ISRRT Safety Culture and General Safety Management Guide for Diagnostic Imaging and Radiation Therapy Departments

SEPTEMBER 2021
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Disclaimer
The ISRRT has produced this guide to facilitate a deeper understanding of the many and varied aspects of managing a Medical Imaging or Radiotherapy Department safely. As such the ISRRT and the authors are indemnified against and are not liable for any damages that may be related to the contents of these guidelines. Users are asked to follow established protocols and procedures of their employer.

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Preface

Remarks from Dr Maria del Rosario Perez (WHO Radiation and Health Unit)

It is my great pleasure to see the culmination of this project of the International Society of Radiographers and Radiological Technologists (ISRRT). I congratulate the ISRRT colleagues for the publication of this comprehensive guide on safety culture and general safety management for diagnostic imaging and radiation therapy departments.

As a global professional body representing radiographers and radiological technologists from all regions of the world, the ISRRT is an organization in official relations with the World Health Organization (WHO) and the successful collaboration has been maintained and expanded over the years.

Clinical research, technological advancements, the global burden of disease and populations that are living longer are all strong reasons that influence the greater demand for radiation technologies and radiological medical procedures. While on one hand, low and middle income countries lack adequate capacity and resources to provide these services, on the other hand high income countries are increasingly facing the risk of overuse or misuse of these technologies.

As the agency within the United Nations system with specific mandate to protect public health and human welfare, WHO’s key objective is the attainment by all peoples of the highest possible level of health.

All UN Member States made a commitment towards the achievement of 17 Sustainable Development Goals (SDGs) by 2030. While all 17 SDGs have implications on health and well-being, the SDG 3 is specifically focused on it: “Ensure healthy lives and promote well-being for all at all ages”.

The 13th WHO General Programme of Work (GPW13) aims to help the world achieve the SDGs and in this regards it sets three targets by 2023: 1 billion more people
benefit from universal health coverage; 1 billion more people are better protected from health emergencies; and 1 billion more people enjoy better health and wellbeing. Fostering safety and quality in the medical use of radiation will contribute to the achievement of this triple billion targets.

I express my appreciation to the ISRRT for its continuous support to the WHO’S agenda of work, in which context the publication of this guide represents a new milestone.

Dr Maria del Rosario Perez
Radiation and Health Unit
World Health Organization
ISSRST Safety Culture and General Safety Management Guide for Diagnostic Imaging and Radiation Therapy Departments

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1. Introduction
This document has been developed to help you answer the question – ‘Is my department safe?’

We hope that you will find this as a useful resource as it has been created to address a number of fundamental considerations such as:

- Assessing working practices and safety measures to create a dynamic safety culture.
- Identifying areas for review on a regular and systematic basis.
- Implementing change and supporting staff.
- Provision of a safe environment and an efficient quality assurance programme.

This document is for the benefit of all personnel working in Imaging and Radiation Therapy Departments as each person has a responsibility to ensure the safety of themselves, patients and colleagues as well as contributing actively to promotion and maintenance of a responsive safety culture. The document will be particularly helpful to Service Managers and Clinical leads of modalities who may be responsible for an individual clinical service i.e., Nuclear Medicine, CT, MRI, Radiation Therapy, or a small imaging department. Throughout this document for the sake of brevity we have used the term ‘Service Manager’.

We have tried to be comprehensive as possible and have provided several references to help stimulate further investigation to assist you in developing your own Safety documentation and Safety Culture.

2. Statement of Intent
Safety in the Imaging and Radiation Therapy Departments is of paramount importance. This document focuses all aspects of the running of a department where lack of safety may ultimately affect the patient, staff and the public and the reputation of the institution. The document will incorporate good management practices.

Ensuring a safety environment is dependent on all those engaged in running and working in a department having a sense of purpose and fostering a safety culture environment. Safety culture is often referred to the way safety issues are approached in the clinical environment. Many authors and related literature support that safety culture encompasses the attitudes, beliefs, perceptions, and values of healthcare professionals and how these are “expressed” in practice.

The ISRRT strongly believes that as an international organisation that it can help promote safety and safety culture by producing a safety guidance document to help inform member societies and the radiography profession on the important elements of safety and the difference between safety and safety culture.
The ISRRT, has been, and is actively engaged in several IAEA and WHO initiatives centred around patient, public and safety as well as promoting safety matters through workshops and articles such as the World Radiography Day Theme for 2019 “The Radiographer is Promoting and Maintaining Safety Culture” https://www.isrrt.org/special-edition-2019

This ISRRT generated document has drawn on the experience of radiographers dedicated toward establishing, maintaining and strengthening a Safety Culture in Medical Imaging.

2.1 Background.
The International Bonn Call for action item 8 calls for medical professionals to Strengthen radiation safety culture in health care. Additionally, the 72nd World Health Assembly (WHA72) adopted a resolution on ‘Global Action of Patient Safety’ with the WHO Director General report detailing the Global action on Patient Safety. In particular, WHA72 R6 Resolution mentions radiation safety in paragraph (6) together with the other areas of patient care where safety challenges are faced. Moreover, in this report to the WHA72 WHO, Director General Dr Tedros Adhanom included RADIATION in a list of 10 examples of patient safety challenges/issues. The ISRRT therefore has produced a document, which can be used to elevate standards and safety in healthcare.

Subsequently the formal action plan ‘WHO Global Patient Safety Action Plan 2021-2030 (Final Draft) was formally adopted at the WHA on the 28 May 2021 which provides a 10-year roadmap and actions to work towards its vision of a world in which no one is harmed in healthcare and every patient receives safe and respectful care, every time, everywhere.

2.2 Where this document fits
This ISRRT document provides a framework for interested parties to adopt. Whilst the content may not be binding in law, it will provide useful guidance information and recommendations for those wishing to promote and maintain safety culture within their institutions.

Safety culture embraces all aspects of the Imaging and Oncology Department, including ionising and non-ionising radiations as well as the delivery of those services. The operations of the departments are dependent on human resources and a host of pharmaceutical, chemical and safe operation of complex machinery and equipment which is used in everyday life. This document covers all critical aspects of safety bringing together several important considerations, policy, procedure, and audit, which will provide the framework of a health safety culture. Additionally, it will address how radiation safety culture in medicine can be strengthened by referring to the work of the IAEA.

Paramount is the health, safety and wellbeing of patients, staff, the public and the environment and therefore ‘Risk Assessment’ and audit are an important component of developing a ‘Safety Culture’.
3. Safety Culture – what is it?

3.1 Introduction
Safety culture has recently attracted the attention of radiation protection professionals, who know that there are challenges in improving radiation safety culture and recognize that there is room for improvement. Safety Culture is defined by the International Atomic Energy Agency (IAEA) as the "assembly of characteristics, attitudes and behaviours in individuals, organisations and institutions which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance." 

3.2 Radiation Safety Culture
Radiation safety culture is a combination of knowledge, skills, beliefs, and practices related to radiation safety and culture. A strong radiation safety culture can reduce radiation exposure through the application of the principles of justification, optimisation, and dose constraints that are the foundation for the International Basic Safety Standards for Radiation Protection. Weaknesses in safety culture have proven to contribute significantly to medical errors and poor-quality medical results. These errors can be expensive and have detrimental impacts on patients and worker performance. A strong radiation safety culture can reduce medical errors, improve diagnosis and treatment, reduce worker exposure and improve efficiency in diagnostic and therapy facilities. Establishing a radiation safety culture is more than rules, it is a change in the individual behaviour, the organisations behaviour and professional behaviour. It is the combination of all these that will improve radiation safety culture in medicine.

One of the “IAEA Bonn Call to Action” activities is to strengthen safety culture in healthcare. The action items were developed after the Bonn International Conference of Radiation Protection in Medicine. The action item is: “Strengthen radiation safety culture in healthcare.”

Radiation safety culture has to some extent always been an essential element in medical practice, it is not a new concept, and we see some of the visual cues in worker protection, were lead aprons and gloves were used for many years to protect the worker from the harmful effects of radiation. As the technology continues to advance, other measures need to be addressed in optimisation and justification. Forcing functions, designed to prevent mistakes, and limitations on equipment, such as interlocks, is one method, but the greatest influence is the strength of the organisation’s culture. What are the expectations of the performance of medical radiation professionals? And what are the expectations of the organisation? And are we practicing a strong radiation protection culture?

4. How do we Accomplish a Safety Culture?

4.1 Introduction
There is a need to know what an effective safety culture looks like and what are the visual cues that a strong radiation safety culture is exhibited. These indicators are always visualized in a strong radiation safety culture as to how organisations operate and by the behavior of staff. These cues are sometimes referred to as traits.
4.2 Traits
Traits are a distinguishing quality or characteristic, typically one belonging to a person, profession, or organisation. The IAEA in its harmonized safety culture model describes the traits and attributes that are observed when a strong culture for safety is present. It lists exemplary behaviours such as individual responsibility for safety, questioning attitude, responsibilities for decision-making, and highlights effective communication and a high level of trust as some of the major indicators of a healthy culture for safety.

With the support of the United States, through extra budgetary funds, the Radiation Protection of Patients Unit, Radiation Safety and Monitoring Section, Division of Radiation, Transport and Waste Safety, Department of Nuclear Safety and Security of the IAEA developed training material to support individuals, and professionals to promote and improve radiation safety culture in their own organisations. IAEA has identified 10 traits that should be evaluated to determine the strength of the safety culture within an organisation. Let us review how these traits can be evaluated in medical facilities that use radiation.

Safety Culture Traits

4.2.1 Traits categorisation – 10 Traits
The traits are:

**Individual responsibility** - All individuals take personal responsibility for safety. Responsibility and authority for safety are well defined and clearly understood. Reporting relationships, positional authority, and team responsibilities emphasize the overriding importance of safety.
Leadership responsibility – Leaders demonstrate a commitment to safety in their decisions and behaviours. Executive and senior managers are the leading advocates of radiation safety and demonstrate their commitment both in word and action. The radiation safety message is communicated frequently and consistently, occasionally as a stand-alone theme. Leaders throughout the organisation set an example for safety. Corporate policies emphasize the overriding importance of radiation safety.

Questioning attitude - Individuals avoid complacency and continuously challenge existing conditions and activities to identify discrepancies that might result in error or inappropriate action. All employees are watchful for assumptions, anomalies, values, conditions, or activities that can have an undesirable effect on facility safety.

Decision making- Decisions that support or affect safety are systematic, rigorous, and thorough. Operators are vested with the authority and understand the expectation, when faced with unexpected or uncertain conditions to place the facility in a safe condition. Senior leaders support and reinforce conservative decisions.

Respectful work environment – Trust and respect permeate the organisation. A high level of trust is established in the organisation, fostered, in part, through timely and accurate communication. Differing professional opinions are encouraged, discussed, and resolved in a timely manner. Employees are informed of steps taken in response to their concerns.

Continuous learning – Opportunities to learn about ways to ensure safety are sought out and implemented. Operating experience is highly valued, and the capacity to learn from experience is well developed. Training, self-assessments, and benchmarking are used to stimulate learning and improve performance. Safety is kept under constant scrutiny through a variety of monitoring techniques, some of which provide an independent “fresh look.”

Problem identification and resolution – The process of planning and controlling work activities is implemented so that safety is maintained. Work management is a deliberate process in which work is identified, selected, planned, scheduled, executed, closed, and critiqued. The entire organisation is involved in and fully supports the process.

Environment for raising concerns – Organisations should focus on achieving and maintaining an environment where employees feel free to raise their concerns directly to their supervisors, as well as ensuring that alternate means of raising and addressing concerns are accessible, credible, and effective.

Work process – The process of planning and controlling work activities is implemented so that safety is maintained. Work management is a deliberate process in which work is identified, selected, planned, scheduled, executed, closed, and critiqued. The entire organisation is involved in and fully supports the process.

Effective safety communication- Communications maintain a focus on safety. Safety communication is broad and includes facility level communication, job-related communication, worker-level communication, equipment labelling, operating experience, and documentation. Leaders use formal and informal communication to convey the importance of safety. The flow of information up the organization is seen as being just as important as the flow of information down the organisation.
4.3 Training and Training Materials

The IAEA developed training materials which utilise techniques for the adult learner, focusing on behavioural changes at the individual and organisational level. The case-based training material is best provided in a team environment with a facilitator trained in the ability to engage through discussion of case studies and identify key areas where improvement is possible. If the facilitator is a member of the organisation, they should exemplify a strong individual safety culture behaviour. They should be good communicators and be able to prioritise a few critical activities and involve the entire team. The course material addresses each trait that is essential in a strong culture of safety. Each module has an overview of the trait, a case study, and a series for questions for discussion on the case study and then how the review of the case study correlates to the situation within the organisation. At the conclusion of the discussion, a digital presentation is provided reinforcing the positive aspects of the trait. The take home message is one or two activities that can be performed by the individual and the organisation to improve the trait. The training material is modular, allowing the information to be shared as a two-day training session or a series of training sessions over time addressing each of the individual traits. There are several case studies at the end that allows the participants to evaluate all the traits in one case study. The material is available at radiation-safety-culture-trait-talks.pdf (iaea.org)

The training material will support the improvements, if provided in the correct forum. There is no real test to understand competency for strengthening radiation safety culture like many other subject matters. Once we become aware thorough situational examples, we can then start to develop a plan for improvement. Educators have acknowledged that facilitated discussion is by far the best methodology. To reinforce the learning objectives, digital presentations created by radiation professions, acknowledge that these achievements can occur.

4.4 Conclusion

Through analysis of the SAFRON (Safety in Radiation Oncology) data, we can see that a contributing factor to almost all medical events is a lack of a strong safety culture. From reports of diagnostic medical events, we see that omissions such as
verification of the patient identity contributed to an unintended exposure. A strong safety culture would have assured that the radiographer who verify the patients identify and procedure before making an exposure and prevent the unjustified examination. In a facility with a strong safety culture, quality assurance and control procedures would be imbedded in the day-to-day activities. It is through these changes; we can improve the safety culture to assure that patients receive the services provided in compliance with the principles of radiation protection.

While practical strategies for strengthening radiation safety culture may seem simple, they are not. Changing behaviour and culture is a significant challenge. Improvements will be slow and difficult to measure, but, if we are to provide the standard of care we expect to receive if we are the patient, we must accept the challenge. Use the material to evaluate the situation, identity opportunities for improvement and measure success.

While practical strategies for creating a radiation safety culture may seem simple, their implementation is not always easy. There are challenges ahead for cultivating an effective and positive radiation safety. The guiding radiation protection principles can be implemented. To keep pace with international standards, healthcare managers must employ modern methods of management to overcome the challenges faced by the institutionalization of safety culture and to make a difference in the healthcare system.

5. Governance Considerations
This important section sets out several key considerations that are fundamental in delivering a safe and effective service.

5.1 Legislation Including National Guidance Framework
Governance is a word used to describe the way that organisations ensure they run themselves efficiently and effectively. It also describes the way organisations are open and accountable to the people they serve for the work they do.

The majority of Healthcare systems throughout the world will have legislation and supporting guidance to facilitate systems that will empower the public, patients and staff to help improve the care it provides by setting out their legal rights and the pledges to the Healthcare system6.

The accountability for such actions will be defined by those agencies commissioning health service provision with the aim of giving a voice to the public, patient and carers ensuring that they are at the centre of healthcare services, from planning to delivery7. Good governance is maintained by the structures, systems and processes which are put in place to ensure the correct management of work, and by the way organisations expect their staff to work. It is about how organisations identify and manage risks, whether in terms of patient care, to staff performance, and to the organisation as a whole including how they manage their finances effectively. Additionally, it also aims
to scrutinise general performance and address poor working practices and other problems. It provides an assurance mechanism for the management organisation, staff, patients and regulators.

5.2 Creating a Governance Framework
Governance can be defined as ‘A system where health bodies lead, direct and control their functions, in order to achieve organisational objectives and safety’.

In the NHS the term ‘Integrated governance’ is sometimes used as ‘Systems, processes and behaviours by which Hospital management lead, direct and control their functions in order to achieve organisational objectives, safety and quality of service and in which they relate to patients and carers, the wider community and partner organisations’.

The structures, systems, processes, and behaviours for ensuring good governance include:

- Documents stating the responsibilities of the Board of Directors, how the organisation will operate and limits of financial responsibility for each level of management.
- Requirement for a statutory board, and requirements on the committees that support the board.
- How line managers operate, including codes of conduct and accountability.
- Business planning.
- Procedural guidance for staff.
- Risk register and assurance framework.
- Internal audit.

Scrutiny by external assessors including the agencies such as a Care Quality Commission, Audit Commission and Monitor.

5.3 Quality Assurance
Quality Assurance (QA) in health care can be defined as the concept that includes the assessment or evaluation of the quality of care; identification of problems or shortcomings in the delivery of care; designing activities to overcome these deficiencies; and follow-up monitoring to ensure effectiveness of corrective steps.

In terms of QA in the use of radiation the IAEA defines this as: ‘Quality assurance consists of structured procedures and actions aimed at maintaining a high level of quality diagnosis or treatment of patients. Increasing complexity of medical technology requires specialized and systematic verifications to ensure quality and effectiveness and avoid accidents.’ It goes on to highlight:-

5.3.1 Diagnostic Imaging
Nuclear medicine and diagnostic radiology provide crucial information for an accurate diagnosis of patients. To ensure adequate diagnostic information can be delivered while radiation exposure of patients is minimized, quality assurance covers infrastructures, human resources and procedures.
5.3.2 Radiation Treatment
The precision and accuracy of radiotherapeutic or metabolic treatments are essential for them to be efficient. Many parameters affect the outcome of radiation treatment. Structured quality assurance procedures may help minimize side effects for patients, while optimizing treatment delivery.

5.3.3 Quality Assurance and ISRRRT
The ISRRRT promotes within the scope of practice for Radiographers/Radiological Technologists to include competence in quality assurance and quality control within a quality assurance framework. This is essential to assure the delivery of safe, cost-effective and high-quality diagnostic imaging and radiotherapy services.

The ISRRRTs Position Statement; ‘Radiographers/Radiological Technologists Role in Quality Assurance and Quality Control as a Team Approach’ defines this further: ‘Quality assurance embraces all aspects of the diagnostic imaging process including a visual check of the equipment and confirmation of careful preparation prior to every patient procedure as well as establishing a routine quality control testing (daily, weekly, monthly, quarterly or annually) programme of equipment. The Position Statement addresses and defines the role of the Radiographer/Radiological Technologist giving the background to the topic, by focusing on the Basic Safety Standards (BSS) published by the International Atomic Energy Agency (IAEA) as General Safety Requirements Part 3, July 2014. The support of the position statement addresses quality assurance for medical exposures highlighting a team approach for medical radiation technologists

5.4 Clinical Audit
Clinical audit is defined as a process that has been defined as "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change (National Institute for Clinical Excellence, UK)." Clinical audit in relation to radiology, as defined within the Basic Safety and Standards Directive /BSSD (European Council Directive 2013/59/Euratom):

“A systematic examination or review of medical radiological procedures that seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where appropriate, and the application of new standards if necessary.”

The ISRRRT considers that the implementation and use of Clinical Audit is an integral part of the delivery and management of medical imaging services. Radiographers and Radiological technologists have a duty of care to participate in clinical audit activities in order to ensure that safe practices are implemented, and corresponding satisfactory patient outcomes are achieved.
Clinical Audit is undertaken using a team approach with all members of the Medical Imaging Department undertaking an important role.

5.5 Patient Informed Consent
This is an important ethical topic as all imaging and radiotherapy procedures and tests require informed consent from the patient or authorised person such as a parent or carer. Patient ‘informed consent’ is based on the fundamental principle that the patient has the right to determine what happens to their own body and that a person must give permission before they receive any type of medical treatment, test or examination. There are a number of steps in the process and issues to be taken into consideration before the radiographer can proceed with the examination.12

Many health authorities throughout the world will have policies and procedures, based on respective laws, for the protection of the individual, which will give guidance on how to operate and gain patient consent in an appropriate manner. This will take into consideration a range of situations including mental capacity to understand the issues involved, particularly for children and vulnerable adults.

It is important that the radiographer establishes an appropriate relationship of trust with the patient and that touching a patient without their consent is, without lawful reason, capable of amounting to a charge of assault to the person. Once the procedure is fully explained and consent is provided a record of the consent should be documented – this will normally include most plain X-ray examinations. For some situations, a range of written and signed consent forms are available for procedures involving radiological interventions, radiotherapy treatments and other situations i.e. children and adults with lack of capacity.

A number of Radiography associations provide helpful information and guidelines.1314

5.6 Continuous Professional Development (CPD)
This can be defined as an ongoing professional activity in which the radiographer/radiological technologist, as a professionally practitioner, identifies, undertakes and evaluates learning appropriate to the maintenance and development of the highest standards of practice within an evolving scope of practice.15

Many ISRRT member organisations have systems in place to help professionals undertake a systematic approach to this requirement which in some countries is a legal requirement to maintain their licence to work as a radiographer/radiological technologist.

Employers should support professionals in this requirement providing learning opportunities, resources, and protected time to pursue studies. Proof that satisfactory CPD has taken place will be undertaken at the individual and corporate level.

5.7 Staff Appraisal and Competency Assurance
Closely linked to CPD is the matter of staff appraisal and the competency and capability of the professional to practice. This applies to radiographers/ radiological
technologist, sonographers and others who are employed in imaging and radiotherapy departments.

Many employers will have in place staff appraisal systems to assess and support their professional employees. Whilst concentrating on clinical capability such appraisals will encompass other attributes. Such appraisals should be undertaken with well-trained managers and provide the staff with:

- a clear understanding of their role and the part they play in their team and organisation
- an agreed set of work objectives
- a plan for acquiring and applying the knowledge and skills they need to do their job well and achieve their organisation's linked objectives.

Successful appraisals require careful planning with objective setting being a key element of good appraisal\textsuperscript{16,17}.

Professionals have a duty of care to work within their capabilities and to alert and seek training in specific areas when lacking the skills to undertake tasks.

5.8 Image Reject Analysis
‘Image reject analysis’ is an important Quality Assurance tool and forms part of the radiology quality assurance programme. Reject analysis is performed by saving all ‘rejected’ images and then evaluating them periodically to determine the cause of the rejects and repeated exposures. The objective is to reduce the number of repeated examinations by correcting technical problems and improving the skills of the staff. Procedures should be established for identifying and analysing all images that were repeated because of problems with quality, positioning, etc. This information should be used for training and guidance to reduce the need for repeated exposures\textsuperscript{18}.

5.9 Imaging Report Audits
The auditing of ‘Imaging Reports’ is practiced by many departments and this especially so when radiographers/radiological technologists are assigned as reporters. Such audits form part of the clinical auditing process. Since the introduction of teleradiology and the outsourcing of reporting, an increased focus on the audit of radiology reports has emerged to instil confidence on referring clinicians and to satisfy commissioners of imaging services. Audit data as well as performance monitoring provide information that may be used to systematically improve the quality of radiology reporting\textsuperscript{19}.

Four major questions arise when considering how this might be achieved:

1. What are the reported rates of discrepancy and are they comparable, appropriate or meaningful?
2. Can acceptable performance levels be determined based on what is reported in the literature?
3. What are the current methods of audit and what are the current classification systems?
4. What would the features of a system that could potentially inform evidence-based interventions be?

As radiographers are now authorised to undertake reporting in specific situations ranging from plain image reporting, ultrasound, CT and MRI procedures it is important that the accuracy of their reports is audited. There are various methods for undertaking this task including periodic double reporting.

5.10 Adverse Events, Near Misses and Lessons Learnt
Keeping an account and having a system that records, monitors and evaluates adverse events and near misses is a vital component of a good governance system. Many organisations will have a systematic and coordinated approach to collecting such information and monitoring the performance of the organisation. This may be undertaken using an electronic reporting system.

It is important that a ‘no blame’ culture is created to encourage everyone to participate and learn the important lessons to prevent further occurrences.

A particular focus on ionising radiation matters is important as many countries will have a reporting mechanism to capture dose errors, adverse events and near misses and to when necessary investigate adverse events.

The IAEA has a voluntary reporting system called SAFRON. This stands for Safety in Radiation Oncology which is an integrated voluntary reporting and learning system in radiotherapy and radionuclide therapy incidents and near misses.

The main goal of SAFRON is to improve the safe planning and delivery of radiotherapy and radionuclide therapy by sharing safety-related events and safety analysis around the world. Information submitted is dependent on facilities registering and sharing incidents that occur in their institutions.

Having started in December 2012, SAFRON has over 170 registered medical facilities and hospitals all over the world. The system has over 1650 incident reports covering various types of incidents including errors and near misses.

To access SAFRON, users need to be registered with NUCLEUS.

To contribute to SAFRON reporting, users need to register with both NUCLEUS and SAFRON. A self-study instructional video is available in the section entitled “User Instructions” below.

**What are the goals of SAFRON?**

- To promote patients’ safety in medical facilities by learning about reported events in an effort to reduce the likelihood of the events being repeated;
- To assist medical facilities in promoting safety culture and improving patient safety through analysis of near misses and incidents;
• To establish a database of safety related resources;
• To provide users with the ability to analyse and benchmark safety improvement efforts.

5.11 Health and Safety Audits
Regular Health and Safety audits form an important part of the governance structure to assure commissioners of services, users, public and staff that the organisation is working safely and in accordance with relevant regulations of the national government and regulatory authorities. See section 7 for more on ‘General Health and Safety’

Such audits will cover a variety of potential hazardous situations including use of equipment, radiation protection as well as general health and safety matters.

5.12 Feedback From Users
It is important that an assessment of the services offered by a department are assessed in a constructive and objective way. Undertaking such assessments using structured surveys will assist in identifying strengths and weaknesses in the services provided and highlight potential issues which may need to be rectified.

Such surveys may include the accuracy of reports, timeliness of undertaking examinations and issuing reports, examination/procedure literature information and patient preparation instructions and the quality of care of patients.

5.13 Accreditation - Independent Appraisal
Evaluation of a Department’s ability to deliver consistently high standards of care by competent staff and in safe environments is undertaken by several institutions. This can be undertaken using the services of various radiology related tailored organisations or more generic accreditation organisations such as the International Organisation for Standardisation (ISO) which offers ISO 9001, which addresses quality management systems.

The radiology specific accreditation systems are composed of a number of quality standards which will be measured based on evidence submitted and the existence of active standard operating procedures (SOPs). Standards will include a variety of specific topics which may be incorporated into different domains such as: Leadership and Management; Clinical; Facilities, Resources and Workforce; Patient Experience and Safety.

This is usually a rigorous process with possible inspections to confirm the evidence submitted and to assess how procedures are implemented.

Many commissioners of services will expect to see some form of independent accreditation and in some countries national governments will have formal accreditation structures, using dedicated regulatory authorities, to assess safety standards and approve the licensing of various health services provided.
6. Roles and Responsibilities in Radiation Protection
The following examples are typical of the UK and may be similar in other countries.

6.1 Employers Duties – Roles and Responsibilities
6.1.1 Radiation Protection Advisor (RPA)
RPAs are contracted by employers and are responsible for the provision of advice to Managers, Heads of Service and Staff regarding ionising radiation matters (including compliance of the Local Rules and national legislation such as the Ionising Radiation Regulations 2017 and Ionising Radiation (Medical Exposure) Regulations 2017) and on practical implementation of this. There is an RPA appointed for each diagnostic imaging facility where work involves ionising radiation.

6.1.2 Medical Physics Expert (MPE)
The MPE is the individual appointed by the employer to support protocol optimisation, effective dose management, evaluation, and QA of radiological equipment and to provide advice on radiation protection concerning the medical exposure.

6.1.3 Radioactive Waste Advisor (RWA)
The RWA is the individual appointed and responsible for advising on radiation protection relating to the storage and disposal of radioactive material and protection of the environment from contamination by radioactive waste.

6.1.4 Radiation Protection Supervisors (RPS)
The RPS is also appointed and responsible to ensure compliance with the arrangements made by the employer under IRR17 in particular supervising the arrangements set out in the local rules.

6.1.5 Operational Heads of Departments, Departmental Managers
The heads of departments and departmental managers have responsibility for informing the RPS, RPA, MPE and RWA of any organisational changes that may have any bearing on work with ionising radiations within the scope of its activities of and overall responsibility for implementing and ensuring adherence to Radiation Safety Policy and specific country regulations including:

- Radiation Risk assessments are carried out, reviewed, documented and the findings implemented
- Having taken advice from the RPA and RPS, responsibility for designating areas as Controlled or Supervised as necessary and ensuring local rules are drawn up for these areas.
- Responsibility for ensuring that staff working with ionising radiation are adequately monitored and that investigations are carried out of any radiation dose over the relevant investigation level.
- Responsibility for ensuring that all staff undertake the radiation safety training appropriate to their role.
• Responsibility for ensuring that systems are in place for the safeguarding of radioactive materials and for the safe disposal of radioactive waste and ensuring that all requirements of the relevant regulations are satisfied.
• Responsible for maintaining a record of training of duty holders under Medical exposure regulations, including staff of other employers who may be carrying out procedures on the employer’s premises under contractual arrangements.
• Radiation emitting equipment in their areas of work and are responsible for ensuring that staff are aware of their responsibilities in law and covered by policy
• Ensuring that safety and protection measures are carried out. They are assisted in this task by the Radiation Protection Supervisor (RPS) who are responsible for the day-to-day enforcement of radiation protection measures for the site or department they are allocated to
• (In conjunction with the RPA), ensuring that systems for radiation safety, including up-to-date Local Rules and procedures, appropriate equipment and security measures are in place
• Seeking the advice of the RPA when planning new or modified radiation facilities
• Ensuring staff are adequately trained to carry out their duties under Policy and that a record of training is maintained, and ongoing competence assured
• Ensuring a suitably trained and experienced RPS is appointed with the advice of the RPA
• Staff who may act as practitioners and operators are identified and that an up-to-date register of practitioners and operators is maintained in each department
• Written procedures are in place for medical exposures
• Risk assessments are carried out
• An appropriate audit system is in place
• An environment for raising concerns so that a safety conscious work environment is maintained in which personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment or discrimination

6.2 All Staff Working with Ionising Radiation or Working in Departments Where Ionising Radiation is Used

Individual workers are required to work with radiation in such a way that they:

• Exercise reasonable care and follow all relevant local rules
• Use, as instructed, any protective equipment and personal dosimeters provided by their employer
• Make such dosimeters available for analysis and recording in line with required procedures
• If a registered classified worker, ensure that their annual medical is within date
• Report to their line manager and RPS any defect in such equipment and dosimeters
• Undertake any specified training and only carry out activities involving radiation for which they have had appropriate training
• Comply with the employer’s procedures and protocols for medical exposures
• Report immediately to their line manager or RPS if any incident occurs in which a patient may have received a radiation exposure greater than intended
• Responsibilities for specific radiation work must be included in job descriptions.
• Report immediately to their RPS any incident in which a member of staff or public is exposed to radiation
• Ensure that an Incident Form is completed to report incidents or near misses, in line with the employer’s Incident Reporting and Management Policy; Reporting the accidental or unintentional exposure of a patient procedure.
• Do not recklessly endanger the safety of themselves or others

Staff are required to follow the organisation’s policy and procedure, failure to do so without extenuating or exceptional circumstances may result in disciplinary proceedings. Any deviation from policy (other than those clinically indicated/justified and previously agreed) must be reported to the relevant line manager and via the local reporting system.

7. General Health and Safety

7.1 Introduction
The Overall health and safety for imaging is covered by the organisation wide approach for safety management and specific requirements for the safe use of medical equipment and substances that may be hazardous to health.

7.2 Roles and Responsibilities
7.2.1 The Hospital Management Team (Hospital wide)
Development and implementation of a Health and Safety Policy this may include the following information (as required by the local legislation)

1) A General Policy to Health and Safety
• to provide adequate identification and control of the health and safety risks arising from our work activities.
• to consult with our employees on matters affecting their health and safety.
• to provide and maintain safe plant and equipment.
• to ensure safe handling and use of substances which may be harmful.
• to provide information on Health & Safety Procedures instruction, training and supervision for employees.
• to ensure all employees are suitably trained to undertake their tasks.
• to prevent accidents and cases of work-related ill health.
• to maintain safe and healthy working conditions.

The policy must be reviewed at regular intervals

2) Details of the organisation responsibilities and contacts
   • Who has overall and final responsibility for health and safety?
   • Who has the day-to-day responsibility for ensuring the policy and how is it implemented.

