

Quality Systems for Medical Imaging

Guidelines for
Implementation and Monitoring



WORLD HEALTH
ORGANIZATION
Regional Office
for the
Eastern Mediterranean

**Quality Systems
For
Medical Imaging**

**Guidelines for
Implementation and Monitoring**

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Preface

Many countries are making efforts to improve and increase population coverage with medical imaging, and among them are the countries of the World Health Organization Eastern Mediterranean Region. Unfortunately, diagnostic imaging is still among the least developed of the branches in health care systems in the Region. The WHO Regional Office for the Eastern Mediterranean continues to support countries to develop, adapt and integrate appropriate technologies for medical imaging. The promotion of the quality of the radiographic and protection aspects of medical imaging are among the priorities of the Regional Office.

This publication aims to cover some of the needs and demands of medical imaging services in many countries. It outlines principles for appropriate medical imaging and contains guidelines, checklists as well as two annexes designed to assist medical imaging centres in self-assessment of their own performance.

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Part I

Implementation and Monitoring of Quality Systems

Introduction

Medical imaging is an essential part of the diagnosis of many diseases and has an important role in the improvement of public health in all population groups. The procedures used often involve the use of powerful and potentially damaging ionizing radiation. Poorly controlled medical imaging equipment, techniques and facilities can cause serious harm to both the operators of the equipment and the patient.

While all clinicians and health administrators are familiar with medical imaging—radiography (X-rays), sonography (ultrasound), scintigraphy/radionuclide, computerized tomography (CT) and magnetic resonance (MR) scanning—because it is an integral part of medical education, few are familiar with the details of quality control which are necessary to produce a high quality image. Even radiologists and radiographers are often unaware of the many details which should be routinely checked and rechecked if a high standard is to be maintained. Particularly in need of guidance are the imaging staff of small, relatively isolated hospitals and clinics and those in small private practices. Busy with their daily work, they become oblivious to slow deterioration in their complex equipment and their own techniques. Their training seldom provides the systematic checks which must be applied if an imaging service is to run smoothly, efficiently and at a consistently high standard.

The staffs of ministries of health and many hospital administrators also need the guidance of this manual. No programme of quality control can be satisfactorily organized and performed without the expenditure of time and, equally important, money. However, it is easy to waste both on inappropriate schemes which have a poor yield and do not improve patient care. This manual will indicate the essentials of a viable and cost-efficient programme of quality assessment, correction and monitoring. All imaging services, regardless of size or location should be encouraged to follow the guidelines in this manual. Many will be unaware of just how poorly they are currently performing in some aspects of their service.

Wherever medical imaging procedures are used it is vital that the maximum diagnostic benefit is obtained while using the minimum possible radiation dose. The implementation of a quality system in a medical imaging service will ensure that only the correct imaging procedures are chosen and are performed by appropriately trained staff. The equipment used will be well maintained and calibrated irrespective of the size and complexity of the medical imaging service. This document provides valuable guidelines for the effective control of all aspects of medical imaging, thus ensuring the most cost-effective use of the available health funding.

Quality control programmes will not be successful unless there is an integrated programme of continuing education. All diagnostic imaging is advancing, often very rapidly. Today's equipment differs radically from that of a decade ago and will be out of date tomorrow. This is particularly true of all scanning—ultrasound, CT, MR and scintigraphy—but even what is commonly described as “plain film radiography” has improved almost beyond recognition in the quality of imaging and therefore of diagnosis.

As equipment improves, so does the diagnostic information which can be derived from the images. It is now possible to image parts of the body, such as the brain, liver, soft tissues and pregnant uterus, in ways which show details invisible a few years ago. Not only form but function can be visualized. Keeping informed and up to date with these advances may, realistically, be almost impossible, but continuing education will be more successful if there is a well thought out and coordinated programme. This should be more than attendance at large conferences for a few weeks each year; continuing education should involve all the staff of a medical imaging service and an additional benefit will be that the staff will learn to work together and realize how much the success of their work depends on the help and guidance of colleagues.

Digital imaging, without the use of conventional films, and teleradiology are developing rapidly. Image quality, imaging techniques and other aspects of quality control will be affected. Currently (1999) digital equipment without film is not often used in small hospitals but it will become more common. It is now very expensive, but when installed there will be many sections of this manual which will remain relevant (e.g. patient care, radiation hazards, reports. Quality control of digital images is very important.

It is important to know that poor image quality is a major source of diagnostic error. In large services with experienced radiologists and radiographers this may be a minor problem. They are able to compensate, to some extent, for an image which is not as good as they would wish. But those with less experience or specialized training will find poor image quality leads to misdiagnosis. Not only will some abnormality be misdiagnosed, but many features, such as hairline fractures or small pulmonary nodules will be invisible. Ultrasonography in particular is very dependent on the combination of good training and good equipment. It is, indeed, difficult to draw a clear line which separates quality control from continuing education.

No administrator should believe that either quality control or continuing education can be successful without the investment of both time and money. Neither is the sole responsibility of the individual. Medical imaging services invest large, often very large sums in the purchase of sophisticated equipment; unless those who use it are kept up to date, much of this capital investment will be wasted. Time is needed to study and learn from others, to discuss and correct problems and to monitor quality. Arranging for this time to be part of the duties (job description) of all staff will be a rewarding investment. Money will be needed to purchase excellent professional journals, CD-ROMs and

reference books, to subsidize attendance at academically recognized meetings and, within larger groups, to invite experts to lecture and spend time in the service with the staff. These requirements not only apply to radiologists, but also to radiographers and clerical staff. All need to be stimulated intellectually and kept up to date. It is in the best interests of the medical imaging service to invest both time and money in their staff. The return may be difficult to calculate but will always exceed expectations.

Quality management system: documentation

General

No medical imaging service can produce high quality service and work unless it is properly managed. High quality management implies good organization and discipline, with complete documentation of all aspects of the imaging service. If they are not already in existence, it may seem a laborious process to lay down and document the guidelines and management rules but, once established, the imaging service, large or small, will work more efficiently and produce a higher quality of service and images.

It is essential to document all agreed policies and procedures in order to provide instruction for every eventuality. This information must not only be kept on file, but must be readily available and understood by all members of the imaging service.

It is equally important to document the objectives, the standards which the imaging service wishes to reach and maintain, and how this is to be done. Inherent in this should be the belief that the patients' benefit and care is the most important aim of any imaging service. This commitment to a high level of professional care should be the basis for any quality management system.

Patient management

All patients, or where necessary, their care-givers, must receive as much information as possible about the examination they are to undergo, the reason for it and the benefit to be obtained. They must be aware of any risk or negative aspects of the imaging procedure. If there are pre- or post-examination requirements, these must be explained and provided in writing. If sedation is involved, the patient and the patient's clinician should be fully informed of the need, the dosage and any post-examination complications.

Good patient care requires that all this information is provided with every consideration for the patients' feelings and with their cooperation.

There must be written procedures to deal with patient complaints to correct any deficits and to document any changes which are made. Feedback from the patients and their friends, as well as from their clinician, is extremely important and should be documented. Effort should be made to obtain such information from all those who come to the imaging department in any capacity. In large departments there may be a staff member

responsible for obtaining this information—documenting complaints, noting compliments and checking waiting times, the way patients are received and welcomed in the department, and how they are cared for during the whole visit.

Staff management

Good personnel management requires that all members of the staff are aware of the aims of the service, the documentation of the procedures and all aspects of patient care. Their work should be regularly reviewed and discussed with them and they should be given every opportunity to advance in their careers in the way they wish, but with guidance as to the path for which they may best be suited. Communication with the staff at all levels is an essential part of good quality management.

General and radiation safety

A well-managed imaging service should be a very safe place in which to work. This implies that there are proper procedures for radiation safety and all other hazards, including fire and natural disasters. There are international, national and usually local regulations for safety in the workplace, and these should be strictly met by any imaging service.

Equipment management

All medical imaging services use expensive and complex equipment. The proper control and management of this huge investment in capital and skill requires that the equipment be properly calibrated, maintained and regularly serviced. Detailed records must be kept not only of routine servicing but any breakdown which may occur. The hours not available for patient care, the reasons for the interruption in service and the difficulties experienced by the staff are as important as the quality of images when the equipment is functioning properly. A graphic representation frequently makes it easier to realize that equipment is wearing out or has developed a recurring fault which requires a significant overhaul. Equally, when equipment is very highly rated, this too should be noted.

The procedures for purchasing new equipment must be documented and agreed by not only the administrative staff but by the radiologists, radiographers, the physicists and those who undertake care and maintenance. This applies not only to obviously expensive equipment such as MR and CT scanners, but even to smaller items such as reception computers.

Good management also requires that every item of equipment is available when needed, ranging from catheters to syringes to wound dressings and including drugs for

routine and emergency procedures. Again, documentation and the allocation of responsibility is the essence of good management, so that there is someone who will ensure that equipment of every sort is available when or if required. Advice and help from other specialized services, such as anaesthesia and pharmacology should always be welcomed. There is an immense range and amount of equipment in any imaging department but even one small missing item may make the difference between life and death for a patient.

Reports and records

The radiological report is the “bedside manner” of a medical imaging service. It is the product by which the referring clinician and the patient will judge the department. This means that it must be clear, easily understood and without technical error; the images must be properly identified and linked to the patients’ clinical information. The reporting radiologist must have good clinical information about the patient, and the radiographer or sonographer who makes the examination must know of any physical or other problems faced by the patient and must understand the reason for the requested imaging examination.

The proper transmission of each report to the referring clinician, a permanent record of it in the department, proper storage and easy access to the images, to enable comparison if the patient returns for subsequent imaging are all part of good management. But the underlying reason, to provide a helpful report giving diagnostic information to the referring clinician and thus aiding patient care, must be the management philosophy.

