy and special needs;
(c) Review the radiation protection policies for patients, staff and the general public;
(d) Discuss the location of the facility and other services involved in patient care and patient movement;
(e) Check the location of other facility off-site services;
(f) Review floor plans for checks on appropriateness/adequacy of areas (including those off-site) for: image examination, control, processing, image interpretation, patients changing their clothes, recovery/post-procedural care, waiting, administration, storage, record filing, engineering services, staff accommodation and amenities;
(g) Check environmental control (e.g. heating and air-conditioning);
(h) Check access to the Internet and the proximity to libraries and laboratories, as applicable;
(i) Confirm physician admitting privileges or access to appropriate clinical services for interventional cases as applicable.

3.2.4. Equipment

3.2.4.1. Equipment policy

The audit team should:

(a) Check that the equipment is appropriate in types and numbers for the services offered;

(b) Review the facility policies and procedures in regard to QA of equipment (equipment purchase, usage and replacement, inventory, appropriate checks before usage, QC, maintenance, particularly with respect to safety and infection control, data protection and backup);
(c) Check the measures for protection and maintenance of data and equipment, and review documentary evidence of preventive maintenance programme;
(d) Confirm that equipment usage is by trained and authorized personnel;
(e) Examine storage facilities for consumables.

3.2.4.2. Equipment inventory

The audit team should:

(a) Check that all types of the facility's equipment are recorded in the equipment inventory, including: imaging equipment/modalities, software and hardware for digital imaging and teleradiology, auxiliary imaging equipment such as viewing devices and contrast pumps, phantoms and dosimetry equipment, medical support equipment such as wheelchairs and trolleys, medical equipment for resuscitation, anaesthesia, sedation and monitoring, and administrative equipment such as computers, printers and software;
(b) Check that sufficient information has been recorded for each piece of equipment (see Section 3.1.4.2);
(c) Review the inventories for contrast agents and drugs;
(d) Check for control of medical gases;
(e) Check procedures for tracking of implanted medical devices (e.g. stents and coils);
(f) Check for protection against power supply fluctuations;
(g) Check for adequacy and maintenance of computer IT network, storage and backup facilities.

3.2.5. Documentation control

The audit team should:

(a) Check the master list of controlled documents and its contents for evidence of unique identification of documents (e.g. date, version number, page numbering and total number of pages) and issuing authority;
(b) Check the availability of up to date documents in offices, imaging rooms, etc.;

(c) Consider policy in regard to regular reviews and amendments to documents;
(d) Check documents for evidence of past reviews.

3.2.6. Patient confidentiality, feedback and complaints

The audit team should:

(a) Check for documented confidentiality policies and procedures;
(b) View signed confidentiality agreements from each staff member in contact with patient data;
(c) Review policies and procedures to address patient complaints;
(d) Review records of patient complaints, the results of investigations into them, and the actions taken in response.

3.2.7. Communications

The audit team should:

(a) Check mechanisms of information flow (e.g. manuals and the radiology information system (RIS)) among staff members, including those with various job responsibilities and working hours;
(b) Discuss with staff the availability of documentation about facility policies and procedures;
(c) Discuss with staff their access to telephones, computers, emails and faxes;
(d) Discuss with personnel their knowledge of the contents of documentation, and how these policies and procedures have been implemented;
(e) Discuss with staff the communication facilities between the radiology facility and the other facilities at the institution.

4. PATIENT RELATED PROCEDURES

4.1. PRINCIPLES AND CRITERIA FOR GOOD PRACTICE

The radiological medical practitioner performing or supervising a radiological examination is responsible for the protection, safety and care of the patient, including justification of the examination and optimization of radiation

protection and clinical outcome. The other health professionals involved in the preparation for, and delivery of, the examination also have specific responsibilities in regard to patient protection, safety and care [4].

4.1.1. Referral of the patient for examination

4.1.1.1. Appropriateness of examination/justification

The radiology consultation begins with the critical task of selection of the examination required.

In health screening programmes of asymptomatic populations, specific justification for a radiological examination should be established by the relevant health authorities.

An examination intended for the health screening of an individual, but not as part of an approved health screening programme, requires justification by the radiological medical practitioner and the referring medical practitioner[5], in accordance with the guidelines of relevant professional bodies.

Justification of the specific examination requested for any individual patient is informed by clinical assessment of the patient, existing guidelines/ criteria for referral and examination availability.

Justification of an examination requires evidence that the diagnostic benefits of the examination outweigh the risks for the patient, particularly if the patient is pregnant or potentially pregnant, breastfeeding or paediatric, and is based on a knowledge of the:

—Indications for available examinations;
—Advantages and limitations of examination options;
—Complementary nature of other examinations;
—Results of prior examinations;
—Risk–benefit considerations including adverse effects;
—Contraindications.

Appropriate clinical information is essential for good quality radiology practice. While it is the responsibility of the referring medical practitioner to ensure that the request contains the necessary information, the facility should

[5] A referring medical practitioner is defined as a health professional who, in accordance with national requirements, may refer individuals for medical exposure to a radiological medical practitioner.

require a written policy and procedure on the verification of requested data and a justification of examination selection.

A radiological medical practitioner (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 medical practitioner for further discussion of the clinical findings and imaging examination options.

4.1.1.2. Quality of the referral

Except for approved health screening programmes, all patients must be referred for an examination by a physician or appropriate health care practitioner.

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

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

The minimal information required is the following:

(a) Patient's name, date of birth, address and contact details, such as hospital ward or phone number;
(b) Study requested;
(c) Clinical indication for examination;
(d) Date of the request;
(e) Referring medical practitioner's signature, printed name and contact details;
(f) Pregnancy status.

4.1.1.3. Referrer education

There should be a process in place to ensure that information regarding examinations — indications, advantages–benefits and limitations–risks — is readily available to the referring medical practitioners to allow appropriate selection and justification of an examination. The process should include regular updating of available information. Information concerning radiation exposure and associated risks is essential, particularly in regard to infants, children and pregnant or potentially pregnant patients.

4.1.1.4. Patient education and consent

Information regarding the potential benefits and risks (such as contrast agent and radiation risks) associated with the relevant examination/s should be

made available to the patient prior to the examination. The patient should be given the opportunity and adequate time to ask questions about the examination and its risks, including radiation exposure in pregnancy, and what other examinations are available. The patient should be aware that they have the option to refuse the examination or to withdraw their consent at any time.

The consent of the patient to undergo examination should be obtained and documented as appropriate.

4.1.1.5. Pre-procedure screening and preparation

Policies and procedures should be in place to identify the clinical conditions relevant to the hazards of specific radiological examinations, such as:

—Contrast media contraindications (e.g. netforium);
—Latex and food allergies;
—Renal impairment;
—Pacemakers and aneurysmal clips;
—Anti-coagulant therapy;
—Pregnancy status.

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

(a) Age;
(b) Infections, particularly with regard to cross-patient contamination, for example, with multiresistant *Staphylococcus aureus* (MRSA) bacteria;
(c) Mobility and transport issues;
(d) Sedation and 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 examination-specific preparation processes (e.g. fasting) are communicated accurately to patients and/or their carers, and that the facility has procedures for managing patients who are inappropriately prepared.

4.1.1.6. Scheduling

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

Once examination scheduling has been confirmed, there should be a mechanism to ensure recall of prior imaging examination images and reports, which should be available to the reporting radiological medical practitioner as soon as practicable.

The monitoring of scheduling efficiency permits optimization of access, throughput and resource allocation.

4.1.2. Identification of the patient

It is crucial that fail-safe mechanisms be in place to ensure that the patient is correctly identified, that the correct examination is performed and that the correct anatomical region is studied. There should be a documented protocol to ensure accurate identification of the patient and the examination performed.

In view of the complexity of patient communications, multiple checks and balances should be in place. Constant vigilance is vital to protect patient safety.

4.1.3. Examinations

4.1.3.1. Patient confidentiality and physical privacy

It is the responsibility of the facility to have policies and procedures in place to ensure that security and confidentiality of patient information and patient physical privacy are respected throughout the patient's stay in the radiology facility. All staff should be aware of their responsibilities and obligations with regard to patient information and privacy.

Patient information includes:

—Biographical data;
—Clinical information;
—Medical images.

The physical environment encompasses:

—Waiting rooms;
—Changing rooms;
—Examination rooms;
—Post-procedure observation areas;
—Counselling rooms.

4.1.3.2. Imaging technique

Protocols and procedures for all imaging examinations should be documented and regularly updated, and they should be readily accessible to imaging staff at all times. All examination protocols should be optimized for image quality and dose, with input from the relevant imaging team members: the radiological medical practitioner, radiographer and medical physicist. The recommended techniques and parameters should be based on the principle of exposing the patient to the least radiation dose necessary to achieve the appropriate diagnostic information (see Section 5). In special populations, such as paediatrics, specific documentation relevant to these populations should be in place.

Recommended radiographic technique factors should be used for preprogramming of equipment, or they should be readily available for use by the radiographer.

Recommended practice for secure storage of image data should be observed, including backup of electronic data and image data management through the Picture Archiving and Communication System (PACS).

It should be ensured that members of staff are aware of current protocols and procedures, and immediately notified when changes are made.

Protocols and procedures should be in place for studies such as:

—Plain radiography;
—Fluoroscopy;
—Mammography;
—Computed tomography;
—Ultrasonography;
—Magnetic resonance imaging;
—PET/CT;
—Image guided procedures;
—Dental radiography.

There should be a documented process to indicate the circumstances in which radiographers or radiological medical practitioners/physicians who are in training should seek further guidance from the supervising radiographer or radiological medical practitioner/physician, respectively, such as:

(a) Unexpected imaging findings;
(b) Difficulties in obtaining the image required because of patient or equipment problems.

Documentation of the details of the examination should include information such as:

(a) Examination demographics:
    —Location, time, equipment, etc.;
    —Identification of radiographer.
(b) Film labelling, including patient identification.
(c) Plain radiography:
    —Laterality;
    —Projections;
    —Exposure factors;
    —Collimation;
    —Field size.
(d) Sectional imaging:
    —Scan parameters;
    —Radiation dose.
(e) Contrast medium:
    —Type;
    —Dosage.
(f) Patient limitations affecting examination quality.
(g) Clinical notes:
    —Adverse reactions and events;
    —Conscious sedation;
    —Type and dosage of medications.

Any deviations from the established protocols should also be recorded.

Infection control involves both patients and staff. Documented policies and procedures should be in place to cover:

(a) Room cleanliness;
(b) Contaminated waste disposal;
(c) General aseptic techniques in radiology;
(d) Sharps protection;
(e) Sterile techniques for interventional procedures;
(f) Sterilization of reused equipment;
(g) Other specific situations, for example, protection of central line sterility, care of immune system compromised patients.

4.1.3.3. Clinical care, patient sedation/anaesthesia and contrast agents

All elements of routine clinical care must be provided for during the patient's stay in the radiology facility including:

—Monitoring of vital clinical signs;
—Routine nursing care, such as maintenance of intravenous (IV) equipment and drainage catheters;
—Safe, comfortable and private physical environment.

The safe use of sedation and anaesthesia requires policies and procedures to be documented with regard to drugs, equipment, personnel and training. There should be a suitably trained and designated staff member (e.g. a nurse), or members, responsible for maintenance and storage of drug and gas supplies and related equipment, and their inventories. Only authorized persons should administer sedation medication and/or anaesthesia. Appropriate monitoring personnel and equipment should be available.

There should be policies and procedures in place giving details of the storage and administration of contrast agents, including who is authorized to administer the contrast agent and the dosages. Prior to contrast media usage, it should be confirmed that the patient has been screened for a history of allergies or risk factors, and that the relevant findings have been recorded. Records of contrast media usage should be kept.

Untoward events must be anticipated and appropriate resources be made available to enable prompt attention to patients and resuscitation if necessary.

Management protocols for critical scenarios, such as contrast medium reactions and cardiopulmonary collapse, should be documented and be readily available, preferably displayed in strategic locations. A suitably trained and designated staff member(s) (e.g. a nurse) should be responsible for the storage and maintenance of resuscitation drug and gas supplies and trolleys/equipment, and their inventories. Staff appropriately trained in resuscitation techniques and equipment usage should be available at all times.

4.1.3.4. Image quality

Good image quality contributes positively to the value of the imaging procedure to patient care, but there is a relationship between image quality and dose, which should be optimized. The quality of the final image is a result of many factors, particularly accurate positioning and appropriate use of technology. Radiography staff should be aware of the positioning and equipment usage factors that contribute to image quality, and of the criteria used to assess image quality.

There should be a radiographer responsible for a radiography image QA programme, with feedback to radiography staff. Regular image reviews and audits for all modalities should be performed and include:

—Repeat rate and analysis of rejected films;
—Peer reviewed critical evaluation of individual image quality by radiographers;
—Evaluation of image quality by radiological medical practitioners.

Critical evaluation can employ criteria such as the:

(a) Image quality criteria for plain radiography, proposed by the CEC [13];
(b) United Kingdom PGMI (perfect, good, moderate, inadequate) method of evaluation of clinical image quality in mammography [25].

The reporting radiological medical practitioner is ultimately responsible for the radiological interpretation, and should be consulted if there are difficulties in obtaining the appropriate image quality.

4.1.4. The imaging report

The imaging report is integral with radiology practice, and all examinations should be reported by qualified and trained radiological medical practitioners/physicians, or trainee radiological medical practitioners/physicians under appropriate supervision.

The report should include:

—The referring medical practitioner's name;
—The patient's name and unique identifier;
—The clinical indications;
—The title of the examination and the date of performance;
—The body part examined and, as appropriate, any laterality;
—A description of the examination technique and views taken;
—A description of the imaging findings;
—A comparison with previous examinations, as appropriate;
—A correlation with complementary examinations;
—The significance of the imaging findings;
—Any correlation with clinical symptoms and findings, if present;
—Conclusions and guidance to further patient management;
—Untoward effects of the examination;
—The name of the reporter and facility, and the date.

4.1.5. Report communication

Communication of the imaging report to the referring medical practitioners is also integral to radiology practice. For this to be effective, mechanisms need to be in place to ensure that there is:

—Reporting and authentication of reports for all completed examinations;
—Completion of reporting within agreed time-frames;
—Communication of the final report to the referring medical practitioner.

Policies and procedures should be in place in regard to communication of reports and specifically of urgent results. A method for identifying urgent results and for ensuring an appropriate response is required. Policies and procedures should be regularly monitored.

All these issues should have documented QC protocols with records of audit.

4.1.6. Continuity of clinical care

The responsibility of the radiological medical practitioner does not end when the patient leaves the radiology facility.

The contributions of the radiological medical practitioner to continued clinical management of patients should include involvement in documented:

—Multidisciplinary clinico-pathologic correlation meetings;
—Tumour boards;
—Morbidity and mortality conferences.

It is strongly encouraged that patient outcomes be regularly and consistently evaluated through internal and external audits. These results should be recorded and used for quality improvement and education.

4.1.7. Accident and incident reporting

Untoward incidents involving patients should be documented promptly.

In accordance with written policies, serious patient safety incidents[6] and patterns of events should be:

[6] Critical event reporting is encouraged on the IAEA's Radiation Protection of Patients web site for interventional radiology [26].

—Recorded;
—Systematically evaluated;
—Acted upon.

Critical incidents (e.g. sentinel events such as a wrong sided interventional procedure) should, in addition, be reported to the institution and the regulatory authorities.

Lessons learned from analysis of these events should be documented, communicated and used for quality improvement.

4.1.8. Retention of records and images

All records and images from imaging examinations should be retained for a period in accordance with local/national regulatory requirements.

The radiology facility should have documented policies and procedures on retention of records and images.

Retained material should be clearly identifiable, stored securely and accessible. A process should be in place for the tracking of records and image files.

The radiology facility should audit compliance with its retention policies and procedures.

4.2. THE AUDIT PROGRAMME

4.2.1. Referral of the patient for examination

4.2.1.1. Appropriateness of examination/justification

The audit team should:

(a) Check for documented guidelines in regard to any screening examinations, both those that are part of and those that are not part of an approved health screening programme;
(b) Check for documented referral guidelines in regard to examination selection/justification, and reference to pregnant, breastfeeding and paediatric patients;
(c) Identify radiological medical practitioners (or delegates) involved in reviewing examination requests;
(d) Check facility processes to contact referring medical practitioners as required;

(e) Check facility processes to change orders as required;
(f) Review policies and procedure documentation in regard to specific examination contraindications.

4.2.1.2. Quality of the referral

The audit team should:

(a) Review a sample of requests for appropriateness of authorizations;
(b) Review a sample of requests for completeness of general and clinical information;
(c) Review a sample of requests for completeness of order accuracy, for example, body part and laterality;
(d) Check that the department has a policy and procedure with regard to confirming accuracy and completeness of request information prior to commencement of the examination.

4.2.1.3. Referrer education

The audit team should:

(a) Review information about justification — the depth and extent of content — prepared for referrers;
(b) Review information on radiation risks;
(c) Check processes for information updates and distribution.

4.2.1.4. Patient education/consent

The audit team should:

(a) Check for the information provided for patient education regarding examinations;
(b) Check for patient consent forms;
(c) Observe the consent process;
(d) Check for compliance with patient consent policies;
(e) Check for consent documentation.

4.2.1.5. Pre-procedure screening and preparation

The audit team should:

(a) Check for documentation on policies and procedures in regard to identifying the clinical conditions relevant to the hazards of specific radiological examinations (e.g. contrast media contraindications);
(b) Interview staff to assess compliance with documentation about policies and procedures on hazards;
(c) Check for documentation on policies and procedures, to identify conditions that may affect the safe conduct of examinations;
(d) Interview staff to assess compliance with documentation on policies and procedures about safe conduct;
(e) Check policies and procedures for examination-specific preparation requirements;
(f) Interview staff to assess compliance with documentation on policies and procedures about examination-specific preparations.