3) A statement on the requirements of employees to:
   • report all health and safety concerns to an appropriate person

4) Information relating to Accidents, first aid and work-related ill health
   • Where Health surveillance is required
   • Where First aid box(es) is/are kept
   • The appointed person(s) / first aider(s)

5) Emergency Procedures – Fire and Evacuation

7.2.2 Service Managers (Departmental level)
Departments must have processes and procedures to comply with local Health and Safety legislation. This will include specific guidance related to the imaging modalities utilised and should include:

• Standard Operating Procedures (SOPs) for the Department to identify risks and hazards and how they are mitigated.

• The information should cover the imaging department and imaging in other areas such as wards and theatres.

7.3 Education and Training
How to undertake risk assessments and development of Risk Registers
7.4 Patient Representation
The support and observations of patients in creating a safe environment is key to providing a comprehensive view of the department. It is suggested that managers should use the local patient forums or consider a form of survey of users to support the health and safety initiatives.

8. Health and Wellbeing of Staff

8.1 Introduction
Effective Health and Safety processes and procedures are the foundation of a safe environment for everybody working in or using the clinical department.

8.2 Roles and Responsibilities
To support the Health and Safety programme of the organisation (Section 7) the departmental manager is responsible for local initiatives. The aim is to produce the most effective system of surveillance and control for the local environment.

8.3 Health and Safety Officers
Departmental Health and Safety Officers or Leads, should be appointed from the team to provide day-to-day oversight of the department. The key task of the role is to identify hazards and risks and report them to the department lead for rectification or mitigation.

8.4 Protective Equipment
Personal Protective Equipment must be provided where hazards are identified for the staff and where appropriate for patients and visitors to the department. The level and type of equipment should be defined in the organisational policy. If no central guidance is available, the manufacturers guidance should be used, and specialist advice sought where required.

8.5 Staff Training
Staff should receive training in general health and safety procedures including the identification of hazards in different working environments.

All staff must be aware of the process for reporting hazards.

8.6 Creating an environment that is safe and conducive to the employee’s good mental health.
This would include steps to deal with and eliminate bullying and harassment. This can be regarded as unwanted behaviour that offends, persecutes, or excludes someone.

Examples of bullying include:

- prolonged sadistic or aggressive behaviour
- humiliating others
• criticising others in public
• lack of respect for others
• cyber bullying using social networking channels

Harassment is unwanted conduct which is related to one of the following: age, disability, gender reassignment, race, religion or belief, sex and sexual orientation and is unlawful in many countries.

Managers and clinical leaders must take reasonable steps to protect employees as they have a number of different legal duties. For example, in the UK, the Health and Safety at Work Act 1974, the Equality Act 2010 and the Protection from Harassment Act 1997, to name but a few examples in law. Managers therefore should ensure that staff and patients/clients are fully aware of the standard of conduct expected of them and of the sanctions that may follow if they do not adhere to those standards.

Employers are responsible for preventing bullying and harassment. If there is a risk to a staff member’s health, the employer has a duty to take whatever precautions are practicable. Employers should:

• have a written policy on dealing with bullying and harassment at work and communicate the policy and procedure to staff
• make all staff aware of how, when and to whom non-physical and physical assaults should be reported
• investigate complaints quickly but thoroughly and assess the facts carefully
• offer support to victims of bullying including counselling if necessary and offer mediation services to both parties if appropriate.

8.7 Staff Wellbeing
The role of a manager and clinical leader is more pressured than ever, through the increasing demands on healthcare. It is vitally important to recognise the need for the wellbeing of the leader and their staff.

This is particularly important in recognising the possibility of staff ‘burnout’, which can be characterised as the experience of long-term exhaustion and diminished interest. Working in a healthcare environment is one of the areas where burnout is a recognised risk. In both the acute and community healthcare setting it is common to see members of the team working while having too little recovery time.

8.7.1 Burnout
This may include:
• Physical and emotional exhaustion leading to an inability to engage fully with many aspects of the job.
• Lack of personal accomplishment giving a feeling of little sense of achievement.

This may be due to a number of causes including:
• Lack of control. An inability to influence decisions that affect work (e.g., workload) or a lack of the resources needed to work effectively.
• Uncertainty of what is expected at work.
• Feeling of a loss of control when at work.
• A stressful workplace such as bullying, feeling belittled

8.7.2 Implementing a Wellbeing Programme
To support staff of all levels, the organisation should consider some form of a Wellbeing programme to:

1. Ensure all members of the team feel they are treated with the same equality, inclusivity, and diversity.

2. Access to different levels of support and services to raise the awareness of the psychology and wellbeing as a process for the individual to benefit from.

3. Awareness of and identifying steps to achieve a work life balance.

4. Support for a person’s mental health with a wide range of tools may range from including access to ‘down time’ and diet and eating well through to one-to-one help to avoid longer term conditions and ‘burn-out.’

5. Recognising stress and building resilience and being able access to support on an individual or organisational level to help make changes.

6. Support to make changes in the workplace to provide increase staff welfare and care.

7. Changing roles or working processes including initiatives developed as a result of the recent COVID-19 pandemic, such as increased or partial working from home.

8.8 Whistle Blowing
All employees should have the freedom to raise concerns outside the host organisation. Within UK legislation, there are processes to protect individuals who raise legitimate concerns to external authorities such as regulatory bodies. This is colloquially known as ‘Whistleblowing’

Public Organisation in the UK are required to implement a policy and procedures to
allow for Whistleblowing and protect the person raising the complaint.

8.8.1 A ‘Whistleblowing’ Policy is intended to cover serious public interest concerns that fall outside the scope of other procedures and may include the belief that something has or may happen that is:

- A criminal offence
- The breach of a legal obligation
- A miscarriage of justice
- A danger to the health and safety of an individual
- Damage to the environment
- Deliberate covering up of/failing to report information
- Other serious public interest concerns, which would come under Policy.

The policy and procedures should identify the process of safeguarding the employee from sanction or discrimination should they raise concerns with external organisations.

9. Medical Equipment – General Aspects

9.1 Introduction
Medical equipment technology plays an integral part in the provision of diagnostic imaging and radiotherapy services. Such equipment may consist of large and complex machines and ancillary equipment.

The procurement, deployment and use of medical equipment and associated devices is a key component of patient and operator safety. To this aim medical equipment should be purchased in accordance with national guidance and used according to the manufacturer’s specification and operating procedures. The procurement process involved and that associated with major equipment and building installations is covered in Section 23.

9.1.1 Common Definitions
These include:
- Medical device - any instrument, apparatus, appliance material including the software necessary for its proper application, intended by the manufacturer to be used in providing clinical care for humans.

- Medical equipment – a term used to describe the sub-group of medical devices that includes electro-mechanical medical Equipment.

- Planned Preventative Maintenance (PPM) – performing planned routine actions which keep the device in working order or prevent trouble from arising.
9.2 Roles and Responsibilities

9.2.1 The Hospital Management Team
The organisation will usually have a detailed policy covering the procurement, selection and standardisation of medical equipment. This may include replacement procedures, decontamination procedures, maintenance & servicing and maintaining an equipment Inventory.

9.2.2 Service Managers (Departmental level)
The manager should devise Standard Operating Procedures (SOPs) for all areas of clinical practice and patient safety. This should include the safe operation and use of the clinical equipment and medical devices used as part of clinical care.

This should include:
- Commissioning including acceptance testing and assurance in combination with the Original Equipment Manufacturers (OEM) guidance and organisation policy.
- Maintenance and servicing schedules
- Radiation protection testing including the ‘critical examination’ to test the major safety systems and an ongoing quality assurance programme
- Education and training in the correct use of the equipment and any restrictions or limitations on its deployment.
- Specialist training with manufacturers guidance and competency assessment

9.3 Certification and Compliance
Imaging and therapy equipment must be purchased from reputable manufacturers and suppliers with ongoing support during the life of the equipment. Additionally, the provision and use of donated or second-hand equipment must take into consideration the WHOs ‘Donation Framework’ and the responsibility of donor and recipients to which the ISRRT endorses through its position statement regarding the donation of medical imaging equipment.

In several countries, there are rules and regulations regarding the certification of medical equipment to ensure that it meets a number of safety standards. In Europe equipment must have a Conformité Européene (CE) mark and in the USA suppliers must comply with the Food & Drug Administration (FDA) recognised standards otherwise such purchase and use of equipment is forbidden.

Additionally, to support the purchase and continual use of equipment National guidance is available from Governments’ and Original Equipment Manufacturers (OEM’s) and trade bodies on the type, use and safety standards of the equipment. These may cover areas such as:
- Legal regulations governing devices, standardised manufacturer’s instructions covering use, operation and safety procedures as a minimum.
- Safety issues – covering new and installed equipment and access to updated safety information
• Replacement parts – detail of the standards and supply chain of accredited parts
• Routine maintenance programmes for the equipment
• Electrical supply - specification of the type and consistency of supply
• Emergency Power Off buttons the requirements for, operation of and type of buttons
• Building specification and design the structural requirements of facilities to house the equipment
• Maintenance programmes
• Risk assessments

In many countries trade associations such as Association of X-Ray Equipment Manufacturers (AXREM) provide medical devices (equipment) designed to meet exacting standards and regulations to provide patient and operator safety. This guide is designed to assist those who purchase, plan and use such medical equipment to understand how they can ensure our members products are installed and maintained safely.

10. Environmental Considerations

10.1 Introduction
In addition to radiation protection measures imaging departments must provide a safe environment for patients and staff. This will include several important considerations such as the maintenance of facilities equipment and plant, ventilation of public areas and space environments where equipment is used, as well as the fabric of the building.

10.2 Roles and Responsibilities
10.2.1 The Hospital Management Team
Development and implementation of an estates and equipment maintenance and environmental cleaning policy.

10.2.2 Service Managers (Departmental level)
Local procedures should be implemented in the department to deliver a safe environment for patients, staff and visitors.

10.3 Environmental Considerations
The main environmental considerations may include:
• Effective and timely waste management with procedures for specialist and hazardous waste to meet local regulations and compliance with the hospitals overall waste management policy and licencing.
• Control of noise to protect individuals from hearing damage and provide an effective ambient environment for providing care and associated services.
• Infection control to the standards of the organisational policy (see Section 20 for detailed guidance).
• Radiation safety to meet the local and legislator standards (see Section 12).
• Generally, building safety to provide a safe environment. This will be part of the overall organisational response but requires department monitoring of the fabric of the building and identification of areas requiring rectification such as areas of damp or mould.
• Water quality monitoring of quality of the water supplied to the department in line with the organisational microbiological testing procedures.
• Monitoring of the effectiveness of heating, ventilation, and air conditioning to provide a comfortable working environment. This is especially important when processing or other vapour releasing chemicals are used (See section 28) These tests of the air handling and legionellae testing should be undertaken as part of the organisation estate maintenance and safety plan.
• Where film processing is still undertaken using potentially harmful chemicals darkroom ventilation and surrounding rooms must be ventilated to recognised standards including the wearing of face masks and PPE when handing chemicals according to the manufacturer’s instructions. Additionally, chemical effluent from the processor must be managed in accordance with local protocols to ensure the water environment remains safe.
• Implementation and ongoing assurance of the department fires safety procedures and equipment.
• Effective signage and demarcated emergency exit routes

11. Managing Risks in the Department

11.1 Introduction
Risk management is a process to determine how to manage any risks recognised. Risks can be managed by maintaining a system of assessment and control.

11.2 Roles and Responsibilities
11.2.1 The Hospital Management Team
To implement processes to manage organisation wide risks. This will include the imaging and therapy departments.

11.2.2 Service Managers (Departmental level)
The manager is responsible for risk evaluation and developing, with support of other professionals in devising was to reduce any risks identified in the clinical department.

11.3 Definitions Used in Assessing Risks:

Risk
A ‘Risk’ is the probability of occurrence of harm and how severe that is.
**Risk Assessment**
Risk Assessment is the overall process comprising a risk analysis and a risk evaluation.

**Risk Control**
Risk Control is the process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels.

11.4 Categories of Risk
Risks in healthcare may be categorised into several major groups:
- a) Potential harm to staff
- b) Potential harm to patients
- c) Potential loss of a service or facility
- d) Unsafe staffing levels
- e) Financial loss
- f) Loss of personally identifiable information
- g) Unfavourable media coverage
- h) Threat of litigation.

11.5 Creation of a Risk Register
Creation of a Risk register which can be created using the following process:
1) identify potential the risks
2) Assess their risk level using the impact and likelihood scores
3) Use this assessment to create a score, which then is given a RAG status – Red, Amber or Green.

11.5.1 Defining risk using the Relative Risk Rating (RAG)
Use a Relative Risk Rating by assessing the Impact (I) and Likelihood (L) of the event. The RAG status is calculated by adding the I and L scores.

11.5.2 Impact Score

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Score</th>
<th>Impact on service and reputation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insignificant</td>
<td>1</td>
<td>no impact on service</td>
</tr>
<tr>
<td>Minor</td>
<td>2</td>
<td>slight impact on service</td>
</tr>
<tr>
<td>Moderate</td>
<td>3</td>
<td>some service disruption</td>
</tr>
<tr>
<td>Major</td>
<td>4</td>
<td>service disrupted</td>
</tr>
<tr>
<td>Extreme/ Catastrophic</td>
<td>5</td>
<td>service interrupted for significant time</td>
</tr>
</tbody>
</table>
11.5.3 Likelihood Score

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Score</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remote</td>
<td>1</td>
<td>may only occur in exceptional circumstances</td>
</tr>
<tr>
<td>Unlikely</td>
<td>2</td>
<td>expected to occur in a few circumstances</td>
</tr>
<tr>
<td>Possible</td>
<td>3</td>
<td>expected to occur in some circumstances</td>
</tr>
<tr>
<td>Probable</td>
<td>4</td>
<td>expected to occur in many circumstances</td>
</tr>
<tr>
<td>Highly probable</td>
<td>5</td>
<td>expected to occur frequently and in most</td>
</tr>
<tr>
<td></td>
<td></td>
<td>circumstances</td>
</tr>
</tbody>
</table>

RAG: Red = Scores of between 16 and 25  
Amber = Scores of between 9 and 15  
Green = Scores of between 1 and 8

11.5.5 A Simple Risk Register Template

<table>
<thead>
<tr>
<th>Area</th>
<th>Risk</th>
<th>I</th>
<th>L</th>
<th>RAG</th>
<th>Mitigation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

The level of risk identified is linked with the risk review frequency such that red risks require review every month and Green every 3 months.

12. Management of Risks Associated with Ionising Radiation

12.1 Introduction
The management of risk associated with ionising radiation forms the central part of all diagnostic imaging and radiation therapy departments with the focus on the protection of the patient, staff and the public including carers. Below in no particular order of priority are a number of important issues and aspects of the management of risks that need to be considered.

12.2 Roles and Responsibilities
These are defined in section Six highlighting legally defined responsibilities. Each country will have their specific codes of practice and guidance documents for the use of ionizing radiation in medicine based on legislation and governing structures.
12.3 Compliance with National and Regional Guidance (General use of Ionising Radiation and Medical/Research Applications).
The ultimate responsibility for such compliance will usually be the responsibility of the CEO/owner of the hospital organisation or Imaging/Therapy centre. However, many of the duties will be delegated to those in senior responsibility in the respective departments. All workers with ionizing radiation responsibilities will have a duty to comply with regulations, schemes of work and local rules.

12.4 Imaging Procedures – Protocols and Procedures
Protocols and procedures relating to the undertaking of imaging and radiotherapy procedures should be established in all departments to enable the safe delivery of ionizing radiation and to undertake such procedures in accordance with pre-determined standards.
Such protocols will give clinical guidance on acceptable criteria for justifying a range of imaging and therapy procedures together with the corresponding image projections/treatments necessary and exposure/contrast media parameters etc.
Protocols will also spell out who can refer and those qualified to undertake such procedures.
Adherence to these protocols, established on evidence-based medicine, is essential.

12.5 Local Rules
These are established with the assistance of the RPA and in most cases are a legal requirement in most countries.
The local rules summarise the key working instructions intended to restrict exposure in radiation areas. They will include at least the following information:\32:

- A description of the area covered by the rules and its radiological designation.
- The radiological hazards, which may be present in the area.
- The formal dose investigation level.
- Names and contact details of responsible people, including the Radiation Protection Supervisor (RPS). The RPS is responsible for supervising working arrangements set out in the Local Rules.
- Detailed working arrangements for the area.
- Contingency plans.

They should be tailored to those controlled and supervised areas in operation and reflect specific room requirements or situations which involve the use of mobile imaging equipment such as theatre or ward radiography.

They must be regularly reviewed and placed on full display with users signed off signifying that they are aware of the requirements.

12.6 Optimisation
According to the Basic Safety Standards (BSS) published by the International Atomic Energy Agency (IAEA) as General Safety Requirements-Part 3, July 2014, once the medical exposure has been authorized and justified the third component is the optimisation of the medical exposure for protection and radiation safety of the patient.
Action number two of the ‘Bonn Call for Action’ is ‘enhance the implementation of the principle of optimisation of protection and safety’. The ISRRT recognizes that radiographers/radiological technologists bear the responsibility for delivering the exposures of ionizing radiation during procedures for diagnosis and therapy. The ISRRT supports the scope of practice of the radiographer/radiological technologist and recognizes that it is appropriate and that they possess the authority to optimise the exposure and alter the examination parameters in the patient’s interest subject to their demonstration of appropriate educational preparation leading to clinical competence and where permissible by regulation/national law.

It is the ISRRT Policy to expect all qualified radiographers/radiological technologists to be competent in the principles and practice of ionizing radiation dose optimisation relevant to their clinical work. As professionals bearing the responsibility for delivering doses of ionizing radiation to patients and in research applications, radiographers/radiological technologists must have authority to exercise their judgment in accepting a referral for exposure. This must include adjusting technique to minimize the exposure to patients, staff and the public while still optimizing a diagnostic or therapeutic outcome.

The ISRRT’s ‘Position Statement of the Radiographer/Radiological Technologist Role in Optimisation of Medical Exposure’ states that: ‘The ISRRT expects all qualified radiographers/radiological technologists to be competent in the principles and practice of ionizing radiation dose optimisation relevant to their clinical work. As professionals bearing the responsibility for delivering doses of ionizing radiation to patients and in research applications, radiographers/radiological technologists must have authority to exercise their judgment in accepting a referral for exposure. This must include adjusting technique to minimize the exposure to patients, staff and the public whilst optimizing a diagnostic or therapeutic result’. The full statement can be found at Optimisation | ISRRT.

The IAEA has much helpful information on this topic.

12.7 Justification

The ISRRT considers authorisation and justification of medical exposure within the Radiographer/Medical Radiation Technologist scope of practice, subject to their demonstration of appropriate educational training leading to clinical competency to carry out the task as trained (see ISRRT’s Position Statement on the Radiographer/Medical Radiation Technologist’s Role in Authorisation and Justification of Medical Exposure as a Team Approach).

Radiographers/Medical Radiation Technologists play an integral part in the authorisation and justification of medical exposure process by communicating the radiation risks to patients and referring clinicians using evidence-based data during their daily practice.

Supporting this position statement is the new International Basic Safety Standards (BSS), which was published by the International Atomic Energy Agency (IAEA) as General Safety Requirements Part 3 in July 2014.
The BSS covers four areas of responsibilities for the protection and safety of patients relating to Justification. First, stating that the person or organisation responsible for facilities and activities that give risk to radiation risk shall have the prime responsibility for protection and safety. Also supporting from BSS is Paragraph 2.40 and 2.41 stating that other parties, such as the referring medical practitioner, medical physicist and Medical radiation technologist (MRT) (Radiographer) shall also have specified responsibilities. The BSS states that justification can be explained as the process of weighing the expected benefits of an exposure against the possible detriment of the associated dose. The benefit versus detriment may relate to the individual and/or to society as a whole.

Justification of the medical exposure procedure for the individual patient is defined in the BSS under paragraphs 3.156 and 3.157. These two requirements of the BSS ensure that the individual medical exposure is justified in advance taking into account the specific objectives of the exposure and the characteristics of the individual involved.

The radiographer/medical radiation technologist as a result of their education and training obtain a thorough understanding and knowledge of Justification. It is within their scope of practice to help with the authorisation when the radiological medical practitioner (radiologist) is unavailable or a MRT/Radiographer working in accordance with the guidelines issued by the practitioner. Radiographer/ Medical Imaging Technologist authorization may be demonstrated by signing or initiating the referral in a predetermined place or by entering an electronic password. The employer’s procedure should describe clearly how authorization is to be demonstrated.

It is recognized that, in addition to radiologists, in some countries the MRT/Radiographer is permitted to act as practitioners for a specific range of diagnostic procedures. In every country, the MRT/Radiographer has a responsibility to contribute to the imaging team to ensure that patients do not receive additional exposure due to duplicate procedures or inappropriate procedures. However, it is not feasible for a radiologist, acting as a practitioner, to review every imaging request and therefore appropriately entitled MRTs/Radiographers can authorise an exposure using written guidelines that a practitioner has written.

The ISRRT Board of Management promotes the scope of practice of a Team approach to Authorisation and Justification as safe and best practice for diagnostic imaging services.

A Justification flow chart and narrative showing and explaining the radiographer/radiological technologist involvement can be found at Justification | ISRRT.

The IAEA have helpful information on this topic.

Justification is supported by the use of clinical support guidelines that have been developed by a number of international professional organisations, which assist the referrer in deciding the most appropriate investigation relevant for the disease process under consideration. This is discussed in Section 2.29 below with details of some of the guidelines published.
12.8 Patient Dose Monitoring
The current International Basic Safety Standards for Radiation Protection and Safety of Radiation Sources (IAEA GSR Part 3) require relevant information from the patient's previous radiological procedures to be taken into account in the justification of medical exposures for an individual patient.

The IAEA initiated a Smart Card project in 2009 with the purpose of motivating both industry and users, alike, to have a methodology for tracking radiation exposure history of individual patients. Currently, automatic exposure monitoring systems have become available in many hospitals, mostly in high-income countries, which facilitates exposure tracking of individual patients.

Currently there is concern that as a result of wider utilisation of radiation exposure monitoring systems, information has become available recently that the number of patients who accumulate effective dose of 100 mSv and higher in a few years from recurrent computed tomography procedures is greater than previously known and might concern nearly one million patients globally per year and one out of five such patients is likely to be below 50 years of age.

As a result, the IAEA has given this concern a major priority and is developing a joint position statement and call for action for strengthening radiation protection of patients requiring recurrent radiological imaging procedures.

Many countries have systems that require Imaging departments to collect and record individual patient doses from a range of relatively high radiation dose examinations and procedures, such as CT and fluoroscopic intervention procedures, with the data collected useful in determining national and regional DRLs.

Monitoring skin dose during a live procedure, such as interventional cardiac procedures, is also important to ensure that absorbed skin dose is kept to a minimum and based on predetermined level.

Monitoring for record keeping of total doses received may be undertaken manually such as recording data on a RIS system. However, this can also be accomplished electronically using one of the electronic dose monitoring systems now available which interface with the imaging equipment. Currently there are more than 15 diverse products commercially available and equipped with features that continue to evolve. The implementation of dose monitoring ranges from an act of compliance requiring minimal support to an essential imaging and workflow tool leveraged by staff ranging from technologists to administrators.

Operators of radiological services have a duty of care to make sure that patients’ radiation doses are captured, stored, and used to create a dose history for an individual patient. Such data should be readily available in determining the justification of further imaging.

The IAEA have helpful resources on this topic\textsuperscript{38}. 

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12.9 Staff Dose Monitoring
A risk assessment may be carried out for those working with ionising radiation and should consider the potential radiation exposures that an individual may receive during the course of their work (including accidental exposures).

This will help to determine:
- estimate likely radiation doses
- identify whether your staff should be subject to personal dose monitoring
- determine whether certain employees should be designated as classified persons

Classified personnel will require monitoring, and this is determined as to how likely they will exceed the three-tenths of the set dose limits. Examples are shown below:

<table>
<thead>
<tr>
<th>Part of the Body</th>
<th>Annual Dose Limit (mSv/y)</th>
<th>Annual doses above which classification would be necessary (mSv/y)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole Body</td>
<td>20</td>
<td>6</td>
</tr>
<tr>
<td>Lens of the Eye</td>
<td>150</td>
<td>45</td>
</tr>
<tr>
<td>Skin</td>
<td>500</td>
<td>150</td>
</tr>
<tr>
<td>Hands, forearms, feet and ankles</td>
<td>500</td>
<td>150</td>
</tr>
</tbody>
</table>

For those staff involved in interventional fluoroscopic or CT image guides procedures or radioisotope preparation and injection a careful risk assessment is necessary.

All imaging rooms using ionizing radiation will be classified as Controlled areas in which classified people will work together with other non-classified employees who are allowed entry under suitable written arrangements and monitoring to ensure exposures are kept as low as possible. Other workers should only be allowed conditional access and only in accordance with prior written arrangements.

Dose monitoring of staff, body, eyes etc., will be undertaken using agreed protocols and using certified laboratories. There is a range of devices available including electronic dose meters, which provide a real time indication of scatter dose received.

There are other issues to consider regarding staff dose monitoring including pregnancy, retention of records,

People who work for more than one employer, medical records and what to do if a worker has an overexposure. There are a number of useful helpful resources to assist in the management of staff doses.
12.10 Pregnancy Rules

Departmental policies and procedures together with patient information leaflets and posters should be readily available to educate staff and patients of the importance of minimising the unborn child to radiation exposure.

X-ray investigations, if medically justified and with certain precautions, can be undertaken during pregnancy. The aim is to minimize the unborn child’s radiation exposure. An unborn child is considered to be more sensitive than adults or children to potential adverse radiation effects. For many examinations such as X ray of the head (including dental X rays), chest and limbs, where the pelvic region is not in the direct beam, the dose to the unborn child can be very low. Doctors may consider delaying procedures that would put the pelvic region and the unborn child in the direct path of the beam. If the procedure is essential to the individual’s health, the doctors take special actions to keep the dose to the unborn child as low as possible. For example, a pregnant patient can have their pelvic region shielded during the procedure\(^4\). \(\text{\textsuperscript{4}}\)

In order to delay procedures that involve irradiation of the pelvic region, the application of the ‘Pregnancy Rule’ should be applied. Two rules have evolved by the ICRP.

Historically the 1970 International Commission on Radiological Protection (ICRP) recommended that “In women of childbearing age, non-urgent x-ray examinations that entailed pelvic irradiation should be restricted to the first ten days of the menstrual cycle” and the practice is known as the 10 Day Rule. The original proposal was for 14 days, but this was reduced to 10 days to account due to the variability of the human menstrual cycle.

In 1984, the International Commission on Radiological Protection (ICRP) recommended which means that radiological examinations, if so justified, can be carried throughout the cycle until a period is missed. Thus, the focus is shifted to a missed period and the possibility of pregnancy. If there is a missed period, a patient should be considered pregnant unless proved otherwise and in such a situation, every care should be taken to explore other methods of getting needed information by using non-radiological examinations.

Different professional organisations and regulatory authorities offer advice on this important topic and in some departments the 10-day rule will still apply for those high dose examinations of the pelvis such as barium enemas and CT abdominal and pelvic examinations\(^4\).

Managers will need to define and implement a ‘Pregnancy Rule’ procedure and ensure that a record is kept of the patient’s response. Additionally, consideration should be given to the use of pregnancy kits to determine if a patient is pregnant.

The International Basic Safety Standards requires the registrants and licensees to ensure that: "signs in appropriate languages are placed in public places, waiting
rooms for patients, cubicles and other appropriate places, to request patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that they are or might be pregnant”. The poster is intended to be used with this purpose.

The IAEA have examples of posters and leaflets about radiation protection\textsuperscript{43}. Other helpful information can be found as produced by many organisations\textsuperscript{44}.

12.11 Equipment and Medical Devices Guidance Policy
It is important that there is a policy that covers all aspects of medical device management, including medical imaging equipment. This should include selection, purchase, acceptance, safety checking, decontamination, maintenance, repair, monitoring, replacement and disposal of medical devices and training.

It is important that medical devices employing radiation to acquire images are not used beyond their useful working life to ensure adequate maintenance and support from manufacturers. This is particularly so when considering the age of fluoroscopic devices where the risk of using higher doses of radiation may be necessary to obtain optimal images affecting significantly local or national DRLs. Owners of medical imaging services should therefore develop a programme for the progressive replacement of equipment before this situation is reached. In determining whether continued use of ageing equipment is justified, and in assigning priorities for equipment replacement, consideration should be given to the following:

- equipment performance (including comparison of recent performance test results with remedial and suspension levels).
- the magnitude of patient doses resulting from the use of that equipment.
- the frequency of use and number of patients likely to be affected by the continued use of the equipment.
- the range of patients likely to be affected by continued use (e.g., age, clinical condition). Such factors enable a determination of risk versus benefit for continued use of the equipment; and
- the cost of replacement. However, cost cannot normally be used as a legitimate reason for patients being subject to risks in excess of those normally encountered for the examinations undertaken\textsuperscript{45}.

Additionally, it is important to keep a history of faults associated with a piece of equipment. All equipment should have a fault record to keep a track of faults and when they were corrected.

12.12 Personal Protective Equipment (PPE)
The use of PPE specific to the radiation protection of staff and members of the public, when they act as carers and assist with a patient, is an essential safeguard against the hazardous effects of ionizing radiation.
Their use and the choice of PPE shielding device to be used, including the amount of lead protection necessary, should be assessed following a detailed risk assessment of the work undertaken which should include the advice of the RPA. Such shielding devices employed will include lead or lead equivalent protective aprons and gloves, thyroid shields, skin guards and the use of lead glass shielding.

Their use will be dependent on the circumstances such as PPE equipment required whilst undertaking mobile radiography, long drawn-out fluoroscopic procedures in cardiology and angiographic interventional procedures.

The care of such devices is also an important consideration with policies and procedures in place to ensure that they are kept in an effective and usable condition. The IAEA provides some general helpful PPE information.

12.13 Patient Shielding
The use of patient shielding including the use of gonad shielding is a topic which is currently (2021) being discussed and debated around the world and their use should be subject to agreed protocols and procedures.

Patient shielding devices that are supplied in several countries are categorised as medical devices due to the fact that they are placed on the patient. Such devices used to protect the gonads, eye, thyroid and breast tissues will have a characteristic mark signifying that they meet certain standards i.e., CE mark. Being medical devices, they will be issued with operating instructions, details of maintenance requirements and when they should be used. It is important that advice is obtained, and written instructions are issued regarding cleaning instructions.

The ISRRT is developing a position statement on ‘patient shielding’ which will provide useful information regarding ‘In Beam’ and ‘Out of Beam’ situations including advice on the use of gonad shielding. The general consensus, with the exception of a particular paediatric patient requiring repeat examinations, is that gonad and fetal shielding is not necessary, and similarly in diagnostic and interventions imaging procedures patient thyroid, eye and breast are also not necessary.

This consensus is based on new risk benefit analysis related to the dose levels used in the modern department and re-evaluation of the lifetime stochastic and hereditary risks. Additionally, it is recognised that the patient dose will increase if an additional image is required due to misplacement of the initial shielding in addition to the fact that shielding may hide pathology over a specific region.

12.14 Staff Training and Competence
Professionals working with ionizing radiation are personally accountable when they use such medical devices and therefore must ensure that they have appropriate training. Employers should publish a standard operating procedure (SOP) which sets out the important considerations to ensure that staff can operate equipment safely.
Such procedures are to ensure all staff are trained in the use of medical devices as deemed necessary by their line manager. An individual who uses the device in a way not intended, or against the instructions of the manufacturer may be liable for any consequences. This procedure will be in compliance with local country requirements which ensures that persons providing care or treatment to service users should have the qualifications, competence, skills and experience to do so safely.

The training provided will be in the safe use of the device itself but not in the clinical interpretation of any result arising from the use of the equipment. The training may be delivered in groups or on an individual basis as deemed necessary and include:-
Relevant assessment of competency in the use of the equipment will be checked by trainers. These can be undertaken either on the imaging room or in a simulated environment i.e., a dedicated training room.
Identified staff will be responsible for checking competency of users on the use of devices after they received appropriate training, confirming clinical competence, and identifying any staff for whom there is a need to provide additional training.
Further training and support must be given when deemed appropriate and / or when identified through incident reporting mechanisms, on an individual and / or group basis.
Before using imaging equipment, a detailed training document should be available for new users who should be signed off as competent to use the equipment.

There are a number of helpful policies available on the internet which also include reference to those items of equipment which rank with a high-risk score following risk assessment50.