Quality of care, audits and corrective action

As already discussed, an imaging service is judged by the patients and by the referring clinicians. Their praise and their complaints are vital information which require action, documentation and follow-up. No department, small or large, can afford to ignore a complaint or refuse to take any action. In addition, the staff of the department must ensure that both internal audits conducted by radiology staff, and external audits conducted by carefully selected and impartial technical specialists, are periodically conducted to ensure continuing compliance of the department with the requirements of the quality management system. If there is a change in procedure, all members of the staff must be informed and in many cases should be allowed to express an opinion as to the best solution to the difficulty. Regular follow-up, to see what is happening, is an essential part of management.

More detailed review, with suggestions and guidelines for these aspects of management are provided in Part II.

Part II

Technical Guidelines



Introduction

This manual cannot provide guidelines and specifications for everything in every medical imaging service, but the principles described are important. There will be many imaging services where the minimum specifications will be exceeded, but small departments should also try to follow them. The guidelines aim to be practical and vary according to the size and scope of each imaging service.

Most countries already follow regional, national or international regulations and the technical requirements in this manual should supplement rather than replace these. Where regulations do not exist, the technical requirements in this manual should become the minimum acceptable standards for medical imaging, regardless of the number of patients or the range of imaging provided.

When changes are needed to meet these minimum standards, it is important that all decisions and necessary actions are not only recorded, but communicated to everyone responsible for any aspect of the imaging service. There must be a follow-up check to make sure that the decisions have been implemented and there must be regular review and updating; this is not a one-time event.

Patient care

Radiation safety

General

Excess exposure to ionizing radiation from X-rays or radionuclides can harm patients, but when used wisely, the benefit of the information provided will outweigh any risk. Nevertheless, every effort must be made to get the most diagnostic information using the minimum radiation dose. This can be achieved not only by choosing the correct technique and exposure to produce a high quality film, but by careful clinical assessment of the patient and then the selection of the best imaging method. Because there is no ionizing radiation, ultrasonography should, where appropriate, be the first choice, or scintigraphy (radionuclide–radioisotope studies) may provide the correct diagnosis with less radiation exposure than X-rays. But for many diagnostic examinations, X-rays are essential and this section provides guidelines which will help to reduce the dose of radiation to the patient. At the same time, this will lessen any risk to the staff.

Indications for imaging

It is the responsibility of the patient's clinician to ensure that any medical imaging requested will provide the information necessary for the best management of the patient's illness. There are very few indications for "routine" imaging of healthy individuals.

There are many different ways of imaging patients, and it is the responsibility of the imaging staff (where possible, the radiologist in charge) to establish, in consultation with referring clinicians, the guidelines for medical imaging. This is particularly important where the imaging procedure involves the use of a contrast agent, is an invasive procedure or has any increased risk or discomfort for the patient.

Every 6 months the staff of the medical imaging service should review the clinical imaging requests to identify inappropriate patterns. When such patterns are identified an effort should be made to correct this by providing relevant information and discussing this with the referring clinician. The ultimate responsibility for the appropriate choice and safety of all imaging lies with the medical imaging service rather than with the referring clinician.

Beam limitation, shielding and quality

The image size (the irradiated area) should be as small as possible while still providing the required clinical information. This should be achieved by careful and accurate beam limitation and consistent use of collimation. This requires precise alignment of the light beam with the X-ray field.

Radiation-sensitive organs such as the gonads should be shielded whenever possible with carefully positioned and appropriately designed lead shields. This is particularly important in the case of pregnant or possibly pregnant patients. In such cases the abdomen must be fully shielded whenever possible. (It is better to use sonography unless the skeleton is to be imaged.)

It is the responsibility of the imaging staff member X-raying any female patient of the appropriate age to inquire about the possibility of pregnancy and to record the date of the last menstrual period (LMP). The radiology service should prominently display notices warning patients in simple language of the risk of radiation (X-rays) at any stage of pregnancy. The notices should be in the general waiting rooms and all patient changing cubicles and toilets, and should be reproduced in all languages and scripts commonly used by patients who utilize the medical imaging services.

The quality of the X-ray beam is important in the reduction of radiation exposure and is affected by the filtration (inherent and added) on the X-ray tube, by the X-ray generator and by the exposure technique selected. It is the responsibility of the medical imaging staff to ensure that the tube filtration complies with international standards. As X-ray equipment is replaced, only high-frequency generators should be installed, regardless of the power output. The exposure technique should be such that the maximum diagnostic benefit is attained with the minimum radiation exposure. To help with this, there should be a carefully calculated exposure chart in each X-ray room to make sure that the best technique is chosen. These charts should be reassessed annually and altered if there is any change in the speed or quality of the films or screens in use in the department.

Film-screen combinations and processing

The medical imaging service should use the fastest film-screen combination possible provided there is no loss of diagnostic information.

Film processing should be maintained at optimum levels.

Fluoroscopy should never be performed without image intensification and even when intensifiers are available, should be kept to a minimum. The fluoroscopy time for each examination should be recorded for every patient. Fluoroscopy of the chest is a highly unreliable examination and should be discontinued.

A secondary-radiation grid (Bucky) is very seldom necessary for the examination of infants and small children and should be used only after careful consideration; the somatic effects of radiation are more harmful on children than on adults.

Non-radiation hazards

General

In addition to the hazards to patients from the use of ionizing radiation, there are many other risks to patient safety that must be considered.

Electrical hazards

The medical imaging service is responsible for ensuring that all electrical wiring with the facility complies with all the relevant local and national regulations and requirements. This is particularly important in darkrooms using manual or “wet” automatic processing. Where invasive procedures involve the use of electrically conducting catheters and guide wires, particular attention must be paid to the requirements for earth-isolation of all electrical equipment. All high-tension wiring and connections must comply with international standards and should be annually inspected by appropriately qualified personnel. Any sign of damage to cables at any time should be reported to the head of the department without delay.

Patient support and immobilization

Tilting tables should have adequate and firm support for the hands and feet of patients, as well as efficient brakes. Moving table-tops must have efficient and easily operated brakes. These should be checked monthly. Where children or other patients are unable to cooperate, specifically designed immobilization devices should be available. Any person helping to restrain or position a patient during an X-ray exposure should be protected with standard lead aprons and lead gloves. These must be checked regularly for damage or radiation leakage (every 3 months) and the results must be documented every time.

Privacy and confidentiality

Medical imaging facilities are frightening to many patients who come for examination; relieving their anxiety will make the examination much easier. Much of the anxiety of patients arises from a lack of understanding and knowledge of the medical procedures which they are expecting. It is the responsibility of the medical imaging service to try to reassure the patient that their privacy, comfort and confidentiality will be preserved throughout the examination procedure.

Information for patients and their clinicians

The medical imaging service should have information leaflets describing in an easy and friendly way any procedure for which specific patient preparation or cooperation is required. If it is necessary for the referring clinician to prescribe sedation or any other medication, there should be a similar information leaflet for this purpose. All such information leaflets may include other useful information which may assist the patient or clinician, such as transport arrangements, directions for finding the facility, duration of the examination, etc.

Patient changing facilities

It is the responsibility of the medical imaging service to provide not only a general waiting area but private changing rooms with arrangements for the security of patients' property. The schedule of examinations should be such that the waiting time for each patient is kept as brief as possible, particularly if the patient is required to undress.

Care following the examination

Following the procedure, the patient and where necessary the patient's doctor or nurse, must be given clear instructions (preferably written) concerning any possible after-effects or complications arising from the examination, and how to manage them. It is usually a good idea to tell the patient if and when they should go back to see their own doctor.

It is the responsibility of the staff of the medical imaging service to ensure that the patient has sufficiently recovered from an invasive procedure to leave the facility safely, either alone or, if necessary, with an escort.

Staff care

Radiation safety

General

All staff of a medical imaging service work where there is a risk of exposure to ionizing radiation, which even in small doses may be harmful if repeated over the long term. Provided that staff are properly trained, the facility is correctly designed, and appropriate protection is available and used, the risk is minimal. It is the responsibility of the medical imaging service to ensure that the working conditions for staff are as radiation free as possible and meet all international and local regulations.

Staff training

Adequate training in radiation safety is a prerequisite for all staff working in the medical imaging service. Where recognized national standards for radiation safety training exist, these must be applied by the medical imaging service. The implementation of radiation safety procedures should be continually reinforced.

Radionuclide disposal

Where radionuclides are used for imaging, it is the responsibility of the medical imaging service to provide proper training and facilities for the safe disposal of all residual radioactive material and any contaminated consumables. National regulatory requirements may apply.

Personal radiation monitoring

It is the responsibility of the medical imaging service to provide a personal monitoring device for any staff member who may be at risk of exposure to radiation; these may, for example, include nurses and operating room or laboratory staff, as well as those in the imaging department. Detailed records must be kept of the measured radiation dose and these records should be reviewed every 3 months. Accumulative records should be maintained throughout the career of the individual in medical radiation technology, or for anyone who is liable to radiation exposure in their work.

If any staff member receives a radiation dose in excess of international limits, expert advice should be sought concerning their health. The medical imaging service must

establish the cause of the excessive exposure and take effective steps to make sure it does not happen again. Written records of all such events should be maintained, together with the way they are to be corrected.

Non-radiation hazards

General

In addition to radiation in a medical imaging service, staff may be exposed to a range of other hazards which may affect their health and well-being. These include infection, electric shock, and especially in dark rooms, inadequate ventilation, chemical contact, mechanical impact, etc. It is the responsibility of the medical imaging service to ensure that all hazards are identified, that the staff are well aware of the potential problem and to ensure that wherever possible the hazard is isolated or eliminated.

Infection control

To reduce the risk of infection, the medical imaging service should provide appropriate protective clothing for all staff members, including where relevant, masks, gloves, and gowns. The effective use of such protection by all staff should be carefully monitored.

Standard procedures should be followed for the sterilization or disposal of all contaminated clothing and equipment.

If any staff member may have been exposed to a significant risk of infection, expert advice should be sought and appropriate corrective measures should be taken to ensure that it doesn't happen again. Records of all such exposures to infection should be maintained.

Electrical hazards

It is the responsibility of the medical imaging service to ensure that all staff members are aware of potential electrical hazards, particularly in darkrooms using manual or "wet" automatic processing.