4.2.1.6. Scheduling

The audit team should:

(a) Assess the clinical training of scheduling staff;
(b) Evaluate the response time to requests for emergency and urgent examinations;
(c) Review image/file storage facilities and assess their capacity and efficiency;
(d) Request retrieval of a random sample of filed images and reports;
(e) Establish that examination images and reports from previous imaging are routinely made available to radiography and radiology staff prior to commencement of examinations;
(f) Check for processes for monitoring the efficiency of scheduling.

4.2.2. Identification of the patient

The audit team should:

(a) Check policies and procedures for verifying patient identification and examination order accuracy;
(b) Evaluate the methodology used to establish accurate patient identification prior to examination (by orderly and receptionist);

(c) Assess that radiography/radiology staff reliably confirm the accuracy of patient identification;
(d) Assess that radiography/radiology staff reliably confirm the accuracy of the examination and anatomical area to be imaged;
(e) Establish evidence that there is a continuous review of staff compliance with the above procedures.

4.2.3. Examination

4.2.3.1. Patient confidentiality and physical privacy

The audit team should:

(a) Check the policies and procedures of the radiology facility regarding security and confidentiality of patient information;
(b) Check the policies and procedures of the radiology facility regarding care of the physical privacy of patients;
(c) Observe handling of patient request forms, file notes and records, to confirm compliance with policies;
(d) Inspect the physical environment of areas for waiting, changing clothes, examination, post-procedure observation and counselling;
(e) Discuss confidentiality and privacy protocols with staff;
(f) Observe patient care in the facility for compliance with personal privacy policies.

4.2.3.2. Imaging technique

The audit team should:

(a) Review the protocols for all imaging examinations, including those for special populations such as paediatric patients, and check for updating of documentation;
(b) Check protocols for optimization of image quality and dose;
(c) Determine the location and availability of documented examination protocols;
(d) Check for availability of printed and electronic copies of radiography technique information and parameters;
(e) Interview staff regarding awareness of, and adherence to, examination protocols;

(f) Ask radiological medical practitioners to provide examples of images of examinations that are tailored to address patient problems (routine and specific);
(g) Interview radiographers or radiological medical practitioners/physicians who are in-training, to discuss protocols for supervision and handling of unexpected imaging findings or for technical difficulties;
(h) Examine images for completeness of labelling and technique details;
(i) Check records for patient- and examination-specific documentation of, for example, contrast usage and scan parameters;
(j) Check records for notes regarding administration of medication for, for example, sedation and resuscitation;
(k) Review policies and procedures for infection control;
(l) Check room cleanliness and facilities for disposal of general and contaminated waste;
(m) Interview staff regarding their awareness of, and adherence to, policies and procedures related to infection control, including sterilization protocols;
(n) Check for provision of sharps protection;
(o) Observe the conduct of relevant examinations for compliance with operator technique, adherence to sterile techniques, patient safety, etc.

4.2.3.3. Clinical care, patient sedation/anaesthesia and contrast agents

The audit team should:

(a) Check that all elements of clinical care are provided for, with written records of monitoring of vital clinical signs, maintenance of IV equipment, drainage catheters, etc.;
(b) Check the physical environment for patient safety and privacy;
(c) Check the policy for use of sedatives and anaesthetics;
(d) Identify the designated staff members and discuss their role in the maintenance of drugs, gases and equipment for sedation and anaesthesia, and their inventories;
(e) Check policies and procedures for storage and administration of contrast agents, as well as staff authorization, dose protocols, etc.;
(f) Discuss contrast protocols with staff;
(g) Check for policies and procedures for the management of untoward events such as contrast medium reactions and cardiopulmonary collapse;
(h) Identify the designated staff members and discuss their role in the maintenance of resuscitation drugs, gases and equipment, and their inventories;

(i) Examine the availability, accessibility and contents of resuscitation resources;
(j) Discuss with staff and examine documentation regarding staff training and competencies for resuscitation;
(k) Check the availability of trained staff for resuscitation.

4.2.3.4. Image quality

The audit team should:

(a) Review a sample of images from different examination procedures and assess the image quality;
(b) Interview staff regarding their awareness of factors contributing to image quality;
(c) Identify the radiographer responsible for the radiographic QA programme, and discuss their roles and responsibilities;
(d) Interview staff regarding their awareness of image quality evaluation criteria for various examination procedures;
(e) Review records of image quality audits, and records of analyses of rejected and repeat images;
(f) Discuss with radiography staff the feedback given to them about their individual performance;
(g) Check for the process regarding provision of feedback by radiological medical practitioners regarding suboptimal images;
(h) Check for the process for discussing image quality difficulties with the reporting radiological medical practitioner.

4.2.4. The imaging report

The audit team should:

(a) Observe the reporting environment to confirm the presence of prior studies and reports, and reviews of them;
(b) Analyse a random sample of examination reports to assess their contents, including clinical indications, a description of the technique used, imaging findings and their correlation, and guidance for further management;
(c) Review a random sample of reports to confirm the presence of final signatures;
(d) Request a sample of reports in which untoward effects have been documented.

4.2.5. Report communication

The audit team should:

(a) Review departmental process documentation for ensuring that all completed examinations are reported and that reports are distributed effectively;
(b) Review a sample of reports to assess whether reports are thorough and timely;
(c) Discuss with staff the methods of report communication;
(d) Check medical records for documentation that urgent and emergency results are communicated appropriately;
(e) Interview referring medical practitioners for their satisfaction with the timeliness, appropriateness and completeness of reporting;
(f) Review audit records of report communication.

4.2.6. Continuity of clinical care

The audit team should:

(a) Examine departmental rosters for multidisciplinary clinico-pathologic correlation meetings, tumour boards and morbidity/mortality conferences, and results recording;
(b) Assess documentary evidence of attendance of radiological medical practitioners and other radiology staff at multidisciplinary clinico-pathologic correlation meetings, tumour boards and morbidity/mortality conferences;
(c) Review examples of tracking of patient outcomes;
(d) Assess documentary evidence of internal and external audits of involvement of individual radiological medical practitioners in reviews of patient outcomes.

4.2.7. Accident and incident reporting

The audit team should:

(a) Examine documented protocols for handling of patient safety incidents and sentinel events;
(b) Review the log book of critical incidents, for example, sentinel reports, their analysis and resulting actions;
(c) Review the log book of serious patient safety incidents for the manner in which the incidents are reported, analysed and responded to;

(d) Request evidence of quality improvement initiatives derived from accident and incident analysis.

4.2.8. Record and image retention

The auditors should:

(a) Review policies and procedures for record and image retention, and confirm that these meet regulatory requirements;
(b) View the location of retained records for security of storage and accessibility;
(c) Check a sample of records for clarity of patient identification;
(d) Check for evidence of tracking and compliance audit records.

5. TECHNICAL PROCEDURES

5.1. PRINCIPLES AND CRITERIA FOR GOOD PRACTICE

The principles and criteria for good practice of the technical aspects of radiology involve the available facility infrastructure, radiation protection and safety, imaging equipment QA processes, optimization in clinical practice, dosimetry, and instrumentation and calibration. All policies and procedures should be documented and regularly updated, and be available to staff at all times.

The imaging modalities and auxiliary support equipment used in radiology include the following:

—Plain radiography;
—Fluoroscopy;
—Image guided interventional procedures;
—Mammography;
—Computed tomography;
—Dental radiography;
—Ultrasonography;
—Magnetic resonance imaging;
—Dual energy X ray absorptiometry (DXA);
—Screen–film systems and cassettes;

—Digital image receptors (computed radiography (CR) or direct digital);
—Image displays (film viewing boxes, workstations and display monitors);
—Hard copy devices (printers and film processors);
—Digital scanners and storage systems.

The following principles and criteria for good practice should be applied as appropriate to all of the above mentioned modalities and equipment.

5.1.1. Infrastructure

A supportive infrastructure is essential to produce the good quality patient images needed for accurate diagnosis, which are obtained with low radiation dose in an environment that is safe for patients, radiology personnel and the public. This infrastructure includes the organizational structure, personnel, management and documentation.

5.1.1.1. Organizational structure

A medical physicist, with competence in diagnostic radiology, has primary responsibility for most of the technical aspects within radiology, including equipment QA, dosimetry and calibration, and, furthermore, the medical physicist provides specialist expertise with respect to radiation protection of the patient.

The medical physicist may also be appointed as the facility's radiation protection officer[7] (RPO). The RPO has responsibility for radiation protection of staff and the public, but not for radiation protection of patients. However, in some institutions, the RPO may be a health physicist and not a medical physicist and, furthermore, may be external to the radiology facility. If the RPO is not a member of the radiology facility, a suitably trained staff member should be appointed as deputy to the RPO and maintain regular, close contact with the RPO. The RPO should report to a Radiation Safety Committee. This committee should meet regularly, and be responsible for the radiation safety policy of the institution/facility, its monitoring and its evaluation. There should be a manual covering all relevant aspects of radiation protection (see Sections 5.1.1.4 and 3.1.2). A

[7] A person technically competent in radiation protection matters relevant for a given type of practice, who is designated by the registrant or licensee to oversee the application of the relevant requirements established in international safety standards. Such a person is also sometimes known as a radiation safety officer.

documented process should exist to regularly review the adequacy of all radiation protection provisions.

5.1.1.2. Personnel

The assurance of quality in image related technical processes undertaken within the radiology facility requires the availability of appropriate staff with adequate training in technical processes, including training in the principles and practice of QA. While requirements will vary with the complexity and size of the radiological facility, the following professionals should be involved in the imaging QA programme:

—Medical physicist(s) competent in diagnostic radiology[8];
—Radiographers[9];
—Quality assurance radiographer(s);
—Service technicians/engineers.

In addition, other staff may also be involved, particularly for digital systems including teleradiology, who may include:

—Nurses;
—Information technology support staff;
—Administrative staff.

There should be documented and appropriate training for all staff (see Section 3.1.3.1).

5.1.1.3. Management support

Quality assurance activities and safety and radiation protection should be supported by the management of the institution and/or facility through:

(a) Ensuring that sufficient time is scheduled for the designated staff to carry out their activities and corrective action follow-up;

[8] Large facilities will have full-time medical physicists available. All practices should have access to a medical physicist; the extent of involvement of the physicist is dependent on the complexity and number of the procedures undertaken. Note that this person is also identified as the medical physics expert in Europe [2].

[9] These include professionals with expertise in MRI and ultrasound.

(b) Ensuring that appropriate equipment is available;
(c) Ensuring that appropriate reference material is available;
(d) Supporting necessary corrective actions.

5.1.1.4. Documentation

Quality assurance policies and procedures for all imaging modalities and auxiliary equipment, as well as radiation protection policies and procedures, should be documented in quality manuals and be readily accessible to staff at all times. Equipment documentation should be complete (see Section 3.1.5).

The following specific documentation is required:

(a) General:
  (i) Equipment and room condition documentation;
  (ii) An operator's manual and user charts/guides;
  (iii) Training manuals for personnel to use equipment;
  (iv) Imaging protocols, including those for procedure optimization, and typical patient dose data (see Sections 4.1.3.2 and 4.1.3.4).
(b) Quality assurance:
  (i) Acceptance testing guides;
  (ii) Quality control protocols and schedules;
  (iii) Image quality evaluation guide, repeat/reject analysis protocol and records of results;
  (iv) Equipment maintenance manuals;
  (v) Equipment disposal documentation.
(c) Radiation protection and safety (see Section 5.1.2):
  (i) Results with details of conduct and frequency of radiation protection surveys and shielding checks;
  (ii) Records of patient radiation protection measures taken (see also Sections 5.1.3–5.1.5);
  (iii) Inventory of available radiation protection devices (e.g. lead aprons and portable shields);
  (iv) Room access control, warning signs and signals documentation.
(d) Dosimetry:
  (i) Inventory of dosimetry equipment and calibration documentation;
  (ii) Calibration methodology manual;
  (iii) Patient dose determinations and diagnostic reference levels (DRLs);
(e) Reports from regulatory inspections and voluntary audits.

5.1.2. Radiation protection and safety

The requirements for radiation protection and safety are found in the International Basic Safety Standards [4]. In addition, there is a requirement for other types of safety including electrical, mechanical and laser safety.

5.1.2.1. Medical exposure

It is required that the following activities occur:

(a) Justification of the examination, which is initiated by the referring medical practitioner but is the final responsibility of the radiological medical practitioner (see Section 4.1.1);
(b) Optimization of procedures, which is the joint responsibility of radiologists, radiographers and medical physicists (see Sections 4.1.3.2, 4.1.3.4 and 5.1.4);
(c) Quality assurance for equipment under the supervision of the medical physicist (see Section 5.1.3);
(d) Patient dosimetry under the supervision of the medical physicist (see Section 5.1.5);
(e) Calibration of instrumentation under the supervision of the medical physicist (see Section 5.1.6).

In addition, there should be documented policies and procedures for:

(a) Risk assessment and management;
(b) Dose audits for common examinations for comparison with relevant DRLs;
(c) Optimization of imaging examinations;
(d) Size adjusted imaging techniques for paediatric patients;
(e) Pregnant or potentially pregnant patients [24, 27–29], which includes:
    —Signage;
    —Verification of pregnancy status;
    —Optimization of examination procedures;
    —Documentation of foetal dose estimates;
(f) Accidents and incidents (e.g. accidental exposures).

Comforters and carers of patients must be provided with adequate radiation protection, as appropriate.

5.1.2.2. Occupational and public exposures

Hazardous areas must be appropriately classified and identified.

Members of staff who are occupationally exposed to radiation must be identified and monitored with personal monitoring devices as specified by local laws and international standards. Records of the results of such monitoring must be kept and made available to the relevant staff.

Protective devices must be available and worn by staff as appropriate.

Policies must be in place for providing radiation counselling, additional shielding and radiation monitoring (as appropriate for the exposure environment) for staff who declare that they are pregnant. If possible, temporary rotation of pregnant staff to environments with no exposure or a lower exposure should be considered.

Visitors must be provided with adequate radiation protection as appropriate.

All X ray equipment, including mobile equipment, must be utilized in rooms with adequate shielding as specified by local laws and following the widely accepted recommendations of national and professional bodies [30, 31]. Calculations must be done for appropriate shielding and then verified by measurements. Changes in functional design or patient workload must be regularly monitored to ensure protection of all staff and members of the public.

Emergency contingency plans must be available for the protection of staff and the public.

5.1.3. Quality assurance processes for imaging equipment

5.1.3.1. Selection of equipment

The first step in good QC of equipment is the selection of high quality equipment appropriate for the required clinical imaging procedure.

Selection of equipment should be undertaken by a team of senior staff, including a specialist radiological medical practitioner, a senior radiographer and a medical physicist. This process will usually involve the drafting of equipment specifications, a tender process and evaluation of the resulting tenders.

Fundamental considerations for equipment specifications should include:

(a) Site requirements and room design;
(b) Radiation shielding (or magnetic and radiofrequency shielding for MRI units);
(c) Technical specifications for equipment performance;
(d) Image quality requirements;
(e) Patient dose implications;

(f) Equipment ergonomics;
(g) Economic considerations, including the cost of purchase and installation, and the ongoing costs for maintenance and supplies;
(h) Availability and quality of service and maintenance;
(i) Integration into a digital environment;
(j) Availability of operating guides.

5.1.3.2. Acceptance testing and the setting of baseline values

Acceptance testing assures the purchaser that new equipment meets the standards specified before purchase. Acceptance testing will be done by the medical physicist and/or by the vendor engineers under the supervision of the medical physicist, as appropriate.

The management of the radiology unit should take action to ensure that equipment meets the agreed standard before the purchase process has been completed.

The establishment of baseline values as part of equipment commissioning ensures that effective standards are established for QC testing of the equipment.

There should be a documented protocol for acceptance testing and baseline measurements, and each piece of equipment should have an acceptance and commissioning report that is available for the life of the equipment (see Section 3.1.4.2).

5.1.3.3. Routine quality control testing

Each equipment modality and piece of associated auxiliary equipment should have an appropriate QC system in place that evaluates equipment performance, stability and safety, as well as image quality. Quality control tests should be carried out regularly, after major repair or maintenance procedures, and whenever a change of performance is suspected. These systems should be documented in a written protocol and include the following elements:

(a) The persons responsible for performing and evaluating tests;
(b) The required QC test equipment;
(c) The minimum frequency of regular QC tests;
(d) The test procedures:
    —Equipment QC tests,
    —Reject analysis,
    —Review of radiographic technique;
(e) Test forms or charts for recording of results;

(f) Performance criteria for all the tests, ideally both remedial and suspension levels;
(g) The corrective actions necessary when the performance criteria are not met:
—The type of corrective action,
—The time-frame for corrective action,
—Verification that corrective action has been effective.

The records of QC test results and corrective actions taken should be readily available.

5.1.3.4. Equipment replacement policy

Equipment that is old, obsolete or poorly maintained may fail to give the required image quality for effective diagnosis, give excessive doses to patients or be dangerous as an electrical or mechanical hazard.

Severely defective equipment must be put out of service. If only a limited number of components of the equipment are defective, the equipment may be allowed to operate in a limited capacity, provided that the overall performance of the equipment is not impaired. Equipment with minor defects may be used for a limited period until repair is possible, as long as its use does not significantly degrade image quality or create a significant hazard to patients or staff.

A policy should exist for the timely repair and/or replacement of defective equipment.

5.1.4. Optimization in clinical practice

Optimization of image quality and patient dose is a dynamic process that aims to give sufficient diagnostic image quality with minimum doses to patients. Optimization involves inputs from the radiological medical practitioner, radiographer and medical physicist. The procedure used for examination optimization should be documented.