12.15 Unit Design and Protective Measures
It is important that a careful assessment and professional advice is given to the design of a unit which will accommodate diagnostic imaging and radiation therapy equipment.
Protective measures regarding access, location and barriers need to be considered to prevent uncontrolled access to such rooms and facilities. The design will include the advice of the users and the RPA as well as the architects.

12.16 Diagnostic Reference Levels (DRLs)
The ISRRT considers that the implementation and use of Diagnostic Reference Levels (DRLs) is an integral part of a radiographic examination. Radiographers and Radiological technologists have a duty of care to apply appropriate exposure parameters and techniques that result in dose levels that comply with those DRLs established in accordance with national, regional and local authorised bodies and local protocols. As such staff should know national and local DRLs for typical examinations in order that good dose optimisation can take place51.

The Joint Position Statement by the IAEA and WHO – Bonn Call for Action
The International Atomic Energy Agency (IAEA) held the "International Conference
on Radiation Protection in Medicine: Setting the Scene for the Next Decade” in Bonn, Germany, in December 2012, with the specific purpose of identifying and addressing issues arising in radiation protection in medicine.

**Action 2** of the Bonn Call for Action calls for the establishment, use of, and regular update of diagnostic reference levels for radiological procedures, including interventional procedures, in particular for children.

The Bonn Call for Action was a response to the IAEA Safety Standards for protecting people and the environment: Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards – General Safety Requirements part 3 No. GSR Part3 published in 2014. The standards describe and define dose constraints and reference levels which are used for optimisation of protection and safety, the intended outcome of which is that all exposures are controlled to levels that are as low as reasonably achievable with economic, societal, and environmental factors taken into account.

Helpful background reading is found in the ICRP 135 publication ‘Diagnostic reference Levels in Medical Imaging’ and the IAEA publications ‘IAEA - About Diagnostic Reference Levels (DRLs)’ and ‘IAEA - IAEA – Diagnostic Reference Levels (DRLs) in medical imaging’.

12.17 Classified Workers

In many countries the radiation exposure of, amongst others, radiation workers may be limited by law to a set of prescribed radiation exposure levels, called Dose Limits. The dose limits for workers aged eighteen or over are shown in the table illustrated in the dose monitoring section.

As part of the system of protection, those who are, or are likely to be, exposed to more than three-tenths of these limits, shown in column three of the table below, are subject to additional control measures, and are known as “Classified Workers”.

In the main most radiographers and radiological technologist will be considered as ‘Non-classified workers’ having a much lower risk profile than those determined as Classified workers.

Classified workers will be subject to a greater degree of control which will include:

- The mandatory provision of personal dosimetry
- The maintenance of dose records
- The mandatory provision of suitable medical surveillance

The IAEA and other agencies provide helpful advice and guidance.

12.18 Controlled and Supervised Areas

A controlled area is one which has been designated by an employer to assist in controlling and restricting radiation exposures. Controlled areas will be designated because the employer has recognised the need for people entering an area to follow special procedures.
The decision to designate an area as a supervised area depends both on the assessment of likely doses in that area and the probability that conditions might change. For example, where an area needs to be kept under review because of the possibility that radioactive contamination might spread, you must designate the area as a supervised area.

From a practical point of view when undertaking radiography outside the main imaging department when undertaking mobile or theatre radiography a supervised area will exist in the immediate vicinity of the imaging equipment during the exposure of ionizing radiation.

Both controlled and supervised areas must have access control with the use of appropriate warning signs as; "Controlled Radiation Area: No Entry to Unauthorised Personnel", and the standard black and yellow trefoil sign denoting a radiation hazard.

The IAEA\textsuperscript{56} and other agencies provide helpful advice and guidance\textsuperscript{57}.

12.19 Referrer, Practitioner and Operator

Some countries adopt legislation to strengthen the protection of the patient being unnecessarily subjected to ionizing radiation as part of a medical investigation. Such legislation may be in addition to a more general set of legislation directed to the protection of persons against ionising radiation\textsuperscript{58}.

A referrer is the individual that requests the radiation exposure and therefore must provide enough clinical information for the exposure to be justified. The practitioner is the person responsible for justifying the radiation exposure and the operator is responsible for carrying out the radiation exposure.

The practitioner and the operator can be the same person. Often this is the radiographer for plain film imaging.

If a request cannot be justified it will be returned to the referrer for additional information or may be declined. An operator cannot irradiate a patient if the radiation exposure cannot be justified. Several international professional organisations have published \textit{referrer and clinical support guidelines} that assist in the justification of imaging requests. These include:-

\begin{itemize}
  \item \texttt{About iRefer | The Royal College of Radiologists (rcr.ac.uk)}
  \item \texttt{iRefer | Hong Kong College Of Radiologists (hkcr.org)}
  \item \texttt{ESR iGuide – Clinical Decision Support for the ESR’s referral guidelines – ECR Today 2020 (myesr.org)}
  \item \texttt{ACR Appropriateness Criteria® | American College of Radiology}
\end{itemize}
13. Control, Management and Administration of Medicinal Products and Contrast Enhancement Agents

13.1 Introduction
There is a wide range of medicinal products and contrast enhancement agents used in Imaging and Radiotherapy departments. In this context the term ‘contrast enhancement agents’ includes iodinated contrast agents, barium products, ultrasound agents using microbubbles, gadolinium and iron oxide products used in MRI and radiopharmaceuticals used in Nuclear Medicine and molecular imaging.

In many countries contrast enhancement agents have been classified as ‘prescription on medicines’ (POM) and therefore their use is governed by legislation, rules and procedures.
Many of the medicinal products found in departments will be used as part of the preparation, necessary during the actual procedure and for the aftercare of the patient. Again, many will be classified as POM and subject to therefore subject careful handling, administration and use.

The ISRRT considers the identification, preparation and/or administration of medication as prescribed by a licensed practitioner to be within the scope of practice for radiographers/radiological technologists subject to their demonstration of appropriate educational preparation leading to clinical competence where the administration of medication is permissible by regulation/national/provincial law. 59

The ISRRT also considers that the administration of oral and intravenous contrast agents is within the scope of practice for radiographers/medical radiation technologists and radiation therapists subject to their demonstration of appropriate educational preparation leading to clinical competency to carry out the task as trained and where the administration of oral and intravenous contrast is permissible by regulation or law60.

There should be an organisational wide policy for managing medicines and contrast enhancement agents across all specialties.
This section will outline general principles and any matters relating specific imaging modalities will be addressed accordingly in these sections.

13.2 Roles and Responsibilities
13.2.1 The Hospital Management Team
Development and implementation of the corporate policy which may include:
- Acquisition of Medicines and Contrast Media
- Storage
- Transportation
- Patient and Carer Information
- Prescribing policies, Staff Groups and Patient Group Directions (PGDs)
- Administration of Contrast and Medicines
- Infection risk identification and Control
- Disposal of Contrast Media and Medicines when used or out of date
13.2.2 Service Managers (Departmental level)
Implementation of a departmental policy and procedures to include:
- Storage and stock management
- Security processes
- The application of medicines and contrast media with modality specific details and administration of the medicine and contrast media by Imaging Practitioners.
- The use of contrast media pressure injectors
- The use of patient group directives (PGD) – if applicable to the local governance procedures

PGDs provide a legal framework that allows some registered health professionals to supply and/or administer specified medicines to a pre-defined group of patients, without them having to see a prescriber (such as a doctor or nurse prescriber).

13.3 Administration of Intravenous Contrast Media (IVC) and Risk Considerations

13.3.1 Risk Considerations
All IVC examinations involves a risk of an adverse reaction to the patient. Most reactions are minor; however, life threatening, and fatal reactions may occur. Things to consider are those related to hypersensitivity, contrast induced-acute kidney injury (CI-AKI) and extravasation of contrast media\textsuperscript{61}.

It is important that before contrast is administered that any possible side effects are explained and that the patient is given the opportunity to provide a history of any previous side effects from previous IVC.

Steps should be taken to minimise the risk for both the injection of iodinated contrast and gadolinium-containing\textsuperscript{62} contrast agents

13.3.2 Competency to Administer
Personnel undertaking intravenous procedures should be trained for the task. Training may be incorporated into the radiography student training programme with many courses available from different institutions. Such courses should include topics covering: Anatomy and Physiology of venepuncture sites; venepuncture of upper extremity; instruments and related equipment; techniques used; actions/ reactions of contrast media; hazards and complications of venepuncture and emergency measures in dealing with adverse reactions.

13.4 Education and Training
This will include:
- Injection techniques for IV contrast media/radiopharmaceuticals procedures. and oral and rectal administration of barium/iodinated contrast products.
- Use of contrast media pressure injectors.
- Resuscitation including assessment and intervention using the Airway. Breathing Circulation, Disability and Exposure (ABCDE) criteria.
13.5 Use of Contrast Media Injectors

13.5.1 Radiographer/ Imaging Technologist Guidelines

As an example:-

- All staff that use pressure injectors should be trained in line with an agreed set of competency standards.
- Assessment of their knowledge and skills should be assessed using a competency framework.
- Training should include safe operation and associated risks.
- A record of the training and accompanying competency assessment should be recorded by the departmental manager.
- Many organisations require 2 trained members of staff to be available when operating a pressure injector.
- The preparation of pressure injectors with contrast media or saline will follow the medicines management guidelines on medicine administration and manufacturer’s guidelines.
- Staff must adhere to strict aseptic technique when filling, connecting and disconnecting pressure injectors in accordance with Aseptic No Touch Technique (ANTT) guidelines.

One of the risks inherent with use of pressure injectors is the risk of introducing large volumes of air into the vascular system. The effects vary depending on site of embolism; however, risk of death or serious harm is high. Following a patient death in the NHS the MHRA released the best practice guidance in 2006:

- A local procedure must be available that includes checks to ensure syringes are correctly filled in accordance with manufacturer’s instructions.
- Staff must ensure that, if the injector design requires syringes to be loaded in such a way that they are initially full of air, the operator first moves the plunger forward to empty the syringe. This is to reduce the risk of an air-filled syringe being mistaken for one full of contrast medium.
- Empty syringes must not be left in the injectors at the end of a procedure. When connecting catheters and syringes, steps must be taken to ensure that no air is introduced into the system
- Staff to be aware of the risks associated with the injection of air into a patient.

13.6 Adverse Reactions

Every institution will have their local guidance as to how to treat patients who sustain a reaction following IV administration. Indeed, many professional organisations issue guidance. All staff performing IV administration must have read the local policies and procedures.
14. Management of Risks Associated with Ultrasound

14.1 Introduction
A range of diagnostic ultrasound equipment is available, from larger multi-functional machines in imaging departments, dedicated mobile or portable units, through to endoscopic and intra-operative equipment. Ultrasound is employed as an alternative to ionising radiation modalities such as CT or fluoroscopy, particularly within screening programmes or for long-term follow-up where serial imaging is required; as a means of assessing anatomy and functionality in real time; in confined spaces such as at the bed-side or for Special Care Baby Unit incubators; in sports as well as emergency care in the field, ambulance or trauma situation, and for many image-guided interventions, both diagnostic and therapeutic. The outcome of ultrasound studies is very much operator dependant and therefore appropriate education is necessary for those undertaking such investigations, along with comprehensive systems for risk management as outlined below.

14.2 Roles and Responsibilities

14.2.1 Schemes of Work and Protocols
Each facility should have a scheme of work, stating the sonographers’ roles and responsibilities. This may include writing the clinical report, providing an interpretation of the findings, correlating to the clinical details provided, recommending further investigations including x-ray, CT, MRI and blood tests, and communicating the findings verbally to clinicians, patients and carers. Additionally, protocols should provide detailed information about the areas to be scanned and reported for each body part or examination type. Protocols should be evidence-based, dated clearly and updated regularly. As new protocols are introduced, the old protocols should be archived, as they may need to be referred to in the future.

14.2.2 Clinical Report Writing
Report writing is an integral part of the examination and should not be separated from the ultrasound examination, as the operator builds up a 3D image in their mind as they undertake the scan, and this cannot be captured by still images nor even video. In the UK, professional guidelines state that the operator should interpret and report the findings of an ultrasound examination (SCoR (Society and College of Radiographers) and BMUS (British Medical Ultrasound Society). Guidelines for Professional Ultrasound Practice SCoR and BMUS, 2020).

The report should communicate the findings of the examination in a clear and concise way to reduce errors in interpretation and the medico-legal consequences of misinterpretation. Sonographers should be aware of best practice guidance from their national professional bodies, in the UK these include the SCoR, BMUS and the Royal College of Radiologists (RCR).

Clinicians reading the report may not understand ultrasound terminology so the sonographer should make sure to provide clear information, avoiding the use of jargon and providing an interpretation of any description.
Sonographers must work within their scope of practice. If unsure of how to word a report or interpret the findings, a second opinion should be sought from a colleague. This should be included within the report. Any additional actions taken must be documented, for instance discussing the findings with the referring practitioner, or referring the patient for further imaging or care.

There are a number of standardised reporting tools available for different clinical areas, to try and develop consistency of report writing. These include the American College of Radiology (ACR) Reporting and Data Systems (RADS) and the International Ovarian Tumor Analysis (IOTA) definitions.

14.3 Specialist Equipment and Modality Specific Information

**Staff risk management; Prevention of work-related musculo-skeletal disorders**

Work-related musculoskeletal disorders (WRMSDs) are prevalent amongst sonographers, so it is important to consider ways to reduce the chance of injury. There are many factors that can help protect sonographers and a plethora of research and guidance is available such as Dodgeon & Newton-Hughes 2003\textsuperscript{66}; Harrison and Harris, 2015\textsuperscript{67}; Monnington et al, 2012\textsuperscript{68}; SCoR, 2019\textsuperscript{69}. All training should include advice on how to optimise the ergonomics and minimise risk of strain.

Employers have a responsibility to ensure that the workplace is safe and provide appropriate equipment to protect sonographers. This includes ergonomic equipment such as a moveable couch and appropriate chair that supports the sonographer to sit upright and get as close to the patient as possible. Other factors that impact on WRMSDs are workload pressures, patient obesity or mobility, psychosocial factors and stress, poor management and lack of control over workload (Harrison and Harris, 2015\textsuperscript{70}).

Key considerations when planning the ultrasound workload are:

- Room design to ensure enough space to optimise the scanning position.
- Mixed ultrasound examination lists where possible, to vary the workload and posture.
- Provision of breaks and time for sonographers to refocus their eyes, stretch and relax. Micro breaks such as resting the scanning hand for a few seconds whilst taking a measurement can be helpful to allow muscle recovery.
- Risk assessments should be undertaken for each sonographer and examination type, as risks will vary for individual circumstances.

Ergonomics includes the ability of the sonographer to adapt the equipment and tasks to suit them and their needs, rather than have to work around equipment. Good ergonomic education and understanding is central to reducing the chance of WRMSDs.

Sonographers can also improve their general well-being and reduce the risks to themselves by warming up before a scanning session, stretching between patients.
and at the end of the ultrasound list, building upper body strength and keeping fit (HSE, 2011).

14.4 Contrast Enhancement Agents

**Ultrasound contrast agents**

Contrast agents for ultrasound have a low incidence of side effects and are well-tolerated by patients. They have few contra-indications; they do not interact with the thyroid and are not nephrotoxic, so it is not necessary to perform laboratory tests of renal function before administering them. The incidence of severe hypersensitivity or allergic events is lower than with current radiographic contrast agents and comparable to MR contrast agents. (Claudon M et al 2008). Furthermore, administration can be repeated due to the excellent tolerance of ultrasound contrast agents.

It is important to note that not all agents have the same licensing indications in different countries, and this should always be checked prior to use. Additionally, the regulation of administration of ultrasound contrast agents will vary dependent on the country and status of the health care professional; this should be checked locally.

14.5 Service Hazards

14.5.1 Control of Infection

Because of the necessity for bare skin contact, the use of scanning gel which may become a contaminant, and the proximity of operator and subject; the transmission of infection is a real risk to both staff and patients, and very high standards of infection control are therefore required (Tunstall 2010). All types of endo-cavity sonograms in particular should have a specific protocol for infection control procedures to reduce or eliminate infection exposure to the patient, operator and equipment. (AXREM, BMUS & SCoR, 2020).

It is important, after every examination, to decontaminate the ultrasound machine and probes carefully to reduce the chance of cross-contamination between patients. Two alerts relating to ultrasound probes have been published, highlighting the risks to patients of inappropriate decontamination (MHPRA, 2009; MHPRA, 2014). Decontamination levels will depend on the nature of the examination and contact with patient body parts, for example intact skin, broken or infected skin surfaces, endo-cavity examinations or intraoperative procedures. For any procedure, immediately after the examination is completed the probe should be wiped clean of any solid matter. If gel or other material is not removed before disinfection or sterilisation of the probe, the procedure can be less effective.

Manufacturer-approved products must be used when selecting which is the most appropriate method of decontaminating each individual probe to prevent damage. Local infection prevention and control teams should also be involved in discussion about the optimal methods for every examination type. In some cases, different products are needed for the probe compared with the machine and cables. Automated systems are recommended as best practice for disinfection of endo-cavity probes or
probes that have been in contact with broken or infected skin or patients with known infections (Bradley et al, 2018). For any decontamination process it is important that all staff are fully trained, audited and comply with local protocols. For disinfection and sterilisation the process should be documented clearly for each patient interaction, to ensure a full audit trail is available should there be any future issues (AXREM, BMUS & SCoR, 2020).

14.5.2 Prevention of Latex Allergic Reactions
When operators wear medical gloves or probe covers containing latex are used, as in endo-cavity examinations, it is important to check for latex allergies. Vinyl alternatives should be available in case of allergy or for the unconscious patient.

14.5.3 Potential Bio-Effects of Diagnostic Ultrasound
Bio-effects of ultrasound have been demonstrated in vitro, and the principle of ALARP (“as low as reasonably practicable) should be used, as in any imaging procedure. The use of Doppler ultrasound is not advised within the developing embryo, as this is the potentially highest intensity mode and the most vulnerable scenario. M mode is a lower-energy alternative that is much under-used and should be considered as a better means of demonstration of cardiac pulsation (RCOG 2015). Otherwise, no detrimental effects of normal intensity diagnostic ultrasound have been proven in clinical use.

14.6 Specific Quality Assurance measurers
14.6.1 Total Quality Management (TQM) of a Diagnostic Ultrasound Service
In its broader sense, this includes monitoring all aspects of service performance, from response to referrals, through technical aspects of the examination, to report delivery and overall patient satisfaction. Thus, total quality assurance incorporates clinical audit and service-user feedback as well as technical testing. It is essential to have a departmental scheme of work to set the standards of service and state the protocols for all the different examinations, so that everyone concerned with service provision is aware of their role and responsibilities. Performance guidelines and departmental protocols should be evidence-based and compliant with any professional body or national standards, so that there is a clear benchmark of expected performance. Clinical governance is the umbrella term for all of these aspects of performance.

14.6.2 Clinical Audit
Ultrasound is one of the only imaging modalities where image assessment and diagnosis occurs in real-time, and it must be recognised that one of its great strengths is the ability to image anatomical structures and in some cases functions in real-time. The subjectivity and operator dependence of ultrasound imaging must be acknowledged within any clinical audit programme, and audit should be viewed as a process rather than simply a means to an end; highlighting both areas of good practice and areas where improvement can be made, identifying resources and educational opportunities to maintain standards and enable continual improvement (RCR & SCoR, 2014).
14.6.3 Equipment Quality assurance (QA)

Technical Quality Assurance (QA) in sonography is a systematic programme to ensure diagnostic ultrasound instruments are operating consistently at their optimum level of performance. In terms of ultrasound equipment, there are four suggested levels of quality assurance (Hartshorne & Summers, 2014)80.

1. Acceptance testing on delivery of new equipment – performed (in the UK) by the regional medical physics department.

2. Safety checks prior to each scanning session – performed by the operator.

3. Monthly performance tests - carried out by ultrasound quality assurance lead or other appropriately trained personnel.

4. Annual performance checks – conducted (in the UK) by the regional medical physics department in conjunction with the NHS Trust or equipment owner.

Acceptance testing of new equipment, along with annual servicing, are professional services beyond the remit of the sonographer or operator; there are standards laid down for these by the Institute of Physics and Engineering in Medicine (IPEM 2010)81. Thus, the most basic, day-to-day, level of QA requires that all equipment users be vigilant for changes that could lead to sub-optimal imaging. This requires staff to undertake a visual check of the Probe (transducer) housing and cables at the start of each session (Dudley et al, 2014)82 to ensure the probe is free from cracks in the transducer housing or damage to the membranous face covering.

Transducer cables comprise very many, sometimes hundreds, of tiny wires, and are highly vulnerable to damage when run over by the cart itself during manoeuvring into position. The Probes containing the transducers and cables are fragile and the best way of ensuring equipment longevity is for the operator to ensure the probes and cables are correctly stowed at the end of each examination to protect them from damage.

The monthly performance tests are more objective than the daily visual checks and are carried out using a test object or tissue-equivalent “phantom”. This is essentially a scannable box containing various items such as wires a known distance apart or structures of a specific known size and depth. The calliper (measurement) accuracy and the axial and lateral resolution of the beam can be checked by on-screen measurements of a sonogram of this object. The results should be logged so that any change over time can be identified, often before an obvious equipment malfunction occurs.

Additional QA measures may be applicable in certain circumstances, for instance in screening programmes, or in vascular services where specialised checks for Doppler ultrasound may be made, and for monitors where images are to be viewed remotely (Kagadis et al, 2013)83. As in other branches of imaging, only medical-grade monitors should be used for image interpretation, and these should be subject to a QA programme to check for any drifting to their settings or performance. These processes and systems ensure that image quality is optimal and data measurements are accurate, helping to provide confidence in the service provided.
14.7 Patient Care
The following applies specifically to ultrasound examination, in addition to the more generic aspects of patient care detailed elsewhere.

14.7.1 Verbal Communication Issues
Good communication skills are essential in sonography. The procedure should always be fully explained before starting, not only as a courtesy to the patient, but also because co-operation is required to execute a high-quality examination. Sonography differs from most other imaging modalities, apart from fluoroscopy, in that the subject and the operator are in close proximity and can often see each other’s faces as the image is produced. The patient may well try to deduce what is happening, sometimes wrongly, if the operator does not explain the procedure, or at least say that the examination may take some time and require the utmost concentration, which may preclude conversation. Communication is therefore key to a quality sonogram, and of course a pre-requisite for valid informed consent (HCPC, 2016)\textsuperscript{84}.

14.7.2 Consent
A valid consent is part of patient-centred care and should be obtained for any examination. The patient should be provided with information about the procedure prior to the examination. When they arrive in the scan room, it is important that the sonographer ensures that the patient understands the voluntary nature of the procedure in addition to:

- Details of the examination
- The benefits and limitations of the examination
- Any consequences of not having the test
- Possible alternative options available
- Any potential side effects or risks

Providing clear communication before, during and after the procedure will reduce the chance of misunderstanding and complaints.

Valid consent presumes that the adult has capacity to consent, in so much as they can:

- Understand the information provided
- Retain that information long enough to decide
- Review the benefits and risks of having the procedure
- Clearly communicate their decision to the practitioner

The UK Department of Health and Social Care (DHSC) advises that “consent is usually a process, rather than a one-off event”. It is essential to check that consent is continuing for a procedure as you progress through an examination. There are specific guidelines for children and those with limited capacity to consent, which sonographers should be familiar with (DHSC 2009)\textsuperscript{85}.

One of the most difficult parts of a sonographer’s role can be communicating the ultrasound findings to patients. There are many occasions, not just in obstetrics, when
unexpected findings must be communicated with the patient. Sonographers should be aware of the approaches that might be used to ensure that the patient fully understands the information and what the next steps are. When explaining findings to patients and their relatives, it is essential to provide clear, honest explanations, whilst working within the individual sonographers’ scope of practice and level of competency.

14.7.3 Self-Care and Good Peer Support
Self-care and good peer support are essential for sonographers. Talking to colleagues and general debriefs can be useful.

14.8 Education and Training
Ultrasound is highly operator dependent and, as such requires appropriate and rigorous academic and clinical education. A recent study by the European Federation of Radiographer Societies (EFRS) found that most ultrasound education in Europe was at postgraduate level (European Qualifications Framework, level 7) or focused courses. In other countries, such as Australia and the UK, Bachelor’s level courses specifically for ultrasound have also been introduced. There is still debate about which academic level is optimal for educating independent reporting sonographers. Focused courses are useful for learning one very specific area of ultrasound practice to a high standard, for example aortic aneurysm screening and for clinicians wanting to extend the clinical examination e.g., podiatrists utilising ultrasound to assess the foot and ankle. A more comprehensive programme of study is required for those who use ultrasound in their daily practice for diagnosing a range of conditions or assessing a number of different body parts.

Any course of study should have clearly defined learning outcomes and should include assessment of clinical competence (CASE 2019). Course content should include all aspects required for safe clinical practice, such as anatomy, physiology, ultrasound technique, interpretation of normal, anatomical variants and abnormal findings. A good understanding of the equipment, safe scanning techniques and use of the equipment, image artefacts and ergonomics is essential. It is also important to provide education on professional issues, including consent, patient-centred and values-based care, report writing, communication, inclusivity, professionalism, audit and quality management.

Some countries have accreditation or approval of ultrasound programmes such as the Consortium for the Accreditation of Sonographic Education (CASE) in the UK and the Australian Sonographer Accreditation (ASA) Registry in Australia. These ensure a minimum standard of education and training is provided and can assist when selecting an education provider.
15. Management of Risks Associated with Magnetic Resonance Imaging (MRI)

15.1 Introduction
Nuclear magnetic resonance can be used to generate both images (magnetic resonance imaging) and chemical spectra (Magnetic resonance spectroscopy) which aid clinical diagnosis.

Clinical MRI systems are typically from 0.2 to 3 Tesla (T) but higher field strength systems operate in clinical research centres. The majority of clinical MR systems are 1.5T superconducting magnets with a cylindrical bore design requiring liquid helium to maintain the stable magnetic field.

The main magnetic field generates a polarised net magnetisation within the body which precesses in the radiofrequency range. A radiofrequency electromagnetic field is transmitted by RF transmit coils at the precessional frequency of the hydrogen nucleus. At this frequency, resonance occurs, and energy is absorbed and emitted by the hydrogen nuclei and received by RF receive coils. The gradient magnetic field cause a positional variation in the resonant frequency which is used to select the section of the body to be excited and to spatially encode the MRI signal emitted from the selected section.

15.2 Roles and Responsibilities

15.2.1 Organisational Responsibility
Within any organisation delivering clinical magnetic resonance imaging there should be documented roles and responsibilities in relation to MRI safety. MR safety should be compatible with relevant health and safety legislation in the jurisdiction and incorporated into the health and safety management of the organisation.

Roles and the responsibilities associated with each role may vary depending on the organisational management structure. Some roles have been defined in national/international guidance and are described below.

<table>
<thead>
<tr>
<th>Roles</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR Responsible Person(s)</td>
<td>This role is defined by MHRA guidelines for the UK. Responsible for operational MR safety, provision of adequate written safety procedures, work instructions, emergency procedures and operating instructions. Role may be undertaken by clinician, medical physicist or lead MR radiographer/technologist.</td>
</tr>
<tr>
<td>Role</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>MR Medical Director or MR research Director</td>
<td>Role defined European and international Societies for MRI. This is lead radiologist with responsibility for clinical/medical aspects of MRI safety</td>
</tr>
<tr>
<td>MR Safety Officer(s)</td>
<td>Lead radiographer/MR technologist responsible for day to day implementation of MR safety policies and procedures. Responsible in conjunction with the MR medical director for operational MR safety, provision of adequate written safety procedures, work instructions, emergency procedures and operating instructions.</td>
</tr>
<tr>
<td>MRI Lead Radiographer</td>
<td>Responsible for management of the MR radiographer and MR support staff.</td>
</tr>
<tr>
<td>MR Safety Expert</td>
<td>Expert scientific MR safety advice supports management of MRI safety. Provides high level advice on scientific, engineering, administration and implementation of MR safety including QA, audit, procurement and installation. This role may be undertaken by an MR physicist or other MR personnel with relevant technical MR expertise. Recommendations for the role of the MRSE are made by IPEM</td>
</tr>
<tr>
<td>MRI Physicist</td>
<td>The MR physicist often takes on the role of the MRSE or aspects of this role.</td>
</tr>
<tr>
<td>MRI Operator</td>
<td>Appropriately trained personnel for the safe operation of the MR system.</td>
</tr>
<tr>
<td>MRI Radiologist</td>
<td>In UK the supervising radiologist is responsible for health and well-being of subjects undergoing MRI. They should be fully conversant with the current clinical aspects of the use of the particular MRI equipment and its effects on the safety, health and well-being of the patient</td>
</tr>
<tr>
<td>MRI Radiographer/Technologist</td>
<td>Typically the MR operator but not exclusively for the majority of clinical MR examinations</td>
</tr>
<tr>
<td>MRI Engineer</td>
<td>Typically employed by the MR manufacturer, operates the MR system for QA, maintenance and identification of faults and repairs</td>
</tr>
</tbody>
</table>

63
### MRI support staff

Provide a patient care role in the MR environment. Must be trained in MRI safety procedures relevant to the role.

---

### 15.3 Specialist Equipment and Modality Specific Information

The key components of the MRI system are described below. Further description and diagrams are available.

<table>
<thead>
<tr>
<th>Components of the MRI System</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main magnet field coil and associated magnetic field shielding</td>
<td>A powerful magnet is used to provide a static uniform magnetic field. With any magnetic field there is an associated fringe field, the extent and steepness of the fringe field depends on magnet design and shielding. Magnetic shielding is part of the magnet design or magnet room design and installation; its function is to restrain the fringe field. The design of the MRI Unit should take into account interaction between the fringe field and the position of equipment sensitive to external magnetic fields. A field plot for the MRI installation may demonstrate the location of the 0.5 mT or 5 gauss line (the area in which electromagnetic fields may be hazardous), the 3mT line (projectile zone). The position of maximum spatial magnetic field gradient (relevant to implant safety) can be found in the MR system manual.</td>
</tr>
<tr>
<td>Shim coils</td>
<td>Generate additional magnetic fields to compensate for inhomogeneity in the main magnetic field.</td>
</tr>
<tr>
<td>Radiofrequency transmit/receive body coil</td>
<td>The main RF coil is situated within the bore of the magnet. Its function is to transmit RF pulses to excite nuclei within a selected volume of the patient. For large areas of the body this coil can also act as a receiver coil for the imaging signal. For smaller or more superficial areas, both the signal-to-noise ratio and the spatial resolution can be improved by using a surface coil placed in close proximity to the area under examination. The body coil typically acts as an RF transmitter and the surface coil used as a receiver. Signal drop-off occurs beyond the circumference of the coil and at a depth greater than the radius of the coil. Phased array coils are now widely available and consist of a number of small coils linked together, to give a greater combined signal and increased anatomical coverage. Large</td>
</tr>
</tbody>
</table>
Arrays have been developed for extended body coverage and predominantly replace use of main system RF coil as a receiver.

### Radiofrequency Shielding

Radiofrequency shielding is part of the installation design of the magnet room which prevents external radiofrequency signals corrupting the MR signal generated by the patient.

### Gradient coils

Magnetic field gradient coils are used to superimpose an additional linearly varying magnetic field along each of the three main axes. These coils vary the main magnetic field strength in a controlled way to provide spatial localisation. They add to, or subtract from, the main magnetic field in a linear fashion, so that the magnetic field strength and the corresponding processional frequency of the nuclei situated at any point along the gradient can be predicted. There are three magnetic field gradient coils that produce linearly varying magnetic fields in 3 orthogonal directions. These are combined with radiofrequency pulses to define a slice of a particular thickness and position. They are also used to encode the MRI signal in the plane of the slice so that signal strength at each location within the slice can be displayed in the image.

### Local receive or transmit/receive coils

Local radiofrequency coils design specifically for different parts of the body are used to receive the MR signal. In some cases these smaller coils can also be used to transmit and receive the MR signal. Phased array coils are now widely available and consist of a number of small coils linked together, to give a greater combined signal and increased anatomical coverage. Large arrays have been developed for extended body coverage.

### Cryostat

Contains the windings for the main magnet field and liquid helium in order maintain superconductivity of the magnet.

### MR system computer

The host computer controls and coordinates the various stages of the examination, operation of radiofrequency pulses and gradient systems to generate pulse sequences, image reconstruction and post-processing.

### Operator console

Allows the operator to control the scanning process, select patient data, sequences/protocols, image display and transfer.