It is often necessary to connect different items of ancillary equipment to the electrical supply. Staff should be made aware that such supply connections can be overloaded. Connecting cables should be positioned so they are not a hazard as the staff perform their duties, particularly where liquids may be spilled, e.g. IV solutions, barium enemas.

Lifting

Staff in a medical imaging service may have to lift heavy and awkward loads, including patients or equipment. Training in correct lifting techniques should be given and all reasonable measures should be taken to avoid injury resulting from lifting. Where necessary, lifting equipment should be provided, especially to transfer patients to or from an X-ray table onto a trolley (gurney) or bed.

Repetitive strain injury

In a medical imaging service some staff may be required to perform work-related activities of a highly repetitive nature involving the risk of repetitive strain injury. Training should be provided in the recognition and avoidance of such injuries, and ergonomically designed furniture or equipment should be provided if needed.

When a staff member is adversely affected by the highly repetitive nature of the task, appropriate relief and training should be provided to help the staff member recover and resume normal duties.

Building and facilities

General

The correct design of medical imaging facilities will reduce radiation and non-radiation hazards and contribute to the care and well-being of patients and staff. In particular, the correct positioning of X-ray equipment in each room is an important aspect of radiation protection. It is the responsibility of the medical imaging service to ensure the optimum design of their facility and to ensure that there is no radiation risk to anyone working or waiting in any room adjoining the X-ray room (including above or below the X-ray room) (see also Room sizes).

Patient facilities

It is the responsibility of the medical imaging service to ensure that corridors and doors leading to all patient areas and examination rooms allow the easy and safe movement of all patients, including those who are handicapped or injured. All patients should receive a friendly greeting at the reception desk and be given clear information and instructions concerning their visit to the imaging service. There must be adequate and pleasant waiting space, with enough room for relatives or accompanying persons. Individual changing cubicles must ensure privacy and permit entrance to the examination room without traversing a public waiting area. The provision of pleasant surroundings and seats with reading material will help the anxious patient. There must be sufficient toilet facilities, including those suitable for the handicapped, and safe storage facilities for patients' clothing and valuables during imaging.

Access and lighting

All corridors leading to and within the imaging facility must be well lit and unobstructed at all times. There must be clear directional signs to each area in the most used local languages and scripts. All doors to the waiting area and examination rooms must be wide enough to allow easy passage of wheelchairs and trolleys without any obstruction or steps.

Lighting in all parts of the facility should be warm and adequate. Air-conditioning should be provided where necessary, and rooms in which patients are lightly clothed should be warm (the optimum temperature is 16–24 °C). The exchange of air in examination

rooms and dark rooms must conform to local and national standards and provide fresh air where possible.

Room sizes

All examination rooms must be of adequate size (the recommended minimum size for a general purpose X-ray room is 18 square metres, with any one dimension not less than 4.5 metres). It is the responsibility of the medical imaging service to ensure that the room size and equipment layout do not contribute to radiation hazards either for staff or patients. The protection for those working in adjoining rooms or in rooms above or below the X-ray room is also the responsibility of the medical imaging service. The controls for the X-ray generator in each room must be behind a fixed radiation-proof barrier, with a radiation-safe window through which the patient can be observed at all times. The exposure switch activating the X-ray generator must be an integral part of the control panel, so that an X-ray exposure can only be made when the operator is in the protected area.

The minimum recommended size for a standard X-ray dark room serving one X-ray examination room is 6 square metres with a minimum dimension of not less than 2 metres; it is better if the darkroom can be 30% larger. Darkrooms must be properly ventilated according to national or international standards and should have an adequate extraction fan which functions whenever the dark room is in use. It is the responsibility of the medical imaging service to ensure that all electrical connections in the dark room comply with national safety regulations and that there is safe storage for all processing chemicals.

There must be adequate and safe storage of patient records and images; this is normally the responsibility of the imaging service unless delegated to an associated record service.

It is the responsibility of the medical imaging service to ensure that in every area of the facility which is used for the interpretation of images, the illumination is controlled through a dimmer switch and there is adequate ventilation meeting or exceeding national and international standards.

Personnel

Recruitment

The effective functioning of any medical imaging service is critically dependent on the quality of the staff members employed; highly qualified and skilled individuals will be needed for many activities. It is the responsibility of the medical imaging service to ensure that only those holding the necessary qualifications and experience are recruited as staff members.

Procedures for the recruitment of staff, including the development of a job description, advertising, interviewing, contracting, remuneration and the induction of new staff, should be formally documented and implemented.

Qualifications, training and experience

While some medical imaging procedures, e.g. invasive angiography, may only be performed by staff members holding the appropriate specialist medical qualifications, other duties may need to be performed by staff members holding management, accounting, technical or safety qualifications and experience.

Specialist requirements

In many countries national or international regulatory requirements will define the qualifications required for the performance of many of the medical procedures conducted in a medical imaging service. Where such requirements exist, these should be closely adhered to by the medical imaging service.

Where specialists qualified in medical disciplines other than diagnostic imaging perform imaging procedures, it is the responsibility of the medical imaging service to provide all additional training and regular monitoring necessary for the correct and safe performance of those procedures. If there are regional or national standards these should be followed.

Some national regulations require that staff members of a medical imaging service (particularly radiologists) have regular (every 3 years) examinations of visual acuity. Records of these examinations and of the prescription of any necessary optical aids, should also be maintained by the medical imaging service.

Training

General

All staff members of the medical imaging service should be given on-the-job training of a general nature, appropriate to the medical imaging service and to specific tasks within the service. Such training should include instruction in radiation safety, fire, earthquake and other disasters, patient emergencies, computing and training in the quality management system of the medical imaging service.

Training records

It is the responsibility of the medical imaging service to maintain detailed records of the qualifications, experience, training and competence of all staff members. Such records should be revised at least annually. Where any individual staff member may, for whatever reason, be at risk of losing competence at certain tasks, the staff records should reflect these changes and any steps taken to re-establish competence. These records should include the details of all general training provided to staff.

Continuing development and education

Medical imaging is a highly specialized and increasingly highly automated field of medicine in which the technological complexity of imaging equipment and procedures is advancing rapidly. Accordingly, it is the responsibility of the medical imaging service to ensure that all staff, particularly medical and technical staff, attend and actively participate in continuing education programmes.

Such programmes may include conferences, seminars, clinical meetings, specialist training courses, in-house training courses, video and CD-ROM and other audiovisual presentations, reference text books and specialized journals, etc. Where specific requirements for continuing development are defined by professional organizations, it is the responsibility of the medical imaging service to provide the time and financial resources to enable staff to fulfil these requirements. Records of all continuing education must be maintained for each staff member.

While continuing education and development applies primarily to medical and technical staff, it is equally important that all other staff members receive continuing development appropriate to their duties within the medical imaging service.

Equipment

Selection and purchase

The purchase of medical imaging equipment is a significant capital expenditure and there will be recurring costs. A carefully planned assessment of the medical needs of the population to be served by the medical imaging service must precede any purchase of equipment. This must include assessment of the population age groups, the likely incidence of trauma, seasonal epidemics, the pattern of local disease and any other factor that may influence the demand for imaging services. Any purchase must also be complementary to the clinical services available locally. It is not effective to provide sophisticated imaging techniques if there are no clinical services which can offer matching patient care, or vice versa. These and the following principles apply also to digital and teleradiology equipment.

The medical imaging service should have formally documented procedures for the selection and purchase of all items of medical imaging equipment and consumables. Factors influencing the selection of equipment include the available space, the electrical and other building services necessary, the staff and their training and experience, and the availability of spare parts and competent maintenance engineers. The selection process must also include a realistic assessment of the running costs and consumables in addition to the initial purchase price. Any structural alterations to existing buildings and facilities will also influence the selection of equipment.

Information and opinions concerning the technical design of each item of equipment under consideration should be sought as widely as possible from professional and independent sources. While the final choice should usually be of the most up-to-date design, the selected equipment should also be well proven. When the specification of the equipment has been decided, quotations should be requested from several manufacturers, who must also be asked to supply the address of other imaging services currently using the equipment they are offering. These users should be contacted to obtain information on the reliability and consistency of the equipment in a working situation. There should also be detailed information of the supplier's service and spare parts organization, where it is based and how readily it is available. The warranty agreement should be detailed and specific.

The final purchase contract should only be completed after the careful consideration of all these factors. The specifications must be fully defined in writing as an integral part of the purchase contract. A contract to provide for continuing service and repair of any

item of equipment for a period of not less than 5 years should normally be specified as part of the purchase agreement.

Final payment should be withheld until the equipment has been fully installed, has been working satisfactorily for a period of not less than 3 months and has been proven to fully comply with all requirements specified in the purchase contract.

Servicing

As previously described, servicing arrangements should be formally included in the purchase agreement. It is the responsibility of the medical imaging service to ensure that all imaging equipment is fully maintained by well trained professional personnel and is in usable, safe condition.

Full records of all repairs, servicing, maintenance and replacement parts used should be maintained for each item of imaging equipment. Data from these records, including records of equipment down time, will contribute to the equipment replacement programme of the medical imaging service.

Calibration: frequency and standards

General

All items of medical imaging equipment, including digital, teleradiology and standard film processing and ancillary equipment, should be subject to formal calibration upon installation and at defined intervals thereafter, even when the equipment appears to be functioning correctly. The purpose of equipment calibration is to ensure confidence in the parameters measured and in the quality of the medical images obtained. The level of calibration may vary according to the relative significance of the parameter being tested.

While calibration should normally be performed by trained medical physicists who will usually require complex instrumentation, other more basic calibration will be necessary on a more regular basis.

Frequency of calibration

The frequency of calibration of each item of medical imaging equipment will vary according to many factors, including the type and model, age and state of repair, frequency of use, performance stability, etc. There will always be a trade-off between quality and cost.

Where the performance of equipment is critical to the medical diagnosis (e.g. CT, MR, high speed angiography and teleradiology), and where safety of staff and patients

may be adversely affected, the calibration schedule will be frequent and detailed. However, where the equipment is more stable and less critical and safety concerns are minimal (e.g. routine radiography), the calibration schedule may be less rigorous.