While all imaging examinations should be optimized, the following require special attention:

—Computed tomography examinations;
—Screening programmes (e.g. mammography);
—Interventional or procedural examinations;
—Examinations involving infants or children;
—Examinations involving pregnant patients;
—Volunteers for research (if applicable).

5.1.5. Dosimetry

5.1.5.1. Dosimetry principles

Provision should be made for the estimation of doses from imaging equipment. A medical physicist is responsible for the acquisition, maintenance and calibration of appropriate dosimetry equipment and specific dosimetry phantoms.

Dose estimates should be in accordance with accepted international protocols [32, 33] and include measurements of:

(a) Incident air kerma, entrance surface air kerma and associated kerma rates;
(b) Kerma area product (KAP);
(c) Relevant quantities for mammography, CT and dental examinations.

5.1.5.2. Patient dosimetry

Protocols should be in place to estimate patient dose or an accepted indication of dose for common procedures, including:

—Plain radiography;
—Fluoroscopy;
—Image guided interventional procedures;
—Mammography;
—Computed tomography;
—Dental radiography.

Patient dose surveys should be regularly scheduled and the results compared with relevant DRLs. Radiography staff should be aware of the importance of collecting the pertinent patient examination information necessary to estimate patient dose for imaging procedures.

An understanding of the effect of size on patient dosimetry is necessary.

In some cases, it is useful to estimate patient dose levels through the use of phantoms. This is particularly the case when evaluating the set-up of automatic exposure control devices. Appropriate phantoms to ensure optimal patient dose should be available to standardize the set-up dose of imaging equipment and to ensure the maintenance of these standards.

Estimating resultant patient doses is an essential part of revising radiological techniques and procedures to optimize image quality.

Dosimetry for those subjected to radiation imaging as part of an imaging research protocol is an essential component of clinical radiological research activities.

Dosimetry methods used to estimate foetal dose should be documented.

5.1.5.3. Occupational dosimetry

Although routine occupational monitoring is typically the responsibility of the RPO, certain situations may require additional personnel monitoring. This may be a specialized process under the supervision of the medical physicist. This includes additional personal monitoring for interventional fluoroscopy examinations, monitoring of pregnant staff, and monitoring incidents of accidental personnel exposures.

5.1.6. Instrumentation and calibration

The QA radiographer(s) and medical physicist should have access to appropriate calibrated instrumentation, phantoms and other test equipment to perform measurements and testing.

In order to ensure the accuracy of dosimetry and QC measurements, the instruments used for testing must be calibrated at regular intervals against accepted standards. The use of an accepted field cross-checking methodology is encouraged as a cost effective way of maintaining acceptable dosimetry standards. The facility should have a calibration policy and a record of equipment calibration and equipment cross-checks.

5.2. THE AUDIT PROGRAMME

Annex III contains checklists for the following equipment-specific areas to assist the auditor in reviewing radiation protection, as well as the general safety and QC practices of the facility:

—Plain radiography;
—Fluoroscopy and image guided interventional procedures;
—Mammography;
—Computed tomography;
—Dental radiography;
—Ultrasonography;
—Magnetic resonance imaging;
—Screen–film systems and cassettes;

— Digital image receptors (CR or direct digital);
— Image display devices (film viewing boxes, workstations and display monitors);
— Image viewing conditions;
— Hard copy devices (printers and film processors);
— Digital scanners and storage systems.

5.2.1. Infrastructure

5.2.1.1. Organizational structure

The audit team should:

(a) Identify the facility's medical physicist;
(b) Identify the RPO and their deputy, if applicable (a deputy being essential if the RPO is not a full-time member of the facility), and discuss documented qualifications and training;
(c) Review the existence, membership and work of the Radiation Safety Committee;
(d) Review the radiation protection manual to ensure that it is current, that it documents all relevant areas of radiation protection, and that it is regularly reviewed;
(e) Seek clarification on the organization of radiation protection from the director of the facility and/or the RPO, as necessary.

5.2.1.2. Personnel

The audit team should:

(a) Review the role of medical physicists in directing and supervising QA activities, radiation protection practice and dosimetry;
(b) Review the role of the RPO with respect to occupational radiation protection and radiation protection of the public;
(c) Review the duties of radiology facility staff to determine their role in QA processes, radiation protection and patient dose data collection;
(d) Review the syllabus and frequency of hospital based radiation protection and safety training programmes for staff;
(e) Determine, through interaction with staff, their practical knowledge of radiation safety principles.

5.2.1.3. Management support

The audit team should:

(a) Review the structure of radiation protection and safety and technical QA management and corrective actions within the radiology facility through written records and discussion with staff;
(b) Determine if sufficient time is provided to the QA radiographer(s) and the medical physicist to carry out their activities and corrective follow-up;
(c) Determine if management supports necessary corrective actions;
(d) Discuss the strengths and weaknesses of the radiation protection and safety and QA programmes with the facility management, medical physicist and QA radiographer.

5.2.1.4. Documentation

The audit team should identify documentation on policy and procedures for QA, radiation protection, dosimetry and general matters as well as reports of regulatory inspections and voluntary audits, and confirm that they are accessible.

5.2.2. Radiation protection and safety

5.2.2.1. Medical exposure

The audit team should:

(a) Review facility policies on:
  (i) Risk assessment and management;
  (ii) Estimation of typical patient dose levels from common examinations and comparison of them with relevant DRLs;
  (iii) Optimization of imaging examination;
  (iv) Size adjusted imaging techniques for paediatric patients;
  (v) Pregnant or potentially pregnant patients;
  (vi) Adverse patient dose incidents.
(b) Examine policies for comforters and carers in controlled areas and supervised areas or other hazardous areas, to ensure that they are consistent with legal requirements or relevant guidelines.
(c) Clarify with the facility director, senior radiographer and medical physicist any aspects of the facility's policy for radiographic examinations of infants, children or pregnant patients, as necessary.

(d) Discuss with staff their knowledge of procedures relating to policies and radiation monitoring for infants, children and pregnant (or potentially pregnant) patients.

5.2.2.2. Occupational and public exposure

The audit team should inspect selected work areas and observe:

(a) Equipment and room conditions;
(b) Availability of manuals and technique guides;
(c) Availability of protective devices (e.g. lead aprons and portable shields) and accessories;
(d) Room access control and warning signs.

The audit team should also:

(a) Review occupational dose monitoring policy and monitoring records;
(b) Review records verifying the integrity of protective devices;
(c) Review policy for pregnant staff, and discuss with the facility director, senior radiographer and RPO;
(d) Discuss with staff their knowledge of radiation monitoring and provision for pregnant staff;
(e) Review the facility's policy for classification and identification of hazardous areas;
(f) Examine policies for visitors in controlled areas and supervised areas or other hazardous areas to ensure that they are consistent with legal requirements or relevant guidelines;
(g) Examine a sample of room shielding design reports and discuss these with the RPO, determine that they are consistent with local requirements and international standards, and ensure that adequate shielding verification methods are applied;
(h) Review emergency contingency plans to ensure that they are consistent with legal requirements or relevant guidelines.

5.2.3. Imaging equipment QA processes

5.2.3.1. Selection of equipment

The audit team should:

(a) Peer review a selection of equipment tender documents;

(b) Discuss the facility's policy for selection of equipment, including maintenance considerations, with the facility director, senior radiographer and medical physicist;
(c) Discuss future selection plans for equipment and possible integration into a digital environment.

5.2.3.2. Acceptance testing of equipment and the setting of baseline values

The audit team should:

(a) Examine available acceptance testing protocols and peer review a selection of these protocols;
(b) Peer review a selection of equipment acceptance documents, and discuss any action that was taken as a response to such reports;
(c) Discuss the facility's policy for acceptance testing with the facility director, senior radiographer and medical physicist.

5.2.3.3. Routine quality control testing

The audit team should:

(a) Discuss the facility's policy for QC testing with the senior radiographer and medical physicist;
(b) Examine available QC testing protocols, and peer review a selection of these protocols;
(c) Peer review a selection of QC records and discuss any action that was taken as a response to such reports (e.g. repeat/reject analysis);
(d) Observe and review staff undertaking a variety of QC tests.

5.2.3.4. Equipment replacement policy

The audit team should:

(a) Discuss with the director of the facility, senior radiographer and medical physicist the facility's policy for equipment replacement;
(b) Examine documentation involving equipment replacement.

5.2.4. Optimization in clinical practice

The audit team should:

(a) Review the facility's policy on imaging examination optimization;
(b) Peer review selected documentation on optimization, including documentation on:
—Computed tomography examinations;
—Screening programmes (e.g. mammography);
—Interventional or procedural examinations;
—Examinations involving infants or children;
—Examinations involving pregnant patients;
—Volunteers for research.

5.2.5. Dosimetry

5.2.5.1. Dosimetry principles

The audit team should:

(a) Review the facility's policy on dosimetry;
(b) Discuss with the medical physicist the methods of patient dose determination, as well as the dose quantities and units used for measurement and dose estimation.

5.2.5.2. Patient dosimetry

The audit team should:

(a) Discuss with the medical physicist the dosimetry protocols used for determining the dose to the patient from different modalities;
(b) Discuss with the medical physicist any software used for dose calculations;
(c) Discuss with the medical physicist and relevant radiographers the conduct of patient dose audits and review records;
(d) Review the use of DRL values for patient examinations;
(e) Review the use of phantoms to determine typical patient doses for appropriate modalities;
(f) Peer review selected dosimetry calculation sheets or software for dose estimates made both with and without phantoms;

(g) Discuss with the medical physicist the dosimetry principles involved in estimating dose parameters for patients, especially when considering patient size and particular organ doses;
(h) Discuss with the medical physicist the dosimetry protocols used as part of imaging research (if applicable);
(i) Peer review a selection of dosimetric records of patients who have been exposed during pregnancy.

If time permits, the audit team should:

(j) Determine the incident air kerma or entrance surface air kerma for a chest radiograph using a standard phantom and automatic exposure control (AEC) conditions for one selected radiographic unit (see Appendix V and Annex IV).
(k) Perform typical phantom dose measurements for both a typical CT examination and a typical mammographic examination (see Appendix V and Annex IV). Compare with similar results obtained in the facility.
(l) Determine the incident air kerma rate or entrance surface air kerma rate for abdominal fluoroscopy using a standard phantom and AEC conditions for one selected procedure (see Appendix V and Annex IV).

5.2.5.3. Occupational dosimetry

The audit team should:

(a) Determine if the medical physicist performs customized, special case, staff dosimetry;
(b) Review examples of customized, special case, staff dosimetry.

5.2.6. Instrumentation and calibration

The audit team should:

(a) Review equipment inventory and calibration documentation to check that it is current and available;
(b) Review the adequacy and suitability of QC instrumentation;
(c) Discuss with the medical physicist the facility's policy for instrument calibration and cross-checks;
(d) Examine the calibration programme for dosimetric instrumentation;
(e) Review the calibration records of the instruments used by the medical physicists;

(f) Cross-check selected dosimetric equipment from the facility using calibrated equipment brought by the audit team;
(g) Discuss the calibration of KAP meters and check selected meter calibrations if time allows.

6. EDUCATION, TRAINING AND RESEARCH PROGRAMMES

6.1. PRINCIPLES AND CRITERIA FOR GOOD PRACTICE

6.1.1. Education and training programmes

Education and training are essential for health professionals involved in diagnostic radiology. These can take many forms, including academic, clinical and miscellaneous. These programmes include all personnel in the multidisciplinary team working in a radiology facility.

The extent and diversity of programmes offered by the facility, coupled with potentially limited resources, require that a professional officer be assigned to oversee the management of education and training within the facility.

6.1.1.1. Academic education programme

While academic education is under the direction of a university or professional body, and is often located in a university setting, full or partial academic programmes may also operate within the radiology facility environment. Examples include professionals enrolled in:

(a) Integrated academic and clinical programmes operating on one campus;
(b) Part-time study with lecture programmes within the facility;
(c) Distance education programmes.

While the quality of academic programmes is generally considered to be beyond the scope of these audit guidelines, it is expected that academic programmes that give basic qualifications to health professionals will have:

— A syllabus that is subject to appropriate review;
— Lecturers with adequate qualifications.

Professionals engaging in such programmes will benefit from the following provisions:

(a) A facility policy to allow release from clinical duties for academic education;
(b) Access to adequate library, Internet and computing facilities;
(c) Adequate lecture facilities, including provision to display images with a satisfactory quality;
(d) A support network that allows discussion of study material.

6.1.1.2. Clinical training programme

Clinical training may be internal to the facility, or it may more typically be under the direction of an external body such as a university or a professional body. It is possible that participants will be required to rotate between different radiology facilities in order to cover all the aspects of training required.

The clinical training programme should:

(a) Have appropriate external accreditation or recognition;
(b) Be under the direction of a recognized body;
(c) Be conducted in a facility that is approved for clinical training;
(d) Have a person responsible for its conduct in the facility;
(e) Be structured and follow a recognized syllabus;
(f) Have identified specially qualified or trained clinical supervisors who are competent to instruct those in the programme;
(g) Be aware of radiation training and monitoring requirements for participants.

To be effective the clinical training programme should:

(a) Have a sufficient number of supervisors to instruct or mentor the number of participants involved;
(b) Be held in a clinical environment that can offer the participants the needed experience;
(c) Be of a sufficient duration to allow adequate skills to be acquired;
(d) Have identified and appropriate assessment.

6.1.1.3. Miscellaneous educational and training programmes

Educational or training programmes that are not formal academic or structured clinical training are common and useful in a diagnostic radiology facility. Such programmes vary in length and should be available to a wide range

of personnel, including those internal and external to the radiology facility. Such programmes could include:

(a) Clinical education (e.g. image evaluation, radiographic techniques, equipment information and resuscitation);
(b) Professional meetings and interdisciplinary meetings;
(c) Statutory and regulatory training (e.g. radiation safety, fire safety, lifting and handling);
(d) Internal and external audit reviews.

6.1.2. Research

Research, including participation in clinical trails, has many benefits for a radiology facility, including its impact on the quality of clinical practice and staff development.

The research programme should:

(a) Comply with a clear policy statement that includes matters of ethics, governance and the role and structure of the research committee of the institute/facility;
(b) Conform to recognized ethical standards for research activities, including those for patient radiation protection and the use of pre-planning patient dose estimates;
(c) Have the infrastructure needed to support the research.

To be effective, a research programme should:

(a) Have high quality scientific personnel with a record in research;
(b) Publish the results of scientific research;
(c) Attract research funding to purchase any necessary materials, technical assistance or machine time;
(d) Allow time for personnel to devote to research activities;
(e) Conduct regular meetings to discuss research matters;
(f) Provide access to, or support for, professional statistical data analysis;
(g) Provide access to adequate library and computing facilities.

When research is limited to small projects for postgraduate students or clinical trainees, it is important that:

—Research activities be coordinated by a designated person;
—Regular research meetings be held;
—Experienced researchers be available to assist students.

6.2. THE AUDIT PROGRAMME

6.2.1. Education and training programmes

The audit team should investigate the organization of education and training within the facility, and identify the officer responsible for this activity.

6.2.1.1. Academic education programme

The audit team should:

(a) Identify and comment on the type and extent of any academic education programmes currently available or supported through the radiology facility involving:
  (i) Radiological medical practitioners;
  (ii) Radiographers;
  (iii) Medical physicists.
(b) Review identified available academic education programmes for the following attributes:
  (i) A policy to allow release from clinical duties for lectures and study;
  (ii) Access to adequate library, Internet and computing facilities;
  (iii) Adequate lecture facilities, including provision to display images with a satisfactory quality;
  (iv) A support network that allows discussion of study material.

6.2.1.2. Clinical training programme

The audit team should:

(a) Identify available clinical training programmes for radiological medical practitioners, radiographers and medical physicists.
(b) Identify whether clinical training is under internal or external direction, and whether rotation of participants is required.
(c) Review identified clinical training programmes for the following attributes:
  (i) Appropriate external accreditation or recognition;
  (ii) Facility accreditation or approval for clinical training;
  (iii) Being under the direction of a recognized body;
  (iv) The suitability of the person responsible for the conduct of clinical training programmes in the facility;
  (v) Their structure and a recognized syllabus;

(vi) Specially qualified or trained clinical supervisors who are competent in instruction;
(vii) Radiation training and monitoring requirements for participants.

(d) Discuss aspects of the clinical training programme with both supervisors and participants to ascertain if the programmes:
(i) Have sufficient numbers of supervisors to instruct or mentor;
(ii) Are held in a clinical environment offering the needed experience;
(iii) Are of a sufficient duration for the acquisition of adequate skills;
(iv) Have identified and appropriate assessment.

6.2.1.3. Miscellaneous educational and training programmes

The audit team should identify the availability of and access to miscellaneous facility programmes, such as:

(a) Clinical education (e.g. image evaluation, radiographic techniques, equipment information and resuscitation);
(b) Professional meetings and interdisciplinary meetings;
(c) Statutory and regulatory training (e.g. radiation safety, fire safety, lifting and handling);
(d) Internal and external audit reviews.

6.2.2. Research

The audit team should:

(a) Determine if research is carried out in the facility, including:
(i) Clinical research, possibly including participation in clinical trials;
(ii) Research projects undertaken by staff as a part of education and training.

(b) Review identified research programmes for the following attributes:
(i) A clear policy statement on ethics, governance, and the role and structure of the research committee of the institute/facility;
(ii) Conformity with recognized ethical standards, including those related to patient dose;
(iii) An infrastructure to support research.

(c) Discuss with relevant staff members:
(i) The availability of high quality scientific research personnel;
(ii) Published research output;
(iii) Adequacy of research funding;
(iv) Adequacy of time allowed for research;

(v) Regularity of research meetings;
(vi) Access to a statistics professional;
(vii) Adequacy of library and computing facilities.

(d) Determine if minor research projects undertaken by staff as a part of education and training have:
(i) A designated coordinator;
(ii) Regular research meetings;
(iii) Access to experienced researchers.