---

15.4 Contrast Enhancement Agents, Medicines and Radiopharmaceuticals

MRI contrast media are gadolinium chelates. Free gadolinium ions are highly toxic and the chelates used to bind the gadolinium ion and can be either macrocyclic or linear.
Macroyclic chelates tend to bind more tightly with the gadolinium ions with improved thermodynamic stability and a lower dissociation rate than linear formulations.

15.4.1 Potential Risks
Gadolinium-based contrast agents have good stability and safety profile however there are some risks associated with these compounds which must be considered. Guidance for MRI contrast media is available from national and internal bodies.90

1. Severe contrast reactions including anaphylaxis: The incidence of acute, severe reactions is much lower (0.0025-0.05%) than with iodinated contrast but precautions and procedures are required to deal with anaphylaxis.91

2. Nephrotoxicity: In equimolar quantities GBCA have similar nephrotoxicity to iodinated contrast agents but in the small volumes used clinically nephrotoxicity is not concerning.87

3. Nephrogenic Systemic Fibrosis: GBCA are associated with this very rare condition in patients with severe renal failure. NSF causes collagen deposition in skin of the extremities and sometimes trunk causing thickening and hardening. Systemic involvement of several tissues and visceral organs including liver, lungs, muscles and heart can occur leading to a life-threatening condition. NSF has been reported exclusively in patients with renal insufficiency. Severe renal impairment is a common factor, and to date there have been no reports of NSF in patients with normal kidney function. Some GBCAs are much more associated with NSF and this has led to classification of GBCA by the FDA and EMEA according to their relative risk. In Europe avoidance of the high risk GBCAs in patients with severe renal impairment has prevented new cases.92,87

4. Gadolinium deposition in the brain and other tissues. Gadolinium has been found to accumulate in very low concentrations in body tissues and organs. This concentration of retained gadolinium is lower in the brain and much lower in the macrocyclic agents. The impact of gadolinium retained in the brain is unknown but investigation to date has not shown adverse neurological effects.87,93

15.4.1 Minimising Risks
Procedures are also required for contrast administration in pregnancy, children, patients with renal impairment and patients at risk of contrast reaction including procedures to mitigate the risks.

15.5 Service Hazards
MRI safety guidance is provided by a number of national and international organisations. These are important and detailed documents providing detailed guidelines on safe MRI practice. MRI managers should be familiar with the guidelines pertaining to their jurisdiction.94
15.5.1 Hazards Associated with the MRI Environment

<table>
<thead>
<tr>
<th>Magnetic fields used during clinical MRI and spectroscopy</th>
<th>Static magnetic field</th>
<th>Time varying gradient magnetic field</th>
<th>Radiofrequency Magnetic field</th>
<th>Other hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dependent Factors</td>
<td>Field strength and fringe fields</td>
<td>Limits and controls of exposure</td>
<td>Limits and controls of exposure</td>
<td></td>
</tr>
<tr>
<td>MRI controlled area</td>
<td>MRI controlled area</td>
<td>Limits and controls of exposure</td>
<td></td>
<td></td>
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<tr>
<td>Limits and controls of exposure</td>
<td>Limits and controls of exposure</td>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Associated hazard</th>
<th>Projectiles</th>
<th>Interaction with implanted biomedical devices and foreign bodies</th>
<th>Acoustic noise</th>
<th>Nerve and muscle stimulation</th>
<th>Heating/Thermal injury</th>
<th>Hazards related to cryogens</th>
<th>Phantom Fluids</th>
<th>Image artefacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Biological effects</td>
<td></td>
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</tbody>
</table>

15.5.2 Safety Considerations
In MRI the patients are subject to a strong static magnetic field, a rapidly changing gradient magnetic field and radiofrequency magnetic field. Each type of magnetic field creates a potential hazard which requires specific preparation for the MRI examination. The exposure of human subjects to the above fields is regulated by strict controls\(^95\).

15.5.3 Static Magnetic Field
The most common type of magnet design in clinical use is the superconducting magnet where the static magnet field is switched on at all times. The hazards associated with the static magnetic field include the projectile effect on ferromagnetic. In addition, there are large potential magnetic forces on ferromagnetic implants or foreign bodies and interference with implanted biomedical devices. This means that access to the static magnetic field must be restricted. In addition, all equipment used must be designed and/or tested for use within the MRI environment.
15.5.4 Gradient Magnetic field
Acoustic noise is generated by the gradient magnetic field during the scanning process and appropriate hearing protection must be provided to the patient to prevent hearing loss. In addition, these time-varying magnetic fields can cause electrical stimulation (nerve stimulation) or induce electrical current in conductors.

15.5.5 Radiofrequency Magnetic field
The radio-frequency magnetic fields deposit energy into the person being scanned at a given rate, depending on the pulse sequence used and the pulse sequence parameter.

The radio-frequency magnetic fields only affect persons inside and close to the bore of the magnet.

The energy deposited has the potential to raise the core body temperature, and may also cause localised heating (e.g., around metallic implants, RF coil cables or monitoring cables). The rate of energy deposition is defined per kilogram of tissue and is known as the specific absorption rate (SAR). Energy deposition is limited by the MRI scanner software but even at permitted levels the patient may experience heating of the body. Radiofrequency induced burns are the most frequently reported incident arising from MRI and effective procedures and manufacturers’ guidance must be followed to prevent RF burns.

15.5.6 Restriction of Access to the MRI Environment
MR environment is the 3D space surrounding the MR magnet that contains both the Faraday cage and the 5 gauss (G) line. Within this volume an item might pose a hazard arising from exposure to the associated electromagnetic fields. Access to this area must be restricted to ensure public safety and is an essential aspect of design of the MRI installation.

15.6 MRI Local Rules and Safety Procedures
Stringent procedures need to be implemented to address each of the hazards to ensure the health and safety of all subjects and personnel. These may be included in local rules and standard operating procedures. Compilation of these procedures should incorporate expert MR safety advice.

15.6.1 MRI Safety Procedures
Procedures should include the following and detailed guidance is available:

- Categorisation, training and authorisation of MRI personnel
- Restriction of access to the MRI environment
  Consideration needs to be given to how different categories of personnel working in MRI and subjects undergoing MRI gain controlled access to the MRI environment.
  Rules of access- local rules
Screening procedures

- Prevention of projectile hazard
  Control of equipment entering the MR environment and labelling of equipment
  Screening for ferromagnetic objects included in screening procedures

- Procedures relating to implanted medical devices
  Screening procedures
  Procedures for identification and documentation of implants
  Procedures for categorising implants MR safe, MR conditional, MR unsafe
  Procedures for scanning MR conditional implants

- Patient related procedures
  Management of MRI under general anaesthesia
  Preparing and screening patients for MRI
  Hearing protection
  Prevention of thermal injury
  Positioning and scanning
  Pregnant Patients
  Claustrophobia
  Medical emergency procedures
  Contrast media and medicines management and administration

- Equipment related procedures
  Management of MR equipment
  Fire procedure
  Quench procedure
  Phantom spillage procedure

15.7 Specific Quality Assurance Measurers
Quality assurance (QA) in MRI is carried out in order to assess whether there are changes in image quality over time.

The MR image is generated using a strong static magnetic field, magnetic field gradients, transmit and receive radiofrequency coils, analogue to digital converters and image reconstruction computers. Any of these aspects of the imaging system has the potential to affect image quality.

QA imaging protocols are designed to be sensitive to degradation in any of these components. QA is assessed using a QA phantom, a standardised imaging protocol (MR Pulse sequence). QA phantoms may be supplied by the manufacturer or alternatively there are a range of commercially test objects that can be used to measure different aspects of image quality such as signal to noise ratio (SNR), image uniformity, geometric distortion, slice positioning, slice thickness and spatial resolution. The same specific phantom for each QA test should be used over time. SNR is the most widely used QA measurement. It is a sensitive measure of image...
quality, which is easy to measure, and many MR systems will provide an automated QA protocol, which will typically assess SNR on a given phantom and coil. Modern MR systems use receive coils with a large array of elements distributed across the coil. A common source of image degradation is failure of one of these elements. QA may be used to detect failure of individual coil elements.

In other clinical applications other measurements are required. MRI for radiotherapy treatment planning requires high tolerance for image distortion because the images are being used to spatially target radiation treatment doses. In MRI screening for breast cancer fat suppression is critical to the detection of breast tumours and so an assessment of the quality of fat suppression may be required.

QA may be performed by the manufacturers’ engineers during routine scheduled maintenance as well as part of the local departmental protocol.

15.8 Patient Care
All the patient related procedures in the local rules and procedures section must be addressed for comprehensive patient care related to MR safety in addition to MR scanning protocols for all clinical applications.

15.8.1 Patient Screening and Patient Preparation
Patient screening is a vital part of the patient preparation process for MRI. Each MRI patient completes a screening questionnaire which is checked with the patient by a member of the MRI team prior to entry into the MRI scanning room. This process will identify implants which are contraindicated or require specific scanning conditions. In addition, all personal affects which pose a hazard are identified and removed. Further information may need to be obtained to identify the make and model of the implant so that the conditions under which MRI can be performed are understood and implemented. Potential artefacts from implants are identified. Each MRI department must have procedures in place for patients who are unable to independently complete the screening questionnaire.

Patient clothing can restrict heat loss, some materials can cause skin burns and image artefacts so that the use of hospital clothing may be more appropriate. When positioning the patient care must be taken to avoid skin surfaces touching such as clasped hands or skin contact between the thighs. This prevents a conductive loop being set up within the patient which has the potential for skin burns. This is avoided by appropriate separation of skin surfaces by clothing or accessory pads.

When a radiofrequency receiver coil is placed around the body part to be imaged care is needed to position the coil safely and accurately. Cables associated with the RF coils should be separated from the patient using accessory pads to prevent patient burns.

During the examination two-way communication is maintained with the patient via the patient call buzzer and the patient/operator intercom. Instructions are given to the patient such as breath holding by the operator.
15.8.2 Claustrophobia
Many patients experience claustrophobia within the MRI scanner, strategies and procedures should be in place to address this problem.

17.8.3 MRI in Young Children and Infants
For young children MRI can often be successfully performed with the assistance of play therapy and in infants by feeding prior to sleep however a number of children will require MRI under general anaesthetic.

15.8.4 MRI in Pregnant Patients
A number of laboratory and clinical research investigations have been conducted to determine the effects of MR imaging in pregnancy. To date, there is no indication that the use of clinical MR imaging during pregnancy has produced any harmful effects to the unborn baby. The main concern is RF heating as it is a teratogen, and this may be of particular concern in the 1st trimester. The 2004 ICNIRP report states that the evidence is not unequivocal and therefore it is advised that MRI in pregnancy may be used for pregnant patients only after risk/benefit analysis, particularly in the first trimester, to investigate important clinical problems or to manage potential complications for the patient or fetus. However, a more recent review of the evidence by the American college of Radiology recommends no special consideration related to the first trimester. To limit RF heating the MHRA recommends that pregnant patients be scanned in Normal Mode whenever possible. If there is a need to scan in Controlled Mode the decision to do so should be based on the information above about risks weighed against the clinical benefit to the patient and made at the time by the referring clinician, an MR radiologist and the patient.

15.8.5 MRI Under General Anaesthetic
Equipment to support anaesthesia and patient monitoring must be designed for the MRI environment. MR training is vital for the wider anaesthetic team. Safety procedures should be in place to address the lack of communication possible between the patient and the operator.

15.8.6 Patient Consent
The principles of consent common to all imaging procedures are applied.

15.9 Education and Training
The requirements to be able to practice as an MRI radiographer/technologist differ across the globe. A review of international MRI qualifications and certification in a range of English-speaking countries summarises a range of approaches. These are predominantly postgraduate programmes for qualified radiographers/imaging technologists with accredited undergraduate training and certification available in the US. The IAC have published standards and guidelines for MRI accreditation for the range of personnel working in MRI including technical staff. A comprehensive competency framework has been developed in New Zealand and in the UK, the organisation Skills for Health have published standards for producing MRI for
diagnostic purposes including knowledge required and performance criteria. In addition, the MHRA MRI safety guidelines incorporate the Skills for Health competency framework for the MR responsible person.

MRI managers should be able to demonstrate evidence of MRI training and competencies for radiographers including training in all aspects of MRI safety.

16. Management of Risks Associated with Nuclear Medicine and Molecular Imaging

16.1 Introduction
Nuclear medicine (NM) and molecular imaging (MI) visualise how the body is functioning, more specifically MI details what is happening at the cellular and molecular level. Nuclear Medicine Molecular Imaging (NMMI) is a type of medical imaging that provides detailed images of what is happening inside the body enabling visualisation, characterisation and quantification. NMMI uses radioactive materials for diagnosis by imaging, and non-imaging techniques and for therapy in many disease processes. The most common Nuclear Medicine Imaging procedures involve Single Photon Emission Computed Tomography (SPECT) and Positron Emission Tomography (PET) Imaging.

Diagnostic Nuclear Medicine involves the use of radioactive tracers to image and/or measure the global or regional function of an organ. The radioactive tracer or radiopharmaceutical is administered to the patient either by intravenous injection, orally or by other routes depending on the organ and the function being studied. The uptake, turnover and/or excretion of the tracer substance is then studied with a gamma camera, SPECT, PET or another instrument. The uptake of the tracer is generally a measure of the organ function or metabolism or the organ blood flow. MI in particular offers unique insights into the human body that enable physicians to personalise patient care.

In terms of diagnosis, MI is able to provide information that can be unattainable with other imaging technologies or that would require more invasive procedures such as biopsy or surgery and to identify disease in its earliest stages and determine the exact location of a tumour, often before symptoms occur or abnormalities can be detected with other diagnostic tests. NMMI assists healthcare providers to gain a better understanding of the pathways of disease, to assess new drugs and to improve the selection of therapy by monitoring patient response to treatment. NMMI are on the forefront of the trend toward personalised treatment of cancer and heart disease, where treatment is individualised on the basis of specific biochemical markers found in the patient. The goal is to identify patients for particular therapies and optimise patient response to treatment while minimizing side effects. With their ability to identify the early signs of disease and other abnormalities, NMMI offer the potential to change medical care from reactive to proactive.
16.2 Roles and Responsibilities
There is a hierarchy of responsibilities within the framework for safety, from governments to regulatory bodies to the organisations responsible for, and the persons engaged in, activities involving radiation exposure. In the case of medical exposures, the medical setting in which such exposures occur, sets the responsibility for protection and safety for patients, with the health professional responsible for the delivery of the medical exposure. Only persons with appropriate competencies are authorized to take particular roles and responsibilities; this applies in particular to persons undertaking the role of the NM medical practitioner, NM radiographer/technologists, or medical physicist\textsuperscript{105,108}. Examples include:

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Government</strong></td>
<td>A Government is responsible for the adoption within its national legal system of such legislation, regulations, and standards and measures as may be necessary to fulfil all its national and international obligations effectively. Specific to medical exposure, the government has the responsibility to ensure that as a result of consultation between the health authority, relevant professional bodies and the regulatory body, the relevant parties are authorized to assume their roles and responsibilities. The prime responsibility for safety rests with the person or Organisation responsible for facilities and activities, that is, usually the hospital management.</td>
</tr>
<tr>
<td><strong>Nuclear Medicine (NM) Radiographer / Technologist</strong></td>
<td>The NM radiographer should be able to undertake the whole range of nuclear medicine procedures. However, the spectrum of NM radiographer skills and responsibilities varies widely from country to country. Responsibilities include, but are not limited to: preparation, quality control testing and administration of radioactive compounds; execution of patient imaging procedures including computer processing and image management; laboratory testing; patient interviews; instruction and preparation for administration of prescribed radioactive compounds for therapy; quality control of instrumentation; participation in quality management programs; and radiation safety. The NM Radiographer is responsible to provide the highest standards of patient care and to deliver the lowest radiation dose to patients, staff and the public without compromising quality. NM radiographers are highly specialised and work alongside other healthcare professionals to play highly responsible roles in patient care, management, imaging and radiation protection. Many NM radiographers have significant non-imaging roles within the radiopharmacy and laboratories and may also have involvement in radionuclide</td>
</tr>
</tbody>
</table>
therapy procedures and PET-CT-aided radiation therapy planning. The NM radiographer exhibits professionalism in the performance of these duties, demonstrates an empathetic and instructional approach to patient care – including quality management – and maintains confidentiality of information as required. The NM radiographer applies knowledge of radiation physics and safety regulations to limit radiation exposure of the general public, patients, fellow workers, and self to as low as reasonably achievable (ALARA).

<table>
<thead>
<tr>
<th>Advanced Practitioner Nuclear Medicine Radiographer</th>
<th>Advanced practitioner responsibilities may include cardiac stress, reporting of nuclear medicine images, requesting of X-ray imaging, and administration of radiopharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>NM Physician/Medical Practitioner</td>
<td>The primary responsibilities of the NM medical practitioner include: Ensuring that each medical exposure is justified by checking if the procedure is necessary with the referring physician. The radiation exposure of patients has to be kept to the minimum required to achieve the intended objective, taking into account the relevant guidance levels for medical exposure using optimised protocols for diagnostic and therapeutic procedures. They need to set criteria to manage the examination of pregnant women, paediatric patients, medico-legal procedures, occupational health examinations and medical and biomedical research.</td>
</tr>
<tr>
<td>Nuclear Medicine Physicist / Medical Physics Expert (MPE)</td>
<td>Medical Physicists typically support acceptance testing when new NM facilities are set up and can assist in dose optimisation, support image protocol set up and QC procedures. Medical Physicists will also need to evaluate radiation incident/accidents if and when they arise.</td>
</tr>
<tr>
<td>NM Team</td>
<td>In the case of NM medical exposures, because of the medical setting in which such exposures occur, primary responsibility for protection and safety for patients lies with the health professional responsible for the delivery of medical exposure. Only persons with the appropriate competencies are allowed to take particular roles and responsibilities; this applies in particular to persons undertaking the role of NM medical practitioner, NM radiographer/technologists, or medical physicist.</td>
</tr>
<tr>
<td>Radiopharmacist</td>
<td>Where present, would oversee the NM laboratory where the radiopharmaceuticals are prepared. Prepare radiopharmaceuticals for patient administration</td>
</tr>
</tbody>
</table>
Perform quality control tests on radiopharmaceuticals prior to administration.
Order/procure consumables required for radiopharmacy procedures.
Maintain radiopharmacy equipment

| Nursing Staff | NM nursing staff members are primarily responsible for patient care while the patient is in the NM department. They would record patients’ vital signs, ensure patient comfort, reassure patient and assist patient throughout the procedure.
Nurses may/may assist in the insertion of intravenous lines

| Administrative staff | Provide patients with appointments
Provide patient preparation leaflets
Assist with dissemination of reports
May be involved with creating orders for consumables on the instruction of the NM radiopharmacist/radiographer/physician

16.3 Specialist Equipment and Modality Specific Information
There are a number of devices used to image or measure function in NM. They vary from a simple scintillation probe to complex equipment which use dual imaging technologies. Examples include:

<table>
<thead>
<tr>
<th>16.3</th>
<th>Specialist Equipment in NM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gamma (Scintillation) Camera</strong></td>
<td>Further to patient administration of a radiopharmaceutical, gamma cameras detect gamma rays using pulse height analysers, this allows the Radiographer to select a range of observed energies by accepting photons which are used to make a scintigraphic image.</td>
</tr>
<tr>
<td><strong>Single Photon Emission Computed Tomography (SPECT)</strong></td>
<td>SPECT imaging uses a dual headed SPECT camera and is a tomographic version of a gamma camera.</td>
</tr>
<tr>
<td><strong>SPECT-CT</strong></td>
<td>The addition of CT to a SPECT gamma camera enables image reconstruction using anatomical localisation from the CT to not only localise but enhance image quality using CT attenuation correction.</td>
</tr>
<tr>
<td><strong>Positron Emission Tomography</strong></td>
<td>PET image acquisition is based on the simultaneous (coincidence) detection of photons. A PET scanner consists of many photon detectors surrounding the patient. During a PET scan millions of coincidence detections are collected, providing information about the distribution of the radiopharmaceutical in tissue.</td>
</tr>
</tbody>
</table>
Today few standalone PET systems are in use, modern hybrid technologies employ CT or MRI as a means of attenuation correction and anatomical image localisation.

<table>
<thead>
<tr>
<th><strong>Positron Emission Tomography</strong>&lt;br&gt;<strong>Computed Tomography (PET-CT)</strong></th>
<th>The addition of CT to PET systems, enable image reconstruction using anatomical localisation from the CT to not only localise but enhance image quality using CT attenuation correction.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Positron Emission Tomography – Magnetic Resonance Imaging (PET-MRI)</strong></td>
<td>PET–MRI systems acquire PET images using coincidence photon detection, however they attenuation correct and localise using MRI technology.</td>
</tr>
<tr>
<td><strong>Gating Systems</strong></td>
<td>Gating systems help reduce motion artefact which can occur during complex imaging procedures where the patient has little or no control over movement. Cardiac and Respiratory gating systems are the most typical systems in use.</td>
</tr>
<tr>
<td><strong>Scintillation probes</strong></td>
<td>Scintillation probes can be used to detect or measure small quantities of radiation, e.g. sentinel nodes in the axilla. Scintillation probes are also used for environmental contamination monitoring.</td>
</tr>
<tr>
<td><strong>Dose calibrators</strong></td>
<td>Dose calibrators also known as ionisation chambers, are an instrument constructed to measure the number of ions within a medium, these are used to measure accurately the amount of radiopharmaceutical to be administered to a patient.</td>
</tr>
<tr>
<td><strong>Gamma Analysers</strong></td>
<td>Manual or automatic counters for samples of different gamma applications usually comprising well-type detectors with lead shielding around the detectors for optimal performance with an energy range usually up to 1000Kev to allow for studies using various radionuclides.</td>
</tr>
</tbody>
</table>

16.3.1 Quality Control and Testing Regimes
All the specialist equipment detailed in table 16.3 must be subject to rigorous Quality control (QC) procedures to ensure that NM and MI equipment is functioning safely and effectively. QC establishes an important part of the quality management in an NM department. QC tests are designed to detect problems before they affect clinical patient studies. They are intended to provide a full evaluation of equipment performance and to ensure that equipment is performing correctly and accurately after service or adjustment.

Quality control is an essential requirement in the process of patient dose optimisation, this helps ensure that exposures are as low as reasonably practicable and image quality is of the highest standard. Image quality is dependent upon the data acquisition
parameters, which must be adapted to the detector system and also the reconstruction algorithm, on the basis of which the acquisition time can be shortened or the administered activity of the radiopharmaceuticals can be decreased.

16.3.2 Acceptance Testing and Maintenance

Initial acceptance / reference testing on specialist NM and MI equipment, is performed at the outset by the manufacturer / suppliers and then by the end user with the support of the Medical Physics Expert (MPE) or Nuclear Medicine Physicist. Any test results not meeting specifications must be questioned and repeated, and appropriate action taken. The instrument should not be accepted until tests prove that the instrument performs as required. A certificate should be provided confirming that the acceptance tests are complete, and that the system has been handed over to the end user.

Quality control tests after repair and maintenance can be performed by the MPE or the competent person / Radiographer who understands the requirements of the QC testing regime and how to interpret the findings. All of these tests are based in many cases on practical guidelines or on the experience of the competent person, the available standards on this topic also need to be adapted to specific instruments.

16.3.3 Decontamination and Radiation Contingency Plan Testing

The use of unsealed radioactive sources in nuclear medicine poses a potential risk of contamination. A considered department design and robust operational procedures will help minimise the occurrence of potential spills of radioactive materials. It is essential that appropriate personal protective equipment is provided and worn, and it is essential that a comprehensive decontamination kit is provided, and its contents checked regularly to ensure all materials are available in the event of a radiation contamination incident.

Regular and routine contamination monitoring procedures must be in place. This will include hand contamination monitoring between the preparation and administration of radiopharmaceuticals. In addition to regular and end of day environmental monitoring using a scintillation detector.

In the event that radiation contamination is present, assessing the extent of the radiation hazard and containing the spread of contamination is essential. Minimising the radiation dose to individuals is priority and continuing to decontaminate to the lowest level possible are principles to follow in managing any incident.

NM staff should be familiar with decontamination techniques to the body; for eliminating or reducing the uptake of radioactivity absorbed into the body; and for decontaminating dry and wet surfaces, equipment, clothing, and bedding.

Radiopharmaceutical dispensing procedures, ventilation scanning, and decontaminating \textsuperscript{131}Iodine treatment areas are identified as the most likely causes of body surface and internal contamination of nuclear medicine staff. Clear and precise procedures must be in place supported by MPE guidance as required.

Contingency planning management forms an important part of handling radiation contamination incidents, as the procedures put in place are intended to reduce the common hazards and / or following when an incident has occurred. It is important to consider that where such incidents are likely to occur, training and staff rehearsal of contingency plan scenarios and review of the appropriate procedures are performed.
16.3.4 Storage, Accumulation and Disposal of Waste
Radioactive materials must be held in accordance with the conditions of a relevant permit. Radioactive sources must be assigned a unique identifier. Appropriate source records must be kept from the point of receipt to ultimate disposal of the source. Radioactive sources must be stored securely in sufficient shielding with a radiation warning sign with the legend “Radioactive materials” or equivalent displayed on or the outside of the store, along with details of the permitted contents.

**Accumulation and Disposal** - Safe disposal of radioactive waste must be in accordance with statutory provisions. All activities capable of generating and accumulating radioactive waste are to be identified; and appropriate procedures implemented to deal with disposal of waste.

Day to day activities must take into account record keeping which details the administration of radioactive materials and the management of any subsequent waste. i.e. waste to designated drain activity. Annual summary records of the waste activity are to be reported in accordance with permits to the relevant environmental agency.

Services must comply with limits and conditions as defined in the permits or exemption conditions. All users must be made familiar with the limits and conditions detailed within the relevant permits as a failure to comply may result in enforcement action. Where necessary, specific instructions should be provided to radiation workers on how waste should be accumulated and disposed of.

16.3.5 Unit Design and Protective Measures
Regulation and guidance relating to radiation protection measures involving facility design may vary country to country, but fundamentally the principles remain the same. Regulation and guidance will advise on the layout, construction and conversions of facilities, but the key importance is that the facility layout can aid in the minimisation of radiation dose exposure to staff, patients and the public.

Generally speaking, the traditional gamma camera NM department may have limited, if any radiation shielding within its walls, and personnel will not have been required to stand behind secondary radiation shields during patient imaging procedures. It is essential that such practical considerations are reviewed and taken into account, particularly if modernising an existing nuclear medicine imaging facility to include PET.

Facility design must also extend to the ‘designation’ of sinks, toilets and drains for the disposal of limited quantities of radionuclides. It is also essential that there are sufficient designated ‘hot toilets’ (to include an alternative toilet in the event of failure).

With any NM and MI facility, there will be a requirement to include design features which seek to minimise the spread of radioactive spills (should they occur) and these will be notable in dispensing and administration area surfaces and flooring, which will be smooth and easy to clean with continuous unbroken coverage of an area. Dispensing and administration areas will also require designation as either ‘controlled’ or ‘supervised’ in accordance with dose limits and guidance. Radiation
warning signs are also required as appropriate and additional signage is recommended advising no eating/drinking in controlled areas.

16.4 Contrast Enhancement Agents, Medicines and Radiopharmaceuticals
The following section focuses on Radiopharmaceuticals for NM and MI. It is however important to note that contrast enhancement agents can be used in conjunction with CT image acquisition as a means of image enhancement in NM SPECT and PET-CT. Consideration in these instances must be made to ensure that the appropriate Contrast Safety Screening Measures are applied as part of the Imaging Procedure (Section 13.3) and that the NM Radiographer / Technologist has the appropriate training and competencies to be able to perform enhanced imaging with Contrast Media.

Radiopharmaceuticals
Within Europe the administration of radioactive substances is governed under Article 28(a) of the EURATOM Basic Safety Standard Directive 2013 (BSSD) which requires licensing for the administration of radioactive substances to persons for the purposes of medical diagnosis, treatment or research.
In Great Britain (GB) The medical exposure aspects of the BSSD were transposed into the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R)

16.4.1 Manufacture and Production Requirements
Radiopharmaceuticals are radioisotopes bound to biological molecules which are used to target specific organs, tissues or cells. To manufacture radiopharmaceuticals for clinical use in humans, the facility has to be compliant with Good Manufacturing Practice (GMP).

Good manufacturing practice (GMP) guidelines have evolved over the last 50 years, compliance has become compulsory for the manufacture of pharmaceuticals (and radiopharmaceuticals). As part of quality assurance systems related to the manufacture of a product, GMP endeavours to ensure that products are consistently manufactured to a quality appropriate for their intended use. The key components that underpin the product quality are:
- Safety
- Efficacy
- Purity
- Uniformity

The GMP regulations require detailed activities and controls to ensure that drug products are consistently manufactured to meet a required specification. These regulations can be summarized under the following general headings:
- People (personnel);
- Premises (and equipment);
- Paperwork (documentation);
- Processes (control of production processes);
- Products (sampling and testing).

GMP is a requirement for the manufacture of radiopharmaceuticals, it should be adopted from the outset considering all potential regulatory requirements. In the absence of local GMP regulations, the World Health Organisation (WHO) GMP guidance is recommended.
Manufacture of Technetium-99m (99mTc) using a Molybdenum-99m (99mMo) Radionuclide generator

In Nuclear medicine SPECT the most prevalently used Radioisotope is Technetium (99mTc). Technetium-99m is desirable due to its relatively short radioactive half-life of 6 hours.

To acquire Technetium-99m for radiopharmaceutical production a Molybdenum-99m radionuclide generator system is required. The daughter radionuclide 99mTc (short half-life) is separated by elution from the parent radionuclide (long half-life) 99mMo, and later used for production of a radiopharmaceutical preparation.

The eluted 99mTc is diluted to the appropriate volume in preparation for administration into a ‘vial kit’ containing the non-radionuclide component of a radiopharmaceutical. The ‘vial kit’ is in the form of a sterilized, validated product to which the appropriate radionuclide is added or in which the appropriate radionuclide is diluted before medical use. In most cases the kit is a multidose vial and production of the radiopharmaceutical preparation may require additional steps such as boiling, heating, filtration and buffering. Radiopharmaceutical preparations derived from kits are normally intended for use within 12 hours of preparation not only having a radioactive ‘half-life’ but also having a ‘shelf-life’. Adherence to GMP is essential throughout all steps of the manufacturing and production process.

Manufacture of 18F-Fluorodeoxyglucose (FDG) using a Cyclotron.

In Nuclear Medicine PET, the most prevalently used Radioisotope is Fluorine - 18(18F). Fluorine-18 is desirable due to its short radioactive half-life of 110 minutes and positron emission properties. 18F is made using either a cyclotron or a linear particle accelerator to bombard a target, usually of pure or enriched 18O water with high energy protons. The 18F produced is in the form of a water solution of 18F Fluoride which is then processed in a chemical synthesis of the radiopharmaceutical, which in PET is commonly Fluorodeoxyglucose (FDG). Adherence to GMP is essential throughout all steps of the manufacturing and production process.

16.4.2 Quality Control (QC)

A radiopharmaceutical is classified as a ‘medicinal product’ and, therefore, its production, characterization and quality control testing must comply with the rules for manufacturing sterile products intended for human injection. Over time, these rules have advanced to ensure that a safe and high-quality product is administered to the patient at all times.

Quality Control for Molybdenum-99m generators in the production of 99mTc

After the generator has been produced, once under the control of the Radiopharmacy team, there are typically six tests which should be performed with example specification parameters detailed below:

- Mo-99 breakthrough – specification: <0.15µCi of M0-99m / mCi of 99mTc)
- Visual Inspection – specification: Clear and colourless
- pH test – specification: pH4.0-pH8.0
- Alumina limit test – specification: <5ppm
- Radionuclidic identification test- specification: identify energy peak at 140keV
- Radiochemical purity test- specification:

After the radioactivity decay, three more tests require completion:
- Sterility – specification: no bacterial growth
- Bacterial endotoxin limit test – specification: no gel clot
- Liquid particle count – specification: <6000 count for size 10µm. <600 particle count for size 25µm

**Quality Control for Cyclotron produced ¹⁸F-Fluorodeoxyglucose (FDG)**

The radiopharmacy team perform the following quality control procedures, example speciation parameters detailed below:

- Visual Inspection – specification: Clear and colourless
- pH test – specification: pH4.5-pH8.5
- Radionuclidic identity and purity test - specification: Sample in dose calibrator-radioactive half-life must be within the range of 105-115 minutes.
- Chemical Purity - The determination of glucose content is achieved by High Performance Liquid Chromatography (HPLC)
- Residual solvents - residual solvent testing must be carried out to ensure that any residual solvent with the potential to be toxic must be within appropriate limits. The acceptable limits are; 0.04% acetonitrile, 0.5% dehydrated alcohol and 0.5% ether present in the final ¹⁸F-FDG product

**After the radioactivity decay, two more tests have to be completed:**
- Sterility – specification: filter integrity test - no bacterial growth
- Bacterial endotoxin test – specification: no gel clot

**16.4.3 Administration**

All radiopharmaceuticals dispensed and administered must be authorized by a suitably qualified medical practitioner. In most countries, authorization for a NM procedure to take place, requires the employer to hold a licence and the medical practitioner to hold a licence. In the UK the licence may only be granted to the practitioner who is clinically responsible for the justification of administrations of radioactive substances.