It is the responsibility of the medical imaging service, in consultation with an appropriately trained and qualified medical physicist, to develop and implement a calibration programme relevant to each individual item of medical imaging equipment. The programme should specify the procedure to be followed, the frequency of calibration, the reference equipment to be used, the performance specifications expected, and the staff members competent to perform the calibration.

Where there are no diagnostic medical physicists, it is always possible to obtain useful guidelines by consultation with an imaging physicist maintaining similar equipment elsewhere.

Traceability of calibration (comparison with standards)

The overall objective of equipment calibration is to ensure that each item of medical imaging equipment continues to function within generally accepted parameters. Any deviation from accepted parameters should be corrected as soon as possible.

Calibration is usually defined as the quantitative assessment of the errors in equipment performance when compared to reference or true values. However the concept of traceable calibration (calibration by comparison to national or international standards) will not normally apply to most items of medical imaging equipment in daily use. If the parameter being calibrated can be readily compared to a traceable reference standard (e.g. processor temperature may be measured using a calibrated thermometer) the concept of traceability should apply. Where this cannot be done without special equipment, e.g. radiographic film density, departmental standards should be developed and applied.

Calibration records

Detailed records of calibration should be kept and these records should, where possible, clearly indicate the numerical results of the calibration, a statement of compliance with specification, and the person responsible for the calibration work.

Note. It simplifies the recognition of developing problems if the results of successive calibrations are presented graphically.

Once calibrated, each item of medical imaging equipment should carry a calibration label or some other means of indicating the calibration status of the equipment and the due date of the next calibration. When the re-calibration of any item of equipment shows a level of performance outside the defined performance specifications, and this is at a level which may cause significant safety or quality control problems, the item should be

withdrawn from service until the repairs or adjustments required to restore the correct performance of the equipment have been made. If it is a fixed item, e.g. an X-ray table, it must be clearly labelled "Do not use". All these instructions and subsequent corrections must be documented.

Maintenance and quality control

Regular maintenance

As discussed (see Equipment selection and purchase) the arrangements for the periodic maintenance of many items of equipment in the medical imaging service should be included in the purchase contract. In addition to the expert scheduled maintenance, it is the responsibility of the staff of the medical imaging service to carry out a wide range of simple maintenance tasks. This may be simple cleaning, daily lubrication or adjustment, or more complex periodic overhaul of equipment. In either case, instructions in the maintenance tasks necessary and in the method to be used should normally be obtained from the equipment manufacturer; such instructions should be formally documented, known to the staff who work in the room and readily available in the same room as the equipment.

Detailed records should be kept of all maintenance tasks completed and the record should indicate the name of the person responsible, the date of the work, the nature of the work completed and any other comments which may be useful to long-term management of the equipment. There must be a clearly documented procedure to notify the equipment manufacturer or service agent when the routine maintenance checks identify significant faults or potential faults in the equipment.

Records should be kept of the time required to maintain each item of medical imaging equipment. Where these records indicate that maintenance time increases and significantly impedes patient examinations, the overhaul or replacement of the medical imaging equipment may be necessary.

Quality control

It is not sufficient to maintain and technically calibrate medical imaging equipment; a range of quality control checks should be regularly completed to find out just how well it works in patient care (see Annex 1 for Equipment quality control schedule). These checks will normally need reference objects or measurement devices that provide useful comparisons of the day-to-day performance of the imaging or processing equipment. Examples include tissue equivalent and other phantoms, step wedges, densitometry and sensitometry equipment, light meters, compression measurement devices, radiation leak detectors, etc.

Quality control records

The primary objective of regular quality control is to confirm that each item of equipment continues to operate within pre-determined and acceptable performance parameters. It follows, therefore, that the limits of the acceptable performance are an integral part of the equipment quality control programme. If the parameters are too widely set or are too liberal, equipment of moderately poor performance may be seen to be acceptable for use. If the parameters are too tightly set, they may represent unrealistic objectives that even the best equipment may not regularly meet. Therefore the performance parameters must be realistically obtainable and properly define the extremes of equipment performance beyond which there is significant loss of image quality and diagnostic value. When acceptable performance parameters have been established for each item of equipment, the regular quality control checks of that parameter will serve to identify any significant loss of performance and the equipment should be overhauled or withdrawn from use.

It is important that these acceptable “parameters” take into consideration the original specifications or capability of the equipment, the age of the equipment and the resulting deterioration in performance. Most important are any adverse effects to the patient which may arise from variable performance such as loss of film quality.

Drugs (including contrast agents)

General

All medical imaging services store and use a wide variety of drugs. These drugs are required not only for contrast examination but for sedation, the relief of pain or anxiety and, rarely, for the treatment of patients who suffer an allergic reaction or acute collapse for any reason (e.g. coronary thrombosis).

Storage and documentation

General

It is the responsibility of the medical imaging service to provide secure storage for all drugs, with proper documentation of their use, particularly of narcotics or other dangerous drugs. The storage and documentation must comply with all local and national regulations. Access to the drug storage must be limited and documented. Nevertheless, emergency drugs must be readily available without delay. The provision of an emergency trolley or “crash trolley/crash cart” which is readily available at all times is recommended in every medical imaging service and is mandatory where contrast or other invasive procedures are carried out. There must be a readily available list of the contents of the emergency trolley, and it must be carefully checked and replenished immediately after use, as well as on a regular schedule (weekly or monthly depending on the size of the imaging service). All equipment in the emergency trolley such as syringes, defibrillators, electrocardiograph, etc. must also be checked regularly with documentation by the responsible individual to ensure that the equipment is working, fully charged where appropriate, complete and ready for use.

Although the radiologist in charge of the imaging service is responsible for the proper provision and care of all drugs in the facility, it is recommended that whenever possible, the assistance of a pharmaceutical department be sought. This will provide expert advice and monitoring.

Contrast drugs and reactions

All drugs used in contrast imaging must be clearly and precisely labelled and, where the same drug is provided in different concentration, these must be clearly segregated. It is the responsibility of the medical imaging service to develop and document detailed

instructions for the use of every contrast drug, including any questions that each patient must answer before the drug is administered. The answers to these questions must be documented in the patient's medical record.

All medical imaging service staff must be informed when any new contrast agent is introduced and be knowledgeable about the indications and possible complications of that drug. All staff who administer contrast drugs must receive training in the use of those drugs, including the dose and the rate of administration. They must be properly trained in cardiopulmonary resuscitation (CPR), including defibrillation, and the specific antidote and supportive therapy. All drug reactions must be documented and reported to the drug manufacturer, and if required, to the appropriate state or national authority.

In hospitals or clinics where emergency teams are available to manage patients who have suffered from cardiac arrest or other acute emergency, all members of the medical imaging service must know how to summon these teams. This procedure must be documented and displayed prominently throughout the facility.

Sedation

There are a variety of medical imaging procedures for which patient sedation is desirable or in some cases essential, for example, angiography and for some patients, magnetic resonance imaging. Those examinations which must be preceded by sedation must be defined by the medical imaging service and documented, as must the drug regime to be adopted. The patient's clinician should be consulted before sedation is prescribed, particularly in the case of infants and young children and any patient who is already receiving other drugs. In some cases the drugs for sedation may be prescribed by the patient's clinician, who must be well informed of the necessity and the depth of the sedation required.

Many patients are anxious before or during examination within scanners, such as MR, some CT and some scintigraphy. Sedation should not be routine for every patient. Explanation and reassurance may make sedation unnecessary, and the medical imaging staff who are responsible for this type of examination should be trained in the methods of reassurance, which should always be tried before sedation is given.

It is recommended that the pharmaceutical and anaesthetic services be asked to review all the sedation protocols and, where possible, monitor the drug control and drug administration procedures in the imaging service.

Informed consent

The medical imaging service is responsible for ensuring that every patient understands the need for imaging and, where appropriate, any discomfort or risk which may be

incurred. Every patient has the right to ask for further information, and if they so choose, to refuse the procedure even if contrary to the doctor's advice.

Imaging procedures vary in the risk for the patients. Many are completely harmless, some use very small harmless amounts of radiation, while others may cause temporary discomfort, e.g. breast compression during mammography or discomfort when X-raying a fracture. Contrast examinations have a varying statistical risk, from the fairly common mild reaction to the very rare cause of death. It is important that every patient is fully advised of any risks and, before contrast examinations, the fact that the patient has been informed should be documented.

Every medical imaging service must establish and document their policy concerning written consent before any imaging procedure. This must ensure that every member of the medical imaging staff knows when and why written consent is to be obtained, who is responsible for discussing the risks with the patient, and who is to obtain and witness the written consent. Every radiologist who performs an interventional procedure is responsible for confirming that the patient has willingly consented and that all the documented policies have been followed. Where there are exceptions to the usual rules, for example an acutely ill, comatose patient, the policy for such cases must be specified and documented. In such cases the circumstances in the individual cases must be recorded in their medical records by the radiologists.

Every medical imaging service must also have strict guidelines for the follow-up of patients after any interventional procedure. These should indicate who is responsible, when the follow-up should be performed and, of particular importance, when any ambulatory patient is allowed to go home and must be escorted if necessary. The same procedure must be followed for patients who are returned to a hospital ward. All those who will subsequently care for the patient following an interventional procedure (such as nurses or relatives) should be fully informed of what care is necessary, what must be observed and what action is to be taken if any complication arises. This information should be given in writing and signed by the responsible radiologist.

The need for written informed consent, when it is necessary and the form it should be given in is controversial. There are often state or national requirements and these must be carefully followed. Where there is any doubt concerning the protocol documented by the medical imaging service, legal advice should be obtained.

Imaging techniques

Effective choices

For many years radiographs (X-rays) were the only way to image the skeleton, organs and soft tissues of a patient. Now there are many alternatives, and to radiography and its specialized techniques such as angiography and CT, must be added ultrasonography, scintigraphy and MR; each method has its own specialized techniques which together offer a bewildering choice of images from which clinicians must select. Now, more than ever before, the radiologist, who is an imaging specialist, should be consulted before the imaging procedure is chosen. It is the radiologist who must recommend the type of imaging best suited to the patient's clinical condition. Although this is an individual decision concerning each patient, it is possible to devise guidelines which can be used by referring physicians when requesting imaging.