Appendix I

AUDIT FLOW CHARTS

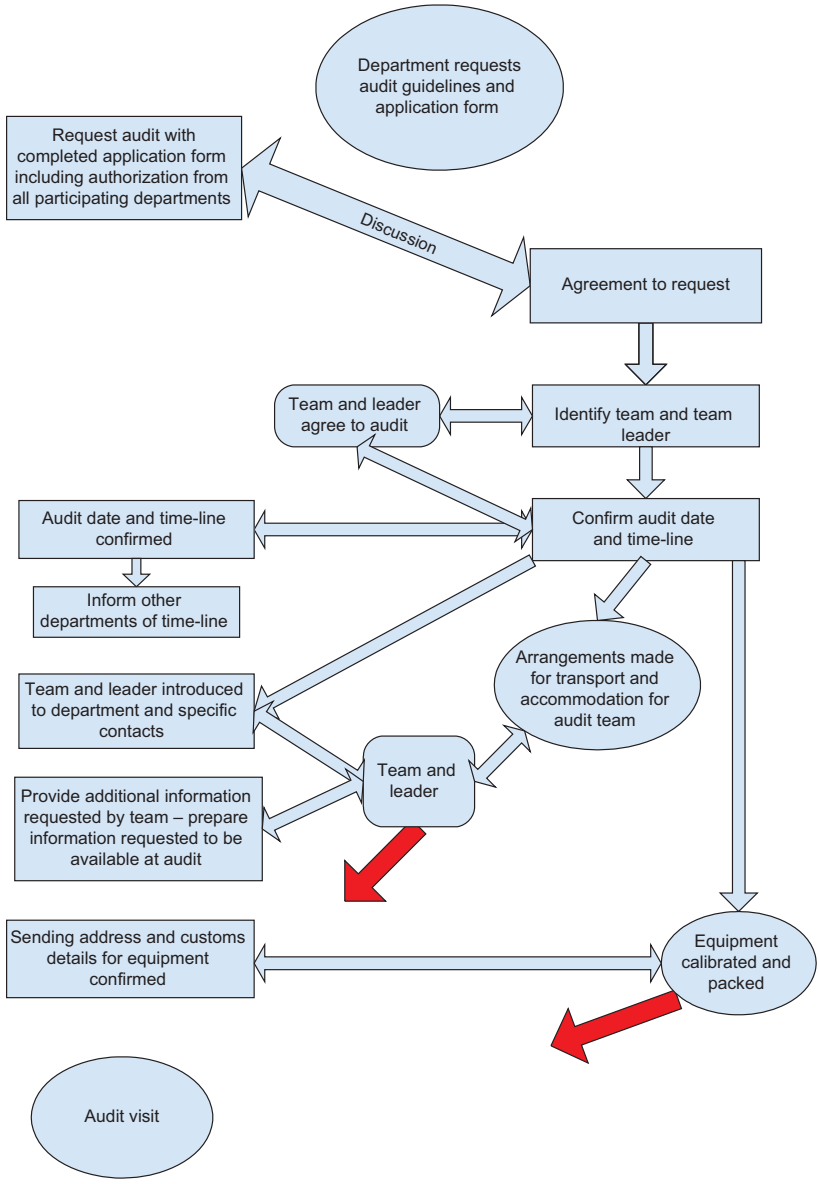

FIG. 1. Schematic diagram of the clinical audit process.

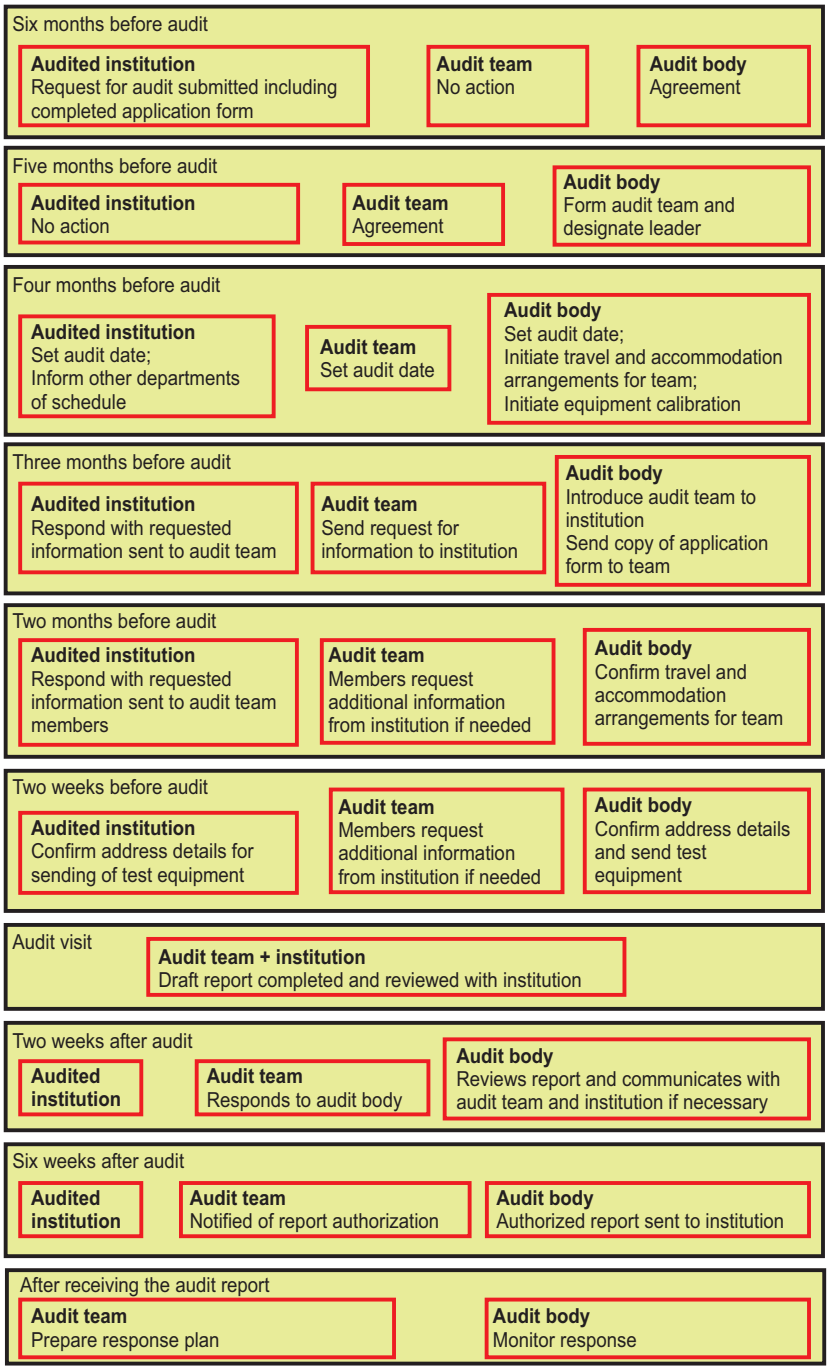

FIG. 2. Time-line of clinical audit process.

Appendix II

SUGGESTED SCHEDULE FOR AN AUDIT VISIT

II.1. SUGGESTED SCHEDULE

A suggested schedule for an audit visit is given below (see also Fig. 3).

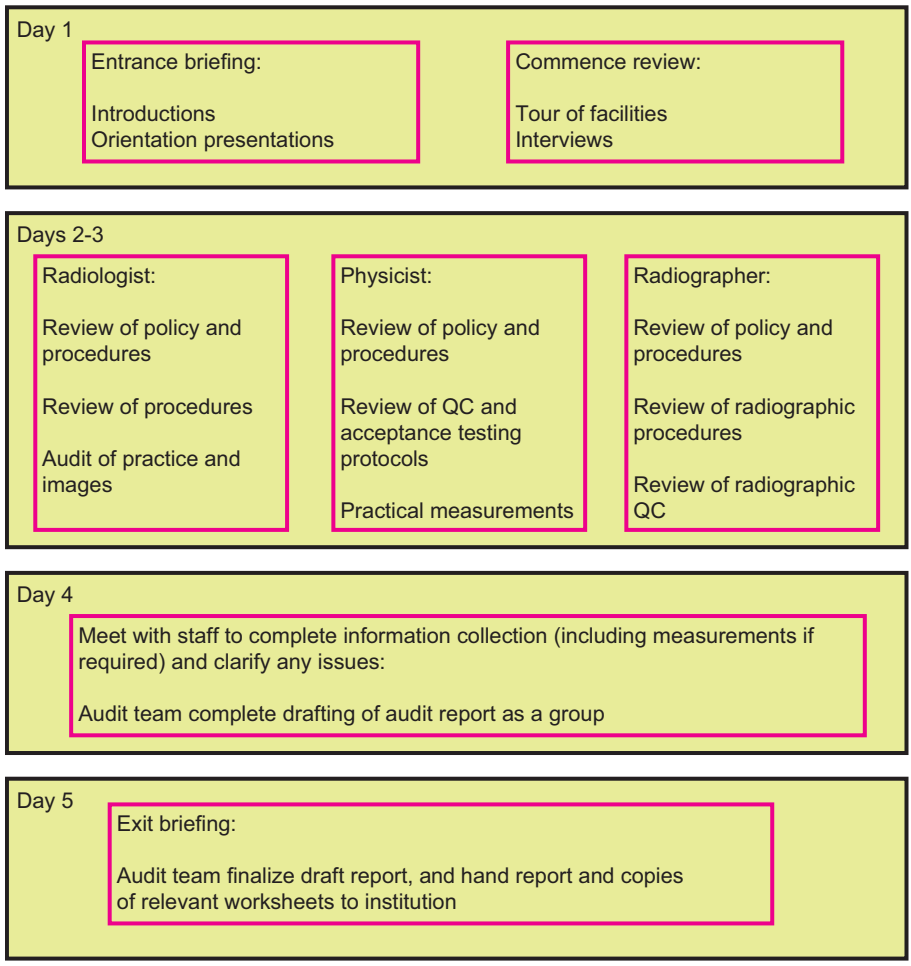

FIG. 3. Programme for a typical clinical audit visit.

Day 1:

Morning: All audit team members and relevant facility/institution personnel are involved in:

—A meeting with key facility/institution personnel;
—An entrance briefing;
—A tour of the facilities.

End of morning: Group audit team discussion time: approximately 30 minutes.
Afternoon: Individual team members to meet with their departmental counterparts and other staff for discussions and a review.
End of afternoon: Group audit team discussion time: approximately one hour.

Day 2:

Morning: Team members continue with discipline-specific reviews.
End of morning: Group audit team discussion time: approximately one hour.
Afternoon: Team members continue with discipline-specific reviews.
End of afternoon: Group audit team discussion time: approximately one hour.

Day 3:

Morning: Team members continue with discipline-specific reviews and clarify any issues.
End of morning: Group audit team discussion time: approximately one hour.
Afternoon: Group audit team commences drafting of audit report.

Day 4:

Morning: Group audit team continues with drafting of audit report. Team members meet with staff as necessary to clarify any issues.
Afternoon: Group audit team completes drafting of audit report.

Day 5:

Morning: All audit team members and relevant facility/institution personnel are involved in an exit briefing and a discussion of the recommendations.
Afternoon: Group audit team to:

—Amend draft report as necessary;
—Give report and copies of audit documents to facility/institution authorities.

Audit team departs.

II.2. REVIEW PROCESS

All team members are to review the following Section 3 (in the main text) items with respect to their own discipline:

(a) Relevant policy and procedure documentation;
(b) Compliance with policies and procedures;
(c) Organizational chart, lines of authority, relevant quality manager(s), and management commitment and support;
(d) Relevant personnel issues, such as qualifications, employment, orientation, training, professional supervision, continuing education, access to publications/information and communication;
(e) Relevant facility issues, such as equipment and available space, condition of equipment and work areas, meeting of patient requirements, meeting of general and radiation safety requirements, inventories and information backup;
(f) Handling of patient confidentiality, information, consent and feedback;
(g) Adverse events recording and response.

The *radiologist in the audit team* is to address Section 4 items by reviewing: request forms; scheduling; imaging examinations; patient verification; images; viewing conditions; reports; contents and storage of patient files; report communication; radiologist QA activities such as audit, multidisciplinary meetings and attendance at conferences; nursing support; training and facilities for contrast use, sedation, anaesthesia, monitoring and resuscitation; and infection control and waste management.

The *radiographer in the audit team* is to address Section 4 and 5 items by reviewing: imaging examinations; patient verification; examination techniques and guidance charts; examination technique records; images and labelling; QC procedures and records; radiographer QA/quality improvement activities, such as image quality reviews; and CPD activities, such as attendance at meetings and conferences.

The *physicist in the audit team* is to address Section 5 items by reviewing: imaging examinations; technique guidance charts and technique records; image quality; QC procedures and records; QA/QC checks of equipment; staff, patient and public radiation protection; room radiation protection and safety; personnel protective devices; patient dose audits; dosimetry data; and QA processes and process.

The *physicist in the audit team* also carries out QA testing of some of the diagnostic radiology systems, such as fluoroscopy, mammography, interventional radiology and CT systems.

Appendix III

AUDIT REPORT FORMAT: SUMMARY

III.1. TITLE PAGE

This title page should include the name and address of the facility and institution audited, the names of the audit team, identifying the leader, the date of the audit and any identification required by the auditing institution.

III.2. EXECUTIVE SUMMARY

The summary will not exceed three pages in length, should indicate the purpose of the audit and should comment on the extent to which the facility/ institution has met the criteria for good practice as outlined in the guidelines, and summary of main recommendations.

III.3. RECOMMENDATIONS

This section of the report will be prepared for three distinct audiences:

(1) The audited facility/institution: These recommendations should address minor or major problems potentially resolvable by the institution.
(2) External organizations (e.g. government agencies): These recommendations should address major problems that may require intervention from outside the institution for resolution and other recommendations that should be brought to the attention of the government.
(3) The auditing body: These recommendations should address issues within the authority of the auditing body, for example, the need for additional training of auditors. (These recommendations will not be distributed outside of the auditing body.)

All recommendations should be prioritized in order of importance as determined by the audit team. Any issues involving serious safety issues should be amongst the highest priority issues and be appropriately highlighted.

While it is the role of the audit team to identify areas for improvement of the services provided by the institution, it is not the responsibility of the auditing body to rectify any deficiencies identified. Rather, its role is to facilitate improvement and learning.

III.4. MAIN BODY

The main body of the report will include:

(a) The names of the individuals involved with the audit:
— Those requesting the audit,
— The heads of the audited departments,
— The contact persons for the audit;
(b) The objectives of the audit as proposed by the facility/institution;
(c) A description of audit activities and findings in the following areas:
— Quality management procedures and infrastructure,
— Patient related procedures,
— Equipment related procedures;
(d) Conclusions;
(e) Annexes:
— A full list of individuals interviewed during the audit,
— The application of the facility/institution,
— Any other documents relevant to the audit.

Appendix IV

AUDIT REPORT FORMS

The completed audit report forms, which follow the issues outlined in Sections 3–6 of these guidelines, will form the body of the report.

The key for this appendix is as follows:

Y – Yes (i.e. available, performed or adequate);
NI – Needs improvement;
N – No (i.e. not available, not performed or not adequate);
NA – Not applicable.

Note that these forms are for field use and relate to appropriate sections as indicated. For example, Form 3.3 relates to Section 3 (Quality management procedures and infrastructure), specifically Section 3.1 (Principles and criteria of good practice) should be read with Section 3.2 (Audit programme), which suggests approaches to verifying Section 3.1, the results of this are then recorded in Form 3.3. Note that the subheading notation is consistent throughout Sections 3.1 and 3.2 and also in Form 3.3 to allow ease of use. A similar approach is used for Forms 4.3, 5.3 and 6.3, which relate, respectively, to Sections 4 (Patient related procedures), 5 (Technical procedures) and 6 (Education, training and research programmes). Soft copies of these forms are available for optimal field application.