Most routine imaging procedures in NM are detailed as imaging protocols, with full guidance on the requirements for the procedure. The authorizing clinician may specify a routine procedure. However, when not clearly detailed in a routine protocol, details must be provided by the clinician as to the amount of radioactivity to be administered, the route of administration, and, if applicable, the rate of infusion.

Prescribing clinicians are ultimately responsible for the safety, quality, and correctness of all radiopharmaceuticals prepared and dispensed for administration under their direction.

Radiopharmacists / Nuclear pharmacists are ultimately responsible for the safety, quality, and correctness of radiopharmaceuticals prepared and dispensed under their supervision.

The preparation, quality control, dispensing, and administration to patients of radiopharmaceuticals is delegated to the Radiographer / Technologist. The radiopharmaceutical type, patient name and the route of administration must be verified before administration. Syringes and outer shields or containers must be labelled for verification of contents.
Pregnancy must be ruled out in patients of childbearing age. Lactation, and breast feeding must also be considered prior to appointment attendance so preparation can be made in advance of the appointment if milk must be expressed. The quantity of each radiopharmaceutical dose must be determined before administration to patients and must be consistent with that requested by the physician or as stipulated in the applicable imaging protocol in line with recommended local and national Dose Reference Levels (DRL’s). The quantity of radioactivity dispensed must be within 10% of the prescribed dose or dose range and final administered parameters must be recorded in the patient’s medical record.

Radiopharmaceuticals must not be used beyond the expiration date or time recommended by the manufacturer.

16.4.4 Post Administration
Post administration patient aftercare guidance can vary dependent upon the radiopharmaceutical administered, route of administration and half-life. It is recommended that an aftercare guidance sheet is provided to the patients to advise those who require specific aftercare guidance. For example, fasting PET-CT patients, may eat normally and drink ‘plenty’ of fluids to encourage excretion of the remainder of the isotope. It is also encouraged that the patient avoids close hugging contact with pregnant persons and small children for the remainder of the day (approximately 8hrs after the test).

16.4.5 Transportation
All products should be transported in line with the relevant national road transportation guidelines for dangerous goods with their country. Typically, the manufacturer of the product will supply as directed within their written procedures when the manufacture process is complete and QP authorization has been issued. In some instances, full QP authorization is not possible due to the short radioactive half-life of some products. In these instances, QP release will be provided soon after via email or fax to the end user. Documentation will be provided declaring confirmation that the product has been released and authorized for patient administration. Packages with a delayed QP release will often be padlocked, and the padlock code will be released only when all QP has passed. The product will be shipped under ambient temperature in a lead-shielded container as appropriate to the radioisotope contained within. For example, F-18 products due to their higher energy require significantly thicker shielding. The shipped product container will be accompanied by the transfer sheet and appropriate radiation trefoil signage and transport index on the container reflective of its contents.
All personnel handling radioactive packages must be appropriately trained and aware of the processes for handling radioactive materials. The consignor must sign to dispatch the container, the transport driver must sign to safely transfer the container, and the consignee must sign to receive the container. All must sign to accept that the package is not visibly damaged at each point in the process.

16.4.6 Molecular Radiotherapy (MRT)
Molecular radiotherapy (MRT) involves the distribution of radiation to malignant tissue via the interaction of a radiopharmaceutical with molecular sites and receptors. This is
a rapidly evolving technique, particularly with regard to quantification of uptake in normal and malignant tissue. Internal dosimetry is essential to the future development of MRT.

Historically, Iodine-131 therapy in differentiated thyroid cancers has been mainstay in many NM imaging settings. However, as MRT techniques and services develop so does the requirement for knowledge skills and training when using such techniques. A holistic approach to patient care is required for therapies and also preparedness in the event that there are concerns when managing therapy patients who may require subsequent patient hospital admission. It is essential therefore to consider carefully all safety aspects including patient aftercare when developing MRT services.

16.5 Service Hazards
The most significant hazard in NM and MI imaging pertain to the use of sealed and unsealed radioactive sources. There are three significant categories when considering radioactive hazards in this environment, and therefore the focus is on protection of the patients and visitors, staff and the protective equipment available.

16.5.1 - Radiation Protection – Patients and Visitors
In the UK, dose optimisation and the application of Diagnostic Reference Levels (DRL’s) help ensure that each individual patients dose is optimised to the patient and referenced against the scanning technology used to acquire the images (Local DRL’s). DRL’s must be detailed locally and readily visible for Radiographers to reference each patient radiation dose against. In hybrid imaging technologies such as SPECT-CT and PET-CT there will be a Radiopharmaceutical DRL and CT DRL for each named procedure.

DRL’s are typically established and reviewed with the assistance of the Medical Physics Team. DRL’s should be clearly displayed for each imaging procedure, reviewed annually and referenced against Local and National DRL’s for the Imaging Scanner used\textsuperscript{120}.

Visitors must also be considered when visiting NM and MI facilities, visitors must be escorted at all times. Visitors may act as escorts when a vulnerable patient requires assistance. In these instances, the visitor may also receive a radiation dose. Documentation of the visitor’s name, whom they escorted and where an electronic personal dosimeter is available to measure dose, this can be used to obtain a reading for record purposes.

16.5.2 Radiation Protection – Staff
Areas in NM and MI are marked as controlled or supervised areas. These areas are operated in accordance with radiation ‘Local Rules’. Radiation local rules provide guidance to operators of imaging equipment or areas where there is risk of radiation exposure. The local rules must detail procedures for using PPE and shielding, controlled area entry, use of the X-ray equipment, use of personal monitoring devices and quality assurance testing. The RPS and departmental managers have key responsibilities under the local rules. Operators of the equipment are also responsible for restricting access into the controlled area. Full details in section 6.0.

Staff working within radiation controlled or supervised areas will be subject to radiation monitoring, section 12.9 details the requirements for radiation monitoring for staff.
16.5.3 Protective Equipment
Reducing radiation dose to staff is as fundamental to radiation safety culture as dose optimisation for patients. It is essential that all staff follow the ALARA principle to ensure doses received are ‘As Low As Reasonably Achievable’. To achieve this the principle of Time, Distance and Shielding are key.

Time
In NM and MI the patient is administered a radiopharmaceutical, after which the patient becomes radioactive. It is therefore essential that preparation in advance of the administration of radiopharmaceutical takes place. Ensure full patient screening is complete. If the patient is to remain in the department, ensure they are comfortable and understand fully the examination ahead. All answers to questions must be provided to the patient in advance as far as practicable to minimise staff contact post administration of radiopharmaceutical.

Distance
When managing the radiopharmaceutical administration, and at all points throughout the imaging procedure, ensure distance is maximised as far as practicable, without compromising patient safety.

Shielding
There are many options available for PPE in NM & MI. Basic examples below

<table>
<thead>
<tr>
<th>PPE in NM &amp; MI</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tungsten 2mm thick syringe guard with lead safety glass</td>
<td>For administration of ⁹⁹ᵐTc</td>
</tr>
<tr>
<td>Drawing up hand dose shields</td>
<td>Reduce hand exposure whilst drawing up from an inverted multidose vial.</td>
</tr>
<tr>
<td>Tungsten 9mm-14mm thick syringe guard with lead safety glass</td>
<td>For purpose of PET isotope administration (511keV)</td>
</tr>
<tr>
<td>Unidose Pigs</td>
<td>To contain single dose ⁹⁹ᵐTc Radiopharmaceuticals</td>
</tr>
<tr>
<td>Multidose Pigs</td>
<td>To contain multidose vials which contain multiple radiopharmaceutical injections – More frequently used in PET</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Handling Forceps</td>
<td>To manoeuvre multidose vials from transport containers into multidose Pig ready for drawing up</td>
</tr>
<tr>
<td>Automated Dose Dispensers</td>
<td>Automated systems for the drawing up and dispensing of Radiopharmaceuticals.</td>
</tr>
<tr>
<td>Automated Dose Injectors</td>
<td>Automated systems for the administration of Radiopharmaceuticals.</td>
</tr>
<tr>
<td>(NB Often dose dispensers and</td>
<td></td>
</tr>
<tr>
<td>injectors are systems which</td>
<td></td>
</tr>
<tr>
<td>operate as one)</td>
<td></td>
</tr>
<tr>
<td>Sharps Shield Container</td>
<td>Typically for $^{99m}$Tc Radiopharmaceuticals sharps bin storage</td>
</tr>
<tr>
<td>Lead Safe</td>
<td>For safe storage of radioactive materials</td>
</tr>
<tr>
<td>Hot Waste Bins</td>
<td>For accumulation of radioactive waste to decay prior to monitoring and disposal.</td>
</tr>
</tbody>
</table>

16.6 Specific Quality Assurance Measures

Quality control checks made on NM and MI equipment are in accordance with quality control schedules as recommended by the Original Equipment Manufacturer (OEM) and Medical Physics Teams. Schedules are typically daily, weekly, quarterly, bi-annually and annually. Quality Control schedules form part of Quality Assurance (QA) programmes, QA helps provides ‘assurance’ that systems are working within the recommended pre-determined parameters thus optimising image quality and assuring there are no artefacts or errors. Action / trigger levels must be set for corrective measures to be instigated. QA is proactive and focuses on ensuring a rigorous schedule whilst QC is the actual testing. QA programmes and schedules are extensive, these are in addition to planned preventative maintenance visits performed by the OEM (typically every 4 months) and associated quarterly and annual physics checks performed by the Medical Physics Team. There are multiple test tools which can be selected for QC and will be predetermined as part of a QA programme. Example QA schedules for NM and PET follow:

**Gamma Camera - Planar and SPECT QA**

Uniformity of the detector is checked on a daily basis. The photopeak is set and checked prior to every study (this is automated in newer systems), an incorrectly set photopeak or lack of uniformity will lead to imaging errors. Camera uniformity is assessed using a flood test. This will demonstrate defects if present in the electronics/crystals of the gamma camera. For example, a defective photomultiplier tube (PMT) will leave an area with no activity ‘a hole’ in the image.

In addition to routine daily planar QC, SPECT QC requires additional corrections due to the rotational tomographic techniques used, this includes centre of rotation correction, rotational sensitivity and mechanical alignment.

Typical Quality Assurance checks for planar gamma camera and SPECT systems
QC Testing for Gamma Camera (Planar and SPECT)

<table>
<thead>
<tr>
<th>Testing</th>
<th>Recommended Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peaking (Check isotope photopeak)</td>
<td>Daily (and per imaging study)</td>
</tr>
<tr>
<td>Field Uniformity (Flood test)</td>
<td>Daily</td>
</tr>
<tr>
<td>With additional radionuclides</td>
<td>Quarterly</td>
</tr>
<tr>
<td>System Uniformity</td>
<td>Weekly</td>
</tr>
<tr>
<td>Rotate all Collimators for checks</td>
<td></td>
</tr>
<tr>
<td>Spatial Resolution and Linearity (bar phantom)</td>
<td>Weekly</td>
</tr>
<tr>
<td>Pixel size gain calibration</td>
<td>Quarterly to Bi-Annually</td>
</tr>
<tr>
<td>Dead time/max count rate</td>
<td>Quarterly to Annually</td>
</tr>
<tr>
<td>Multiple window spatial registration</td>
<td>Quarterly to Annually</td>
</tr>
</tbody>
</table>

QC Testing for Gamma Camera (SPECT) additional to the above

<table>
<thead>
<tr>
<th>Testing</th>
<th>Recommended Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre of rotation correction</td>
<td>Weekly</td>
</tr>
<tr>
<td>Rotational sensitivity</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Mechanical alignment</td>
<td>Annually</td>
</tr>
<tr>
<td>Esser / Jaszczak SPECT Phantom</td>
<td>Annually</td>
</tr>
</tbody>
</table>

PET–CT and SPECT CT QA

Hybrid systems using additional CT or MRI technologies to compliment SPECT or PET, require due consideration for the QA schedule. PET-CT provides the best example as a hybrid technology widely in use. Daily and weekly quality control checks are required as part of the QA schedule. To carry out the PET QC, typically a Ge-68 rod source or Ge-68 solid phantom can be used to assess system performance. This is broken down further as seen in the table below.

QC Testing for PET-CT

<table>
<thead>
<tr>
<th>Testing</th>
<th>Recommended Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Singles</td>
<td>Daily</td>
</tr>
<tr>
<td>Coincidence</td>
<td></td>
</tr>
<tr>
<td>Dead time</td>
<td></td>
</tr>
<tr>
<td>Timing</td>
<td></td>
</tr>
<tr>
<td>Energy</td>
<td></td>
</tr>
<tr>
<td>Normalisation</td>
<td></td>
</tr>
<tr>
<td>CT Air Calibration</td>
<td>Daily</td>
</tr>
<tr>
<td>Update Gain</td>
<td>Weekly</td>
</tr>
<tr>
<td>Standardised Uptake Value (SUV) Phantom</td>
<td>Weekly</td>
</tr>
<tr>
<td>CT Water phantom</td>
<td>Weekly</td>
</tr>
<tr>
<td>Normalisation</td>
<td></td>
</tr>
<tr>
<td>Well Counter calibration</td>
<td>Quarterly</td>
</tr>
<tr>
<td>ACR (Esser) or NEMA Phantom - to measure contrast uniformity and resolution</td>
<td>Annual</td>
</tr>
</tbody>
</table>
16.7 Patient Care
Over 30 million nuclear medicine procedures are performed annually: this translates to somewhere in the world, a new procedure starts every second\textsuperscript{121}. An increasing number of patients benefit from the exponential rise in nuclear medicine procedures performed around the world.
Patient care encompasses both the physical and psychological well-being of the patient. The patient must be correctly identified, and the radiographer must introduce themselves to the patient and explain their role in the imaging procedure and check/obtain informed consent. The radiographer must also ensure that the necessary patient preparation is completed prior to commencing the study.
Specific patient needs and special requirements should be addressed. Patient confidentiality must be ensured, and the relevant legal requirements observed with respect to data protection. Ensure patient surveillance, comfort, privacy and safety.
Responsibilities of a NM Radiographer from a protection point of view include; identifying the patient prior to starting any procedure, informing and explaining the procedure to the patient, verifying that the patient is not pregnant and ensuring that a patient in lactation is given information about discontinuing nursing. The procedure must be performed using an optimised protocol and ensuring patient protection, the radioactivity to be administered must be calculated for individual patients, especially for children. The administered radiopharmaceutical and its activity must be verified prior to administration. Any accompanying persons and staff nursing a patient after a nuclear medicine examination or therapy must be informed.
Once the procedure is complete, it is important to communicate to the patient what to do next. Clear explanation must be given to the patient regarding specific aftercare. Ensure that the patient is aware of when/how their results will be communicated to their referring doctors\textsuperscript{106}.

16.8 Education and Training
The requirements to be able to practice as a NM radiographer in every country across the world differ. Usually, they comprise both theoretical and practical knowledge and experience. The scope of practice may also vary considerably depending on governmental laws, economics and cultures. The skills and competence considered necessary must ensure that NM procedures will be conducted at an appropriate level. According to the EANM Benchmark Document\textsuperscript{106} on Nuclear Medicine Technologists’ Competencies;

Nuclear Medicine Technologist Knowledge, Skills and Competencies for EQF Level 6 include:
1 Establishment of a nuclear medicine department and equipment installation
2 Departmental organisation
3 Patient care and welfare
4 Instrumentation quality assurance (imaging, non-imaging and radiation protection instruments)
5 Radiopharmacy including PET and SPECT
6 Performance of imaging including PET and SPECT
7 Hybrid imaging
8 Performance of in vitro tests
9 Radiopharmaceutical therapy procedures
The knowledge, skills and competencies required to achieve these competencies are well spelt out in this document\textsuperscript{106}.

NM practice and patient care can only benefit if education can be streamlined across the globe. In the interest of patient safety and safety culture, as a minimum the general standards for Nuclear Medicine practice should be adhered to. With the advances in hybrid imaging, it is also essential either for Nuclear Medicine practitioners to be trained in the other imaging modalities or arrangements should be in place for access to practitioners in other modalities to provide a service in Nuclear Medicine facilities.

17. Management of Risks Associated with Lasers and Other Ablative Technologies and Therapeutic Devices

17.1 Introduction
A number of interventional procedures are available which involve the use of lasers in the treatment of vascular disease such as percutaneous transluminal angioplasty and other treatment areas using percutaneous ablation such as percutaneous intradiscal laser ablation in the lumbar spine\textsuperscript{122}.

Other ablative technology therapies that may be used in the treatment of tumours that deliver several forms of energy via a needle like probe include radio waves (radiofrequency ablation) or microwaves (microwave ablation), to destroy cancerous tissue. Additionally, cold gas may be used to freeze the tumour (cryoablation).\textsuperscript{123}

The use of these devices and technologies has their own unique potential hazards to both the patient and the operator. This section will focus on the use of lasers, but readers are advised to study the manufacturers operating instructions regarding all these technologies before they are employed and take into consideration all recommended safety procedures.

Lasers are now widely used during the course of our daily lives. They can be found at home, in the workplace and they are used for many different applications. Lasers are a valuable scientific tool in material, pharmaceutical and forensic research. They play an important role in the areas of medicine and industry, as well being used for entertainment purposes since the mid-1960s\textsuperscript{124}.

Many government bodies will have available guidance documents for the safe use of medical and surgical laser devices\textsuperscript{125}. 
A classification scheme for lasers\textsuperscript{126} has been widely published which indicates the potential risk of adverse health effects, where the higher the class number, the greater the laser radiation hazard posed by the laser. In practice, the risk also depends upon the conditions of use, exposure time and the environment. However, potential risks may or may not actually lead to adverse health effects, so with the help of classification, users may select appropriate control measures to minimise the risks. The table below provides a brief summary of the classification scheme and an explanation of potential harm:-

<table>
<thead>
<tr>
<th>Term</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1 laser</td>
<td>Laser classified as Class 1 - safe</td>
</tr>
<tr>
<td>Class 1M Laser</td>
<td>Laser classified as Class 1M – considered Safe provided optical instruments are not used.</td>
</tr>
<tr>
<td>Class 2 Laser</td>
<td>Laser classified as Class 2 - Visible lasers. Safe for accidental exposure (&lt; 0.25 s) provided able to turn head and blink.</td>
</tr>
<tr>
<td>Class 2M Laser</td>
<td>Laser classified as Class 2M - Visible lasers. Safe for accidental exposure (&lt; 0.25 s) providing optical instruments are not used.</td>
</tr>
<tr>
<td>Class 3R Laser</td>
<td>Laser classified as Class 3R - Not safe. Low risk.</td>
</tr>
<tr>
<td>Class 3B Laser</td>
<td>Laser classified as Class 3B - Hazardous. Viewing of diffuse reflection is safe.</td>
</tr>
<tr>
<td>Class 4 Laser</td>
<td>Laser classified as Class 4 - Hazardous. Viewing of diffuse reflection is also hazardous. Fire risk.</td>
</tr>
</tbody>
</table>

17.2 Roles and Responsibilities

17.2.1 The Hospital management team
Compliance will all legal, statutory and good practice requirements relating to safety of lasers, in addition a Laser Protection Advisor (LPA) and Laser Protection Supervisor (LPS) must be appointed if any Class 3 or Class 4 lasers are purchased and used. Where Class 3 or above lasers are to be used, it is facility is registered with any regulatory body for ‘treatment of disease, disorder and injury’

17.2.2 Service Managers (Departmental level)
Managers are responsible for informing the Employer as soon as possible if any Class 2, Class 3 or Class 4 lasers are to be purchased.

17.2.3 Laser Protection Advisor
A Laser Protection Adviser (LPA), with appropriate scientific background and knowledge of laser safety will normally be appointed if any Class 3 or Class 4 lasers are to be purchased or used.

The LPA will:
- Maintain an inventory of all class 3 and class 4 lasers.
• Produce a prior risk assessment before any new laser can be used clinically.
• Approve the appointment of laser protection supervisors (LPS) and maintain a list of current LPSs.
• Approve local rules, including an authorised users list before being distributed by the radiation protection committee.
• Visit annually all areas in which lasers are used and produce a written report of their findings, which will be sent to the LPS.
• Approve the purchase or loan of any laser.
• Approve the use of any related fume extraction facilities required.
• Produce an exceptions report for the radiation protection committee.
• Produce an annual report on all matters relating to laser safety, which will be presented to the laser protection committee.

17.2.4 Laser Protection Supervisor
A Laser Protection Supervisor (LPS) will be appointed in writing if any Class 3 or Class 4 lasers are to be purchased or used.

The LPS is empowered to veto the use of a particular laser if he/she is not satisfied that the safety procedures are being followed or that the laser equipment itself is not safe.

The LPS will:
• Produce Local Rules, with the LPA, for each laser and each location in which class 3 or class 4 lasers are used.
• Ensure that all staff involved in the use of lasers have read the Local Rules and signed to acknowledge that they have read and will obey them.
• Annually review the local rules.
• Attend an approved LPS course and regular update courses as required by the LPA.
• Inform the LPA of any unsafe working practices or any changes in working practice.
• Inform the LPA of any incident or serious incident relating to the use of the laser.
• Identify training needs.
• Arrange Quality Assurance checks of lasers by Medical Physics Department.

17.2.5 Authorised Users
Authorised Users are laser operators who are trained and deemed competent to activate the laser.

Authorised Users will:
• Have their competence assessed by the LPA or UM for any laser used.
• Follow the Local Rules or local procedure for lasers used.
• Record use of any laser classified at Class 2 or above in the Patient medical records and Laser Log.
17.3 Local Rules
Detailed Local Rules must be drawn up for each area in which a class 3 or 4 laser is to be used. The local rules should be specific to each optical radiation device and the clinical application.

The purpose of local rules is to ensure that all employees are working in a safe environment and that all patients and clients are treated safely. All staff who are involved with optical radiation equipment should read the document.

The local rules will also define the operational aspects.

17.3.1 Operational Aspects
The following aspects should be adhered to which include:

- Defined region and limits of a controlled area
- Appropriate warning signs must be displayed indicating the presence of the laser.
- Any door interlocks must be checked before each laser session.
- Laser operation must be checked prior to patient arrival.
- The laser may only be operated by a user who has received appropriate training.
- Clear verbal notice must be given before lasing when anyone other than the operator and patient are in the room.
- Correct eye protection, if directed in the local rules, complying with BS EN 207, is available for and worn by all persons in the room.
- Fume extraction facilities must be used.
- A risk assessment must be undertaken.

17.4 Quality Assurance Programme
In addition to regular equipment servicing by the manufacture/supplier, or other appropriately trained organisation, the hospital/clinic should ensure that appropriate quality assurance checks are undertaken on the laser. A detailed record of quality assurance checks should be kept.

The quality assurance programme may be divided into two specific components:

1. Routine quality assurance, undertaken by the authorised user on a daily or weekly basis, or when appropriate.
2. Quality assurance undertaken once or twice a year by specialist hospital staff (e.g., physics, electro-biomedical engineering department etc.), or by the equipment manufacturer or their representative.

Details of those components that require checking and tests need to be specified by the LPA. Examples are specified by many governmental organisations.\textsuperscript{127}.
17.5 Education and Training
Operators of these devices, in addition to standard medical device training device training, should receive specific training related to the safety requirements of using lasers.

18. Management of Risks Associated with Radiation Therapy

18.1 Introduction
Radiation therapy (also called radiotherapy) is a type of cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumours. Radiotherapy equipment include linear accelerators, Cobalt-60 units, Tomotherapy, Cyberknife, gamma knife, proton therapy, low to orthovoltage x-ray units and brachytherapy units. There are two ways to deliver radiation to the location of the cancer. External beam radiation is delivered from outside the body by aiming high-energy rays (photons, protons or particle radiation) to the location of the tumour. This is the most common approach in the clinical setting. Internal radiation or brachytherapy is delivered from inside the body by radioactive sources, sealed in catheters or seeds directly into the tumour site. This is used particularly in the routine treatment of gynaecological and prostate malignancies as well as in situations where retreatment is indicated, based on its short-range effects.

18.2 Roles and Responsibilities
Roles and the responsibilities associated with each role may vary depending on the government policies, educational and training structure of radiographers in the individual countries. Some roles that have been defined in national/international guidance are described below.

<table>
<thead>
<tr>
<th>Roles</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Radiographer/Radiation Therapist/Radiological Technologists</td>
<td>Therapeutic Radiographers are professionals who are trained to manage the various systems and equipment required in the delivery of radiation therapy to patients. This encompasses the safe and accurate delivery of the prescribed radiation dose to patients and working as part of the multidisciplinary cancer team, to supports patients and their families through their cancer journey. Therapeutic Radiographers are also responsible in performing Simulation, treatment planning and mould room procedures. Therapy Radiographers may also be involved in advising patients on pre-treatment</td>
</tr>
</tbody>
</table>
preparation procedures and possible side effects of radiation treatment.

<table>
<thead>
<tr>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advance Practitioner Therapeutic Radiographer</td>
<td>An Advanced Practitioner Therapeutic Radiographer (APTR) role indicates working beyond one’s traditional scope of practice underpinned by expert evidence-based knowledge. The APTR roles were developed in response to drivers such as increased demands for service and emerging technologies and are underpinned by increased autonomy in RT practice. The advanced practitioners in therapy include but not limited to breast, head and neck, brachytherapy and palliative treatment.</td>
</tr>
<tr>
<td>Medical Physicist</td>
<td>Medical physicists provide the scientific and technical support in a radiation oncology department. They are involved in the implementation of radiation safety and quality assurance program for equipment and physical aspects of all radiation sources ie. radioactive materials and radiation producing machines used in radiation oncology departments. This may include performances specification, acceptance testing, calibration of sources to ensure that all equipment meet international and national standards. They are also responsible for the design of new radiation oncology facilities and the commissioning of new equipment.</td>
</tr>
<tr>
<td>Radiation Oncologist</td>
<td>Radiation oncologists are medical specialists who are qualified to give radiation therapy. The radiation oncologist’s role is to determine the suitability of radiation therapy for each patient, and to give the final approval for the radiation therapy plan. During the course of treatment, the radiation oncologist is also responsible for reviewing patients for side effects management.</td>
</tr>
<tr>
<td>Medical Dosimetrist</td>
<td>Medical Dosimetrists are responsible for the development, optimization, and monitoring of patient treatment plans and provide oversight to high-level treatment procedures.</td>
</tr>
</tbody>
</table>
18.3 Specialist Equipment and Modality Specific Information

There are a number of devices used in radiation therapy imaging and treatment delivery. Examples of the equipment used in radiotherapy include\textsuperscript{135,136,137,138}:

<table>
<thead>
<tr>
<th>Specialist Equipment</th>
<th>Modality Specific Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Linear Accelerator</td>
<td>A medical linear accelerator (LINAC) is the most commonly used device for external beam radiotherapy. It delivers high-energy x-rays or electrons to the treatment area while sparing the surrounding normal tissue. The LINAC can be used to treat all body sites, using conventional techniques, Intensity-Modulated Radiation Therapy (IMRT), Volumetric Modulated Arc Therapy (VMAT), Image Guided Radiation Therapy (IGRT), Stereotactic Radiosurgery (SRS) and Stereotactic Body Radio Therapy (SBRT)</td>
</tr>
<tr>
<td>Conventional Simulator</td>
<td>A simulator is a diagnostic x-ray source configured to mimic the geometric beam delivery configuration of a radiotherapy LINAC. The x-ray source is mounted on a rotating gantry, similar to a linear accelerator, with a detector rotating in the opposite position of the gantry at the far side of the patient. This approach allows fluoroscopic imaging from multiple angles, which facilitates positioning the patient so that the centre of gantry rotation can be placed in the tumour area. Once this position is selected, radiographs are taken from all desired beam angles. These radiographs are taken as a record for comparison with future portal films (taken during treatment) and as an aid for the physician in refining each beam shape\textsuperscript{139}.</td>
</tr>
</tbody>
</table>
| CT Simulator          | It is the use of CT imaging modalities to scan an area of the body to be treated with radiation. The CT images acquired during the CT scan will be used to design the best and most precise treatment plan for radiation treatment delivery. CT Simulation allows the oncologists to determine the treatment area, while minimizing dose to the surrounding critical
structures. Contrast enhancement agents may be given during the simulation procedures to aid in the delineation of target volumes and organs at risk.

<table>
<thead>
<tr>
<th>Brachytherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brachytherapy is a type of radiation therapy that’s used to treat cancer. Brachytherapy procedure involves the placing of radioactive material directly inside or next to the tumour for treatment. Brachytherapy allows oncologists to deliver higher doses of radiation to more-specific areas of the body, compared with the conventional form of radiation therapy.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tomotherapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tomotherapy is a radiation treatment modality that combines treatment planning, CT image-guided patient positioning and treatment delivery into one integrated system. The equipment used for Tomotherapy looks much like a computed tomography (CT) system. During treatment, the patient lies on a couch that moves continuously through a rotating ring. Radiation is delivered from all angles as the ring turns and the couch moves through the gantry.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cyber knife</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Cyber knife is a type of radiation treatment modality that is fully robotic. It delivers high doses of precisely targeted radiation to destroy tumours or lesions within the body. It uses a robotic arm to deliver highly focused beams of radiation. The flexibility of the robotic arm makes it possible to treat areas of the body, such as the spine and spinal cord, that can’t be treated by other radiosurgery techniques.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MR-LINAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnetic Resonance Imaging Guided Linear Accelerator (MRI-LINAC) uses magnetic resonance imaging, or MRI, together with radiotherapy to treat cancers throughout the body, with specific advantages for soft-tissue tumours. The radiation delivery on the MRI-LINAC is fully integrated with the MRI. This means the system can deliver treatment radiation beams and monitor the target area at the same time. The unique combination of technologies gives our physicians greater control over the delivery of radiation because</td>
</tr>
</tbody>
</table>
they can see the internal anatomy and tumour. They can fine-tune the radiation treatment plan and personalize and adapt each treatment in ways they never could before.

| Proton Therapy | Proton therapy is a type of radiation therapy modality that uses protons rather than x-rays to treat cancer. Proton is a positively charged particle. At high energy, protons can destroy cancer cells. Synchrotron or cyclotron are used to speed up protons. The high speed of the protons creates high energy. This energy makes the protons travel to the desired depth in the body to deliver the targeted radiation dose in the tumour. With proton therapy, there is less radiation dose outside of the tumour. |
| Radiation treatment planning (RTP) | Radiation treatment planning (RTP) is the process in which a team consisting of radiation oncologists, therapeutic radiographers/medical dosimetrists/physicists come together to generate a clinically acceptable treatment plan, utilizing clinical knowledge including, but not limited to, anatomy and physiology; radiation biology and oncology; radiation safety and protection, physics and technology to plan the appropriate external beam radiotherapy or internal brachytherapy treatment technique for a patient with cancer. |

18.4 Service Hazards
Equipment safety and patient safety is paramount in therapeutic radiographers’ practice for the safe and effective delivery of radiotherapy. Therapeutic radiographers are the gatekeeper in the delivery of high doses of radiation and ensuring the wellbeing of patients during simulation and treatment delivery procedures. While radiation therapy involves the use of radiation and radioactive sources, advancement in technology has improved the safety regulations and checkpoints during treatment delivery. It is thus important that the treatment centres must follow certain rules and regulations to keep patients, staff, and visitors safe. Safety of patients during treatment can be assured in several ways. Before treatment is delivered to the patient, the treatment plan developed needs to be approved by the radiation oncologist in collaboration with the radiographers/dosimetrist/medical physicist. The planning parameters need to be counter checked and audited before treatment is given. Quality-assurance procedures need to be performed on the equipment/treatment machines to ensure that the treatment will be delivered as planned.
18.4.1 Radiotherapy Treatment Process
Radiotherapy is a complex multi-step procedure and a high level of accuracy is required at every step of the process. At each process, there are handovers and interaction between different professional groups for data transfer and calculations that can present risk of errors. Thus, when errors do occur, the consequences can be significant as it may involve large numbers of patients and may result in severe reactions or even death in the worst-case scenario. With the recent advancement in radiotherapy technology, the improvement in technology has changed the way in which radiotherapy is planned and delivered. The use of 4D CT and CT-based treatment planning such as 3D conformal and intensity modulated radiation therapy (IMRT) have improved treatment delivery. However, with the rapid adoption of new technology and increased patient throughput, it may create an environment with more potential for treatment-related incidents to occur especially if the personnel are not trained to perform the tasks\textsuperscript{140}.