It is the responsibility of the medical imaging service to provide these guidelines on the most effective choices for imaging a wide variety of common clinical conditions. These guidelines may be based on the numerous well-considered recommendations of groups such as the WHO, The Royal College of Radiologists of the United Kingdom, or the Royal Australasian College of Radiologists. Each medical imaging service must, in consultation with the referring clinician, adapt from these recommendations the guidelines appropriate to their own clinical practice. These guidelines must be regularly reviewed and updated by radiologists and clinicians together.

The wrong choice of imaging causes harm to the patient in several ways. There may be failure to make the correct diagnosis, unnecessary radiation exposure, the administration of unrequired contrast drugs or, rarely, actual harm. Often the failure to make the correct imaging choice leads to several other examinations, increasing the cost and in some cases the radiation exposure. Because the available alternatives and techniques are constantly changing, it is difficult to keep up with all the professional advances unless the medical imaging service provides regular review of current techniques. This should affect all levels of staff in the medical imaging service, not only the radiologists but also the radiographers, nursing staff and even clerical/reception staff. All should participate in appropriate continuing education. As already described (see Continuing development and education) the medical imaging service should therefore provide time and financial support for a continuing educational programme aimed at improving the choice of images. This is not a waste of time or money but an essential part of maintaining a high quality of imaging.

Refusing an imaging request

There will be occasions when the imaging service does not agree with the request of the referring clinician, a judgement which must always be made with reference to the patient's benefit and health. In some instances, the radiographer or sonographer may feel that the examination requested is not technically possible or, rarely, not in the best interest of the patient. The request must then be referred to the radiologist or, if there is no radiologist available, the difficulty must be explained and discussed with the referring clinician before any examination is carried out. In many cases, a modified or alternative examination may be possible. Very rarely, perhaps when there is a very experienced radiographer and a very inexperienced clinician, it may be necessary to obtain the opinion of another (preferably senior) clinician. All discussions and opinions must be documented.

When there is a radiologist available and he or she does not agree with the clinician's request, the same consultative procedure must be followed. If agreement cannot be reached and the radiologist believes that the examination is not warranted, he or she may refuse, but must record the reason and opinion in the patient's record (which may be in the form of an official radiology report). All medical imaging services must have an established procedure, which is documented and known to all members of the staff and provides clear guidelines for all such difficult events (see also Ethics).

Standard (routine) images and protocols

It is the responsibility of every medical imaging service to develop and document guidelines for the radiographers and sonographers, indicating the standard images which will be the initial examination for each patient. These will be based on the clinical condition of the patient, not on the anatomical sight. Such guidelines should apply to all ages and all imaging, including ultrasonography and scintigraphy, and will be the basis on which the interpreting radiologist will decide whether or not additional images must be obtained. Whenever possible the images should be shown to a radiologist before each patient leaves the facility.

The choice of standard images will vary not only with the clinical condition of the patient, but because of the preferences of individual radiologists. These may be included in the guidelines after consultation and agreement within the medical imaging service and, in some instances, the referring clinician. The prime responsibility for the images provided lies with the radiologists and not with the referring clinicians who may nevertheless indicate their own needs and preferences so that the patients receive the best examination.

Non-standard procedures

The majority of imaging procedures will follow well recognized techniques and may be judged by comparison with the work of other imaging groups. However, there will always be new techniques which may not have been generally approved within the profession. It is the responsibility of the medical imaging service to discuss and then document all non-standard procedures. If these follow a research protocol, this should have been approved previously by a recognized Human Research Committee. If working within an academic or similar institution the medical imaging service can be assured of guidelines from such a group, but private practices or public health facilities should consult the nearest academic institution, their national professional association or other recognized organization before embarking on any research programme. Every patient involved must be made fully aware that their imaging is part of a research study, probably with unproven benefits. They must be also aware of any potential risk and of any available alternative. No patient should be included in a research study unless they are fully informed and have given written consent.

Documentation of all research or non-standard imaging procedures is absolutely essential. It must be detailed, specific and cover every aspect. Research must be closely supervised by the responsible radiologist and when concerned with radiographic or other imaging technique, by the technical supervisor in charge.

Reports and records

General

There are normally three components in the patient's imaging record. The actual image, e.g. the radiograph or scan, the request form or letter received from the referring clinician and the radiologist's report. When the request is made by telephone, the information should immediately be documented by the medical imaging service.

The first step in the interpretation of any medical image must be to match the image or images with the patient information (request) received from the referring clinician. Every image should therefore include patient identification, preferably photographed or digitally inscribed on the image. It is helpful if this data is recorded in the same location on every size of radiograph or in a standard way on every scan. Images from ultrasound, CT or MR should also include technical information recording the exact way in which the image is obtained so it can be replicated at some other time.

Image identification

All images should include:

- the patient's name, including given name, initials and family name
- a hospital or similar identification number, if there is one
- the date of the examination
- the laterality of the image (left side, right side, etc.).

If space permits, the initials of the radiographer or sonographer responsible should be included on the image (this is desirable but not mandatory).

If equipment is available to record exposure factors on every radiograph, these should be included, provided no clinical part of the image is obscured.

On the majority of medical images the above data will be part of the image which cannot be altered without damaging the image surface. If any change is made, it must be clear and legible and both the change and the individual responsible should be noted on the patients' referral record and report. If the identification data is recorded on the film in pencil or by a similar method, and later clarified, e.g. with white ink, the original inscription should remain visible.

It is the responsibility of the medical imaging service to ensure that all images are correctly identified and the required procedures must be carefully documented. It is also their responsibility to ensure that all the reports are based on the correct images of the patient concerning whom the report is issued. All members of the staff of a medical imaging service will be involved in this process and all must be aware of their responsibility and the sometimes dire consequences which may follow if a report is issued based on the wrong images.

Reports

Although the most important information on any report from a medical imaging service is the radiologist's interpretation of the image, it is essential that the following information is included somewhere in or on the report; some details will be provided by the referring clinician:

- the patient's name and, if appropriate, identification number
- the date of the examination
- the name of the referring clinician
- the clinical diagnosis and any other relevant patient information
- the type of procedure and the total number of images provided
- the name or identification of the staff member who performed the procedure
- the contrast drug or any other medication administered, including the time, the dose and the method of administration
- any adverse reaction to medication and the response provided
- the date and type of any previous images with which the current examination has been compared
- the name of the radiologist providing the report, the date and the facility where it was performed.

Also

- if more than one radiologist reviewed the images, this must be noted
- if there is more than one page for the report, the sequential pages must be numbered and identified with the patient's name, number and date

if any report is altered after completion, the change must be noted and signed by the individual who makes the alterations; if not the author of the original report then the copy should be sent to the originating radiologist.

When the report is completed a permanent copy must be retained by the imaging service. The original report must be transmitted as quickly as possible to the referring clinician. If the report is given by telephone or fax, the date, time and transmitting individual must be documented and the original report should be sent to the referring clinician as soon as possible. If transmitted electronically it is the responsibility of the medical imaging service to ensure that it is received accurately and completely and that the patient's privacy has been maintained.

If the imaging reveals the need for urgent clinical response (e.g. a tension pneumothorax or misplaced tracheal tube) the radiologist must at once notify the clinician or nursing staff and then document the information and the action taken, including the exact time the staff were notified.

Storage and retrieval

Whether the completed image is stored by the medical imaging service, given to the referring clinician or to the patient will be an individual or local decision, sometimes controlled by local or national regulation. Similarly, how long the images should be retained will probably be regulated. Whatever protocol is adopted it is the responsibility of the medical imaging service to document the instructions and to ensure that all members of the staff follow them. The referring clinician and the patient should be reminded that medical images are a very important part of each patient's medical record. They may be needed at some future date for comparison and this may affect subsequent patient management.

Disposal

Radiographs and other films may contain a significant amount of toxic substances and in some instances, valuable silver or other materials. Sale or disposal of medical images must be strictly in accordance with local and national regulations.

Computers

Computers are increasingly used in many aspects of diagnostic imaging and it is the responsibility of the medical imaging service to ensure that all the appropriate members of the staff are able to work with their computers accurately and rapidly to complete their assigned tasks.

Quality of care, audits and corrective action

General

There are four essential steps to the improvement of quality of care:

- Find out what is wrong. Conduct an audit.
- Discuss the problem. Decide on solutions.
- Correct the problem. Take action.
- Follow up after an interval to ensure the corrective action is effective and has been maintained.

Audit

The medical imaging service must take active steps to learn what is actually happening within their service. Problems and deficiencies must be actively sought if they are to be recognized. The discovery process must be ongoing and must investigate all aspects of patient care and service management. This will involve all members of the staff and often the referring physicians. When initiated it will seem to many to be an unwanted added burden, even unnecessary. However, if the reasons for these working reviews are explained and understood by all, and if they are aware that the objective is to improve the medical imaging service and not to criticize the individuals, there is little doubt that all the staff will cooperate. It is very important to look back every year and recapitulate what has been learned and what corrections have been made. The results may surprise everyone.

The activities within the medical imaging service can either be audited internally, by the members of the staff, or externally by experts who visit the facility for a period and provide an unbiased report and indicate what corrections must be made. Both internal and external audits are essential if the quality of care is to be improved and subsequently monitored. No audit will be successful unless it is systematic and documented.

External audit

There may be national requirements for external quality care audits and there must be full cooperation with these surveys. These are likely to involve a visit over several days

during which experts review every aspect of the medical imaging service and question all the staff. Thereafter there will be a full report and it is the responsibility of the senior radiologists of the medical imaging service to allow all members of the staff to review and comment on the external audit report. Then, preferably jointly with all the medical imaging staff, corrections and solutions must be developed and implemented. Documentation of each stage is essential, as is compliance after an appropriate interval.

If there are no nationally required audits, similar reviews may be conducted by national professional organizations.