3.3. QUALITY MANAGEMENT PROCEDURES AND INFRASTRUCTURE AUDIT REPORT FORMS

Audit criteria	Adequacy	Comments	Summary
3.3.1. Mission and vision of diagnostic radiology facility			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc.
3.3.1.1. Objectives of the facility			
Quality manual	☐ ☐ ☐ ☐ Y NI N NA		
Mission statement	☐ ☐ ☐ ☐ Y NI N NA		
Facility service objectives	☐ ☐ ☐ ☐ Y NI N NA		
Role in teaching and research	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Facility financial structure	☐ ☐ ☐ ☐ Y NI N NA		***QUAADRIL guideline references:*** 3.3.1.1. Objectives of the department The role of the diagnostic radiology facility 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 quality manual. (Cut and paste the pertinent QUAADRIL guideline into the summary to support the recommendations.)
Meeting of objectives	☐ ☐ ☐ ☐ Y NI N NA		
Adequacy of objectives	☐ ☐ ☐ ☐ Y NI N NA		
Annual activity plan	☐ ☐ ☐ ☐ Y NI N NA		
Vision statement and long term objectives	☐ ☐ ☐ ☐ Y NI N NA		
3.3.1.2. Patient demographic data and facility workload			
Demand for imaging services: Examination data and trend information	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Patient age data	☐ ☐ ☐ ☐ Y NI N NA		
Emergency/urgent service data	☐ ☐ ☐ ☐ Y NI N NA		
Staffing data and plans	☐ ☐ ☐ ☐ Y NI N NA		
Funding mechanisms	☐ ☐ ☐ ☐ Y NI N NA		
Development plans	☐ ☐ ☐ ☐ Y NI N NA		
3.3.2. Quality management system			***Summary:*** Indicate positive findings.
Quality manager	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Quality manager roles and responsibilities	☐ ☐ ☐ ☐ Y NI N NA		***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Quality assurance committee	☐ ☐ ☐ ☐ Y NI N NA		
Quality assurance committee records	☐ ☐ ☐ ☐ Y NI N NA		
Quality management activity coverage	☐ ☐ ☐ ☐ Y NI N NA		
Quality management staff	☐ ☐ ☐ ☐ Y NI N NA		
Quality manual or equivalent	☐ ☐ ☐ ☐ Y NI N NA		
Quality manual review process	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Quality audit programme	☐ ☐ ☐ ☐ Y NI N NA		
3.3.3. Structure of the diagnostic radiology facility			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
3.3.3.1. Personnel			
Range of staff employed/contracted	☐ ☐ ☐ ☐ Y NI N NA		
Trainee and supervisory staff	☐ ☐ ☐ ☐ Y NI N NA		
Staff qualifications	☐ ☐ ☐ ☐ Y NI N NA		
Staff training	☐ ☐ ☐ ☐ Y NI N NA		
Professional supervision	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Policy and procedures for staff management: recruitment, job descriptions, orientation, etc.	☐ ☐ ☐ ☐ Y NI N NA		
Staff performance appraisals	☐ ☐ ☐ ☐ Y NI N NA		
Continuing professional development records	☐ ☐ ☐ ☐ Y NI N NA		
Continuing professional development activities: internal and external	☐ ☐ ☐ ☐ Y NI N NA		
Individual staff record documentation	☐ ☐ ☐ ☐ Y NI N NA		
3.3.3.2. Facility organization and management			
Senior management commitment to QA/quality improvement	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Quality manual documentation	☐ ☐ ☐ ☐ Y NI N NA		
Organizational chart and lines of authority	☐ ☐ ☐ ☐ Y NI N NA		
Interfacility organizational structure	☐ ☐ ☐ ☐ Y NI N NA		
Hours of operation, staff numbers and rosters	☐ ☐ ☐ ☐ Y NI N NA		
3.3.3.3. Premises			
Cleanliness	☐ ☐ ☐ ☐ Y NI N NA		
Patient comfort, privacy and special needs	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Policies for patient, staff and general public radiation protection	☐ ☐ ☐ ☐ Y NI N NA		
Patient care, movement and access	☐ ☐ ☐ ☐ Y NI N NA		
Floor plans	☐ ☐ ☐ ☐ Y NI N NA		
Environmental control	☐ ☐ ☐ ☐ Y NI N NA		
Internet, library and laboratory access	☐ ☐ ☐ ☐ Y NI N NA		
Physician admitting privileges	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
3.3.4. Equipment			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
3.3.4.1. Equipment policy			
Equipment types and numbers: imaging, software/hardware, auxiliary, QA, dosimetry, medical and administrative	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for equipment QA: before usage, QC and maintenance, safety and infection control	☐ ☐ ☐ ☐ Y NI N NA		
Preventive maintenance records	☐ ☐ ☐ ☐ Y NI N NA		
Staff authorization and training	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Policy and procedures for data protection and backup	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with data protection and backup policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for equipment purchase, usage and replacement	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with equipment purchase, usage, and replacement policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		
3.3.4.2. Equipment inventory			
Equipment coverage: imaging, software/ hardware, auxiliary, QA, dosimetry, medical and administrative	☐ ☐ ☐ ☐ Y NI N NA		
Equipment details: listed in Section 3.1.4.2	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Contrast agents, drugs and medical gases	☐ ☐ ☐ ☐ Y NI N NA		
Method of tracking implanted medical devices	☐ ☐ ☐ ☐ Y NI N NA		
Power supply protection	☐ ☐ ☐ ☐ Y NI N NA		
Information technology network, support, storage and backup facilities	☐ ☐ ☐ ☐ Y NI N NA		
3.3.5. Documentation control			***Summary:*** Indicate positive findings.
Master list document coverage	☐ ☐ ☐ ☐ Y NI N NA		
Master list document unique identification	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Document distribution and availability	☐ ☐ ☐ ☐ Y NI N NA		***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Documents up to date?	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for document review and amendments	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with document review/ amendments policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		
3.3.6. Patient confidentiality, feedback and complaints			***Summary:*** Indicate positive findings.
Policy and procedures for patient confidentiality	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Staff confidentiality agreements	☐ ☐ ☐ ☐ Y NI N NA		***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Policy and procedures for patient complaints	☐ ☐ ☐ ☐ Y NI N NA		
Complaints records, analysis and response	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
3.3.7. Communication			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Intrafacility communication mechanisms	☐ ☐ ☐ ☐ Y NI N NA		
Document availability and access	☐ ☐ ☐ ☐ Y NI N NA		
Technology access	☐ ☐ ☐ ☐ Y NI N NA		
Staff knowledge of policies and procedures and of other documentation	☐ ☐ ☐ ☐ Y NI N NA		
Interfacility communication effectiveness	☐ ☐ ☐ ☐ Y NI N NA		

4.3. AUDIT REPORT FORMS FOR PATIENT RELATED PROCEDURES

Audit criteria	Adequacy	Comments	Summary
4.3.1. Referral of patient for examination			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc.
4.3.1.1. Appropriateness of examination/justification			
Screening examination guidelines	☐ ☐ ☐ ☐ Y NI N NA		
Documented examination guidelines	☐ ☐ ☐ ☐ Y NI N NA		
Process to verify requested data and justify examination selection	☐ ☐ ☐ ☐ Y NI N NA		
Process to change orders	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Policy and procedures for specific examination contraindications	☐ ☐ ☐ ☐ Y NI N NA		***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
4.3.1.2. Quality of referral			
Sample request authorization	☐ ☐ ☐ ☐ Y NI N NA		
Sample request: completeness of general information — patient identification, study, date, referrer identification and contact	☐ ☐ ☐ ☐ Y NI N NA		
Sample request: completeness of clinical information — history, examination indication and pregnancy status	☐ ☐ ☐ ☐ Y NI N NA		
Sample request: completeness of order accuracy — body part, side, etc.	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Sample request: referrer signature and contact details	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for confirming accuracy of request prior to examination	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures on request accuracy	☐ ☐ ☐ ☐ Y NI N NA		
4.3.1.3. Referrer education			
Information availability	☐ ☐ ☐ ☐ Y NI N NA		
Information extent and depth	☐ ☐ ☐ ☐ Y NI N NA		
Radiation information (infancy, childhood and pregnancy status)	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Information update protocol	☐ ☐ ☐ ☐ Y NI N NA		
Information distribution	☐ ☐ ☐ ☐ Y NI N NA		
4.3.1.4. Patient education/consent			
Information availability and content	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for patient consent	☐ ☐ ☐ ☐ Y NI N NA		
Consent discussion	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with consent policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
4.3.1.5. Pre-procedure screening and preparation			
Policy and procedures for identifying 'hazardous' clinical conditions: e.g. allergies or renal impairment	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for hazardous clinical conditions	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for identifying 'safety' clinical conditions: e.g. age, infection or mobility relevant	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for clinical safety	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for examination specific preparation: fasting, etc.	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Compliance with examination preparation policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		
4.3.1.6. Scheduling			
Scheduling of staff clinical training	☐ ☐ ☐ ☐ Y NI N NA		
Request response times, emergency and urgent	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for retrieval of prior imaging examinations and reports	☐ ☐ ☐ ☐ Y NI N NA		
File storage capacity and efficiency	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with retrieval policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Processes for monitoring scheduling efficiency	☐ ☐ ☐ ☐ Y NI N NA		
4.3.2. Identification of the patient			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Policy and procedures for checking patient identification and order of examinations	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for patient identification	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for checking order of examinations	☐ ☐ ☐ ☐ Y NI N NA		
Adequacy of methodology	☐ ☐ ☐ ☐ Y NI N NA		
Reliability of patient identification and examination order: check made by radiographer/radiological medical practitioner	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Audit process	☐ ☐ ☐ ☐ Y NI N NA		
4.3.3. Examinations			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc.
4.3.3.1. Patient confidentiality and physical privacy			
Policy and procedures for security and confidentiality of patient information	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for care of physical privacy of patients	☐ ☐ ☐ ☐ Y NI N NA		
Handling of file notes, records, etc.	☐ ☐ ☐ ☐ Y NI N NA		
Privacy of waiting areas, examination rooms, etc.	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Staff awareness of protocols	☐ ☐ ☐ ☐ Y NI N NA		***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Compliance with policy and procedures for confidentiality	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for physical privacy	☐ ☐ ☐ ☐ Y NI N NA		
4.3.3.2. Imaging techniques			
Protocols for various imaging examinations: plain, fluoroscopy, mammography, CT, ultrasound, MRI, PET/CT, image guided procedures, dental, etc.	☐ ☐ ☐ ☐ Y NI N NA		
Policy and protocols for examinations in special populations, e.g., paediatric patients	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Evidence of recommendations for exposure optimization, and staff awareness of these	☐ ☐ ☐ ☐ Y NI N NA		
Evidence of compliance with optimization recommendations	☐ ☐ ☐ ☐ Y NI N NA		
Protocol availability	☐ ☐ ☐ ☐ Y NI N NA		
Availability of documentation about radiography technique	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for examination protocols	☐ ☐ ☐ ☐ Y NI N NA		
Tailoring of examinations by radiographer/ radiological medical practitioner	☐ ☐ ☐ ☐ Y NI N NA		
Supervision of trainee radiographers/trainee radiological medical practitioners	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Examination labelling and record completeness: details of machine, radiographer, patient, examination factors, contrast, limitations, adverse reactions, sedation, medication, etc.	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for control of infections	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with infection control policy and procedures: cleanliness, waste, sharps, aseptic and sterile techniques, sterilization, etc.	☐ ☐ ☐ ☐ Y NI N NA		
4.3.3.3. Clinical care, patient sedation/anaesthesia and contrast agents			
Provision of clinical care: monitoring, intravenous lines, etc.	☐ ☐ ☐ ☐ Y NI N NA		
Safety of physical environment	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Policy and procedures for sedation/ anaesthesia	☐ ☐ ☐ ☐ Y NI N NA		
Staff member for sedation/anaesthesia control	☐ ☐ ☐ ☐ Y NI N NA		
Availability, management and inventory of sedation/anaesthesia equipment	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for contrast agent usage	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with contrast agent policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		
Policy and procedures for critical event management	☐ ☐ ☐ ☐ Y NI N NA		
Staff member responsible for critical event management	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Availability, management and inventory of critical event equipment	☐ ☐ ☐ ☐ Y NI N NA		
Staff training for critical event management	☐ ☐ ☐ ☐ Y NI N NA		
Availability of critical event staff	☐ ☐ ☐ ☐ Y NI N NA		
4.3.3.4. Image quality			
Sample image quality	☐ ☐ ☐ ☐ Y NI N NA		
Staff awareness of factors contributing to image quality	☐ ☐ ☐ ☐ Y NI N NA		
Designated radiographer for radiographic QA	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Quality assurance programme for radiographers	☐ ☐ ☐ ☐ Y NI N NA		
Staff awareness of criteria for evaluation of image quality: CEC, PGMI, etc.	☐ ☐ ☐ ☐ Y NI N NA		
Records of image quality audits, reject and repeat analysis	☐ ☐ ☐ ☐ Y NI N NA		
Staff performance: feedback experience	☐ ☐ ☐ ☐ Y NI N NA		
Feedback given by radiological medical practitioner on image quality	☐ ☐ ☐ ☐ Y NI N NA		
Supervision of image quality issues provided by radiological medical practitioner	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
4.3.4. The imaging report			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Availability of prior examinations and reports at time of reporting	☐ ☐ ☐ ☐ Y NI N NA		
Completeness of examination report: referrer, patient and reporting physician identification, and reporter signature and date	☐ ☐ ☐ ☐ Y NI N NA		
Completeness of examination report: clinical indications and examination	☐ ☐ ☐ ☐ Y NI N NA		
Completeness of examination report: examination findings, correlation and relevance	☐ ☐ ☐ ☐ Y NI N NA		
Completeness of examination report: advice about further investigations	☐ ☐ ☐ ☐ Y NI N NA		
Completeness of examination report: recording of adverse effects, incidents, etc.	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
4.3.5. Report communication			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Policy and procedures for report communication	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with policy and procedures for report communication, e.g., timeliness	☐ ☐ ☐ ☐ Y NI N NA		
Confirmation that patient reports are communicated	☐ ☐ ☐ ☐ Y NI N NA		
Handling of urgent results	☐ ☐ ☐ ☐ Y NI N NA		
Referring medical practitioner satisfaction	☐ ☐ ☐ ☐ Y NI N NA		
Audit process	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
4.3.6. Continuity of clinical care			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Rosters for multidisciplinary clinico-pathologic, tumour board and morbidity/ mortality meetings	☐ ☐ ☐ ☐ Y NI N NA		
Attendance at meetings and record keeping	☐ ☐ ☐ ☐ Y NI N NA		
Tracking of patient outcomes	☐ ☐ ☐ ☐ Y NI N NA		
Internal/external audits of radiological medical practitioner review processes	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
4.3.7. Accident and incident reporting			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Policy and procedures for safety incidents and sentinel events: recording, analysis and response	☐ ☐ ☐ ☐ Y NI N NA		
Safety incident log book	☐ ☐ ☐ ☐ Y NI N NA		
Sentinel event log book	☐ ☐ ☐ ☐ Y NI N NA		
Resultant quality improvement initiatives	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
4.3.8. Record and film/image retention			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Policy and procedures for record and image retention	☐ ☐ ☐ ☐ Y NI N NA		
Regulatory requirement compliance	☐ ☐ ☐ ☐ Y NI N NA		
Storage security and accessibility	☐ ☐ ☐ ☐ Y NI N NA		
File identification	☐ ☐ ☐ ☐ Y NI N NA		
File tracking	☐ ☐ ☐ ☐ Y NI N NA		
Compliance with retention policy and procedures	☐ ☐ ☐ ☐ Y NI N NA		