18.4.2 Contrast Enhancement Agents
Contrast enhancement agents may be given during the simulation procedures to aid in the delineation of target volumes and organs at risk. All centres should have treatment guidelines to manage injector and reactions to contrast media injections including extravasation.

The key points from these guidelines should include\textsuperscript{141}:  
\begin{itemize}
  \item a. Risk factors should be assessed for all patients prior to IV contrast administration  
  \item b. eGFR should be check and assessed for all patients, a minimum eGFR of >60 ml/min/1.73m\textsuperscript{2} is recommended.  
  \item c. Metformin should not be stopped unless eGFR is <60 ml/min/1.73m\textsuperscript{2} and in consultation with the referring clinic.  
  \item d. Cannulas should be left in situ for at least 30 minutes post injection for all high-risk patients.  
\end{itemize}

18.4.3 Control of infection
18.4.3.1 Tattooing
In the preparation of treatment area for radiotherapy, markings on patients’ skin are required to serve as reference points to help in the reproducibility of patients’ daily treatment set-up. Both non-invasive (marker pen, henna) and invasive methods (tattoo) are available for use as marking on patients. Tattoos are defined as the introduction of exogenous pigments into the dermis to produce a permanent design. Adverse reactions to tattooing are relatively rare but acute local inflammation is the most common complication and other allergic reaction such as contact dermatitis, and inflammatory or immune responses may also occur. It is important to ensure the practice of aseptic technique and use of disposable needles for each individual patient. Care should also be taken to ensure that the tattoo ink used is not contaminated when used on each individual patient\textsuperscript{142}.
18.4.3.2 Cleaning and Disinfecting of Immobilisation devices and surfaces
During radiotherapy procedures, patients may come into bare skin contact with standardised immobilisation devices and treatment equipment. The transmission of infection can be a real risk to both staff and patients. High standards of infection control are therefore required. All equipment or surfaces that is in contact with patients’ bare skin should be wipe down with 70% alcohol disinfectant after each patient’s use.\(^\text{143}\).

18.5 Treatment Room Design and Equipment Risk Management

18.5.1 Radiotherapy Treatment room design
Design of radiotherapy treatment room can be divided into 3 groups:

i. External beam radiotherapy
ii. Low dose-rate (LDR) brachytherapy and
iii. High dose-rate (HDR) brachytherapy

\textit{i. External beam radiotherapy - Linear Accelerator}

The treatment room shielding should be designed in accordance with the recommendations of NCRP Report 151\(^\text{144}\) and the local Regulatory Authority guidelines. Below is the recommendation from NCRP Report 151.

<table>
<thead>
<tr>
<th>Room Type</th>
<th>Typical Shielding</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Energy Linear Accelerator</td>
<td>• 1.5-3m concrete</td>
</tr>
<tr>
<td>Primary Barrier</td>
<td></td>
</tr>
<tr>
<td>High Energy Linear Accelerator</td>
<td>• 1-1.5m concrete</td>
</tr>
<tr>
<td>Secondary Barrier</td>
<td></td>
</tr>
<tr>
<td>High Energy Linear Accelerator</td>
<td>• With maze 0.5 - 2cm inner lead layer 2-4cm BPE 1cm outer lead layer  • No Maze 5-9cm inner lead layer 15-25cm BPE 1cm outer lead layer</td>
</tr>
<tr>
<td>Door</td>
<td></td>
</tr>
<tr>
<td>Ir-192 HDR Suite</td>
<td>• ~50cm concrete</td>
</tr>
<tr>
<td>PET/CT Room</td>
<td>• 1-2cm lead  • 15-20cm concrete</td>
</tr>
</tbody>
</table>
Radiation warning sign should be posted on the treatment room door warning of the radiation hazard, in accordance with Regulatory guidelines. A door interlock should be installed on all radiation treatment room to prevent any unauthorized access into the treatment room. The treatment console area should be located immediately outside the treatment area looking the treatment room door to prevent any unauthorized access during treatment delivery. The console area should include intercom and closed-circuit television system to monitor patients during treatment delivery.

Safety of the radiographers operating the linear accelerator is also important. To prevent personnel outside of the treatment room to be exposed to the x-rays, the linear accelerator is located in a room with lead and concrete walls to shield off high-energy x-rays. The linear accelerator must only be turn on by therapeutic radiographers from outside the treatment room. Although the accelerator only emits radiation when it is turned on, it is important that the radiographers and staff follow strict guidelines to minimise the risk of accidental exposure\textsuperscript{145}.

\textit{ii. Low Dose Rate (LDR) Brachytherapy}

LDR brachytherapy should employ either manual or remote after loading equipment except for some situations such as permanent implants for radiation protection purposes. The procedures will require a source storage and preparation room, treatment room, planning room and patient room. For remote control brachytherapy, it can be performed in the ward where manual brachytherapy is performed. These facilities should not be located too far away from each other in order to reduce the distance in which the patient and sources have to be transported. Facility design should incorporate features to avoid elevator transport of patients containing radioactive sources\textsuperscript{146}.

\textit{iii. High Dose-Rate (HDR) brachytherapy}

HDR brachytherapy must be done in a properly shielded and secured area located within the radiotherapy department. The room should be shielded according to recommendations in NCRP Report 151\textsuperscript{144}. A door interlock is required to prevent unauthorized access into the room. Access to the irradiation room shall be furnished with a visible signal at
the entrance indicating whether the radiation source is on or off. A HDR brachytherapy facility will require a procedure room, a radiographic imaging system, treatment room and treatment planning area. The relative proximity of these facilities can significantly influence procedure flow and efficiency of treatment delivery. The (HDR) brachytherapy equipment should be provided with a device to return sources manually to the shielded position in the event of an emergency.

With the introduction of new advanced radiotherapy technology such as MRLINAC or Proton Therapy and adaptive treatment, it will introduce new challenges and potential risks in treatment delivery. Radiographers need to be equipped with new knowledge and skills to manage these changes in technology.

18.6 Specific Quality Assurance Measurers

Quality Assurance is a planned and systematic action necessary to provide adequate confidence that a product or service will satisfy the given requirements for quality. A good quality control program will specify:

- Type of tests to be performed and parameters to be tested.
- Equipment to be used.
- Geometry of the tests
- Frequency of the tests to be perform.
- Staff who will be performing the tests and the training required
- Expected results, tolerance and action levels, and actions required when tolerance levels are exceeded.

It is important to put in place QA measurers to reduce the likelihood of errors and accidents occurrence during radiation treatment. Radiation treatment-specific quality assurance guidelines have been published by a number of worldwide organizations such as the World Health Organization (WHO), the International Atomic Energy Agency (IAEA), and the International Commission on Radiological Protection (ICRP) 147, 148, 149, 150. Radiation safety protocols need to be observed for all stages of radiation treatment delivery such as during patient preparation, patient immobilization, tumor localization, treatment planning, dose calibration, daily patient setup, treatment delivery and verification to ensure safe delivery of treatment. The therapeutic radiographers need to be equipped with the necessary skills and competences in radiation protection requirements.

18.6.1 Quality Assurance for Conventional and CT Simulator

To ensure accuracy in treatment delivery, the simulator should consistently produce highest possible quality and accurate geometric information. The quality of the images will directly affect the oncologist's ability to accurately define target volumes and surrounding organs at risk. The evaluation of a CT scanner performance will consist of an evaluation of radiation dose received by patients, radiation safety electromechanical components and image quality. The QA tests perform for conventional simulator and CT simulator are summarized by Figure (1-3) below151.
**Figure 1 - Quality Assurance of Conventional Simulators (taken from AAPM TG40)**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Procedure</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>Localizing lasers</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Distance indicator (ODI)</td>
<td>2 mm</td>
</tr>
<tr>
<td>Monthly</td>
<td>Field-size indicator</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Gantry/collimator angle indicators</td>
<td>1°</td>
</tr>
<tr>
<td></td>
<td>Cross-hair centering</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Focal spot-axis indicator</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Fluoroscopic image quality</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td>Emergency/collision avoidance</td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Light/radiation field coincidence</td>
<td>2 mm or 1%</td>
</tr>
<tr>
<td></td>
<td>Film processor sensitometry</td>
<td>Baseline</td>
</tr>
<tr>
<td>Annual</td>
<td>Mechanical checks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Collimator rotation isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Gantry rotation isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Couch rotation isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Coincidence of collimator, gantry</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Couch axes and isocenter</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Table-top sag</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Vertical travel of couch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiographic checks</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure rate</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td>Table-top exposure with fluoroscopy</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td>kVp and mAs calibration</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td>High and low contrast resolution</td>
<td>Baseline</td>
</tr>
</tbody>
</table>

The tolerances mean that the parameter exceeds the tabulated value (e.g., the measured isocenter under gantry rotation exceeds 2-mm diameter).

**Figure 2 - Test specifications for electromechanical components of the CT Simulator (Taken from AAPM TG 66)**
<table>
<thead>
<tr>
<th>Performance parameter</th>
<th>Test objective</th>
<th>Frequency</th>
<th>Tolerance limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alignment of gantry lasers with the center of imaging plane</td>
<td>To verify proper identification of scan plane with gantry lasers</td>
<td>Daily</td>
<td>±2 mm</td>
</tr>
<tr>
<td>Orientation of gantry lasers with respect to the imaging plane</td>
<td>To verify that the gantry lasers are parallel and orthogonal with the imaging plane over the full length of laser projection</td>
<td>Monthly and after laser adjustments</td>
<td>±2 mm over the length of laser projection</td>
</tr>
<tr>
<td>Spacing of lateral wall lasers with respect to lateral gantry lasers and scan plane</td>
<td>To verify that lateral wall lasers are accurately spaced from the scan plane. This distance is used for patient localization marking</td>
<td>Monthly and after laser adjustments</td>
<td>±2 mm</td>
</tr>
<tr>
<td>Orientation of wall lasers with respect to the imaging plane</td>
<td>To verify that the wall lasers are parallel and orthogonal with the imaging plane over the full length of laser projection</td>
<td>Monthly and after laser adjustments</td>
<td>±2 mm over the length of laser projection</td>
</tr>
<tr>
<td>Orientation of the ceiling laser with respect to the imaging plane</td>
<td>To verify that the ceiling laser is orthogonal with the imaging plane</td>
<td>Monthly and after laser adjustments</td>
<td>±2 mm over the length of laser projection</td>
</tr>
<tr>
<td>Orientation of the CT-license tabletop with respect to the imaging plane</td>
<td>To verify that the CT-license tabletop is level and orthogonal with the imaging plane</td>
<td>Monthly or when daily laser QA test reveals rotational problems</td>
<td>±2 mm over the length and width of the tabletop</td>
</tr>
<tr>
<td>Table vertical and longitudinal motion</td>
<td>To verify that the table longitudinal motion according to digital indicators is accurate and reproducible</td>
<td>Monthly</td>
<td>±1 mm over the range of table motion</td>
</tr>
<tr>
<td>Table indexing and position</td>
<td>To verify table indexing and position accuracy under scanner control</td>
<td>Annually</td>
<td>±1 mm over the scan range</td>
</tr>
<tr>
<td>Gantry tilt accuracy</td>
<td>To verify accuracy of gantry tilt indicators</td>
<td>Annually</td>
<td>±1° over the gantry tilt range</td>
</tr>
<tr>
<td>Gantry tilt position accuracy</td>
<td>To verify that the gantry accurately returns to nominal position after tilting</td>
<td>Annually</td>
<td>±1° or ±1 mm from nominal position</td>
</tr>
<tr>
<td>Scan localization</td>
<td>To verify accuracy of scan localization from pilot images</td>
<td>Annually</td>
<td>±1 mm over the scan range</td>
</tr>
<tr>
<td>Performance parameter</td>
<td>Test objective</td>
<td>Frequency</td>
<td>Tolerance limits</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------</td>
<td>-----------</td>
<td>-----------------</td>
</tr>
<tr>
<td>Radiation profile width</td>
<td>To verify that the radiation profile width meets manufacturer specification</td>
<td>Annually (This test is optional if the CTDI accuracy has been verified)</td>
<td>Manufacturer specifications</td>
</tr>
<tr>
<td>Sensitivity profile width</td>
<td>To verify that the sensitivity profile width meets manufacturer specification</td>
<td>Semiannually</td>
<td>±1 mm of nominal value</td>
</tr>
<tr>
<td>Generator tests</td>
<td>To verify proper operation of the x-ray generator</td>
<td>After replacement of major generator component</td>
<td>Manufacturer specifications or Report No. 39 recommendations</td>
</tr>
</tbody>
</table>

*Depending on the goals and prior clinical experience of a particular CT-simulation program, these tests, frequencies, and tolerances may be modified by the medical physicist.

**Figure 3- Test specifications for image performance evaluation**

<table>
<thead>
<tr>
<th>Performance parameter</th>
<th>Frequency</th>
<th>Tolerance limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT number accuracy</td>
<td>Daily—CT number for water Monthly—4 to 5 different materials Annually—Electron density phantom</td>
<td>For water, 0±5 HU</td>
</tr>
<tr>
<td>Image noise</td>
<td>Daily</td>
<td>Manufacturer specifications</td>
</tr>
<tr>
<td>In-plane spatial integrity</td>
<td>Daily—x or y direction Monthly—both directions</td>
<td>±1 mm</td>
</tr>
<tr>
<td>Field uniformity</td>
<td>Monthly—most commonly used kVp Annually—other used kVp settings</td>
<td>within ±5 HU</td>
</tr>
<tr>
<td>Electron density to CT number conversion</td>
<td>Annually—or after scanner calibration</td>
<td>Consistent with commissioning results and test phantom manufacturer specifications</td>
</tr>
<tr>
<td>Spatial resolution</td>
<td>Annually</td>
<td>Manufacturer specifications</td>
</tr>
<tr>
<td>Contrast resolution</td>
<td>Annually</td>
<td>Manufacturer specifications</td>
</tr>
</tbody>
</table>

*Depending on the goals and prior clinical experience of a particular CT-simulation program, these tests, frequencies, and tolerances may be modified by the medical physicist.
18.6.2 Quality Assurance for Linear Accelerator

Quality assurance of the linear accelerator is very important to ensure that the equipment does not deviate significantly away from its baseline values. This is based on the underlying principle that the dose delivered to the patient should be within 5% of the prescribed dose. Therapeutic radiographers may be involved in performing the daily QA for Linear accelerator. The daily QA checks on the machine are performed to make sure that the radiation output constancy across all energies and that the machine is working properly (144) (151). The daily checks may include checking the door interlock, radiation warning light and the audiovisual monitor is working well. Radiographers may also check that the Sulphur hexafluoride (SF6) pressure, water temperature and level is all in order.

QA gadgets are used to perform daily checks on the field size, collimator isocentre variation, accuracy of the optical range finder and laser light and the laser-isolight coincidence as shown in the table below. Below is a list of the QA activities that need to be performed for the Medical Linear Accelerator. For daily QA checks, it needs to be performed before the start of first treatment delivery.

**Fig 4. Quality assurance of Medical Linear Accelerators (taken from AAPM TG40)**

<table>
<thead>
<tr>
<th>Frequency</th>
<th>Procedure</th>
<th>Tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>Dosimetry</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>X-ray output constancy</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Electron output constancy</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Mechanical checks</td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Locating laser</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Distance indicator (DID)</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Safety interlocks</td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Audiovisual monitor</td>
<td>Functional</td>
</tr>
<tr>
<td>Monthly</td>
<td>Dosimetry</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>X-ray output constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Electron output constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Backup monitor constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>X-ray central axis dosimetry parameter (PDD, TAR)</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Electron central axis dosimetry parameter constancy</td>
<td>3 mm at therapeutic depth</td>
</tr>
<tr>
<td></td>
<td>X-ray beam flatness constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Electron beam flatness constancy</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>X-ray and electron symmetry</td>
<td>3%</td>
</tr>
<tr>
<td></td>
<td>Safety interlocks</td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Emergency off switches</td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Wedge, electron cone intercepts</td>
<td>Functional</td>
</tr>
<tr>
<td>Mechanical checks</td>
<td>Light radiation field coincidence</td>
<td>2 mm or 1% on a side</td>
</tr>
<tr>
<td></td>
<td>Gantry/collimator angle indicators</td>
<td>1°</td>
</tr>
<tr>
<td></td>
<td>Wedge position</td>
<td>2 mm (or 2% change to transmission factor)</td>
</tr>
<tr>
<td></td>
<td>Tray position</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Application position</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Field-size indicators</td>
<td>3 mm</td>
</tr>
<tr>
<td></td>
<td>Couch-lax centering</td>
<td>3 mm diameter</td>
</tr>
<tr>
<td></td>
<td>Treatment couch position indicators</td>
<td>3 mm/°</td>
</tr>
<tr>
<td></td>
<td>Lack of wedges, blocking tray</td>
<td>Functional</td>
</tr>
<tr>
<td></td>
<td>Tare symmetry</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Field light intensity</td>
<td>Functional</td>
</tr>
<tr>
<td>Annual</td>
<td>Dosimetry</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>X-ray/electron output calibration constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Field-size dependence of X-ray output constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Output factor constancy for electron applicators</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Central axis parameter constancy (PDD, TAR)</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Off-axis factor constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Transmission factor constancy for all treatment accessories</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Wedge transmission factor constancy</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>X-ray output constancy vs gantry angle</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Electron output constancy vs gantry angle</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Off-axis factor constancy vs gantry angle</td>
<td>2%</td>
</tr>
<tr>
<td></td>
<td>Arc mode</td>
<td>Manufacturer’s specifications</td>
</tr>
<tr>
<td>Safety interlocks</td>
<td>Follow manufacturers test procedures</td>
<td>Functional</td>
</tr>
<tr>
<td>Mechanical checks</td>
<td>Collimator rotation isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Couch rotation isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Coincidence of collimator, gantry, couch axes with isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Coincidence of radiation and mechanical isocenter</td>
<td>2-mm diameter</td>
</tr>
<tr>
<td></td>
<td>Table-top sag</td>
<td>2 mm</td>
</tr>
<tr>
<td></td>
<td>Vertical travel of table</td>
<td>2 mm</td>
</tr>
</tbody>
</table>
In addition to daily QA checks, the medical physicist will conduct more detailed monthly and annual checks of the linear accelerator as shown in the above figures. Modern linear accelerators are also equipped with internal checking systems that will not allow the machine to be turned on unless all the prescribed treatment requirements are met.

18.7 Patient Care
Patient care for oncology patients encompasses both the physical and psychological well-being of the patient. Before performing any procedures, the patient must first be correctly identified using double identifier. It is important for the therapeutic radiographers to introduce themselves to the patient and explain their role in the procedures and check/obtain informed consent before proceeding with treatment procedures. As a therapeutic radiographer, we play a key role in the safe delivery of treatment to the patient. The role and responsibilities include:

- Correctly identifying the patient prior to treatment occasion.
- Correctly administering the radiation dose to patients, including the correct set up and delivery.
- During treatment, therapeutic radiographers need to continuously observes the patient using a closed-circuit television monitor. 2-way audio communication is also necessary at the console area and treatment room so that the patient can communicate with the radiographer or vice versa whenever necessary. Port films (x-rays taken with the treatment beam) or other imaging tools such as cone beam CT are to be checked regularly based on departmental protocol to ensure that the treatment position doesn't vary from the original plan.
- Inform the physician in case you are concerned about an unusual reaction of patient.
- Inform the physicist in case you are concerned about an unusual event related to a treatment unit or treatment parameters.
- As therapeutic radiographers have daily contact with the patients, it is important for us to be able to observe subtle changes in a patient’s demeanor or side effects to refer patients for timely care or intervention by the nurses or oncologists. This may have an important effect on the patient’s overall experience with radiation oncology.

18.8 Education and Training
Training and education requirements to practice as a therapeutic radiographer varies from country to country across the world. Usually, education and training comprise of both the theoretical and practical knowledge. However, in many countries the profession of therapeutic radiographers is not recognised and there is no formal education programme for therapeutic radiographers. The radiation therapy curriculum is often a very short component of a broader programme such as diagnostic imaging, nursing or science programme. The curriculum is often limited in academic content and clinical training experience. The scope of practice may also vary considerably depending on governmental laws, economics, and cultures. The
skills and competency acquired must ensure that radiotherapy procedures will be delivered at an appropriate level.

According to the IAEA Document on “A Handbook for the Education of Radiation Therapists (RTTs)”; the education programmes for therapeutic radiographers should include theoretical knowledge of professional disciplines to enable them, as practitioners to apply their knowledge in a clinical setting. It is recommended that any programme developed from the curriculum should have a minimum of 2 years duration in order to ensure the acquisition of sufficient knowledge and clinical competencies necessary for the accurate preparation and delivery of radiation treatment. However, a 3-4-year degree programmes is recommended to ensure the development of therapeutic radiographers as a key member of the multidisciplinary team and to allow for knowledge competencies in advanced radiotherapy techniques and dosimetry152.

Radiotherapy practice and patient care can only benefit if therapeutic radiographers education can be streamlined across the globe. In the interest of creating safe practice, at least the general standards for therapeutic radiographers' education and training should be adhered to.

19. Protection of Children and Vulnerable People

19.1 Introduction
Child protection and the protection of vulnerable adults is an essential responsibility for all professionals engaged in the health care of patients. Many countries will have safeguarding legislation with respect to the employment of staff and volunteers that that encounter children and vulnerable adults153. This will cover of all areas of society including the health sector. Additionally, staff have a duty to report suspected injuries to children and vulnerable adults

This section will focus on what is pertinent in diagnostic imaging and radiotherapy in both the private and public health care settings154.

19.2 Roles and Responsibilities
19.2.1 Service Managers Responsibility (Departmental level)
Managers who are responsible for recruiting staff, who will work with children and vulnerable adults, have a responsibility to comply with any country legislation to ensure that staff that they recruit and employ only those who have had official checks. In some countries, this process is called ‘Disclosure and Barring Service checks which require an enhanced DBS check155.
19.2.2 Staff Responsibility
Staff should be alert to the possibility of witnessing injuries to children and vulnerable adults. They should be familiar with any country legislation and hospital/departmental policy for reporting such concerns.
It is important that all staff be given training to feel confident and competent in reporting child protection concerns through the correct channels. Some members of the imaging workforce, for example, sonographers may be overlooked when child protection is given, and it is important to include them as they may well become aware of a possible child protection issue during the imaging process.
If any member of staff observes anything untoward during a child’s examination, the appropriate staff must be informed. This might include a safeguard lead and the original referrer, and a record kept of the issues which raised the concern such as bruises, bites or burns or other relevant issues.

19.3 Legislation and Compliance
This will be dependent on legislation within each country and statutory requirements, staff will need to be familiar with their responsibilities. Each health authority should have a Safeguarding policy to clearly define the context of the legislation and everyone’s responsibilities.

19.4 Staff Training
Training of staff related to safeguarding, and the reporting of suspected safeguarding concerns to children and vulnerable adults, should be organised by the relevant health employer, which will reflect the corporate standards. Useful standards related to the imaging of children have been published by many radiography professional organisations.

20. Control of Hazardous Substances and Hazardous Materials

20.1 Introduction
Hazardous Substances and materials used within Imaging departments must be identified, documented and appropriate safety processes implemented. This are defined as control measures. The UK Legislation is the Control of Substances Hazardous to Heath (COSHH)

20.2 Roles and Responsibilities
20.2.1 The Hospital Management Team
- Development and implementation of the corporate policy which may include the process of purchasing specialist goods.
- The control and safety measures to be implemented by Departments.
- The Control of Substances Hazardous to Health Regulations (COSHH) require the employer to identify ALL hazardous or potentially hazardous substances which may be used in the workplace, or that may be produced by a process, e.g. end product, by-product, etc., or that may be emitted during any process. This may include gases, vapours, organic compounds, and other products.
• The employer must conduct a risk assessment of these substances, evaluate the risk of exposure to people, and where necessary, take appropriate precautions to prevent or control that exposure.
• Provide guidance to the exposure limit for individual substances (WEL) UK limits are defined in the following guidance https://www.hse.gov.uk/coshh/basics/exposurelimits.htm

20.2.2 Service Managers (Departmental level)
The manager should undertake the assessment of the Hazard, assess the level of risk and implement procedures to eliminate or minimise the hazards identified with individual substances. This is a combination of processes including:
• Hazard Assessment for products used in the department
• Records of stock
• Review of Safety data and procedures for each item identified as Hazardous using Material Safety Data Sheets (MSDS)
• Provision of Protective Equipment

20.3 Control of Substances hazardous to Health (COSH) Guidance
Many countries will have specific guidance relating to COSH which may be linked to legislation. In the UK, the Health and Safety Executive (HSE) COSHH guidance on risk assessment is found at https://www.hse.gov.uk/toolbox/harmful/coshh.htm

20.4 Training Records
Records of training must be kept within the Department to include:
Where an employee is likely to be exposed to a substance identified as hazardous to health information should be available within the department giving:-
• Details of that substance
• Safe systems of work
• Emergency procedures and First Aid arrangements
• Material Safety Data Sheets for the substance, provided by the manufacturer or supplier.

Note
PPE and spillage kits should be available prior to handling of the substance.
21. Control of Infection

21.1 Introduction
The Control of Infection is one of the key components of Patient and Staff Safety. This section will outline the requirements covering general control and specific measures for viral pandemic infections including the current COVID-19 emergency.

21.2 Roles and Responsibilities
21.2.1 The Hospital Management Team
The overall policy and common measures across organisations is the responsibility of the Hospital Management Team. These are usually defined in the Control of Infection Policy and procedures. These procedures may also define the initiatives to provide surveillance and active reduction in the risk of infection occurring as well as measures the infection control measures.

21.2.2 Service Managers (Departmental Level)
The manager is responsible for the maintenance of a safe clinical and operational environment. This is achieved through the implementation of the infection control procedures identified by the organisation and recommendations of manufacturers or safety agencies.

21.3 Education and Training
The local processes should be implementing with appropriate training and ongoing review measures to ensure consistence of the preventative actions.

21.4 General Infection Control Procedures
The control of infection is a combination of a number of measures which to provide a safe environment.

The key measures can be defined as:

1. Achieving optimum hand hygiene
2. Using personal protective equipment
3. Decontaminating equipment
4. Achieving and maintaining a clean clinical environment
5. Safe handling of sharps and disposal of clinical waste

21.5 Key Procedures
A number of important procedures are set out below.

21.5.1 Hand Hygiene
Health care workers must ensure that their hands can be decontaminated effectively by:

- Removing all wrist jewellery and stoned rings when in the clinical area
- Ensuring they are ‘bare below elbows’ in all clinical areas
- Ensuring that nails are short and clean and free from false nails and nail varnish.
• Covering any minor wounds or skin lesions with a waterproof dressing.

Hands must be decontaminated in all of the following circumstances:

• Immediately before every episode of direct patient contact or care, including aseptic procedures.
• Immediately after every episode of direct patient contact or care.
• Immediately after exposure to body fluids.
• Immediately after any other activity or contact with a patient’s surroundings that could potentially result in hands becoming contaminated.
• Immediately after removal of gloves.
• Liquid soap should be used for routine hand hygiene (i.e. in between patients).
• However, alcohol hand gel is a suitable alternative for routine hand hygiene if the hands are not visibly contaminated
• Alcohol gel should be applied after washing with soap and water to disinfect hands before an aseptic procedure is carried out

21.6 Safe Use of Personal Protective Equipment (PPE)
PPE is intended to protect both patient and the health care worker from the risk of cross infection.

21.6.1 Protective Clothing
Protective clothing must:-

• Be readily available and easily accessible
• Be appropriate for the task/procedure being undertaken
• Fit appropriately
• Be compatible with any other item of protective equipment being worn simultaneously
• Be disposable where possible, if not disposable it must be decontaminated and maintained as necessary

21.6.2 Selection of Appropriate Protective Clothing
This should follow a risk assessment of the procedure. The following factors should be considered:

• The nature of the task
• The risk of contamination
• The barrier efficacy of the protective clothing

All imaging and therapy staff must be trained in the appropriate use of PPE and follow local and governmental agreed procedures for either airborne\(^{159}\) (droplet) or aerosol situations\(^{160}\). The ISRRT has specific COVID-19 guidance\(^{161}\) with many organisations providing similar advice\(^{162}\).

21.6.3 Personal Protective Equipment – Donning
PPE should be put on (Donning) in the following order\(^ {163}\):-
21.6.4 Personal Protective Equipment – Doffing
PPE should be removed (Doffing) in the following order:-

e) Non sterile gloves
f) Apron
g) Eye protection
h) Face mask/respiratory
i) Protective clothing should be disposed of into the clinical waste stream.

21.6.5 Gloves
Nitrile gloves should be worn when there is a risk of exposure to body fluids, secretions/ excretions, broken skin or mucous membranes.
Sterile gloves are required for invasive procedures or contact with sterile sites.
Gloves must be put on immediately before an episode of care and removed as soon as the activity is completed
Hands must be decontaminated immediately following removal of gloves
Gloves must be single use items

21.6.6 Aprons and Gowns
Disposable plastic aprons must be worn to reduce the risk of clothing being exposed to blood, body fluids, secretions or excretions.
Disposable aprons should also be worn where contact with contaminated items such as the patient’s bed linen is likely.
Plastic aprons must be worn as single use items
If gloves are worn, aprons must be removed after gloves.
If caring for a patient in standard isolation, the apron must be removed and discarded inside the side room.
Disposable water repellent gowns must be worn if there is extensive risk of splashing onto clothing.
Full length gowns must be worn when caring for patients considered high risk

21.6.7 Face, Eye and Respiratory Protection
Facemasks and eye protection should be worn where there is a risk of splashing of fluids or debris into the face or eyes.
Respiratory protection is required when there is a risk of infection during aerosol generating procedures such as intubation or succioning.
Filter masks (FFP3) are to be worn when during aerosol generating procedures when caring for a patient suspected of known to have tuberculosis.
Hands must be decontaminated immediately following the removal of any PPE

21.7 Decontamination of Equipment
Shared equipment used in the clinical areas must be decontaminated appropriately after each use.
Single use equipment must not be re-used
Used instruments and equipment must be decontaminated in accordance with manufacturer's guidelines.

21.8 Safe Handling of Sharps and Environmental Cleaning
The organisations policy for handling and disposal of sharps (including use of approved safety containers) should be adopted.

The Department environment must be visibly clean, free from dust and spillage and levels of cleaning must be increased during outbreaks of infection where the pathogen concerned survives in the environment and environmental contamination may be prolonging spread of infection.

22. Moving and Handling

22.1 Introduction
Manual handling incidents can pose risk to the safety and wellbeing of Staff and Service Users.

The following activities should be considered as a risk:

- Activity that involves transporting or supporting of a load including lifting, putting down, pushing, pulling, carrying or moving it.
- Activity that could lead to musculoskeletal strain or injury

This could include:
Activities that include potential long periods of static position, regular stooping, twisting, bending or other poor posture. The risk of injury increases significantly with any combination of these.

22.1.1 Definitions
- Manual Handling - The Manual Handling Operations Regulations 1992 states: “manual handling operations” means any transporting or supporting of a load (including the lifting, putting down, pushing, pulling, carrying or moving thereof) by hand or by bodily force”.
- Load - This is any movable object. This includes patients, equipment,
trolleys, wheelchairs etc.

- Ergonomics - The means by which the working environment and working practices are altered to more suitably match the individual, thus reducing risk of injury

- Minimal Lifting - Minimal lifting techniques are those, which employ the use of mechanical lifting devices. Manual lifting should become the last resort when all other options have been exhausted.

- Minimal Assistance - Guiding a partially sighted or blind service user.

- Competent Person - The HSE defines a competent person as someone who has had sufficient training, experience, knowledge, skills and other qualities to comply with the requirements of the legislation.