Internal audit

There are many aspects of routine daily work which need to be checked at regular intervals. These intervals may be daily, weekly or longer, or sometimes random and unannounced. These audits will only be successful if they are carried out following checklists which indicate everything which needs to be reviewed (see also Annex 2 on Issues to be addressed by internal auditors).

Checklists should be compiled after consultation with the staff responsible for the activities and they should all be informed and involved in the review process. Individuals must be designated who will be responsible for the regular checks and who will collect and document the results. The findings after each review must be presented to all who work in the specific area, and their comments and views on how to correct deficiencies should be obtained. Solutions should be decided by those who do the work rather than always imposed by their supervisors. Nevertheless, it is the responsibility of the senior radiologists to ensure that those checklists exist, that the checks are carried out and that solutions are found and implemented. It is the senior radiologists' responsibility also to check again after an interval to ensure that the corrections are continuing and have proved satisfactory.

Feedback from patients and clinicians

An important source of information to be used in the quality improvement process should be the comments, compliments and complaints of patients and referring physicians. These should be actively sought and simple questionnaires are a good way to elicit comments. However, there should always be space for the personal suggestions of patients or clinicians. It is important that all this feedback information is documented and reviewed periodically. This will show when a pattern of complaints is developing and indicate the need for significant corrective action or, alternatively, when complimentary will confirm that the current way of work is satisfactory and should be continued.

Information from patients and clinicians is very important and in a large medical imaging service one or more members of the staff may be largely occupied in gaining the maximum benefit from this information, collected from all who come to or who have contact with the facility.

Ethics

General

All the staff of a medical imaging service are bound by the same high ethical standards of the medical profession as regards patient care (see Patient management, and Patient care), patient privacy (see Patient care), informed consent (see Informed consent), research (see Non-standard procedures), and impartial service to all people regardless of race, beliefs, sex and national origin. Within any medical imaging service there are many day-to-day decisions which, often unintentionally, are decided in accordance with ethical guidelines. Imaging services have special areas for which these ethical guidelines must be decided and documented.

Choice of imaging procedure

As already stated (See Effective choices) the choice of the best imaging procedure for each patient is the responsibility of the imaging service, usually of the radiologist. Many referring clinicians have firm, often conservative ideas which influence their imaging requests. It is very difficult for clinicians to keep up to date with recent advances in imaging. Many are unaware of the risks of some imaging procedures and many clinicians tend to forget the inherent risks of ionizing radiation and contrast agents. To be aware of these factors is the responsibility of the imaging service.

When faced with an inappropriate request, the radiologist should, whenever possible, resolve this by discussing the alternatives with the patient's clinician. There should be clearly documented policies covering the most effective imaging choice (see Imaging techniques) which will support the radiologist's recommendations. It is equally important that all other staff are aware of these guidelines and bring to the attention of the radiologists all cases which do not meet the criteria laid down by the medical imaging service. In every instance, the patient's well-being and safety must be weighed against the optimum way to obtain the diagnostic information. Provided the diagnosis can be reliably made, e.g. by sonography compared with CT, neither the cost of the examination nor the radiologist's time should enter into the equation. As already stated (see Patient care, and Effective choices) the imaging procedure which will provide the best information using the least radiation should always be the first choice. If it is also the least expensive that, too, is to the patient's benefit but this should not be a major consideration.

However, there will occasionally be patients whose clinical conditions undoubtedly need an expensive examination but who cannot pay or can only afford a less expensive

procedure which is a less medically satisfactory alternative. The ethical solution to this dilemma can only be that the best investigation for the patient must be performed, even if the patient pays less than the usual charge.

It is occasionally possible that the referring clinician is unwilling to accept the radiologist's advice (that some other imaging procedure would be the best way to resolve the patient's problem) and will not agree to change the original request. Ethical guidelines for such a situation should clearly state that it is the radiologist who is responsible for whatever imaging is performed (see Imaging techniques) and decision can only be made based on the patient's well-being. The radiologist is entitled to refuse, and sometimes must, to perform the imaging requested by the clinician. It is then essential that the patient is told why the examination is not performed and that the circumstances are documented. The patient should be asked to return to the referring clinician. If the patient's condition is serious and delay will compromise the health of the patient, the radiologist should, after discussion with the patient, perform whatever examination is considered best, sending the report to the referring clinician. Again the circumstances should be documented, preferably in the patient's medical record and based on the medical imaging service guidelines.

The guiding principles can be summarized: the imaging procedure performed must be one which is in every way the best for the patient.

Examinations requested by non-medical sources

Many insurance companies or employers ask for a chest or other imaging examination on an individual who is clinically healthy. It is the responsibility of the medical imaging service to inform the individual of any potential radiation or other hazard and to obtain a written consent to the imaging procedure. This consent must also clarify and indicate to whom or to what organization the report is to be sent. Disclosure of a patient's clinical status to a third party (other than the responsible clinician) is unethical unless the patient is aware that this will happen (and has given permission). The same documentation should be obtained when the request comes for any legal or similar disclosure. Local and national regulations will guide the release of information to lawyers, police or other authorities. In every instance, a written consent from the patient must be received unless the law clearly states that this is not required, e.g. in cases of suspected child abuse. With these exceptions, the radiologist should not release any information or images without a signed release from the patient. It is the responsibility of the medical imaging service to make sure that there is a full record of all reports which are released and the circumstances, including the time, the date, where they were sent and the signature of the recipient. Many medical imaging services will only release copies of the images, not the original; this decision must be covered by the ethical guidelines of the service.

Sensitive procedures

There are many imaging procedures carried out on patients by members of the opposite sex, most commonly by male radiologists or radiographers examining female adults and children.

It is in the best interest of both parties that a third person of the same sex be present at all times; this will usually be a female member of the medical imaging service staff (nurse, radiographer, sonographer) with a female patient. If there is any hesitation on the part of the patient, or if the patient so requests, a female relative, the spouse or a female friend may be allowed in the examination room provided they are suitably protected if there is any risk of radiation exposure. The documented policies of the medical imaging service should not allow any option; female patients should *always* be accompanied by their spouse or another female when the examination requires sensitive physical contact or when the patient so requests. It may be added that this is also important for the radiologist or radiographer, to avoid any risk of accusation of impropriety (see also next paragraph).

The medical imaging service guidelines should clearly state also when it is acceptable for a male radiographer to radiograph a fully gowned (or covered) female patient without a female chaperone being present (e.g. for chest or spinal X-ray examination). Similar rules are equally important for the imaging of all children by male staff, which in the majority of cases should be observed by a nurse, relative or female friend.

There are often requests to allow husbands or other relatives to observe obstetrical ultrasonography; whether this is permitted or not should be defined in the medical imaging service policy guidelines.

All the staff of the imaging service must be fully aware of the documented guidelines and this information must be continually reinforced. Random quality control checks may have to be carried out to ensure proper management of all these sensitive ethical issues.

Part III

Checklists



Introduction

Up to now this manual has provided reasons and standards for quality care. The following checklists make it easy for any medical imaging service to review and check its own compliance with the minimum requirements for quality and medical imaging.

The relevance of each question to any specific medical imaging service will depend on the scope, size and complexity of that service. Questions are listed under the same broad headings as in the manual, each section focusing on specific areas of quality management. Some sections will equally apply to any medical imaging service. For example the requirements for equipment management are universal. Other sections will fully apply only to large urban medical imaging services which provide a full range of imaging and some will only partly apply to small rural medical imaging services which provide a narrow range of basic imaging.

The checklists use terms such as “adequate”. Details of what is considered adequate will vary, but in general, facilities and procedures will be regarded as adequate when they meet applicable radiation safety standards and other regulatory requirements and do not lower the overall performance of the imaging service.

These checklists cannot cover everything, but the questions are a useful summary of all factors considered to be of importance to the quality of a medical imaging service. It is suggested that extra questions are added to these pages if there is any aspect of a particular service which needs a constant reminder.

Patient care

- Is there a clearly defined staff member holding overall responsibility for patient care, including radiation safety?
- Have guidelines for medical imaging been developed and documented, and have these been circulated and discussed with referring clinicians?
- Does the medical imaging service hold copies of all relevant local, national or international regulations or requirements for radiation safety?
- Are regular reviews of requests for imaging conducted to identify patterns of inappropriate requests?
- When inappropriate patterns of requests are identified, is any corrective action taken? If corrective action is taken, is it followed up and checked after an interval?
- Are beam limitation, collimation and precise light beam alignment routinely used to minimize the irradiated area?
- Is the accuracy of the above equipment regularly checked?
- Are records kept of the above checks and do the records identify the date of the check and the person responsible?
- Is a range of gonad shields available and are these routinely and correctly used?
- Are notices warning patients of the risk of radiation during pregnancy prominently and widely displayed within the medical imaging service?
- Are the above notices available in a range of languages and scripts relevant to and readable by the population of the region?
- Do the staff of the medical imaging service request from relevant patients the date of their last menstrual period?
- Is the abdomen of pregnant or possibly pregnant patients shielded during other X-ray examinations wherever possible?
- Does the X-ray tube filtration comply with international standards?
- Does the imaging service have only high frequency X-ray generators?
- Is an exposure technique chart available for the imaging staff and do they use it?

- Is the fastest film-screen combination consistent with optimum imaging quality routinely used?
- Is all darkroom equipment, e.g. screens and cassettes, regularly cleaned?
Does all fluoroscopy use image intensification?
- Is fluoroscopy kept to a minimum and is the fluoroscopy time recorded for every examination for every patient?
- Is the use of a secondary radiation grid (Bucky) restricted in the examination of infants or children?
- Does the medical imaging service hold copies of all relevant local, national or international regulations and requirements for electrical safety?
- Is the medical imaging equipment fitted with appropriate earth isolation, particularly when electrically conducting catheters or guide wires are used during invasive procedures?
- Are all high tension wiring and connections inspected at least annually by appropriately qualified personnel?
- Are records of the above checks available?
- Are tilting examination tables fitted with really strong foot and hand patient supports?
- Are the brakes on moving examination tables checked at least monthly?
- Are immobilization devices available for use when required?
- Are all persons who may assist in restraining or positioning patients during an X-ray examination protected by standard lead aprons and gloves? Are they large enough for the local population?
- Are the lead gloves and aprons tested for radiation safety every 3 months? Are the test results documented?
- Are leaflets describing the medical imaging procedures and providing specific patient preparation instructions available?
- Do the medical imaging staff make every effort to relieve the anxiety of patients prior to examination?
- Are private changing rooms provided for patients and are there arrangements for security of patients' property?