5.3. AUDIT REPORT FORMS FOR TECHNICAL PROCEDURES

Audit criteria	Adequacy	Comments	Summary
5.3.1. Infrastructure			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc.
5.3.1.1. Organizational structure			
Is the designated medical physicist suitably qualified and experienced?	☐ ☐ ☐ ☐ Y NI N NA		
Is the designated RPO suitably qualified?	☐ ☐ ☐ ☐ Y NI N NA		
Has a deputy RPO been designated (if appropriate), with suitable training?	☐ ☐ ☐ ☐ Y NI N NA		
Does the RPO report to the Radiation Safety Committee?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Does the Radiation Safety Committee meet regularly and is it responsible for the radiation safety policy of the institution/facility, the monitoring of that policy and its evaluation?	☐ ☐ ☐ ☐ Y NI N NA		***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Is a radiation safety manual available, does it adequately describe relevant aspects of radiation safety, is it regularly reviewed and is it updated as necessary?	☐ ☐ ☐ ☐ Y NI N NA		
Is the current structure of radiation safety satisfactory?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.1.2. Personnel			
Is the role of the medical physicist, in directing and supervising QA activities, radiation protection and dosimetry, clearly described and operative?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Is the role of the RPO in relation to oversight of occupational radiation protection and radiation protection of the public clearly described and operative?	☐ ☐ ☐ ☐ Y NI N NA		
Are the duties of radiographic staff in QA processes, radiation protection and collection of patient dose data clearly described?	☐ ☐ ☐ ☐ Y NI N NA		
Syllabus of hospital based radiation safety training programmes	☐ ☐ ☐ ☐ Y NI N NA		
Frequency of refresher radiation safety training	☐ ☐ ☐ ☐ Y NI N NA		
Practical knowledge of radiation safety principles	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.1.3. Management support			
Is sufficient time made available for QA and safety and radiation protection activities?	☐ ☐ ☐ ☐ Y NI N NA		
Is appropriate equipment available?	☐ ☐ ☐ ☐ Y NI N NA		
Are corrective actions taken within the radiology facility?	☐ ☐ ☐ ☐ Y NI N NA		
Is management support evident?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.1.4. Documentation			
Is facility documentation current, available and accessible for radiation safety requirements, QA policies and procedures, and dosimetry?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.2. Radiation protection and safety			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
5.3.2.1. Medical exposure			
Are risk assessment and management policies consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		
Are typical patient dose levels from common examinations estimated and compared with relevant dose reference levels (DRLs)?	☐ ☐ ☐ ☐ Y NI N NA		
Are optimization policies consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		
Is the facility policy for pregnancy suitable?	☐ ☐ ☐ ☐ Y NI N NA		
Is signage for pregnancy adequate?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Is verification of pregnancy status suitable?	☐ ☐ ☐ ☐ Y NI N NA		
Are staff aware of policy for pregnant patients?	☐ ☐ ☐ ☐ Y NI N NA		
Are policies for comforters and carers in hazardous areas consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		
Are charts or procedures available for adjustment of X ray parameters appropriate for paediatric patients?	☐ ☐ ☐ ☐ Y NI N NA		
Are policies for adverse patient dose incidents consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.2.2. Occupational and public exposures			
Are equipment and room conditions adequate, clean and safe?	☐ ☐ ☐ ☐ Y NI N NA		
Are manuals and technique cards/guides available?	☐ ☐ ☐ ☐ Y NI N NA		
Are protective devices (e.g. lead aprons and portable shields) and accessories available?	☐ ☐ ☐ ☐ Y NI N NA		
Are room access control and warning signs appropriate?	☐ ☐ ☐ ☐ Y NI N NA		
Are occupational dose monitoring policy and records adequate?	☐ ☐ ☐ ☐ Y NI N NA		
Is shielding design consistent with local requirements and international standards?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Is policy for pregnant staff suitable?	☐ ☐ ☐ ☐ Y NI N NA		
Is policy for pregnant staff known and understood by staff?	☐ ☐ ☐ ☐ Y NI N NA		
Are policies on classification and identification of hazardous areas consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		
Are policies for visitors in hazardous areas consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		
Are the methods used to verify shielding adequate?	☐ ☐ ☐ ☐ Y NI N NA		
Is there a policy in place to adequately monitor radiation shielding?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Are emergency contingency plans consistent with legal requirements or relevant guidelines?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.3. Imaging equipment QA processes			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc.
5.3.3.1. Selection of equipment			
Is the equipment purchase process consistent with local needs, resources and best principles?	☐ ☐ ☐ ☐ Y NI N NA		
Is maintenance planning well considered?	☐ ☐ ☐ ☐ Y NI N NA		
Is there planning for integration into a digital environment?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.3.2. Acceptance testing and setting of baseline values			***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Do protocols exist for acceptance testing and baseline measurements?	☐ ☐ ☐ ☐ Y NI N NA		
Do acceptance reports confirm that equipment performance is consistent with tender specifications?	☐ ☐ ☐ ☐ Y NI N NA		
Are baseline measurements made as a basis for QC testing?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.3.3. Routine QC testing			
Do quality control protocols exist for all modalities and auxiliary equipment?	☐ ☐ ☐ ☐ Y NI N NA		
Have responsible persons been identified to perform QC testing at regular intervals?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Is required test equipment available for QC measurements?	☐ ☐ ☐ ☐ Y NI N NA		
Do radiographer QC tests include reject analyses?	☐ ☐ ☐ ☐ Y NI N NA		
Are radiographic techniques reviewed regularly?	☐ ☐ ☐ ☐ Y NI N NA		
Are quality control tests appropriately documented?	☐ ☐ ☐ ☐ Y NI N NA		
Are appropriate QC test criteria applied?	☐ ☐ ☐ ☐ Y NI N NA		
Do staff display an adequate understanding of QC testing principles and procedures?	☐ ☐ ☐ ☐ Y NI N NA		
Is corrective action taken and verified in response to QC results?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.3.4. Equipment replacement policy			
Does an equipment replacement policy exist and is it documented?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.4. Optimization in clinical practice			
Does an appropriate policy on examination optimization exist?	☐ ☐ ☐ ☐ Y NI N NA		
Have optimization processes been demonstrated through documentation?	☐ ☐ ☐ ☐ Y NI N NA		
Is optimization seen as a team activity?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.5. Dosimetry			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
5.3.5.1. Dosimetry principles			
Are dosimetry principles based on international standards using a suitable reference?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.5.2. Patient dosimetry			
Are protocols in place to estimate the appropriate patient doses for required examination procedures?	☐ ☐ ☐ ☐ Y NI N NA		
Is appropriate software used for dose estimates?	☐ ☐ ☐ ☐ Y NI N NA		
Are patient dose audits regularly performed and the results compared with appropriate DRLs?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Have appropriate DRL values been selected for common procedures?	☐ ☐ ☐ ☐ Y NI N NA		
Are patient dose estimates from phantom measurements consistent with good practice?	☐ ☐ ☐ ☐ Y NI N NA		
Do dosimetry calculations appear to be appropriately documented and performed?	☐ ☐ ☐ ☐ Y NI N NA		
Is the effect of patient shape on patient dose recognized?	☐ ☐ ☐ ☐ Y NI N NA		
Are dosimetry estimates for those involved in clinical research performed and documented?	☐ ☐ ☐ ☐ Y NI N NA		
Are dose estimates of foetal dose performed and documented in an acceptable way?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Are audit team estimates of patient doses from phantom measurements consistent with good practice for CT and mammographic examinations?	☐ ☐ ☐ ☐ Y NI N NA		
Are audit team estimates of patient doses from phantom measurements using AEC devices consistent with good practice for chest radiography and abdominal fluoroscopy?	☐ ☐ ☐ ☐ Y NI N NA		
5.3.5.3. Occupational dosimetry			
Does the medical physicist perform customized, special case, staff dosimetry?	☐ ☐ ☐ ☐ Y NI N NA		
Are there peer review examples of special case staff dosimetry?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
5.3.6. Instrumentation and calibration			***Summary:*** Indicate positive findings. ***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Is a calibration programme available for dosimetric instrumentation?	☐ ☐ ☐ ☐ Y NI N NA		
Is medical physicist instrumentation traceable to calibration standards?	☐ ☐ ☐ ☐ Y NI N NA		
Are calibration records available, including records of cross-checks?	☐ ☐ ☐ ☐ Y NI N NA		
Are instruments cross-checked by the audit team within acceptable tolerances?	☐ ☐ ☐ ☐ Y NI N NA		
Are equipment KAP meters calibrated in situ?	☐ ☐ ☐ ☐ Y NI N NA		

6.3. AUDIT REPORT FORMS FOR EDUCATION, TRAINING AND RESEARCH PROGRAMMES

Audit criteria	Adequacy	Comments	Summary
6.3.1. Education and training programmes			***Summary:***
Can an officer responsible for education and training be identified?	☐ ☐ ☐ ☐ Y NI N NA		Indicate positive findings.
6.3.1.1. Academic programme			***Important quality improvement initiatives would be:***
Does an academic education programme exist for radiological medical practitioners?	☐ ☐ ☐ ☐ Y NI N NA		— Recommendation 1; — Recommendation 2; — Etc.
Does an academic education programme exist for radiographers?	☐ ☐ ☐ ☐ Y NI N NA		
Does an academic education programme exist for medical physicists?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Does a policy exist to allow release from clinical duties for lectures and study?	☐ ☐ ☐ ☐ Y NI N NA		***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Is there access to adequate library, Internet and computing facilities?	☐ ☐ ☐ ☐ Y NI N NA		
Are there adequate lecture facilities, including provision to display images with a satisfactory quality?	☐ ☐ ☐ ☐ Y NI N NA		
Are qualified lecturers available?	☐ ☐ ☐ ☐ Y NI N NA		
Is there a support network that allows discussion and provides study materials?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
6.3.1.2. Clinical training programmes			
Does a clinical training programme exist for radiological medical practitioners? Comment on responsibility for the programme and if multiple locations are involved.	☐ ☐ ☐ ☐ Y NI N NA		
Does a clinical training programme exist for radiographers? Comment on responsibility for the programme and if multiple locations are involved.	☐ ☐ ☐ ☐ Y NI N NA		
Does a clinical training programme exist for medical physicists? Comment on responsibility for the programme and if multiple locations are involved.	☐ ☐ ☐ ☐ Y NI N NA		
Does the programme have appropriate external accreditation or recognition?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Is the programme conducted in a facility that is accredited or approved for clinical training?	☐ ☐ ☐ ☐ Y NI N NA		
Does the programme have a person responsible for its conduct in the facility?	☐ ☐ ☐ ☐ Y NI N NA		
Is the programme structured and does it follow a recognized syllabus?	☐ ☐ ☐ ☐ Y NI N NA		
Have specially qualified or trained clinical supervisors been identified for the programme who are competent to instruct those enrolled in the programme?	☐ ☐ ☐ ☐ Y NI N NA		
Does the programme meet the radiation training and monitoring requirements of the participants?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Are there sufficient numbers of supervisors to instruct or mentor the participants involved?	☐ ☐ ☐ ☐ Y NI N NA		
Is a programme held in a clinical environment that can offer the participants the required experience?	☐ ☐ ☐ ☐ Y NI N NA		
Is the programme of sufficient duration to allow adequate skills to be acquired?	☐ ☐ ☐ ☐ Y NI N NA		
Is the form of assessment used appropriate?	☐ ☐ ☐ ☐ Y NI N NA		
6.3.1.3. Miscellaneous programmes			
Clinical education (e.g. image evaluation, radiographic techniques, equipment information and resuscitation)	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Professional meetings and interdisciplinary meetings	☐ ☐ ☐ ☐ Y NI N NA		
Statutory and regulatory training (e.g. radiation safety, fire safety, lifting and handling)	☐ ☐ ☐ ☐ Y NI N NA		
Internal and external audit reviews	☐ ☐ ☐ ☐ Y NI N NA		
6.3.2. Research			***Summary:*** Indicate positive findings.
Is clinical research, possibly including participation in clinical trials, carried out?	☐ ☐ ☐ ☐ Y NI N NA		
Are research projects undertaken by staff as a part of education and training?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Has the research programme a clear policy statement that includes matters of ethics, governance, and the role and structure of the research committee of the institute/facility?	☐ ☐ ☐ ☐ Y NI N NA		***Important quality improvement initiatives would be:*** — Recommendation 1; — Recommendation 2; — Etc. ***QUAADRIL guideline references:*** (Cut and paste the pertinent QUAADRIL guidelines into the summary to support the recommendations.)
Does the research programme conform to recognized ethical standards, including the use of patient dose estimates for research?	☐ ☐ ☐ ☐ Y NI N NA		
Is sufficient research infrastructure available?	☐ ☐ ☐ ☐ Y NI N NA		
Are good quality scientific personnel with a record in research available?	☐ ☐ ☐ ☐ Y NI N NA		
Is research output published?	☐ ☐ ☐ ☐ Y NI N NA		
Does research attract adequate research funding?	☐ ☐ ☐ ☐ Y NI N NA		

Audit criteria	Adequacy	Comments	Summary
Is there sufficient time for research activities?	☐ ☐ ☐ ☐ Y NI N NA		
Are there regular research meetings?	☐ ☐ ☐ ☐ Y NI N NA		
Is there access to a statistician?	☐ ☐ ☐ ☐ Y NI N NA		
Is there access to adequate library and computing facilities?	☐ ☐ ☐ ☐ Y NI N NA		
Do minor research projects undertaken by staff as a part of education and training have a research coordinator?	☐ ☐ ☐ ☐ Y NI N NA		
Do minor projects have regular research meetings?	☐ ☐ ☐ ☐ Y NI N NA		
Do staff undertaking minor projects have access to experienced researchers?	☐ ☐ ☐ ☐ Y NI N NA		

Appendix V

NOTES ON PHYSICIST MEASUREMENTS

V.1. SUGGESTED AUDIT EQUIPMENT KIT

It can be difficult for an auditor to bring a full set of equipment and phantoms, owing to its size and weight, to assist in an audit. However, as a minimum, a calibrated dosimeter is highly recommended, to allow a cross-check of the calibration instruments at the host facility.

V.1.1. Instruments

The following instuments can be useful for an audit:

(a) An electrometer;
(b) Detectors (calibrated) for:
  —Entrance beam,
  —Scatter radiation,
  —CT equipment,
  —Mammography equipment,
  —KAP meter;
(c) A kVp timer meter;
(d) Sensitometry equipment and a densitometer;
(e) A photometer;
(f) Aluminium foils for the main X ray and mammography energies;
(g) A magnifying glass (×4);
(h) Miscellaneous items, such as a tape measure and lead markers.

V.1.2. Phantoms

The following phantoms can be useful for an audit:

(a) A CDRH (Center for Devices and Radiological Health) chest phantom [32];
(b) An ANSI (American National Standards Institute) abdomenal phantom [32];
(c) For mammography:
  (i) An ACR (American College of Radiology) mammography phantom (suggested as a possibility in an IAEA mammography QA protocol [34] and very common worldwide);
  (ii) Sheet(s) of 45 mm total thickness of polymethyl-methacrylate (PMMA) [34];

(d) A CT phantom (made from PMMA — a 16 cm diameter head phantom and a 32 cm diameter body phantom).

V.2. SUGGESTED MEASUREMENTS

The suggested measurements by the physicist auditor are described in Section 5.2 and are summarized below. Suggested worksheets for the measurements are provided in Annex IV. Note that there is limited time available and that the number of measurements should be adjusted to the scope of the activities of the facility/institution.

V.2.1. Cross-checks for measuring instruments

Cross-checks should be made for the following:

(a) During the audit, cross-checks should be made of selected dosimetric instruments, as time allows:
  (i) Instruments for entrance surface air kerma measurements (these can be done as part of a dosimetry check for a chest and abdomen phantom, as specified in Section 5.2.5.3);
  (ii) Instruments for measurements of scattered radiation (these could be done in connection with a dosimetry check for CT dosimetry, as specified in Section 5.2.5.3);
  (iii) Instruments for mammography and CT (these could be done as part of a dosimetry check for these modalities, as specified in Section 5.2.5.3);
  (iv) At least one KAP meter in situ [32].
(b) If time permits, a cross-check of available kVp meters could also be useful during the audit period.

V.2.2. Phantom dosimetry

The resident medical physicist could also be asked to demonstrate dosimetry measurements with phantoms associated with the following examination types:

(a) Chest;
(b) Abdominal fluoroscopy;
(c) Mammography;
(d) Computed tomography, including verifying a dose–length product (DLP) indicator, if possible.

V.2.3. Other measurements

The other tasks for the physicist auditor are as follows:

(a) Examine a mammography film exposed with an image quality phantom (see Section 5.2.5.3);
(b) Examine the film reading conditions (this may involve making measurements);
(c) Review a demonstration by local staff of how to set up an AEC system;
(d) Review a demonstration by local staff of some QA measurements, such as a half-value layer (HVL) measurement or an entrance air kerma measurement;
(e) Verify the displayed DLP for the CT examination sequences.

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Annex I

APPLICATION FORM

IAEA Clinical Audit Application Form
Contact information

Institution requesting the audit

Name	
Address	
Country	

Institution contact person

Name			
Position			
Telephone		Fax	
email			

Facility (department) to be audited and to coordinate the process

Head of Department			
Name			
Telephone		Fax	
email			

Other department to be involved in the audit			
Head of Department			
Name			
Telephone		Fax	
email			

Other department to be involved in the audit			
Head of Department			
Name			
Telephone		Fax	
email			

Radiologist contact person			
Name			
Telephone		Fax	
email			

Medical physics contact person			
Name			
Telephone		Fax	
email			

Radiographer or administrative contact person			
Name			
Telephone		Fax	
email			

Department Vision Statement and immediate objectives

Patient demographic data: estimated population served	
Annual total number of procedures	
Hours of department operation	
Provision of emergency services	**Yes/No**
Full-time equivalent staffing level	

Annual number of procedures by modality and patient type		
Modality	**Adult procedures**	**Paediatric procedures**
Plain radiography		
Fluoroscopy		
Mammography		
Computed tomography		
Ultrasonography		
MRI		
PET/CT		
Image guided procedures		
Dental		

List of equipment			
Equipment type	**Identifying number**	**Year of manufacture**	**Year of installation**
Plain radiography			
Fluoroscopy			
Mammography			
Computed tomography			
Ultrasonography			

MRI			
PET/CT			
Image guided procedures			
Dental			

Please extend table as necessary.

Annex II

LIST OF ITEMS REQUESTED TO BE AVAILABLE ON-SITE

Arrange for a private room to be available for the auditors to discuss or work on matters concerned with the audit during their site visit, as well as for them to have access to a printer and paper for the draft report.

Copies of the following documents, under their related headings, should be available for review by the audit team at the start of the audit period. Access to similar documents, if requested, will be appreciated.

II–1. TECHNICAL PROCEDURES

II–1.1. Quality assurance infrastructure

The following items are required:

—Documentation of the roles and responsibilities of radiographers and medical physicists;
—Syllabuses of the radiation safety training programmes undertaken by staff.

II–1.2. Radiation protection and general safety

The following items are required:

—The radiation safety manual used;
—A sample of the shielding design for an X ray installation;
—A sample of occupational dose monitoring records;
—A statement of pregnancy policy, and associated records.

II–1.3. Equipment quality assurance processes

The following items are required:

—A tender document or equivalent for the purchase of a CT scanner or similar piece of equipment;
—An acceptance report for a major piece of equipment;
—Protocols for a regular QC programme;
—A statement of the equipment replacement programme policy.

II–1.4. Calibration of instrumentation

Instrument calibration records and protocols are required.

II–1.5. Dosimetry

Relevant dosimetry documentation, including phantom dose studies and patient survey results, are required.

II–1.6. Optimization

Documentation of examination optimization processes is required.

Annex III

EQUIPMENT-SPECIFIC CHECKLIST FORMS FOR SECTIONS 3–5

The audit team members should use the equipment-specific checklist forms as internal tools to assist them in conducting the audit review. The assessments made using these checklists will be summarized on the audit report forms given in Appendix IV.

The key for this annex is as follows:

Y — Yes (i.e. available, performed or adequate);
NI — Needs improvement;
N — No (i.e. not available, not performed or not adequate);
NA — Not applicable.