22.1.2 Provision and Use of Work Equipment Regulations (PUWER 1998)
HSE: - guidance stating that all equipment provided and used in the course of your employment should be checked prior to its first use and on a regular basis.

22.1.3 Lifting Operations and Lifting Equipment Regulations (LOLER 1998)
HSE: - guidance stating that all equipment used for lifting a person whether a hoist, and any material sling used, or lifts in buildings must be checked by an appropriately qualified person/engineer every 6 months.

22.1.4 Identification of Hazards and Risks
The Manual Handling Operations Regulations (1992) establishes a clear hierarchy of measures:
1. Avoid hazardous manual handling operations so far as is reasonably practicable
2. Assess any hazardous manual handling operations that cannot be avoided
3. Reduce the risk of injury so far as is reasonably practicable
4. Review any assessment if there is reason to suspect that it is no longer valid, if there has been change in the manual handling operations or an injury has occurred.

22.2 Roles and Responsibilities
22.2.1 The Hospital Management Team – (Hospital wide)
Development and implementation of a Moving and Handling Policy to cover all aspects the regulations, provision of training and equipment and define local processes and procedures for assessment and practice.

22.2.2 Service Managers (Departmental level)
Have the responsibility for the following:
- To implement manual handling regulations within their workplace
- To seek additional advice or training on manual handling risk management
when necessary
- To ensure their staff are aware of, trained sufficiently, and competent in matters relating to manual handling, posture and ergonomics, records are kept of this training.
- To ensure full and sufficient risk assessments of manual handling activities within their departments are carried out. These must be documented and reviewed regularly.

22.3 Risk Assessment (RA) details
The assessment must take account of:-
1. The task
2. Individual capabilities
3. Load
4. Working environment
5. Equipment

No manual handling activity is completely safe. However, using these guidelines as part of a well thought out risk assessment will reduce the risks from manual handling activities. Weights to be lifted may need to be reduced below the guideline values if there are environmental or other factors that could have an adverse effect on the activity or if it involves twisting or bending.

The following chart gives guideline weights for lifting and lowering, of inanimate loads, which assumes that the handling is taking place in reasonable working conditions with a load that is easily grasped with both hands by a reasonably fit, well-trained individual.
An assessment of manual handling activities can be through considering five specific areas – Task, Individual, Load, Environment and Other Factors, (TILEO).

22.3.1 Key Factors to Consider
The elements to consider are:-
- The Task
  Does the activity involve twisting, stooping, bending, excessive travel, pushing, pulling or precise positioning of the load, sudden movement, inadequate rest or recovery periods, team handling or seated work?
- The Individual
  Does the required activity involve such things as twisting, stooping, bending, or, pushing/pulling.
- The Load
  Is the load heavy, unwieldy, difficult to grasp, sharp, hot, cold, difficult to grip, are the contents likely to move or shift?
- The Environment
  Are there space constraints, uneven, slippery or unstable floors, variations in floor levels, extremely hot, cold or humid conditions, poor lighting, poor ventilation, gusty winds, clothing or Personal Protective Equipment that restricts movement?
- Other Factors
  Is the equipment clean and fit for purpose?
  Are staff that are to use the equipment trained and competent to do so?
  Are instruction manuals readily accessible in all areas where equipment is to be used?
  Has equipment been regularly serviced and inspected?

22.4 Patient Lifting Considerations
Care should be taken to provide staff and patients with the correct information as to the movements required to safely transfer to the examination couch or other location. Procedures should be developed following a risk assessment. Sufficient members of the team should be present to reassure the patient and undertake the lifting procedure.

22.5 Manual Lifting
If you need to lift something manually:-
- Reduce the amount of twisting, stooping, and reaching
- Avoid lifting from floor level or above shoulder height, especially heavy loads
- Adjust storage areas to minimise the need to carry out such movements
- Consider how you can minimise carrying distances
• Assess the weight to be carried and whether the worker can move the load safely or needs any help – maybe the load can be broken down to smaller, lighter components.

Helpful advice is given by many countries Health and Safety government bodies which should be consulted\textsuperscript{164}.

22.6 Moving and Handling Equipment
The type and amount of equipment needed will vary according to the specific needs of care service users.

Equipment may include:

1. Hoists
2. Transfer Boards such as ‘Pat Slides’
3. Wheelchairs
4. emergency evacuation equipment
5. Bariatric equipment

22.7 Staff Training
In many countries such as the HSE identify the need for training to be relevant to the type of work carried out and should cover:

• manual handling risk factors and how injuries can happen
• how to use mechanical aids\textsuperscript{165}
• how to carry out safe manual handling, including good handling techniques\textsuperscript{166}
• systems of work relevant to the worker’s tasks and environment
• practical work so the trainer can identify anything the trainee is not doing safely and put it right

The content of any training in good handling technique should be tailored to the tasks the workers carry out\textsuperscript{167}.

23. Buildings and Facilities Infrastructure with Environmental Considerations Combined with Equipment Procurement and Building Installation Projects/Schemes

23.1 Introduction
Imaging and radiotherapy equipment must be housed in buildings that are safe, environmentally friendly, and have the appropriate services for the clinical care provided. This may include provision of High Voltage power and specialist radiation protection measures. This is achieved by a process of design, planning for equipment procurement and installation and then maintaining the infrastructure. See Section 9 relating to General aspects of Medical Equipment.
23.2 Roles and Responsibilities

23.2.1 The Hospital Management Team (Hospital wide)
The Imaging and Therapy Departments are usually part of a larger healthcare provider organisation. These larger organisations have defined responsibilities and operate the estate services functions. This service group will supervise and undertake the maintenance of the facilities in compliance with legal requirements.

Within the UK this is covered by regulations such as the Health and Safety at Work Act and provisions of the regulations defined by the Health and Safety Executive (HSE). The compliance rules are usually defined in the organisational Estates Services Policy. This document will identify the current standards and legislative compliance requirements.

23.2.2 Service Managers (Departmental level)
At service level the manager or clinical lead will be responsible for the safety of patients and staff through implementation of the measures identified in the organisation wide policy.

These local actions and procedures will include measures to ensure the department and clinical facilities operate in a safe regime including such processes as:-

- Maintenance of air conditioning and air handling systems.
- Electrical safety procedures.
- Safe use of medical gases.
- Maintenance of the fabric of the physical environment to protect occupants from slips and trips and falls and the other possible injury.
- Safe for handling and disposal of a clinical and other waste.
- Selection, installation and commissioning of new major equipment including:
  o Defining what equipment is required and how it will be operated
  o Preparation of a specification
  o Pre-purchase questionnaire – to confirm compliance with safety standards and legislation.
  o Defining the building work required
  o Maintenance requirements

23.3 Legislation and Compliance
The estates policy will identify and provide steps for compliance with the appropriate legislation and regulations. Systems and activities covered by the policy may include:

23.3.1 Safety Systems
These will include:-

- Fire Safety Procedures
- Staff Attack Systems
- Decontamination Procedures
- Management of Medical Gases
- Portable Appliance Testing (PAT)
23.3.2 Infrastructure Considerations
These will include:-
- Management and Control of Asbestos
- Management and Control of Contractors
- Management of Doors including Automatic Doors
- Management of Drains and Sewerage Systems
- Management of Electrical Systems
- Management of Heating and Ventilation
- Management of Passenger Lifts and Lifting Equipment

23.4 Planning – room design and Infrastructure
The planning of Diagnostic and Therapy facilities will use a template to identify the infrastructure and equipment within the overall design of the building. The states are: Initial Design based on a specification and planning brief – This defines what the facility is to be used for the patient, clinical and administration workflow.

23.4.1 Example of Project Stages for a New Installation
This will include:-
- Project outline and business case for funding
- Detailed design of the building and services such as electrical supply
- Installation equipment specification this includes:
  o Major medical equipment such as Linear Accelerators and shielding requirements
  o Minor equipment that are fixed components such as cupboards and specialist equipment located in the room.
  o Identification of loose items such as desks and chairs.
- Creating the project timeline and detailed plan
- Construction
- Commissioning – checking compliance with the design specification and certification of the equipment for safety and radiation protection assurance.

23.4.1.1 Defining the Equipment and Installation
The specific stages in defining the technical equipment and specifics of installation are:-
- The equipment specification
- Identifying the Room Design and Infrastructure
- Developing Equipment and services requirements through Room Data Sheets
- Identifying the Maintenance of Equipment requirements
- Staff Training
23.4.1.2 Identification of Key Individuals and Infrastructure Requirements
This will include:-

- Room data sheets
- Room plans – with sign off
- Commissioning requirements to include identification of legal and statutory requirements and H&S issues, rules and codes of conduct including stop and start procedures etc.
- Development of a Project Plan which is agreed by all parties including
- Risk assessments – Local radiation rules
- Commissioning and Mobilisation stage including Critical exam, MEGAN checks and Acceptance tests by Medical Physics
- IM&T plan – connection with PACS & RIS
- Staff training

23.5 Procurement Stages
This will include:-

23.5.1 The Tendering Process
- Tendering rules and frameworks – using local or national systems- OJEC or NHS Supply Chain using National Framework (UK and European Economic Community)
- Expressions of interest – via a Pre-Qualification Questionnaire (PQQ)
- Invitation to Tender
- Equipment evaluation – technical and costs including lifetime costs
- Final selection process
- Award of contract/business – traditional purchase, lease or managed equipment service, adherence with National regulations i.e. NHS conditions of contract for the purchase of goods (September 2010) and other relevant regulations i.e. CE mark and electrical safety standards etc. (UK)
- PACS & RIS connectivity issues

23.5.2 Pre-Qualification Questionnaire
Completed at the beginning of the tendering process which will make sure that only suppliers who meet the minimum requirements are invited to a tender.
The PPQ documents will provide:-

- An overview of the contract, including contract length and value
- An explanation on how the questionnaire will be evaluated
- Which companies who will be invited to the next stage, which is the Invitation to Tender (ITT)
23.5.3 Invitation To Tender (ITT)
The ITT will be issues to those suppliers who have been successful in the PPQ evaluation process.

This is a detailed document and will contain specific instructions:

- criteria against which the tender will be evaluated, for example price and quality
- certificates to be signed confirming agreement with the purchaser's policies and terms
- contract terms and conditions between the purchaser and successful company
- pricing schedule where the provider enters prices in a standard format so they can be compared with other bids
- quality or technical questions

23.5.4 Award of Tender
Confirmation to supplier or prime contractor

23.5.5 Project Control and Completion
Establishing a project team and control of the development through a project planning methodology such as Projects in a Controlled Environment (PRINCE 2).

This process identifies actions and control process to allow visibility of complex projects and manage the completion of the programme.

23.5.6 Useful Tools and Resources
As indicated, it is important that there is clarity in what is required and expected from equipment suppliers and what contactors are expected to deliver in terms of facilities and resources. Some useful resources are found in the Appendix section and are also available on the ISRRT educational courses series\textsuperscript{168}.

**Appendix A** - Generic Operational and Technical Specification for a General X-ray Room with DDR – Dual Detector System

**Appendix B** - Room Data Sheet – (based on the NHS Activity Room Data Base for rooms but others are readily available in different countries\textsuperscript{169})

**Appendix C** - Tender Evaluation Template

23.7 Maintenance Considerations
Equipment used as part of clinical care has defined maintenance schedules created by the original equipment manufacturer (OEM). These identify the items to be maintained, service schedules required and detailed procedures for the maintenance actions.
23.8 Staff training
Staff training should be undertaken for the installation, upgrade or modification for any clinical equipment. This should be in line with guidance from the OEM.

24. Departmental Housekeeping and Ergonomics

24.1 Introduction
The departmental areas must provide a safe working environment for all aspects of the clinical process. Where new facilities have been specifically designed to the clinical workflow the oversight and the latest standards of safety may be included as part of the design. For both older non purpose designed and newer dedicated commissioned developments there is still the overarching need to provide a 'safe environment for care services'.

24.2 Roles and Responsibilities

24.2.1 The Hospital Management Team (Hospital wide)
Provision of infrastructure processes to ensure safety of the services provided to the clinical area. This may include such processes as testing of water supplies for contaminants and bacteria, assurance of non-contamination by asbestos and a hospital wide fire safety and response plan including local evacuation procedures.

24.2.2 Service Managers (Departmental level)
The department should have processes, procedures, and equipment for maintaining a clean and safe environment which will include:

- Reducing the risk of physical injury or harm to individuals in the area.
- This will include any security devices, procedures, and fires prevention measures.

24.3 Legislation and Compliance
The department should also have procedures for the recording of effective environmental safety and actions required for local and legislative compliance these could include:

- Accident Reports in compliance with hospital policy and legislation
- Building Surveys to identify risks and preventative maintenance in addition to maintaining a n ambient environment for patients and staff.
- COSHH Assessments
- Fire Risk Assessment and maintenance record of the Fire Safety Equipment
- Hazard and Near Miss Reports
- Health and Safety Audits
- Indoor Air Quality Inspections to assess the air handling/change capacity of the ventilation systems with specific emphasis where chemicals are being used.
- Lift and Hoist Inspections
Portable appliance testing (PAT) of electrical devices and Fixed Wire Testing

24.4 Fire Prevention and Procedures
Staff must undertake regular structure training in fire hazard awareness and fire safety training. Environment measures such as automatic smoke detection devices and alarms and extinguishers and other firefighting equipment periodic and routine assessment. Weekly checks should be made of the security and safety processes in the unit and the Fire Escape exit routes.

24.5 Prevention of Slips, Trips and Falls
The department should be regularly assessed for any defective floor covering or absence of handrails or supports to minimise the risk of patient or staff falling as a result of either a slip or a fall. A record of such rectification of defects should be recorded and held within the unit.

25. Financial and Budgetary Controls

25.1 Introduction
Financial management is a key process for organisations. It identifies the income and expenditure across all services. Allocation resources to services and individual departments is made through setting a budget. A key part of business planning is being able to identify costs, income, and expenditure.

25.2 Roles and Responsibilities
25.2.1 Hospital Management Team (Hospital wide)
To define policies and procedures for the management of financial resources including capital investment.

The corporate financial policy and procedures sometimes called Standing Financial Instructions (SFI’s) is the process where the organisation defines the rules and processes for compliance with legislation and how finances are managed. It will also identify measures to prevent fraud and wastage of funds that could be spent on patient care. These may include
- Banking Procedures and Security
- Defining rules and limits for Capital Expenditure
- The process of Budget setting, Control and Reporting
- Preparation and Approval of Business Plans and Budgets
- Tendering and contracting procedures
- Ordering and stock control
- Asset Registers and security of Assets
- How Charitable Funds are received and managed
25.2.2 Service Managers (Departmental level)
The service manager may be the budget holder for the service or managing part of a larger divisional budget. The management of the budget will be within the levels set and operate within the organisations Standing Financial Instructions. Managers will be responsible for the financial management of the services through a combination of local systems. This could include the assessment of performance against budget and may use some or the following parameters:

1. Budget Variance
2. Pay costs and expenditure
3. Non pay expenditure including such as consumables, maintenance of equipment
4. Business Plans
5. Any Cost Improvement Plan
6. Profitability measures (Commercial Sector organisations)

25.3 Legislation and Compliance
Service leads as accountable for their budgets are required to comply with organisations standing financial instructions.

25.4 Asset Management
The physical assets within the department should be recorded on an asset register. This information can be used to determine the working life and create a replacement programme.

25.5 Budget Preparation
Departmental budgets are prepared as a subset of the overall organisational financial plan. The budget is developed identifying the current and future expenditure (usually within the next 12 months) for maintaining and developing the services.

A typical budget may include:
- Pay expenditure identified for each staff group delivering all aspects of the clinical, operational, administration and support services for the imaging or therapy department.
- Non-Pay expenditure for such items as Equipment Maintenance, Consumables such as Catheters, Contrast Media, PPE.
- Capital expenditure for identified equipment replacement or developments (usually identified by specific business cases).

26.6 Procurement
The purchasing of goods will be in line with the organisations policy for procurement. This process will be developed to comply with local legislation. There may be set expenditure limits that the Service Manager can purchase items or define the level of expenditure requiring different competitive tendering or direct purchasing.
25.7 Stock Control
Stock, such as catheters held locally with the department should be managed through maintain a record of purchases and use. Where items have a defined use by date systems of stock rotation should be used to ensure all items are used within the stated time period.

25.8 Fraud prevention
Managers should maintain processes to eliminate the opportunity of fraudulent activity.

26. Data Security and Information Governance (IG)

26.1 Introduction
The management and security of information is key to information governance as part of the overall governance processes of the imaging and Therapy department.

26.2 Roles and responsibilities
26.2.1 The Hospital Management Team (Hospital wide)
The management board should create the organisational strategy and guidance for data handling and information systems.

This could include specific guidance such as:

26.2.2 Legislation & Compliance
- Definitions of compliance with data protection legislation - UK legislation is the Data Protection Act 2018 the General Data Protection Regulations (GDPR)
- Appointment of a clinical assessor for patient related information collection and storage – UK legislation term is the Caldicott guardian.
- Guidance on the legal obligation of request for individual’s information held by the organisation - UK legislation is the subject access request.
- Rules and guidance for the release of personal identifiable information.

26.2.3 IG Policies and Procedures
- Requirements for a data protection legislation impact assessment where request for clinical a personal information is made by an individual.
- Information on the rules of the freedom of information from public bodies – government legislation such as UK legislation.
- Guidance on the copyright documents and data including information as part of clinical or operational research.
- Preparation and maintenance of an information asset register covering items of data and data collection systems.
- Establishment of maintenance of a secure data receiving area for paper based or electronic transmission’s which are printed in hard copy.
• Use of the organisational internet procedures for communication by email
• Use and limitations of the WhatsApp or other messaging service.
• Guidance on rules on the use of text messaging.
• Guidance on photography, video and audio recording including patients and staff.
• The use of smart card security devices.
• Use of mobile computing and security requirements.
• Guidance on the risks of electromagnetic interference to medical devices buy mobile phones.
• Third party agreements with software suppliers.
• Disposal of equipment to ensure confidentiality.

26.2.4 Data control and retention polices
• Disposal of medical records including both electronic media and paper records.
• Rules for retention of records including storage retrieval and archiving.
• Procedures for clinical audit and medical research information collection.
• Approved systems and software and software security including virus and malware prevention.

26.3 Service Managers (Departmental level)
The service manager will be responsible for the local implementation of the organisation wide guidance through local processes and procedures. At Department level this could include:

26.3.1 Security
• Ensuring the physical environment where information is managed, read, stored and retrieved is physically secure and working practices do not allow patient information to be overlooked or over heard by patients or visitors.
• Implementing local controlled access to systems and storage areas through locks and password protection of computerised systems and electronic clinical records.
• Password controls – using the organisation wide policy for type i.e., Alphanumeric with specific configuration and use of special characters, duration before change or process of and forced change.
• Use of smart cards linked to qualification and management as part of corporate policy.

26.3.2 Virus and other software security
• Keeping the software up-to-date and implement upgrades and new virus definitions as realised by the organisation IM&T service or software provider updates.
26.3.4 Electronic Data Storage
- Implementing processes to use defined storage systems including security controlled and assured Cloud Computing based service.

26.3.5 Backup systems and maintenance
- Implementing backup systems for data storage and local disk drives with regular activation of the backup routines.

27. Communications

27.1 Introduction
Communication both internal and external is particularly important in the healthcare setting. This is due to many circumstances where the organisation may be subject to change or operational pressures. There are many types of communication utilised in managing clinical environments and there are specific hospital wide and local processes that can be used to ensure all the imaging team is fully aware organisational, strategy development, issues and good news.

27.2 Roles and Responsibilities
27.2.1 Hospital Management Team
To develop a communications strategy for both internal and external communications. This will usually identify key development issues and the strategic direction for the organisation in terms of how the vision is communicated to staff and the wider public and interested parties. It will also identify communications leads and channels of communication to staff groups and the media.

27.2.2 Service Managers (Departmental level)
The key responsibility is to provide the members of the team with the latest information on what is happening within the wider organisation and sharing information that affects the local working environment.

27.3 Team Briefing
A common approach is to hold regular team updates or briefings which may be held weekly or monthly depending on the organisation. The use of team briefing allows all members of the imaging team to be aware of developments and keeping up to date with what is happening across the organisation as a whole. It is a way of establishing and maintaining two-way communication between the organisation management and the service delivery teams.

27.4 Staff Input
The opportunity to contribute to the discussion and provide comment is a key measure of the effectiveness of a communication process and the Team Brief can be used to gather feedback and discussion to help the Hospital management team refine the strategic or operation choices and decisions.
Additionally, it is important that daily communications are undertaken at sub departmental levels so that daily workload and tasks are allocated and planned, and everyone is aware of their responsibilities. This is particularly important when handing over patient care and activity from one shift to another.

27.5 Record Keeping

It is important to keep a record of the information shared and feedback, comment provided from members of the team to provide accurate exchange with the Hospital Management. This provides a common unambiguous approach where everyone can see an open welcoming communications process.
28. Acknowledgements

28.1 List of authors
The ISRRT Board of Management are grateful for the many people who contributed to the content of the document and in particular the following who made major contributions:

<table>
<thead>
<tr>
<th>Name</th>
<th>Topic</th>
<th>Details</th>
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Appendix A - Generic Operational and Technical Specification for a General X-ray Room with DDR – Dual Detector System

Narrative setting the scene and putting the project in context

The acquisition of a General X-ray DDR Room, with dual detectors, within the newly established X-ray Department will be configured to support rapid clinical diagnosis from established General Practitioners and other clinical specialities within a community-based healthcare environment.

The X-ray Room will be capable of undertaking a range of plain x-ray examinations direct from GPs and clinics within the Health Centre. The unit will also be used to supplement the plain imaging service currently available from Hospital X.

In carrying out plain radiography examinations standard techniques will be employed as well as adaptation of techniques. The vast majority of procedures will be undertaken on patients who are capable of walking into the unit but there may be a need to x-ray some patients while they are sitting in their wheelchair and an elevating x-ray table is essential.

At least one of the digital acquisition detectors must be portable, preferably using wireless technology, or alternatively an integrated CR reader may be considered for examinations requiring preferably the use of a smaller detector.

Images will be captured using DDR technology and passed immediately to PACS for local viewing in the Health Centre clinical stations and for reporting within the X-ray Department or elsewhere.

It is expected that the unit will be provided with a General Operator Workstation which will control the X-ray generator and review of acquired images on a single high specification monitor.

The equipment must be ergonomic in design and user friendly to permit a high efficiency of patient throughput without compromising on quality.

The equipment must be suitable for the examination of erect projections of knees and ankles with adequate stoke of the ceiling tube column to facilitate this requirement.

The equipment should be flexible, easy to manoeuvre and offer a wide coverage of the X-ray table and provide as an option full lower limb and full spine radiography.

The supplier will be responsible for ensuring that their equipment is fully DICOM compatible and will give an undertaking that they can connect to the Agfa RIS and PACS system which is hosted by Blackpool Victoria Hospital and maintain such connections after any service visits or software upgrades. It is expected that the total cost of any enabling/interface work required is included in the tender price and that it will meet this requirement from the day of installation.

It is expected that the vertical Bucky grid specification will be such that as this unit will be able to undertake high kVp chest examinations at 180 FFD as well as standard projections at 100cm FFD and that the grid is removable.

The room will also be supplied with a range of first line QA equipment necessary to meet the guidelines of IPEM Report 91 at no extra cost including digital image acquisition.

Clinical requirement and Workload

The X-ray Service will operate a standard 5 day working week with an anticipated volume of 60 patients per day.

Examination type done within this room

Chest (using high kVp technique)

Abdomen

Upper extremity radiography: hands, wrists, forearm, humerus, elbow and shoulder

Lower extremity radiography: feet, ankles, tibia & fibula; knee and femur.

Erect views of knees & ankles (i.e. tube must extend close to floor level)

Spine radiography – Cervical, Thoracic, Lumbar and Sacral

Pelvic radiography: Hips (inc. cross table lateral), upper femur, SIJ’s

Examination of patients in wheelchairs
Non-Bucky, table Bucky and vertical Bucky
Full leg length and spinal examination for joint alignment capability (as an optional extra)

Installation requirements
A new Imaging facility is expected to be adequate to accommodate the new equipment. This project is likely to be a conventional installation based on a generic layout in a new build facility. The supplier will be responsible for specifying the pre-installation work requirements in relation to this equipment.

DICOM
All equipment should have a DICOM conformance statement. DICOM modes must be supported without the need for further software installation or software purchases;
- Modality Push
- Modality Work list
- Print Service
- PACS Push
- Performed Procedure Step
- Storage Commit
- Modality Pull
- PACS Pull
- Modality verification

Direct Digital Radiography System – 2 Detectors

<table>
<thead>
<tr>
<th>Specification</th>
<th>X-Ray Generator</th>
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<tbody>
<tr>
<td>Core Components:</td>
<td>X-Ray Generator</td>
</tr>
<tr>
<td></td>
<td>X-Ray Tube and 3D Support</td>
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<td></td>
<td>Elevating Table with a removable X-Ray Detector – preferably wireless</td>
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<tr>
<td></td>
<td>Vertical Bucky with an Integrated X-ray Detector</td>
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<td></td>
<td>Acquisition Workstation – with single monitor for generator control and image review</td>
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<td></td>
<td>The removable detector must be flexible for all examinations requiring adaption of standard radiographic techniques - however a an integrated CR solution will be considered</td>
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<tr>
<td>X-Ray Generator:</td>
<td>High frequency generator with a minimum nominal output of 60kW, kV range 40 to 150 with a mAs range 0.5 to 800 and reproducible short exposure times of 1ms.</td>
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<tr>
<td></td>
<td>The operation of the X-ray generator and detectors must be integrated</td>
</tr>
<tr>
<td></td>
<td>The generator must be able to be operated in all these modes:- kV-mA-mAs, kV-mA-(AEC)</td>
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<tr>
<td></td>
<td>Automatic exposure control</td>
</tr>
<tr>
<td></td>
<td>The operation of the X-ray generator and detector must be integrated</td>
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<tr>
<td></td>
<td>It must be possible to use the X-ray tube independently of the detectors</td>
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<td></td>
<td>Ergonomic control desk with high performance monitor with controls for pre-selection of exposure parameters e.g. mAs and kVp or individual adjustment of kVp, mAs and time and review of acquired images.</td>
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<tr>
<td></td>
<td>Post exposure readout of mAs when AEC used and dose are product</td>
</tr>
<tr>
<td></td>
<td>Anatomical programme selection of exposures with manual override</td>
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<tr>
<td></td>
<td>Built in design safety feature linked to incorrect AEC selection/usage to terminate exposure beyond a pre-defined factor.</td>
</tr>
<tr>
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<td>A means of recording dose area product is mandatory (DAP) – should be linked to PACS image.</td>
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| **Exposure Control:** | The system must have an automatic exposure control (AEC)  
The manufacturer must provide advice on suitable exposure levels to set the AEC  
The AEC must have a back up timer to terminate the exposure after a preset time/factor in case of equipment failure  
Advice should be provided on suitable exposure parameters (mAs, kV and target / filter combination) for operation of the automatic exposure control (AEC) system on the associated x-ray unit. |
| **X-ray Tube and Housing** | Dual focus – 0.6/1.0 mm or near equivalent with 2.5 mm Al total beam filtration and designed to accommodate the maximum power output of the X-ray tube  
Pre-selectable additional copper filters.  
Tube housing to support generator display and control of exposures factors on X-ray tube/LBD assembly – preferably with examination pre selection capability  
Ergonomic control handles and switches to support CTS movements  
FFD measuring tape |
| **X-ray Table, Bucky Mechanism for Detector assembly** | Flat x-ray tabletop with low attenuation features (lower than 0.75 mm Al at 100kVp – maximum 1.5mm Al above 100 kVp)  
Height adjustable 4-way floating top patient table.  
Movements should be in longitudinal, transverse and diagonal planes with access to all four sides of the table by staff.  
The table height range must cover 60 to 80cm  
The lateral coverage using the table and detector movement must be at least ±10cm  
The longitudinal coverage using the table and detector movement must be at least ±30cm  
Hand and foot switches for table movements and height adjustments with safety table lock controls to avoid uncontrolled table movement whilst patient mounting or leaving the table  
There must be an anti height (crash) lowering feature to prevent movement should there be an obstruction  
Must accommodate heavy patients - i.e. weight restriction 225 kg or higher Intelligent control of FFD when adjusting x-ray table height  
Table Detector tray with Bucky mechanism and AEC device  
Removable Bucky Gird – 12/40 ratio focused at 115cm or equivalent stationary type  
Grid storage facility  
Table Bucky design to accommodate removable DDR detector with removable grid capability.  
Automatic beam collimation linked to the examination selected which should not normally exceed the detector area  
Minimum table top to receptor top distance should not exceed 55mm  
The tabletop must be sealed to prevent the ingress of bodily fluids  
Accessories to include a horizontal cassette holding device, foam mattress and an abdominal compression device  
The patient table must be designed with a view to patient transfer by hoist, PATSLIDE, or similar device |
| **Ceiling suspended x-ray** | Power assisted servo movements  
Variable height telescopic adjustment to accommodate standing knees |

*Please state the range of table movement and height adjustments and the location/s of table movement controls and the limitations of any longitudinal table extension for CPR*
| **tube system (CTS)** | Motorised movement tracks should allow for maximum coverage of the room.  
Pre-selectable radiographic positions preferred to facilitate automated positioning of X-ray tube and detector with anti-crash features and remote control features  
Intelligent control of FFD when adjusting x-ray table height  
Pre-selected centring/stops for table Bucky and vertical Bucky and vertical Bucky FFD locations.  
Tube angulation should allow for techniques such as erect radiography at 180cms FFD and should rotate through the vertical and horizontal axis.  
Intelligent control of required central x-ray beam angulation to detector when adjusting central beam (tube alignment)  
Remote control device  

*Please specify height range, room coverage of tube and angulations.* |
| **Light Beam Diaphragm (LBD)** | Light Beam Diaphragm with-in built Diamentor and facility to accommodate LBD mounted beam filtering accessories.  
Ergonomically designed control features and preferably featuring exposure control of the x-ray generator form the LBD.  
Ability to perform diagonal work though if wanted (controlled by a switch or key)  

*Please specify height range, room coverage of tube and angulations.* |
| **Vertical Bucky** | Vertical Bucky  
Fixed Detector – preferably 43x43 cm  
Adjustable height to allow for e.g. paediatric chest examination and AP knees  
Tilting mechanism to facilitate horizontal orientation of the Bucky mechanism and table top  
Rotation of Bucky housing around the vertical axis to facilitate anatomical alignment of structures along the long axis is preferred  
Detector tray with Bucky mechanism and AEC device  
Removable Bucky Girds – 12/40 ratio one focused for chest radiography 180cm and one for abdominal radiography 115cm or equivalent stationary type  
Grid storage facility  
Adjustable patient support grips for lateral chest radiography  
Ergonomically designed and positioned controls  
Intelligent control of FFD when adjusting x-ray Bucky height  
Intelligent control of required central x-ray beam angulation to detector when adjusting central beam  