- Is the average time patients have to wait for an examination monitored and is the average time acceptable? What do patients think?
- If sedation is required, do the patient and relatives or caregivers realize that the patient will be sedated and how long it will last? Are the referring physicians consulted?
- Before and following the examination, is the patient advised of any possible after-effects or of the possibility and nature of complications, and given clear instructions on what to do if anything occurs?
- Is similar advice about complications and after-care given to those who will look after the patient, and to the patient's clinician, and is it in writing?
- Following an invasive examination, is the patient's recovery closely monitored and are guidelines for this monitoring and the release of the patient documented?

Staff care

- Is the person responsible for radiation safety in the medical imaging service clearly identified?
- Have all staff of the medical imaging service been given adequate training in radiation safety and are records kept of the training given?
- Is training in radiation safety reinforced on an ongoing basis?
- Where radionuclides are used, is specific training in the safe use and disposal of these substances and any contaminated materials provided?
- Are copies of any regulatory guidelines for the use of radionuclides readily available in the medical imaging service?
- Are all staff members who may be exposed to radiation provided with a personal radiation monitoring device, and are these devices routinely and correctly worn?
- Are records kept of the radiation dose measured on the personal monitoring devices, and are these records reviewed at least every 3 months?
- Are the accumulated records of radiation dose throughout the career of each staff member kept by the medical imaging service?
- In the event a staff member receives a radiation dose in excess of international limits, is expert advice sought in relation to the health of the staff member?
- Is the cause of excessive exposure established and is effective corrective action taken?
- Are records kept of the corrective action taken? Is the action followed up after an interval?
- Has a hazard identification survey of the medical imaging service been completed and have all hazards identified been isolated or eliminated where possible?
- Is the relevant clothing and other equipment necessary to reduce the risk of infection, available for staff of the medical imaging service? Do they use it appropriately?
- Are procedures for the correct sterilization or disposal of contaminated clothing and equipment documented and implemented?

- In the event that a staff member is exposed to a significant risk of infection, is expert advice sought in relation to the corrective measures to be taken?
- Are records of these events and actions kept?
- Have all staff been made aware of potential electrical hazards, particularly when working in the dark room?
- Are all electrical fittings, including supply connections and connecting cables, correctly maintained and positioned?
- Have the staff of the medical imaging service been given training in techniques for lifting heavy loads, including patients?
- Have the staff of the medical imaging service been made aware of the causes and the symptoms of repetitive strain injury?
- Is advice given on how to minimize the risk of repetitive strain injury and is this advice routinely followed?
- Have any ergonomic studies of the medical imaging service being conducted as an aid to reducing the potential for repetitive strain injury?

Building and facilities

- Is there a clearly identified person responsible for the servicing, maintenance and repair of the buildings of the medical imaging service and all facilities provided within?
- Is there ready access to the buildings of the medical imaging service for all patients, including injured or handicapped patients?
- Are all patients given a friendly reception and greeting by the staff of the medical imaging service?
- Are patients given clear information and instructions concerning their visit to the medical imaging service?
- Is there an adequate area set aside for patients and relatives awaiting an examination?
- Do the patient cubicles provide adequate privacy for patients and allow entrance to the examination room without traversing a public area?
- Are the toilet facilities available to the patients clearly marked and adequate?
- Are there sufficient signs and other information giving patients directions to various patient areas within the medical imaging service? Are they clear and in local languages and scripts?
- Are all doors and corridors within the medical imaging service wide enough to allow easy passage of wheelchairs and trolleys?
- Is there adequate lighting in both the patient waiting area and the examination rooms?
- Is the medical imaging service well ventilated with the required adequate air exchange rates in the examination rooms, and particularly in the darkroom, and does the ambient temperature in the building remain in the range 16 °C to 24 °C?
- Are the examination rooms of sufficient size to allow easy access to the patients and the equipment?
- Are staff or patients in rooms adjacent or near the X-ray rooms safe from radiation?
- Are the controls, particularly the exposure switches, for each X-ray generator located behind fixed radiation-proof barriers?

- Do these protective shields have a window that allows the observation of a patient during the X-ray exposure? Is the window the right height for the radiographers to see through?
- Are patients made aware of items which can be damaged by magnetic resonance equipment? Can their personal items be safely stored?
- Is the dark room of adequate size and in compliance with the established guidelines?
- Is the dark room adequately ventilated and does it meet relevant electrical and other regulatory requirements?
- Does the medical imaging service provide adequate facilities for the safe storage of patient records, X-ray films and other images, as well as copies of imaging reports (if not stored elsewhere)?
- Is the film viewing area within the medical imaging service equipped with a dimmer switch, enabling the control of ambient lighting levels? Is the area accessible to staff who need to consult with a radiologist?
- Are the viewing panels evenly illuminated and all of equal intensity?
- If a digital system is used, is the quality of the viewing monitors routinely and regularly checked? Are these quality reviews documented?
- Similarly, is the quality of any teleradiology system regularly checked and recorded?

Personnel

- Is there a documented procedure for the recruitment and induction of new staff?
- Are detailed job descriptions available for each staff member of the medical imaging service?
- Are the limits of authority and responsibility of staff members clearly defined and documented, particularly in relation to reporting and diagnosis?
- Do the staff of the medical imaging service hold the specialist medical or other qualifications required by regulation for them to perform their duties?
- If specialists qualified in medical disciplines other than radiology perform imaging procedures, are these persons given relevant additional training by the staff of the medical imaging service?
- If required, have all the radiologists in the medical imaging service had a recent (in the last 3 years) assessment of their visual acuity?
- Have appropriate optical aids been prescribed where needed, and are records available of the individual's visual acuity and of any prescribed optical aids?
- Have all the staff of the medical imaging service been given on-the-job training in radiation safety, fire, earthquake, other disasters and patient emergencies?
- Are the staff of the medical imaging service well trained in computing and quality management, with ongoing programmes?
- Are detailed records kept of the qualifications, experience, training and competence of all staff members of the medical imaging service?
- Are these records reviewed with each staff member at least annually and amended where necessary?
- Do all medical and technical staff of the medical imaging service actively participate in continuing education programmes and are records kept of these activities and of individual attendance?
- Are continuing education opportunities available to administrative and support staff of the medical imaging service, and have they all attended?

- Does the medical imaging service have available to staff a range of current and appropriate reference textbooks, specialist journals, videos and CD-ROMs, for the purpose of continuing education of all aspects of the service? (Many journals are available on the Internet.)

Equipment

- Are the procedures followed by the medical imaging service for the selection and purchase of medical imaging equipment clearly defined and documented?
- Prior to the purchase of medical imaging equipment, is an assessment of the medical needs of the population and the available clinical services carried out by the medical imaging service?
- Does the equipment, selection and purchasing procedure of the medical imaging service include an assessment of the available space, the electrical and other services needed, the skills of staff needed, the availability of spare parts and maintenance engineers and the warranty provided?
- Does the selection process include an assessment of the running cost (including staff) and the cost of consumables in addition to the initial purchase price and a service contract?
- Is information obtained from professional and other independent sources prior to the final selection of the item of medical imaging equipment?
- Is each item of medical imaging equipment purchased by the medical imaging service usually well proven by others prior to purchase?
- Are the performance specifications, the delivery date, the support services and warranty arrangements, payment dates and the initial and continuing costs specified in detail in the purchase agreement?
- Are detailed records kept of all servicing and repairs completed on each item of medical imaging equipment?
- Does the medical imaging service employ well-trained maintenance engineers who regularly service the medical imaging equipment?
- Does the medical imaging service record and monitor equipment down time and does this information contribute to the equipment replacement programme?
- Does the medical imaging service have a formally documented programme for the calibration of medical imaging and film processing equipment at defined intervals?
- Are the services of trained medical physicists used by the medical imaging service in the development of the calibration programme?

- Are factors including the type and model, age and state of repair, frequency of use and performance stability of the medical imaging equipment considered in the development of the calibration programme?
- Are the procedures for the calibration of the medical imaging equipment clearly documented?
- Do the procedures define the reference equipment to be used and the performance specifications expected?
- Is calibration of the medical imaging equipment performed by appropriately trained and qualified staff?
- Are detailed records kept of equipment calibration and do these records include the date of calibration, the numerical results and the name of the person responsible for completing the calibration?
- Are the numerical results presented graphically to enable the identification of trends in equipment performance?
- Does each item of medical imaging equipment carry a label, or is there a record in the room or some other means of indicating the calibration status of the equipment?
- If the calibration of an item of medical imaging equipment reveals a significant fault in the equipment, is the equipment withdrawn from use until repairs or adjustments correcting the faults have been made?
- Does the medical imaging service have clearly defined and documented procedures for the routine maintenance of equipment including cleaning, lubrication or simple adjustment?
- Are the medical imaging service's procedures for the routine maintenance of equipment consistent with the manufacturer's recommendations?
- Are detailed records kept of the routine maintenance carried out and do these include a summary of the work done, the date it was done and the name of the person responsible?
- Is the equipment manufacturer or agent immediately notified if routine maintenance work identifies significant faults in the equipment?
- Is there a formal programme for quality control checks on all items of medical imaging and processing equipment in the medical imaging service?

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- Does the medical imaging service own or have access to an appropriate range of reference objects (phantoms) and measurement devices necessary for completing all quality control checks of the equipment?
 - Are parameters of acceptable performance defined for each quality control check performed?
 - Are these parameters realistic and are factors including the age of the equipment, the original specifications and the performance history considered in setting the parameters?
 - Are records kept of what action is taken when equipment performance falls outside the acceptable parameters?