FORM FOR A RADIOGRAPHIC X RAY FACILITY QA PROGRAMME

Form RXR — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of an operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Evaluation of facility assembly		
Indicator lights	☐ ☐ ☐ ☐ Y NI N NA	
Mechanical integrity	☐ ☐ ☐ ☐ Y NI N NA	
Beam limitation assessment		
X ray field/light beam alignment	☐ ☐ ☐ ☐ Y NI N NA	
X ray field/light beam centring	☐ ☐ ☐ ☐ Y NI N NA	
Light beam/Bucky centring	☐ ☐ ☐ ☐ Y NI N NA	
Light beam diaphragm (collimator) field size calibration	☐ ☐ ☐ ☐ Y NI N NA	

Form RXR — Items to be reviewed by auditor		Adequacy	Comments
	Distance and scales	☐ ☐ ☐ ☐ Y NI N NA	
	Film changer alignment and collimation	☐ ☐ ☐ ☐ Y NI N NA	
Evaluation of focal spot performance		☐ ☐ ☐ ☐ Y NI N NA	
Performance of automatic exposure control (AEC) system		☐ ☐ ☐ ☐ Y NI N NA	
	Operation backup timer	☐ ☐ ☐ ☐ Y NI N NA	
	Resultant film density	☐ ☐ ☐ ☐ Y NI N NA	
	Consistency of chambers	☐ ☐ ☐ ☐ Y NI N NA	
	Repeatability (reproducibility) (mA·s/OD)	☐ ☐ ☐ ☐ Y NI N NA	
	Reproducibility performance (varying with kVp and phantom thickness)	☐ ☐ ☐ ☐ Y NI N NA	
Tube potential (kVp accuracy and reproducibility)		☐ ☐ ☐ ☐ Y NI N NA	
Beam quality (HVL) assessment		☐ ☐ ☐ ☐ Y NI N NA	
Radiation output			
	Repeatability (output reproducibility)	☐ ☐ ☐ ☐ Y NI N NA	
	Reproducibility (linearity; impact of generator changes such as kV, mA, time, mA·s and focal spot)	☐ ☐ ☐ ☐ Y NI N NA	
Repeatability and linearity		☐ ☐ ☐ ☐ Y NI N NA	

Form RXR — Items to be reviewed by auditor	Adequacy	Comments
Timer accuracy	☐ ☐ ☐ ☐ Y NI N NA	
Image quality (phantom)	☐ ☐ ☐ ☐ Y NI N NA	
Artefact evaluation	☐ ☐ ☐ ☐ Y NI N NA	
Technique charts	☐ ☐ ☐ ☐ Y NI N NA	
Repeat analysis	☐ ☐ ☐ ☐ Y NI N NA	
Visual checklist	☐ ☐ ☐ ☐ Y NI N NA	
Tomographic performance assessment		
Cut height	☐ ☐ ☐ ☐ Y NI N NA	
Angle of swing	☐ ☐ ☐ ☐ Y NI N NA	
III. Radiation Protection and Safety		
Radiation protection equipment available, accepted, calibrated and passed QC test	☐ ☐ ☐ ☐ Y NI N NA	
Room shielding checked	☐ ☐ ☐ ☐ Y NI N NA	
Quality control of immobilization devices: storage and replacement	☐ ☐ ☐ ☐ Y NI N NA	
Control of access to X ray room	☐ ☐ ☐ ☐ Y NI N NA	
Checks of warning lights/signs	☐ ☐ ☐ ☐ Y NI N NA	
Checks of door interlocks	☐ ☐ ☐ ☐ Y NI N NA	

Form RXR — Items to be reviewed by auditor	Adequacy	Comments
Radiation protection surveys (e.g. what is done, including frequency, methods and records, and actions taken as a result)	☐ ☐ ☐ ☐ Y NI N NA	
IV. Patient Dosimetry		
Dosimetry equipment and methodology	☐ ☐ ☐ ☐ Y NI N NA	
Patient dose estimates and reference values	☐ ☐ ☐ ☐ Y NI N NA	
Equipment based dosimetry (e.g. kerma–area product (KAP) and input kerma (K_i) display)	☐ ☐ ☐ ☐ Y NI N NA	
Dosimetry in pregnancy	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A FLUOROSCOPIC AND/OR INTERVENTIONAL FLUOROSCOPIC X RAY FACILITY QA PROGRAMME

Form FIF — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Evaluation of facility assembly		
Indicator lights	☐ ☐ ☐ ☐ Y NI N NA	
Mechanical integrity	☐ ☐ ☐ ☐ Y NI N NA	
Beam limitation assessment	☐ ☐ ☐ ☐ Y NI N NA	
Evaluation of focal spot performance	☐ ☐ ☐ ☐ Y NI N NA	
Performance of automatic exposure control (AEC) system	☐ ☐ ☐ ☐ Y NI N NA	
Image quality (phantom)	☐ ☐ ☐ ☐ Y NI N NA	

Form FIF — Items to be reviewed by auditor	Adequacy	Comments
Accuracy and reproducibility of kVp	☐ ☐ ☐ ☐ Y NI N NA	
Beam quality (HVL) assessment	☐ ☐ ☐ ☐ Y NI N NA	
Radiation output rate	☐ ☐ ☐ ☐ Y NI N NA	
Performance of image display monitor	☐ ☐ ☐ ☐ Y NI N NA	
Technique charts	☐ ☐ ☐ ☐ Y NI N NA	
Repeat analysis	☐ ☐ ☐ ☐ Y NI N NA	
Visual checklist	☐ ☐ ☐ ☐ Y NI N NA	
III. Radiation Protection and Safety		
Radiation protection equipment available, accepted, calibrated and passed QC test	☐ ☐ ☐ ☐ Y NI N NA	
Room shielding checked	☐ ☐ ☐ ☐ Y NI N NA	
Quality control of immobilization devices: storage and replacement	☐ ☐ ☐ ☐ Y NI N NA	
Control of X ray room access	☐ ☐ ☐ ☐ Y NI N NA	
Checks of warning lights/signs	☐ ☐ ☐ ☐ Y NI N NA	
Checks of door interlocks	☐ ☐ ☐ ☐ Y NI N NA	
Radiation protection surveys (e.g. what is done, including frequency, methods, records and actions taken as a result)	☐ ☐ ☐ ☐ Y NI N NA	

Form FIF — Items to be reviewed by auditor	Adequacy	Comments
IV. Patient Dosimetry		
Dosimetry equipment and methodology	☐ ☐ ☐ ☐ Y NI N NA	
Patient dose estimates and reference values	☐ ☐ ☐ ☐ Y NI N NA	
Equipment based dosimetry (e.g. kerma–area product (KAP) meter, KAP display, etc.)	☐ ☐ ☐ ☐ Y NI N NA	
Dosimetry in pregnancy	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A MAMMOGRAPHY QA PROGRAMME

Form MAM — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of an operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Evaluation of facility assembly	☐ ☐ ☐ ☐ Y NI N NA	
Beam limitation assessment		
X ray/light field alignment	☐ ☐ ☐ ☐ Y NI N NA	
X ray/film alignment	☐ ☐ ☐ ☐ Y NI N NA	
Evaluation of focal spot performance/high contrast resolution	☐ ☐ ☐ ☐ Y NI N NA	
Performance of automatic exposure control (AEC) system		
Operation backup timer	☐ ☐ ☐ ☐ Y NI N NA	
Resultant film density	☐ ☐ ☐ ☐ Y NI N NA	

Form MAM — Items to be reviewed by auditor		Adequacy	Comments
	Consistency (reproducibility) (mA·s)	☐ ☐ ☐ ☐ Y NI N NA	
	Device breast thickness and kVp calibration	☐ ☐ ☐ ☐ Y NI N NA	
Artefact evaluation		☐ ☐ ☐ ☐ Y NI N NA	
Image quality (phantom) and threshold contrast		☐ ☐ ☐ ☐ Y NI N NA	
Tube potential (accuracy and reproducibility of kVp)		☐ ☐ ☐ ☐ Y NI N NA	
Beam quality (HVL) assessment		☐ ☐ ☐ ☐ Y NI N NA	
Radiation output repeatability		☐ ☐ ☐ ☐ Y NI N NA	
Radiation output rate		☐ ☐ ☐ ☐ Y NI N NA	
Non-uniformity of X ray field		☐ ☐ ☐ ☐ Y NI N NA	
Technique charts		☐ ☐ ☐ ☐ Y NI N NA	
Repeat analysis		☐ ☐ ☐ ☐ Y NI N NA	
Compression		☐ ☐ ☐ ☐ Y NI N NA	
Visual checklist		☐ ☐ ☐ ☐ Y NI N NA	
General condition of equipment and room		☐ ☐ ☐ ☐ Y NI N NA	
Accuracy of stereotactic device		☐ ☐ ☐ ☐ Y NI N NA	

Form MAM — Items to be reviewed by auditor	Adequacy	Comments
III. Radiation Protection and Safety		
Radiation protection equipment available, accepted, calibrated and passed QC test	☐ ☐ ☐ ☐ Y NI N NA	
Room shielding checked	☐ ☐ ☐ ☐ Y NI N NA	
Control of access to X ray room	☐ ☐ ☐ ☐ Y NI N NA	
Checks of warning lights/signs	☐ ☐ ☐ ☐ Y NI N NA	
Checks of door interlocks	☐ ☐ ☐ ☐ Y NI N NA	
Radiation protection surveys (e.g. what is done, including frequency, methods, records and actions taken as a result)	☐ ☐ ☐ ☐ Y NI N NA	
IV. Patient Dosimetry		
Dosimetry equipment and methodology	☐ ☐ ☐ ☐ Y NI N NA	
Patient dose estimates and reference values (mean glandular dose to standard patient)	☐ ☐ ☐ ☐ Y NI N NA	
Equipment based dosimetry (e.g. mGy display)	☐ ☐ ☐ ☐ Y NI N NA	
Dosimetry in pregnancy	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A COMPUTED TOMOGRAPHY QA PROGRAMME

Form CTQ — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Facility assembly evaluation		
Visual inspection	☐ ☐ ☐ ☐ Y NI N NA	
Audible/visual signals	☐ ☐ ☐ ☐ Y NI N NA	
Mechanical integrity	☐ ☐ ☐ ☐ Y NI N NA	
Alignment light accuracy	☐ ☐ ☐ ☐ Y NI N NA	
Alignment of table to gantry	☐ ☐ ☐ ☐ Y NI N NA	
Table/gantry tilt	☐ ☐ ☐ ☐ Y NI N NA	

Form CTQ — Items to be reviewed by auditor	Adequacy	Comments
Slice localization from radiograph (scout image)	☐ ☐ ☐ ☐ Y NI N NA	
Table incrementation accuracy	☐ ☐ ☐ ☐ Y NI N NA	
Slice thickness	☐ ☐ ☐ ☐ Y NI N NA	
Artefact evaluation	☐ ☐ ☐ ☐ Y NI N NA	
Computed tomography number assessment	☐ ☐ ☐ ☐ Y NI N NA	
High contrast resolution	☐ ☐ ☐ ☐ Y NI N NA	
Low contrast resolution	☐ ☐ ☐ ☐ Y NI N NA	
Image uniformity	☐ ☐ ☐ ☐ Y NI N NA	
Noise	☐ ☐ ☐ ☐ Y NI N NA	
Video display	☐ ☐ ☐ ☐ Y NI N NA	
Hard copy display	☐ ☐ ☐ ☐ Y NI N NA	
$CTDI_{vol}$	☐ ☐ ☐ ☐ Y NI N NA	
Warm-up procedure	☐ ☐ ☐ ☐ Y NI N NA	
Data display, data transfer and data manipulation	☐ ☐ ☐ ☐ Y NI N NA	

Form CTQ — Items to be reviewed by auditor	Adequacy	Comments
III. Radiation Protection and Safety		
Protective devices checked	☐ ☐ ☐ ☐ Y NI N NA	
Room shielding checked	☐ ☐ ☐ ☐ Y NI N NA	
Quality control of immobilization devices: storage and replacement	☐ ☐ ☐ ☐ Y NI N NA	
Control of access to X ray room	☐ ☐ ☐ ☐ Y NI N NA	
Checks of warning lights/signs	☐ ☐ ☐ ☐ Y NI N NA	
Checks of door interlocks	☐ ☐ ☐ ☐ Y NI N NA	
Radiation protection/scattered radiation surveys (e.g. what is done, including frequency, methods and records, and actions taken as a result)	☐ ☐ ☐ ☐ Y NI N NA	
IV. Patient Dosimetry		
Dosimetry equipment and methodology	☐ ☐ ☐ ☐ Y NI N NA	
Patient dose estimates and reference values	☐ ☐ ☐ ☐ Y NI N NA	
Equipment based dosimetry (e.g. CTDI or DLP display)	☐ ☐ ☐ ☐ Y NI N NA	
Dosimetry in pregnancy	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A SCREEN–FILM AND PROCESSOR QA PROGRAMME

Form SFP — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of darkrooms	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Condition of cassettes and screens	☐ ☐ ☐ ☐ Y NI N NA	
Relative speed of intensifying screens	☐ ☐ ☐ ☐ Y NI N NA	
Darkroom fog (darkroom and safelight integrity)	☐ ☐ ☐ ☐ Y NI N NA	
Processor monitoring		
Developer temperature	☐ ☐ ☐ ☐ Y NI N NA	
Base + fog (gross fog)	☐ ☐ ☐ ☐ Y NI N NA	
Film speed (midpoint)	☐ ☐ ☐ ☐ Y NI N NA	
Contrast index	☐ ☐ ☐ ☐ Y NI N NA	
Replenishment rate	☐ ☐ ☐ ☐ Y NI N NA	

Form SFP — Items to be reviewed by auditor		Adequacy	Comments
Chemical safety			
	Disposal	☐ ☐ ☐ ☐ Y NI N NA	
	Silver recovery	☐ ☐ ☐ ☐ Y NI N NA	
	Contamination kits	☐ ☐ ☐ ☐ Y NI N NA	
	Storage	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A COMPUTED OR DIGITAL RADIOGRAPHY QA PROGRAMME (Detector and Reader Components)

Form CDR — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in developing protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Detector dose indicator		
Repeatability (signal outputs for the same technique)	☐ ☐ ☐ ☐ Y NI N NA	
Reproducibility/linearity (signal outputs for varying kVp and mA)	☐ ☐ ☐ ☐ Y NI N NA	
Image uniformity	☐ ☐ ☐ ☐ Y NI N NA	
Artefacts	☐ ☐ ☐ ☐ Y NI N NA	
Cassette condition (CR)	☐ ☐ ☐ ☐ Y NI N NA	
Low contrast sensitivity	☐ ☐ ☐ ☐ Y NI N NA	

Form CDR — Items to be reviewed by auditor		Adequacy	Comments
Limiting spatial resolution		☐ ☐ ☐ ☐ Y NI N NA	
Threshold contrast detectability		☐ ☐ ☐ ☐ Y NI N NA	
Erasure cycle efficacy and/or ghosting		☐ ☐ ☐ ☐ Y NI N NA	
Scaling errors		☐ ☐ ☐ ☐ Y NI N NA	
Dark noise		☐ ☐ ☐ ☐ Y NI N NA	
Performance of automatic exposure control (AEC) system			
	Operation backup timer (guard)	☐ ☐ ☐ ☐ Y NI N NA	
	Sensitivity	☐ ☐ ☐ ☐ Y NI N NA	
	Image receptor dose	☐ ☐ ☐ ☐ Y NI N NA	
	Repeatability (reproducibility) (mA·s/OD)	☐ ☐ ☐ ☐ Y NI N NA	
	Reproducibility performance (varying with kVp and phantom thickness)	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A VIEWING CONDITIONS (ANALOGUE) QA PROGRAMME

Form VCA — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Film viewer (viewing box) condition (cleanliness, etc.)	☐ ☐ ☐ ☐ Y NI N NA	
Luminance	☐ ☐ ☐ ☐ Y NI N NA	
Uniformity	☐ ☐ ☐ ☐ Y NI N NA	
Film viewer (viewing box) variation	☐ ☐ ☐ ☐ Y NI N NA	
Room illumination	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A VIEWING CONDITIONS (DIGITAL) QA PROGRAMME

VCD — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Image display monitor condition	☐ ☐ ☐ ☐ Y NI N NA	
Grey scale (using standard test pattern)	☐ ☐ ☐ ☐ Y NI N NA	
Resolution	☐ ☐ ☐ ☐ Y NI N NA	
Uniformity	☐ ☐ ☐ ☐ Y NI N NA	
Minor variations	☐ ☐ ☐ ☐ Y NI N NA	
Room illumination	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A QA PROGRAMME FOR HARD COPY PRINTERS

Form HCP — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of an operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Variation of self-calibration or optical density over time	☐ ☐ ☐ ☐ Y NI N NA	
Optical density calibration	☐ ☐ ☐ ☐ Y NI N NA	
Image quality (e.g. standard test pattern)	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A QA PROGRAMME FOR DENTAL PRACTICES

Form DPQ — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of an operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Dental system constancy test (intraoral only)	☐ ☐ ☐ ☐ Y NI N NA	
Visual checklist	☐ ☐ ☐ ☐ Y NI N NA	
Repeat analysis	☐ ☐ ☐ ☐ Y NI N NA	
Tube head: boom stability	☐ ☐ ☐ ☐ Y NI N NA	
Panoramic field alignment	☐ ☐ ☐ ☐ Y NI N NA	
Collimation	☐ ☐ ☐ ☐ Y NI N NA	
Half-value layer	☐ ☐ ☐ ☐ Y NI N NA	

Form DPQ — Items to be reviewed by auditor	Adequacy	Comments
Focal spot (at installation only)	☐ ☐ ☐ ☐ Y NI N NA	
Timer accuracy and reproducibility	☐ ☐ ☐ ☐ Y NI N NA	
Accuracy and reproducibility of kVp	☐ ☐ ☐ ☐ Y NI N NA	
Linearity of mA	☐ ☐ ☐ ☐ Y NI N NA	
Exposure reproducibility	☐ ☐ ☐ ☐ Y NI N NA	
Technique chart evaluation	☐ ☐ ☐ ☐ Y NI N NA	
III. Radiation Protection and Safety		
Protective devices checked	☐ ☐ ☐ ☐ Y NI N NA	
Room shielding checked	☐ ☐ ☐ ☐ Y NI N NA	
Control of access to X ray room	☐ ☐ ☐ ☐ Y NI N NA	
Warning lights/signs checked	☐ ☐ ☐ ☐ Y NI N NA	
Door interlocks checked	☐ ☐ ☐ ☐ Y NI N NA	
Radiation protection surveys (e.g. what is done, frequency, methods and records, and actions taken as a result)	☐ ☐ ☐ ☐ Y NI N NA	

Form DPQ — Items to be reviewed by auditor	Adequacy	Comments
IV. Patient Dosimetry		
Dosimetry equipment and methodology	☐ ☐ ☐ ☐ Y NI N NA	
Patient dose estimates and reference values	☐ ☐ ☐ ☐ Y NI N NA	
Dosimetry in pregnancy	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A QA PROGRAMME FOR ULTRASOUND