*Please state the Bucky height range and range of angulation of the vertical Bucky.* |
| **Detectors and Housing:** | Detector efficiency – DQE greater than 65%  
Each image must have an associated number to indicate the level of exposure to the detector  
At least one side of the table detector must be at least 40cm  
The maximum size of the pixel pitch must be 200 µm  
A preview image must be displayed in less than 10 seconds  
A full image suitable for quality assurance must be displayed in less than 30 seconds (non sub sampled and fully post processed)  
The detector must be ready to acquire a second image within 10 seconds of an exposure  
If one side of the detector is less than 40cm the detector must be rotatable by 90° |
| **Review Workstation and Post Processing:** | Light as possible and robust and preferably wireless  
The removable detector assembly must be provided with a clip-on anti-scatter grid assembly and be robust to allow for standing feet radiography  
High quality monitor, touch screen, at least 19 inches with a preferred 1.2MP resolution for clinical review capability (image review and generator control)  
Workstation fully supports individual user login and access rights  
The following image processing must be provided:-  
- Image Processing customised to match exam  
- Image annotation  
- Electronic Collimation  
- Window and Level  
- Zoom and Roam  
- Image Flip  
- Image Rotation – including rotation of image in small degrees  
- Image Inversion  
- Magnification to include the whole screen for just the image  
- Distance and angle measurement including Cobb’s angles  
- An indication to flag if an image has been mirrored  
- An indication of which images have been sent to PACS/printed  
- A test pattern must be included as standard and be available for the user. This will allow the user to undertake quality assurance of the secondary class display monitor  
- The image display must be calibrated to match the DICOM greyscale display function and therefore allow quality control of images  
- The system must have an image reject analysis software package including reject categorisation. Only the administrator must be able to delete the rejected images  
- The system must automatically set image parameters based on the selected exam information  
- Exam parameter input tables which are logical and easy to use  
- User friendly image algorithm functions e.g. LUT and GOP which are comprehensive and effective  
- The software must allow the user to change the order in which separate views are acquired  
- It must be possible to attach exam specific notes to an image (i.e. radiographer notes)  
- The system should enable post display of radiographic examinations undertaken by category with corresponding exposure and dose parameters in such a format to export in an Excel spreadsheet to enable DRL calculations  
- Monitor calibration capability |
| **PACS/RIS Links** | Routine to complete study and sending images to PACS is flexible and effective  
The radiographer can be reopened a study once sent and closed to add further images  
Image views and exams can be taken in any order (i.e. all the lateral first then all the APs)?  
Correction of wrongly ID images easily undertaken by administrator  
Facility for the super user configure the system  
Provision of an off line tool available for configuring the system |
| **Data Storage** | The computer system must be able to store 1500 images  
A USB slot should be provided for export of interesting images  
Newly acquired images be protected if there is a power failure |
| Examination protect function                  | Auto delete function, to facilitate altering the %.         | DVD/CDs written as DICOM files with inherent auto-reader                  |
| Safety:                                       | In normal operation the collimator must limit the area of the X-ray beam to within the area of the detectors (shutters should automatically detect collimated area and adapt to suit) | The whole system must be quick and easy to clean between patients The system must be supplied with a dose area product (can be calculated or measured) Paediatric dose saving features |
| Accessories                                  | Please include a range of first line QA equipment necessary to meet the guidelines of IPEM Report 91 to include:- LBD/Beam alignment test tool | kVp meter dose/dose rate and timer meter 1 mm copper sheeting Test tool for detector pixel dropout a test pattern must be included as standard and be available to allow the user to undertake quality assurance of the secondary class display monitor |
| Lead Rubber sheeting                         | Lead Rubber sheeting                                       | Gonad Shields Foam mattress Detector holder on mobile platform for positioning in vertical and horizontal positions Clip on grid device Compression device for table and vertical Bucky |
| Radiation Safety                             | The room should be capable of undertaking full lower limb and spine radiography | Both hardware and software options should be detailed and costed as an option |
| Radiation Safety                             | Please list the dose saving features which are designed into the equipment for the reduction of patient and staff dose. Please indicate what generator safety features are included to prevent accidental overexposure due to equipment malfunction or user error |

**Additional Information**

- Please indicate the minimum room dimensions required for equipment offered. (Length, Width and Height)
- Please indicate equipment weight – all components individually
- Please indicate number and dimensions of support cabinets
- Please state any positional restrictions
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please indicate equipment ventilation / air conditioning requirements.</td>
<td></td>
</tr>
<tr>
<td>Please indicate Pre installation room requirements including power supply requirements</td>
<td></td>
</tr>
<tr>
<td>Please indicate Lead Time from order to delivery</td>
<td></td>
</tr>
<tr>
<td>Please indicate Installation time</td>
<td></td>
</tr>
<tr>
<td>Please indicate Number and Location of service engineers</td>
<td></td>
</tr>
<tr>
<td>Please indicate Typical response time for call-outs</td>
<td></td>
</tr>
<tr>
<td>Please indicate Latest time on a working day to guarantee engineer on site same day</td>
<td></td>
</tr>
<tr>
<td>Guaranteed Uptime</td>
<td></td>
</tr>
<tr>
<td>Please state your definition of uptime and the remedy available to the PCT if guaranteed uptime is not achieved</td>
<td></td>
</tr>
<tr>
<td>Warranty period for equipment offered</td>
<td></td>
</tr>
<tr>
<td>Please state any warranty exclusions</td>
<td></td>
</tr>
<tr>
<td>Routine maintenance – frequency and duration</td>
<td></td>
</tr>
<tr>
<td>Normal working hours for engineers</td>
<td></td>
</tr>
<tr>
<td>Out of hours charges (per hour)</td>
<td></td>
</tr>
<tr>
<td>Question</td>
<td>Answer</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Type and cost of maintenance contracts offered</td>
<td></td>
</tr>
<tr>
<td>Remote diagnostics available and from where?</td>
<td></td>
</tr>
<tr>
<td>Location of spare parts and delivery timescales</td>
<td></td>
</tr>
<tr>
<td>Current number of UK sites with the offered equipment installed?</td>
<td></td>
</tr>
<tr>
<td>Duration of clinical applications training</td>
<td></td>
</tr>
<tr>
<td>Number of staff who will be trained on the system and basic cost</td>
<td></td>
</tr>
<tr>
<td>Please show any incremental costs for additional training</td>
<td></td>
</tr>
<tr>
<td>State the minimum dimensional requirements for delivery access</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B - Room Data Sheet

General Comments

<table>
<thead>
<tr>
<th>Project:</th>
<th>Generic Anywhere X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
<td>RAD Radiology</td>
</tr>
<tr>
<td>Room:</td>
<td>E0124C DR General X-Ray</td>
</tr>
<tr>
<td>Room Number:</td>
<td>RF.03</td>
</tr>
</tbody>
</table>
| Activities: | 1) Patient may arrive on foot or in a wheelchair.  
2) Positioning/repositioning patients for examination.  
3) Using radiation protection equipment.  
4) Imaging x-ray examination of patient.  
5) Clinical hand washing.  
6) Displaying notices.  
7) Using marker/wall board.  
8) Storing small items of equipment.  
9) Access to RIS to complete x-ray exam records |
| Personnel: | 1 x Rad 1 x Patient |
| Planning Relationships: | Adjacent to Processing area. |
| Space Data: | Area (m²): 32.00  
Height (mm): 3,100 |

Notes: Direct Digital Radiography  
In the absence of changing cubicle, privacy screen is required.  
Radiation protection as required.  
Lighting control panel(s) depending on specific function of the room giving variable levels of illumination.  
Socket outlets at two metre intervals on each wall.  
Lamp indicator repeat call situated overdoor on outside entrance of the room.

CLIENT CONFIRMATION OF EQUIPMENT OF EQUIPMENT TYPE REQUIRED, NAMELY DDR or CR type.

Room Environmental Data

<table>
<thead>
<tr>
<th>Project:</th>
<th>Generic Anywhere X-ray</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department:</td>
<td>RAD Radiology</td>
</tr>
</tbody>
</table>

137
<table>
<thead>
<tr>
<th><strong>AIR</strong></th>
<th><strong>Requirements</strong></th>
<th><strong>Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Winter Temperature (Deg C):</td>
<td>21</td>
<td></td>
</tr>
<tr>
<td>Summer Temperature (Deg C):</td>
<td>23</td>
<td></td>
</tr>
<tr>
<td>Mechanical Ventilation (Supply ac/hr):</td>
<td>5.0</td>
<td>Mechanical ventilation (supply): Up to 6 ac/hr depending on local conditions.</td>
</tr>
<tr>
<td>Mechanical Ventilation (Extract ac/hr):</td>
<td></td>
<td>Mechanical ventilation (extract): To suit overall design of area</td>
</tr>
<tr>
<td>Pressure Relative to Adjoining Space:</td>
<td>POS</td>
<td></td>
</tr>
<tr>
<td>Filtration (%DSE and % Arrestance):</td>
<td>/</td>
<td></td>
</tr>
<tr>
<td>Humidity (%RH):</td>
<td></td>
<td>Humidity control to suit equipment.</td>
</tr>
</tbody>
</table>

**General Notes:**

<table>
<thead>
<tr>
<th><strong>LIGHTING</strong></th>
<th><strong>Requirements</strong></th>
<th><strong>Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Service Illumination (Lux):</td>
<td>400</td>
<td>Floor. Dimming facilities are required.</td>
</tr>
<tr>
<td>Service Illumination Night (Lux):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Illumination (Lux):</td>
<td></td>
<td>20-100 Couch Variable. Local examination luminaire either fixed or mobile to provide 1000 lux.</td>
</tr>
<tr>
<td>Colour Rendering Required:</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Standby Lighting Grade:</td>
<td>B</td>
<td>Lighting of the level and quality one third to one half that provided by normal lighting.</td>
</tr>
</tbody>
</table>

**General Notes:**

<table>
<thead>
<tr>
<th><strong>NOISE</strong></th>
<th><strong>Requirements</strong></th>
<th><strong>Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Privacy Factor Required (dB):</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Mechanical Services (NR):</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>Intrusive Noise (NR Leq):</td>
<td>35</td>
<td></td>
</tr>
<tr>
<td>*Acceptable Sound Level [L10dB(A)]:</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>*Speech Privacy Required:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Quality Which Cannot Be Tolerated:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(* alternative format)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**General Notes:**

<table>
<thead>
<tr>
<th><strong>SAFETY</strong></th>
<th><strong>Requirements</strong></th>
<th><strong>Notes</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hot Surface Max. Temp (Deg C):</td>
<td>43</td>
<td></td>
</tr>
<tr>
<td>Hot Water Max. Temp (Deg C):</td>
<td>41</td>
<td></td>
</tr>
</tbody>
</table>

**General Notes:**
<table>
<thead>
<tr>
<th>FIRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enclosure:</td>
</tr>
<tr>
<td>Automatic Detection:</td>
</tr>
</tbody>
</table>
Room Design Character

| Surface Finish (HTM 56): 3 i.e. Impervious, jointless, smooth |
| Surface Finish (HTM 61): 2 i.e. Hard, impervious, jointless, smooth |
| Surface Finish (HTM 60): 3: Smooth, imperforate |
| HTM 58) Two sets of doors: 1x1500mm One & a half leaf, plain flush, lockable. Bed access. And 1x 900mm, Single leaf, plain flush, lockable. Person access. Both- Radiation proof. Direct access from changing cubicles - optional. |
| HTM 55) In accordance with radiation protection advice, solar control, blackout or dim-out facilities are required. |
| HTM 57) N/A |
| N/ |
## Schedule of Components by Room – DR General X-ray (Sample)

<table>
<thead>
<tr>
<th>Project:</th>
<th>RAD Radiology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room:</td>
<td>E0124C DR General X-Ray</td>
</tr>
<tr>
<td>Room Number:</td>
<td>RF.03</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quantity</th>
<th>New</th>
<th>Trans</th>
<th>Total</th>
<th>Code</th>
<th>Description</th>
<th>Alt. Code</th>
<th>Grip</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>CAL007</td>
<td>PUSH BUTTON staff emergency call, reset &amp; integral /adjacent indicator lamp, wall mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>CAL020</td>
<td>LAMP repeat staff emergency call, wall mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>CL0005</td>
<td>CLOCK impulse, wall mounted ILLUMINATED SIGN</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>LG073</td>
<td>&quot;IN USE&quot; ILLUMINATED SIGN &quot;DO</td>
<td>ES0023</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>LG074</td>
<td>NOT ENTER, SOCKET outlet switched 13amp</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>OUT005</td>
<td>single, wall mounted SOCKET outlet switched 13amp</td>
<td>ES0001</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>6</td>
<td>6</td>
<td>OUT010</td>
<td>twin, wall mounted OUTLET isolator to be to</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>OUT079</td>
<td>equipment manufacturers specification, SOCKET outlet computer data, wall/trunking mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>OUT121</td>
<td>SOCKET outlet telephone, wall mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>OUT215</td>
<td>CONNECTION UNIT, unswitched, to equipment</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>OUT900</td>
<td>manufacturers specification, EARTH TERMINAL BOX</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>OUT901</td>
<td>SHELF, 200W 360D</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>SHEE221</td>
<td>STORAGE UNIT, lower, cupboard, 2 door, 1 shelf,</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>STF127</td>
<td>550H 600W 450D, HTM63</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>STF158</td>
<td>STORAGE UNIT, lower, 3 drawer, 550H 600W 450</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>D. HTM63</td>
<td>D, HTM63</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>SUP900</td>
<td>EMERGENCY STOP switch button, wall mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>SWC062</td>
<td>STOP/START button, wall mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>SWC063</td>
<td>TAP bib 2x12mm, mixer, double lever action, swivel nozzle, HTM64TBH2</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>TAP337</td>
<td>WASTE, flush, grated, metal, 32mm, no plug, HTM 64</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>WAS100</td>
<td>TRAP, bottle, 32mm, HTM64</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>WAS107</td>
<td>BASIN, medium, hospital pattern, vitreous china, no tap holes, no overflow, concealed waste, 500W 400 D, HTM64LBHM</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>WAS110</td>
<td>WORKTOP, cantilevered from wall, 1200x650mm, HTM63</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>WKT144</td>
<td>DISPENSER, paper towel, wall mounted</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>DIS013</td>
<td>DISPENSER, disinfectant solution Med. Alcohol Gel, lever action, wall mounted</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>DIS026</td>
<td>SOAP, lever action, wall mounted</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>DIS030</td>
<td>HOLDER, sharsps bin, wall mounted</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>HOL901</td>
<td>HOOK, hat &amp; coat, 1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>HO0024</td>
<td>RACK, x-ray lead apron, 5 hangers hinged, wall mounted</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>RAC196</td>
<td>SCREEN shielding, radiation proof, 2mm lead, solid/glass, 2000mm height, 2100mm long, angle</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>SCR061</td>
<td>X-RAY CS, ceiling suspensions, with telescopic tube of column &amp; rotating/tilting arm</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td>XRA010</td>
<td>X-RAY CS RAIL, ceiling suspensions, 2455mm (3655 w/optional extension rail)</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

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## Schedule of Components by Room

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Trans</th>
<th>Total</th>
<th>Code</th>
<th>Description</th>
<th>Alt. Code</th>
<th>Gap</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA024</td>
<td>X-RAY TRANSFORMER CABINET for generator, 65 kW with options for 50, 80,100kW, 1950H 590W 570 D. (Part of XRA020)</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA901</td>
<td>CONSOLE, operator, DR unit, control desk mtd.</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA903</td>
<td>DETECTOR SUPPORT ASSEMBLY, DR system 526 x 662 x 416mm (H x w x D)</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA949</td>
<td>PATIENT TABLE DIRECT RADIOGRAPHY</td>
<td>XT5001</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA950</td>
<td>XRAY CHEST STAND DIRECT RADIOGRAPHY</td>
<td>XT5002</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA968</td>
<td>DESK CONTROL CONSOLE X-RAY</td>
<td>XT5007</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>CHA002</td>
<td>CHAIR, height adjustable, medium back, swivel, 5 star base, on castors</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>2</td>
<td>2</td>
<td>2</td>
<td>CHA017</td>
<td>CHAIR, upright, upholstered, stacking</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>H0004</td>
<td>HOIST PATIENT, sling type, mobile</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>HOL006</td>
<td>HOLDER, sack, with lid foot operated, medium, freestanding, 875H 432W 385D</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>HOL900</td>
<td>HOLDER, bin sack, clinical waste, 50 L., 580x445x395 mm (HxWxD)</td>
<td>BW5006</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>IMG928</td>
<td>WORKSTATION RIS</td>
<td>XF0028</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>LIO015</td>
<td>LUMINAIRE observation/examination, mobile, 1000 lux</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>TEL902</td>
<td>TELEPHONE HANDSET</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>TRO133</td>
<td>TROLLEY, dressing/instrument, stainless steel, buffered, 870H 750W 450D</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>1</td>
<td>XRA902</td>
<td>CPU, Operator Console, DR system, under control desk</td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>
Appendix C – Tender Evaluation Template

**GENERIC PCT - X-ray Scheme**

**General X-ray Room with DDR- Clinical and technical evaluation**
*(Ceiling Tube Suspension system or Ceiling Floor Track Table system with Vertical Bucky)*

An important part of the procurement process is to **evaluate the equipment** in order to gain an understanding of what is currently available and which solution(s) would be of most benefit to the hospital.

The **clinical and technical evaluation should be conducted in conjunction with the configuration sheet(s) relevant to each supplier** and the Operational Requirement (OR).

The scoring mechanism is a method of determining whether the system **meets** the Operational Requirement (OR).

Scoring should be on a scale of 0 to 3 against the base level of acceptability (score 1), i.e. the operational requirement, and **not against each other model**.

**Scoring System:**

0 – fails to meet Operational Requirement.
1 – **Meets Operational Requirement.**
2 – Exceeds Operational Requirement.
3 – Significantly exceeds Operational Requirement, gives significant additional value. (with supporting evidence)

Essential features:

Each user should determine what features are absolutely essential, as opposed to desirable, for their operational requirements.

<table>
<thead>
<tr>
<th>Supplier/Manufacture</th>
<th>Equipment Type</th>
<th>Clinical visit location</th>
<th>Date of visit</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Below are the criteria to be scored:

<table>
<thead>
<tr>
<th>Feature:</th>
<th>Things to look out for when scoring:</th>
<th>Score</th>
<th>Essential</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System processes</strong></td>
<td>Start-up time from switch on to operational acceptable?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Shut down time acceptable?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the Diamentor (post exposure meter) link acceptable?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is cumulative dose available on the user interface (that includes rejected images)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the dose information (KV, mAs, DAP) exported to PACS?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Operator Console – Generator Workstation</strong></td>
<td>Is it user friendly?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure button location easily accessible and operated</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Visual display of exposure factors readily visible</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AEC selection criteria clear and user friendly</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>AEC selection criteria comprehensive for patient type</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post examination mAs displayed on console following AEC facilitated exposure</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post examination dose displayed on console</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Individual choice of KVp, mAs and time available</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ease of altering exposure factors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sufficient pre-programmed anatomical projections?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the exposure parameters adapted for the patient type (child etc)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Radiation isolation available (X-ray enable/disable button)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Image Review and System Workstation</strong></td>
<td>Size of monitor and image acceptable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clarity and brightness of the monitor</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| **Good layout of the screen and functions**  
  Touchscreen? |  |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post exam dose and exposure parameters shown on images</strong></td>
<td></td>
</tr>
<tr>
<td><strong>The following image processing must be provided:</strong></td>
<td><strong>Image Processing customised to match exam</strong></td>
</tr>
<tr>
<td><strong>Image annotation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Electronic Collimation</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Window and Level</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Zoom and Roam</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Image Rotation and Flip</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Image Inversion</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Rotation of image in small degrees possible</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Can the tools be configured on the system for normal and superusers?</strong></td>
<td></td>
</tr>
</tbody>
</table>
| **Other Tools to include:** | **Magnification**  
  Can you use the whole screen for just the image? |
| **Distance and angle measurement** |  |
| **Is there an indication whether the image has been mirrored?** |  |
| **Is there an indication of which images have been sent to PACS/printed?** |  |
| **System set up functions:** | **Are the exam parameter input tables logical and easy to use** |
|  | **Are the image algorithm functions e.g. LUT and GOP comprehensive and effective** |
| **PACS/RIS Links** | **Are these effective** |
|  | **Routine to complete study and send images to PACS flexible and effective**  
  Can the radiographer |  |
|  | **Study can be reopened once sent and closed to add further images** |
| **Can the views and exams be taken in any order (i.e all the lateral first then all the APs)?** |
| **Correction of wrongly ID images easily undertaken by administrator** |
| **Can the super user configure the system?** |
| **Is there an offline tool available for configuring the system?** |

| **Data Storage** |
| **Capacity of hard disc space, how many examinations will be on line,** |
| **Will newly acquired images be protected if there is a power failure** |
| **Auto delete function, can you alter this %** |
| **Examination protect function** |
| **Are DVD/CDs written as DICOM files with inherent auto-reader?** |

| **Table Features – User Friendliness and Safety** |
| **Does table controls (side table and/or floor) positions suit your workload?** |
| **Are there safely features to prevent unintentional movement of the table top** |
| **Table movement weight acceptable?** |
| **Is there anti height lowering feature to prevent movement should there be an obstruction** |

| **Table movements** |
| **Consider smoothness and max-min height adjustments** |
| **Is manual handling acceptable for all table movements, including transfer of patients from wheel chairs and trolleys** |

<p>| <strong>Table Bucky and AEC Mechanism</strong> |
| <strong>Is this user friendly</strong> |
| <strong>Is there a sensing mechanism to prevent double exposure should the cassette not be removed after exposure or when the tray is not fully positioned in the ready position</strong> |</p>
<table>
<thead>
<tr>
<th>Table Dimensions</th>
<th>Is cassette sensing available to facilitate automatic coning of the x-ray beam</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Can the grid be easily removed Is there storage for it in the unit?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Is the tray deep enough to enable cassette markers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Will the tray easily accommodate transverse and longitudinal orientation of a 35x43 cm cassette</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Can the FFD be automatically fixed at a predetermined height to the Bucky tray irrespective of the height of the table to the floor</td>
<td></td>
</tr>
<tr>
<td>Table Accessories</td>
<td>Are these useful in terms of aiding positioning and reduction of scatter</td>
<td></td>
</tr>
<tr>
<td>CTS or Tube Column/LBD</td>
<td>Responsive system – is it servo driven</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Was the vertical stroke sufficient to facilitate standing knee and ankle radiography</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the tube column movements (rotation and linear) smooth and easy to perform</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the mechanical/electrical stops effective for table and vertical Bucky central positioning and erect FFDs for chest and standard radiography</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Are the LBD controls user friendly</td>
<td></td>
</tr>
<tr>
<td></td>
<td>What other dose reduction facilities come as standard</td>
<td></td>
</tr>
<tr>
<td>Generator – Major Features</td>
<td>Was the power output sufficient for all expected examinations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Was the shortest exposure time sufficient to reduce movement unsharpness in the most challenging situations e.g. restless baby chest</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Was there evidence of consistent dose output for the same exposure factors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Was the Diamentor built into the LBD</td>
<td></td>
</tr>
<tr>
<td><strong>Vertical Bucky/Sensor Plate Assembly System</strong></td>
<td><strong>Is tilting available</strong></td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Are movements and the positioning of controls and locking mechanisms user friendly?</strong></td>
<td><strong>Is there a remote control as standard?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Are there hand gips and are these suitable and adjustable?</strong></td>
<td><strong>Can the grid be removed?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is there storage in the unit?</strong></td>
<td><strong>Was the cassette holder easily removed and replaced?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Can adjustments be made to the cassette holder to accommodate both large and small cassettes?</strong></td>
<td><strong>Can the height of the vertical Bucky and CTS be interlinked to facilitate maintenance of central beam to Bucky centre?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Can the detector follow the tube (alignment)?</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sensor Detector System</strong></th>
<th><strong>Anatomical coverage - at least one side of the detector must be at least 40cm</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The maximum size of the pixel pitch must be 200 µm</strong></td>
<td><strong>A preview image must be displayed in less than 10 seconds</strong></td>
</tr>
<tr>
<td><strong>A full image suitable for quality assurance must be displayed in less than 15 seconds (non sub sampled and fully post processed)</strong></td>
<td><strong>The detector must be ready to acquire a second image within 10 seconds of an exposure</strong></td>
</tr>
<tr>
<td><strong>If one side of the detector is less than 40cm the detector must be rotatable by 90°</strong></td>
<td><strong>For systems not using slot scanning or air gap technique the detector assembly must include a removable anti-scatter grid</strong></td>
</tr>
<tr>
<td><strong>Sensor Detector Removable System</strong></td>
<td>Is the weight acceptable</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td></td>
<td>Is the cable flexible</td>
</tr>
<tr>
<td></td>
<td>Is transfer between table and vertical Bucky easily accomplished</td>
</tr>
<tr>
<td></td>
<td>Is the detector manoeuvrable</td>
</tr>
<tr>
<td></td>
<td>Is the detector surface cleanable without damage to the unit</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Safety</strong></th>
<th>In normal operation the collimator must limit the area of the X-ray beam to within the area of the detector</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Can you perform diagonal work though if wanted (controlled by a switch or key)?</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The whole system must be quick and easy to clean between patients</td>
<td></td>
</tr>
<tr>
<td></td>
<td>The system must be supplied with a dose area product (can be calculated or measured)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Full Lower Limb/Spine Imaging</strong></th>
<th>Was this demonstrated?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Can this be done supine and standing?</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Were there any particularly positive aspects of the system?</strong></th>
<th><strong>Were there any particularly negative aspects of the system?</strong></th>
<th></th>
</tr>
</thead>
</table>

| **Overall impression. Please state your overall impressions of the system.** |  |
### 30. Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>18f</td>
<td>Fluorine – 18</td>
</tr>
<tr>
<td>99mMo</td>
<td>Molybdenum-99m</td>
</tr>
<tr>
<td>99mTc</td>
<td>Technetium-99m</td>
</tr>
<tr>
<td>ACR</td>
<td>American College of Radiology</td>
</tr>
<tr>
<td>AEC</td>
<td>Automatic Exposure Control</td>
</tr>
<tr>
<td>ALARA</td>
<td>As low as reasonably achievable</td>
</tr>
<tr>
<td>ANTT</td>
<td>Aseptic No Touch Technique</td>
</tr>
<tr>
<td>APTR</td>
<td>Advance Practitioner Therapeutic Radiographer</td>
</tr>
<tr>
<td>ASA</td>
<td>Australian Sonographer Accreditation</td>
</tr>
<tr>
<td>AXREM</td>
<td>Association of X-Ray Equipment Manufacturers</td>
</tr>
<tr>
<td>BMUS</td>
<td>British Medical Ultrasound Society</td>
</tr>
<tr>
<td>BPE</td>
<td>Borated Polytherene</td>
</tr>
<tr>
<td>BSS</td>
<td>Basic Safety Standards</td>
</tr>
<tr>
<td>BSSD</td>
<td>Basic Safety and Standards Directive</td>
</tr>
<tr>
<td>CASE</td>
<td>Consortium for the Accreditation of Sonographic Education (UK)</td>
</tr>
<tr>
<td>CE</td>
<td>Conformité Européene</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>CI-AKI</td>
<td>Contrast induced-acute kidney injury</td>
</tr>
<tr>
<td>COHSS</td>
<td>Control of Hazardous Substances Hazardous to Health</td>
</tr>
<tr>
<td>CPD</td>
<td>Continuous Professional Development</td>
</tr>
<tr>
<td>CR</td>
<td>Computerised Radiography</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>DBS</td>
<td>Disclosure and Barring Service</td>
</tr>
<tr>
<td>DDR</td>
<td>Direct Digital Radiography</td>
</tr>
<tr>
<td>DHSC</td>
<td>Department of Health and Social Care (UK)</td>
</tr>
<tr>
<td>DQE</td>
<td>Detector efficiency</td>
</tr>
<tr>
<td>DRLs</td>
<td>Dose Reference Levels</td>
</tr>
<tr>
<td>ECR</td>
<td>European Society of Radiologists</td>
</tr>
<tr>
<td>EFRS</td>
<td>European Federation of Radiographer Societies</td>
</tr>
<tr>
<td>eGFR</td>
<td>Estimated glomerular filtration rate</td>
</tr>
<tr>
<td>EQF</td>
<td>European Qualifications Framework</td>
</tr>
<tr>
<td>ESR</td>
<td>European Society of Radiologists</td>
</tr>
<tr>
<td>EURATOM</td>
<td>European Atomic Energy Community</td>
</tr>
<tr>
<td>FDA</td>
<td>Food &amp; Drug Administration</td>
</tr>
<tr>
<td>FDG</td>
<td>Fluorodeoxyglucose</td>
</tr>
<tr>
<td>FFD</td>
<td>Film Focus Distance</td>
</tr>
<tr>
<td>FFP</td>
<td>Filtering Face Piece</td>
</tr>
<tr>
<td>GB</td>
<td>Great Britain</td>
</tr>
<tr>
<td>GBCA</td>
<td>Gadolinium-Based Contrast Agents</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>HDR</td>
<td>High Dose Rate</td>
</tr>
</tbody>
</table>
HPLC  High Performance Liquid Chromatography
IAEA  International Atomic Energy Authority
ICRP  International Commission on Radiological Protection
IG  Information Governance
IGRT  Image Guided Radiation Therapy
IMRT  Modulated Radiation Therapy
IOTA  International Ovarian Tumour Analysis
IPEM  Institute of Physics and Engineering in Medicine
IRMER  Ionising Radiation Medical Exposure Regulations (UK)
IRR  Ionising Radiation Regulations (UK)
ISO  International Organisation for Standardisation
ITT  Invitation To Tender
IVC  Intravenous Contrast Media
KeV  kiloelectric volt
KVp  Kilo Volage Peak
LBD  Light Beam Diaphragm
LDR  Low Dose Rate
LINAC  Linear Accelerator
LOLER  Lifting Operations and Lifting Equipment Regulations
LPA  Laser Protection Adviser
LPS  Laser Protection Supervisor
mCi  Millicurie
MEGAN  Model of Emissions of Gases and Aerosols from Nature
MHRA  Medicines and Healthcare Products Regulatory Agency
MI  Molecular imaging
MPE  Medical Physics Expert
MRI  Magnetic Resonance Imaging
MRI-LINAC  Magnetic Resonance Imaging Guided Linear Accelerator
MRT  Molecular Radiotherapy
MSDS  Material Safety Data Sheets
mT  miliTesla
NHS  National Health Service (UK)
NM  Nuclear Medicine
NMMI  Nuclear Medicine Molecular Imaging
OEM  Original Equipment Manufacturer
OJEC  Official Journal of the European Community
PACs  Patient Archive and Communication System
PET-CT  Positron Emission Tomography- Computerised Tomography
PGD  Patient Group Directions
POM  Prescription of Medicines
PPE  Personal Protective Equipment
PPM  Planned Preventative Maintenance
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PQQ</td>
<td>Pre-Qualification Questionnaire</td>
</tr>
<tr>
<td>PUWER</td>
<td>Provision and Use of Work Equipment Regulations</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QC</td>
<td>Quality control</td>
</tr>
<tr>
<td>RADS</td>
<td>Reporting and Data Systems</td>
</tr>
<tr>
<td>RAG</td>
<td>Relative Risk Rating</td>
</tr>
<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
</tr>
<tr>
<td>RCR</td>
<td>Royal College of Radiologists</td>
</tr>
<tr>
<td>RF</td>
<td>Radio Frequency</td>
</tr>
<tr>
<td>RIS</td>
<td>Radiology Information System</td>
</tr>
<tr>
<td>RPA</td>
<td>Radiation Protection Advisor</td>
</tr>
<tr>
<td>RPS</td>
<td>Radiation Protection Supervisor</td>
</tr>
<tr>
<td>RTP</td>
<td>Radiation Treatment Planning</td>
</tr>
<tr>
<td>RWA</td>
<td>Radioactive Waste Advisor</td>
</tr>
<tr>
<td>SAFRON</td>
<td>Safety in Radiation Oncology</td>
</tr>
<tr>
<td>SAR</td>
<td>Specific Absorption Rate</td>
</tr>
<tr>
<td>SBRT</td>
<td>Stereotactic Body Radio Therapy</td>
</tr>
<tr>
<td>SCoR</td>
<td>Society and College of Radiographers</td>
</tr>
<tr>
<td>SFI’s</td>
<td>Standing Financial Instructions</td>
</tr>
<tr>
<td>SNR</td>
<td>Signal to Noise Ratio</td>
</tr>
<tr>
<td>SOPs</td>
<td>Standard operating procedures</td>
</tr>
<tr>
<td>SPECT</td>
<td>Single Photon Emission Computed Tomography</td>
</tr>
<tr>
<td>SRS</td>
<td>Stereotactic Radiosurgery</td>
</tr>
<tr>
<td>T</td>
<td>Tesla</td>
</tr>
<tr>
<td>TQM</td>
<td>Total Quality Management</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>UM</td>
<td>Unit Manager</td>
</tr>
<tr>
<td>VMAT</td>
<td>Volumetric Modulated Arc Therapy</td>
</tr>
<tr>
<td>WEL</td>
<td>Workplace Exposure Limits</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
<tr>
<td>WRMSDs</td>
<td>Work-related musculoskeletal disorders</td>
</tr>
</tbody>
</table>
31. References

2. International Atomic Energy Agency. Radiation Protection and Safety of Radiation Sources: International
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4. IAEA Traits accessed 2021-03-31 https://www.iaea.org/newscenter/news/iaea-issues-harmonized-model-for-
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18. Radiology Consulting and Accreditation Services | NationalRad
19. UKAS : Imaging Service Accreditation
20. Donation of Medical Imaging Equipment | ISRR
21. In which countries is CE marking required? – Clever Compliance Support - Compliance system and CE marking
   information (ce-check.eu)
22. Medical X-ray Imaging | FDA

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