Drugs

- Does the medical imaging service have facilities for the secure storage of all drugs?
- Is there appropriate documentation recording the use of drugs, particularly narcotics or any other dangerous drugs?
- Is access to the drug storage facility controlled and are those staff members entitled to access clearly defined?
- Is there an emergency trolley or some other means of making emergency drugs and equipment available to the staff of the medical imaging service without delay?
- Are the contents of the emergency trolley checked and restocked after use, as well as regularly, and are records kept of these checks?
- Is the equipment on the emergency trolley regularly checked by an appropriately trained and responsible person to ensure its correct operation and readiness at any time, day or night?
- Do the staff of the medical imaging service seek the advice and assistance of a person trained in pharmacology as to the appropriateness of the drugs available and used in the medical imaging service?
- Are all stocks of drugs used in contrast imaging clearly and unambiguously labelled including a precise description of the concentration of each item?
- Are containers of different concentrations of the same drug segregated to reduce the risk of confusion?
- Are detailed written instructions available for the procedure for checking, preparation and administration of contrast media and other drugs?
- Are appropriate numbers of staff in the medical imaging service trained in emergency procedures including CPR and defibrillation?
- Is there at least one CPR trained staff member always available when the medical imaging service is caring for patients?
- Are all adverse reactions to drugs carefully recorded and reported in accordance with regulatory requirements?

- Is the procedure for attending to patient emergencies in the medical imaging service well rehearsed and effective?
- Is the use of drugs for the purpose of sedating patients carefully considered in consultation with the referring clinician?
- Are all patient imaging enquiries in relation to their medical imaging examination appropriately answered by the staff of the medical imaging service?
- Does the medical imaging service have a documented protocol for advising patients of any risks or discomfort associated with the medical imaging examination they are about to undergo?
- Are records kept of the advice given to patients prior to the medical imaging examination?
- Are clear guidelines available advising the staff of the medical imaging service which examinations will require prior written consent of the patient?
- Are these guidelines consistent with any relevant regulatory requirements?
- Are procedures for the follow-up of patients who have had an interventional examination clearly documented and implemented?
- Are those persons responsible for the care of the patient following any interventional examination given clear written instructions concerning any checks or observations necessary, and any action to be taken if complications occur?

Imaging techniques

- Does the medical imaging service have formally documented guidelines for the correct selection of the most appropriate imaging procedure for each patient?
- Are these guidelines made available to referring clinicians?
- Is full consideration given to the patient's clinical indications, the radiation dose and the cost-benefit of the examination?
- Does the final decision on which imaging technique, if any, is best for the patient, rest with the radiologist?
- Are the protocols for the selection of the proper imaging techniques consistent with the guidelines established by groups such as the WHO, the various Colleges of Radiology, and other similar national committees? Are the protocols regularly updated?
- Are guidelines developed and documented which assist radiographers in deciding which standard examinations will be initially performed?
- Do these guidelines cover patients of all ages and do they apply to each imaging technique?
- Do detailed guidelines exist for conducting any non-standard imaging procedures and do these include special arrangements for experimental or research procedures?
- Have all research protocols been approved by an independent review body?
- If a patient is involved in research studies, are they fully informed by the medical imaging service of this fact?
- Is all research work closely supervised by the radiologist accepting clinical responsibility for the work?

Reports and records

- Is each request for medical imaging checked by the medical imaging service for completeness, and are all telephoned requests formally documented?
- Are all radiographic films or other medical images clearly marked with at least the patient's identification, date of examination and, where necessary, details of the patient's positioning?
- If the medical images are recorded digitally are the requirements for the unique identification of the image fulfilled?
- If any changes are made to the image identification details, is there a clear record of who made the change and why?
- Is a random audit completed by the staff of the medical imaging service to determine compliance with the criteria for image identification?
- Does the diagnostic medical imaging report from the medical imaging service include the patient's name, date of examination, name of referring clinician, clinical diagnosis, other relevant information, imaging technique used, number of pages in the report, name of the staff member who performed the procedure, type, time and dose of any contrast media or other drugs used, details of any adverse reaction to drugs, details of any action taken, the date and type of any previous images considered, and the name of the radiologist or radiologists responsible for the report?
- Are the reports promptly available to clinicians? Have they been checked and authenticated by the responsible radiologist?
- Is a permanent copy of each medical imaging report retained by the medical imaging service?
- If the report is transmitted by phone, fax or other electronic means, is the correct receipt of all details of the report confirmed?
- Is a hard copy of each report dispatched in addition to those electronically transmitted?
- Does the medical imaging service provide adequate facilities for the secure storage of medical diagnostic images, medical imaging reports and patient notes, and other relevant patient information (if not stored elsewhere)?

- Is the retention period for stored records defined and is this in accordance with any regulatory requirements?
- If the radiographic images are given to the patient, is the patient advised of the importance of these items and given instruction on their correct storage?
- Are documented procedures available for the confidential and environmentally acceptable disposal of medical images that are no longer required?
- If the medical imaging service uses a computing system to generate, process or store records, are staff given formal training on the use of the computing system?

Quality of care, audits and corrective action

- Does the medical imaging service have an established programme for internal audits or assessment to continually monitor the quality of the service?
- Are the internal audits completed by trained staff knowledgeable in medical imaging? Are they independent of the medical imaging service?
- Are records kept of the audit findings and of the corrective actions taken to address any lapses in the quality of performance?
- Are staff of the medical imaging service given instruction in the reasons for and in the objectives of internal audits? Do they know the results of each audit?
- Is a detailed checklist developed and used in the internal audit process?
- Is any corrective action that may arise from an internal audit fully discussed and explained to all relevant staff of the medical imaging service?
- When corrective action from audit findings has been taken, is there a later check to make sure it remains effective?
- Does the medical imaging service have a method of recording all complaints (or compliments) received from either patients or clinicians on any aspect of their service?
- Are records kept of all responses and corrective actions taken after each complaint?
- Does the medical imaging service periodically conduct surveys of their patients' and clinicians' satisfaction, or otherwise?
- Are records kept of the survey results and of any action taken to correct any deficiencies?
- Does the medical imaging service receive regular external audits of the quality management and technical performance of its operation, and are all problems so identified responsibly addressed?
- Are the results of internal and external audits, patient surveys, and customer complaints fully discussed at all management and professional levels in the medical imaging service?



Annexes



Annex 1

Equipment quality control schedule

General checks

Darkroom cleanliness	Daily
Processor quality control	Daily
Intensifying-screen cleaning and quality control	Weekly
Darkroom safe lights	Semi-annually
Film-screen contact	Semi-annually
Repeat film analysis	Monthly
View-box light output	Monthly
Digital monitor quality	Monthly
Fixer retention rate analysis	Monthly
Lead apron, gloves and radiation shield continuity	Annually

Specialist medical physics checks

- Primary radiation barriers in walls, floors and ceilings should be checked initially and then 5-yearly thereafter or when equipment is replaced to ensure appropriate radiation protection and containment.
- Warning lights and signs should be installed at the entrance to the X-ray rooms and adjacent to X-ray controls. The lights should be checked monthly.
- Personal radiation monitoring dosimeters worn by any staff member who may be exposed to X-rays should be monitored and reported monthly.
- Total filtration of the incident primary X-ray beam and X-ray tube leakage radiation performance measurement should be checked every year or whenever the tube is replaced.

- Light beam diaphragm accuracy, alignment, delineation and illumination performance measurement should be checked every 3 months.
- Focus skin distance (FSD) and focus film distance (FFD) measurement or estimation should be checked annually.
- Automatic exposure device, brightness control, image intensifier and digital subtraction imaging systems performance and precision measurement should be checked every 6 months or whenever any part is replaced.
- X-ray generator and tube KVp output and linearity measurement and monitoring should be checked every year or whenever any part is replaced.

Note. It is acknowledged that each country and even each county or state within individual countries, will usually have clearly defined legislative or other guidelines governing the use of X-rays and other radiation for medical purposes. Thus it is not possible to specify in this document precise criteria for the technical performance of X-ray equipment or even the exact frequency at which some of the more demanding medical physics checks and measurements should be made. Instead the above list of items should be checked and monitored by qualified and trained personnel using appropriate and calibrated equipment, at whatever frequency may be defined in local or national regulations. If no intervals are so defined, those suggested above are recommended as the minimum requirement.

Annex 2

Issues to be addressed by internal auditors

Accommodation and safety

- Is there a floor plan of the rooms in the medical imaging service?
- Does the floor plan indicate:
 - room size and function?
 - location of services?
 - location of entrances and emergency exits?
 - location of emergency equipment?
 - location of essential items of equipment?
- Are records kept of:
 - room temperatures?
 - ventilation air exchanges?
 - humidity in film and chemical storage areas?
- inspections of emergency equipment?
- Is the responsibility for safety, including radiation safety, clearly defined?
- Have the staff of the medical imaging service been trained in:
 - first aid including CPR and defibrillation?
 - emergency evacuation?
 - use of safety equipment?
 - avoiding radiation and other hazards?
 - handling potentially infectious substances?
- Is the medical imaging service equipped with the following:
 - first aid kit?
 - eye wash facilities?

- safety shower?
- personnel protection items?
- fire extinguishers?
- emergency trolley with oxygen and suction equipment and emergency drugs?
- Are all emergency exits clearly marked in local languages and scripts and kept free from obstruction?
- Are compressed gas cylinders, volatile solvents, processing chemicals, drugs etc. stored in a safe and appropriate manner?
- Does the medical imaging service have a formal system for recording accidents?

Quality Systems for Medical Imaging

Guidelines for
Implementation and Monitoring

No medical imaging service can produce high quality work unless it is properly managed. Quality management implies good organization and discipline, with complete documentation of all aspects of the imaging service. Guidelines and management rules therefore need to be established if the quality of medical imaging services is to be improved. This publication aims to cover some of the needs and demands of the medical imaging services, both in developing and developed countries. It outlines principles for appropriate medical imaging and contains guidelines as well as checklists designed to assist medical imaging centres in self-assessment of their performance.