Form UQP — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physics in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual report	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Physical and mechanical integrity	☐ ☐ ☐ ☐ Y NI N NA	
Fidelity of display monitor	☐ ☐ ☐ ☐ Y NI N NA	
Calliper distance accuracy		
Vertical	☐ ☐ ☐ ☐ Y NI N NA	
Horizontal	☐ ☐ ☐ ☐ Y NI N NA	
Depth of penetration/visualization	☐ ☐ ☐ ☐ Y NI N NA	
Dead-zone depth	☐ ☐ ☐ ☐ Y NI N NA	

Form UQP — Items to be reviewed by auditor	Adequacy	Comments
Image uniformity	☐ ☐ ☐ ☐ Y NI N NA	
Axial resolution	☐ ☐ ☐ ☐ Y NI N NA	
Lateral resolution	☐ ☐ ☐ ☐ Y NI N NA	
Elevation resolution	☐ ☐ ☐ ☐ Y NI N NA	
Anechoic object imaging	☐ ☐ ☐ ☐ Y NI N NA	
Qualitative evaluation of Doppler functionality	☐ ☐ ☐ ☐ Y NI N NA	

FORM FOR A QA PROGRAMME FOR MRI

Form MRI — Items to be reviewed by auditor	Adequacy	Comments
I. General		
General condition of equipment and room	☐ ☐ ☐ ☐ Y NI N NA	
Availability of operator's manual	☐ ☐ ☐ ☐ Y NI N NA	
Training of personnel to use equipment	☐ ☐ ☐ ☐ Y NI N NA	
Imaging protocols and involvement of medical physicist in development of protocols	☐ ☐ ☐ ☐ Y NI N NA	
Acceptance testing policies, procedures and/or manual report	☐ ☐ ☐ ☐ Y NI N NA	
Quality assurance policies, procedures and/or manual	☐ ☐ ☐ ☐ Y NI N NA	
II. Quality Assurance (Acceptance Tests, Frequencies, Responsible Persons, Performance Criteria and Corrective Actions Taken)		
Frequency	☐ ☐ ☐ ☐ Y NI N NA	
Table positioning	☐ ☐ ☐ ☐ Y NI N NA	
Set-up and scanning	☐ ☐ ☐ ☐ Y NI N NA	
Geometric accuracy	☐ ☐ ☐ ☐ Y NI N NA	
High contrast resolution	☐ ☐ ☐ ☐ Y NI N NA	
Low contrast resolution	☐ ☐ ☐ ☐ Y NI N NA	
Artefact analysis	☐ ☐ ☐ ☐ Y NI N NA	

Form MRI — Items to be reviewed by auditor	Adequacy	Comments
Visual checklist	☐ ☐ ☐ ☐ Y NI N NA	
Magnetic field homogeneity	☐ ☐ ☐ ☐ Y NI N NA	
Slice position accuracy	☐ ☐ ☐ ☐ Y NI N NA	
Slice thickness accuracy	☐ ☐ ☐ ☐ Y NI N NA	
Radiofrequency coil checks		
Volume radiofrequency coils	☐ ☐ ☐ ☐ Y NI N NA	
Surface radiofrequency coils	☐ ☐ ☐ ☐ Y NI N NA	
Interslice radiofrequency interference	☐ ☐ ☐ ☐ Y NI N NA	
III. MRI Safety		
MRI safety policies and procedures	☐ ☐ ☐ ☐ Y NI N NA	
Site access restrictions		
Zoning	☐ ☐ ☐ ☐ Y NI N NA	
MRI personnel and non-MRI personnel	☐ ☐ ☐ ☐ Y NI N NA	
Screening of patients and non-MRI personnel	☐ ☐ ☐ ☐ Y NI N NA	
Screening of MRI personnel	☐ ☐ ☐ ☐ Y NI N NA	
Screening of device and object	☐ ☐ ☐ ☐ Y NI N NA	

Form MRI — Items to be reviewed by auditor		Adequacy	Comments
	MRI safety of accompanying family or personnel	☐ ☐ ☐ ☐ Y NI N NA	
Issues related to time varying gradients of magnetic field			
	Induced voltages	☐ ☐ ☐ ☐ Y NI N NA	
	Auditory considerations	☐ ☐ ☐ ☐ Y NI N NA	
	Thermal considerations	☐ ☐ ☐ ☐ Y NI N NA	
	Screening of MRI personnel	☐ ☐ ☐ ☐ Y NI N NA	
Cryogen related issues		☐ ☐ ☐ ☐ Y NI N NA	

Annex IV

WORKSHEET FORMS FOR PHYSICS PROCEDURES

The audit team members should use the following worksheet forms for physics procedures as internal tools to assist them in conducting the audit review.

TECHNIQUE OBSERVATION SHEET

Radiographer/physicist _____

Technique demonstrated _____

Step 1: What guidelines were used? Were they clear? Were they documented? Were they appropriate?
Step 2: Technique demonstration. Radiographer: Was the task accurately performed? Physicist: Was the rationale for the task understood and were the results interpreted?
Step 3: Monitoring the record process. Were the results documented adequately?
Step 4: Follow-up response. Was the suggested follow-up action appropriate? Did it suggest an understanding of the reason for the procedure?

K_i Phantom: Chest 1

DETERMINATION OF INCIDENT AIR KERMA USING THE CDRH CHEST PHANTOM

User: _____ Date: _____

Hospital or clinic name: _____

1. X ray equipment

X ray facility and model: _____ Room No.: _____

Imaging using screen–film combination Imaging using digital image receptor

Screen–film combination: _____ Image receptor model: _____

Film processor model: _____

Developer and fixer (brand name): _____.

2. Dosimeter and phantom

Dosimeter model: _____ Serial No.: _____ Date of calibration: _____

Calibration coefficient[1] N_{K,Q_0} : _____ ☐ mGy/nC ☐ mGy/reading

Reference conditions: HVL (mm Al): _____ Field size (mm × mm): _____

Pressure P_0 (kPa): _____ Temperature T_0 (°C): ____

Manufacturer of phantom: _____ Serial No.: _____.

3. Exposure conditions

□ AEC □ Manual AEC setting:_____ mA setting:_____ Tube voltage (kV): ___

Manual or (if available) post-exposure mA·s: _____

[1] This is the calibration coefficient for the whole dosimeter, including the detector and the measurement assembly. For systems with separate calibration coefficients for the detector and measurement assembly, the overall calibration coefficient is calculated as a product of the two separate calibration coefficients.

K_i Phantom: Chest 2

Tube focus to tabletop distance d_{FTD} of vertical Bucky from the

X ray focus: _____ mm

Distance d_m of dosimeter from vertical Bucky: _____ mm

Anteroposterior (AP) chest thickness, t_P = 225 mm.

4. Dosimeter reading and calculation of incident air kerma

Dosimeter reading (M_1, M_2, M_3): _____ Mean dosimeter reading $\overline{M}$: _____

Pressure P (kPa): ___ Temperature T (°C): ____ $k_{TP} = \left(\frac{273.15+T}{273.15+T_0}\right)\left(\frac{P_0}{P}\right) =$ _____ [2]

HVL (from Section 5 below) = _____ mm Al $k_Q =$ _____

Calculated value of air kerma, $K(d) = \overline{M} N_{K,Q_0} k_Q k_{TP} =$ _____ mGy

Calculated value of incident air kerma, $K_i = K(d)\left(\frac{d_{FTD} - d_m}{d_{FTD} - 225}\right)^2 =$ _____ mGy.

5. Determination of HVL

Dosimeter readings should be obtained for filter thicknesses that bracket the HVL. The first and last readings, M_{01} and M_{02}, are made at zero filter thickness.

Filter thickness (mm Al)	Dosimeter reading, M (mGy)	Average dosimeter reading, $\overline{M}$, at zero thickness
0.00		$(M_{01} + M_{02})/2$ = _____ mGy
0.00		Interpolated HVL: _____ mm Al

[2] For dosimeters with a semiconductor detector, $k_{TP} = 1$.

INDIRECT ASSESSMENT OF INCIDENT AIR KERMA AND ENTRANCE SURFACE AIR KERMA

User: _____ Date: _____

Hospital or clinic name: _____

1. X ray equipment

X ray facility and model:
_____ Room No.: _____

Imaging using screen–film combination ☐ Imaging using digital image receptor ☐ Examination: _____

Screen–film combination: Image receptor model: _____

_____

Film processor model:_____

Developer and fixer (brand name): _____.

2. Calculated incident air kerma and entrance surface air kerma

Tube focus to tabletop distance, d_{FTD}: _____ mm

Distance, d, of dosimeter from tube focus:_____ mm

Patient	Weight (kg)	Tube voltage (kV)	Tube loading (mA·s)	Patient thickness, t_P (mm)	Field size (mm × mm)	Tube output $Y(d)$ at distance d [a] (mGy/(mA·s))	Incident air kerma, K_i [b] (mGy)	Entrance surface air kerma, K_e [c] (mGy)

[a] The value of $Y(d)$ is interpolated from measured values of tube outputs.

[b] Incident air kerma, $K_i = Y(d)P_{It}\left(\frac{d}{d_{FTD} - t_P}\right)^2$ = _____ mGy.

[c] Entrance surface air kerma, $K_e = K_i B$ = _____mGy.

Phantom:
Fluoro 1

DETERMINATION OF ENTRANCE SURFACE AIR KERMA RATE FOR A FLUOROSCOPY INSTALLATION

User: _____ Date:_____ Under table couch ☐ Over table couch ☐ C arm ☐

Hospital or clinic name: _____

1. X ray equipment

X ray facility and model: _____ Room No.: _____

Image intensifier model: _____ Anti-scatter grid ☐ Yes ☐ No

2. Dosimeter and phantom

Dosimeter model: _____ Serial No.: _____ Date of calibration: _____

Calibration coefficient[1] N_{K,Q_0}: _____ □ mGy/nC □ mGy/reading

Reference conditions: HVL (mm Al): _____ Pressure P_0 (kPa): _____ Temperature T_0 (°C): ____

[1] This is the calibration coefficient for the whole dosimeter, including the detector and the measurement assembly. For systems with separate calibration coefficients for the detector and measurement assembly, the overall calibration coefficient is calculated as a product of the two separate calibration coefficients.

Phantom:
Fluoro 2

Manufacturer of phantom: _____ Serial No.: _____

☐ 200 mm water ☐ 300 mm water ☐ 185 mm PMMA ☐ 278 mm PMMA.

3. Exposure conditions for phantom

Focus-to-intensifier distance: _____ mm Focus-to-chamber distance: _____ mm

Ambient conditions: Pressure, P (kPa): _____ Temperature, T (°C): _____ k_{TP} = _____.

Phantom: Fluoro 3

4. Dosimeter reading and calculation of entrance surface air kerma rate

Selected option	Tube voltage (kV)	Tube current (mA)	Filtration (mm Al)	Manual or auto-mode setting[a]	Field size (mm × mm)	Dosimeter readings, $\dot{M}_1$, $\dot{M}_2$, $\dot{M}_3$ (mGy/min)	Mean dosimeter reading, $\overline{\dot{M}}$ (mGy/min)	k_Q	Entrance surface air kerma rate, $\dot{K}_e$[b] (mGy/min)

[a] Enter M (manual) or auto-mode details.

[b] For water phantom use the following formula: $\dot{K}_e = \overline{\dot{M}} N_{K,Q_0} k_Q k_{TP}$, where $k_{TP} = \left(\frac{273.2+T}{273.2+T_0}\right)\left(\frac{P_0}{P}\right)$.

For PMMA phantom use the following formula: $\dot{K}_e = \overline{\dot{M}} N_{K,Q_0} k_Q k_{TP} \frac{B_w}{B_{PMMA}}$, where $k_{TP} = \left(\frac{273.2+T}{273.2+T_0}\right)\left(\frac{P_0}{P}\right)$; k_{TP} = 1 for systems with automatic temperature and pressure corrections and for semiconductor dosimeters.

P_{KA} Patient: Fluoro 1

DETERMINATION OF AIR KERMA AREA PRODUCT

User: _____ Date: _____

Hospital or clinic name: _____

1. X ray equipment

X ray facility and model: _____ Room No.: _____

Image intensifier model: _____.

Anti-scatter grid: ☐ Yes ☐ No

2. KAP meter

KAP model:_____ Serial No.: _____ Calibration date: _____

Calibration coefficient, N_{P_{KA},Q_0}: _____ ☐ Gy·cm^2/C ☐ Gy·m^2/reading

Reference conditions: Beam quality: _____ HVL (mm Al): _____

Pressure P_0 (kPa): _____ Temperature T_0 (^{o}C): ____.

P_{KA} Patient: Fluoro 2

3. KAP reading and calculation of air kerma area product

Ambient conditions: Pressure, P (kPa): _____ Temperature, T (°C): ____ k_{TP} = _____

Examination details	Tube voltage (kV)	AEC setting	KAP meter reading, M	k_Q	Air kerma area product, P_{KA} [a] (Gy·cm^2)	Fluoroscopy time (s)

[a] $P_{KA} = MN_{P_{KA},Q}k_{TP}$, where $k_{TP} = \left(\frac{273.2+T}{273.2+T_0}\right)\left(\frac{P_0}{P}\right)$.

Phantom:
MGD 1

CALCULATION OF INCIDENT AIR KERMA AND HVL

User: _____ Date: _____

Hospital or clinic name: _____

1. Dosimeter reading at tube loading $P_{It,auto}$ and calculation of incident air kerma

Dosimeter readings under manual control, M_1, M_2 and M_3 _____

Mean dosimeter reading, $\bar{M}$: _____ at tube loading, P_{It}: _____ mA·s

Calculated dosimeter reading, M_{auto}, at $P_{It,auto}$ ($M_{auto} = P_{It,auto}\ (\bar{M}/P_{It})$): _____ mGy

Pressure (kPa): ____ Temperature (°C): ____ $k_{TP} = \left(\frac{273.2+T}{273.2+T_0}\right)\left(\frac{P_0}{P}\right) =$ _____[1]

HVL (from Section 2 below) = _____ mm Al $k_Q =$ _____

Calculated value of incident air kerma $K_i = M_{auto} N_{K,Q_0} k_Q k_{TP}$ _____ mGy.

2. Determination of HVL

Dosimeter readings should be obtained for filter thicknesses that bracket the HVL. The first and last readings are made at zero filter thickness.

Filter thickness (mm Al)	Dosimeter reading (mGy)	Average dosimeter reading $\bar{M}$ at zero thickness
0.00		$(M_{01} + M_{02})/2$ = _____ mGy
0.00		Interpolated HVL: _____ mm Al

[1] For dosimeters with a semiconductor detector, $k_{TP} = 1$.

Phantom:
MGD 2

3. Mean glandular dose for 45 mm PMMA phantom

The conversion coefficient $c_{D_{G50},K_{i,PMMA}}$ should be interpolated from Table 8.5 in Ref. [IV–1] for the measured value of the HVL and the factor s from Table 8.6 in Ref. [IV–1] for the selected target–filter combination:

$c_{D_{G50},K_{i,PMMA}}$: _____ mGy/mGy s: _____

Mean glandular dose, $D_G = c_{D_{G50,},K_{i,PMMA}} sK_i$ = _____ mGy.

Phantom:
CT1

MEASUREMENT OF $C_{a,100}$, $C_{PMMA,100,c}$, $C_{PMMA,100,p}$ AND CALCULATION OF C_w

User: _____ Date: _____

Hospital or clinic name: _____

1. X ray equipment

CT scanner model:_____ Room No.: _____.

2. Ionization chamber, electrometer and phantom

Dosimeter model: _____ Serial No.: _____ Calibration date:

_____

Calibration coefficient ☐ mGy·cm/nC ☐ mGy·cm/reading

N_{P_{KL},Q_0}:[1] _____

Reference conditions: Beam quality: _____ HVL (mm Al): _____

Pressure, P_0 (kPa): _____ Temperature, T_0 (°C): ____

Manufacturer of phantom: _____ Serial No.: _____

Conditions during measurement:

Pressure (kPa): ____ Temperature (°C): ____ $k_{TP} = \left(\frac{273.2+T}{273.2+T_0}\right)\left(\frac{P_0}{P}\right) =$ _____.

[1] This is the calibration coefficient for the whole dosimeter, including the detector and the measurement assembly. For systems with separate calibration coefficients for the detector and measurement assembly, the overall calibration coefficient is calculated as a product of the two separate calibration coefficients.

Phantom: CT2

3. CT air kerma index $C_{a,100}$

Scanner settings (tube voltage, beam filter, etc.)	Nominal slice thickness, T (mm)	Number of slices, N	Tube loading, P_{It} (mA·s)	Dosimeter readings, M_1, M_2, M_3	Mean dosimeter reading, $\bar{M}$	Calculated value of $C_{a,100}$ (mGy)	Calculated value of ${}_nC_{a,100}$ (mGy/(mA·s))

The CT air kerma index is calculated using[1]: $C_{a,100} = \frac{10}{nT} M N_{P_{KL},Q_0} k_Q k_{TP}$; ${}_nC_{a,100} = \frac{C_{a,100}}{P_{It}}$.

[1] The factor of 10 in the formulas for $C_{a,100}$, $C_{PMMA,100,c}$ and $C_{PMMA,100,p}$ takes account of the use of a dosimeter calibration in mGy·cm and a slice thickness specified in mm.

REFERENCE TO ANNEX IV

[IV–1] INTERNATIONAL ATOMIC ENERGY AGENCY, Dosimetry in Diagnostic Radiology: An International Code of Practice, Technical Reports Series No. 457, IAEA, Vienna (2007).

Annex V

CONTENTS OF THE ATTACHED CD

Comprehensive Clinical Audits of Diagnostic Radiology Practices: A Tool for Quality Improvement

Audit report template

Audit report forms

Audit application form

List of items requested to be available on-site

Equipment-specific checklist forms

Worksheet forms for physics procedures

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