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ACC-CD-37-01

Criteria for the Accreditation of Medical Diagnostic Imaging Facilities

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1 Background Information

1.1 Process Overview

This guidance document specifies the accreditation criteria for medical diagnostic imaging facilities seeking accreditation from KENAS. It is intended that after four years and on a need basis the content of this document will be revised.

1.2 Purpose

This guidance document has been prepared by a technical working group for medical diagnostic imaging facilities and authorized for adoption by KENAS. It supplements ISO 15189 standard and provides specific additional guidance on accreditation requirements for use by KENAS assessors and medical diagnostic imaging facilities.

1.3 Scope

This document covers the application of ISO 15189 for accreditation of the following groups of medical diagnostic Imaging modalities.

a) General Radiography
b) Fluoroscopy:
c) Mammography,
d) Dental radiography
e) Computed Tomography (CT) scanning
f) Ultrasound
g) Magnetic Resonance Imaging (MRI)
h) Nuclear medicine and Positron Emission Tomography scanning (PET),
i) Interventional radiology
j) Teleradiology

The criteria in this document will be applied in conjunction with those in the Assessor Guide and Terms of Reference ACC-CD-02-01, procedure for Management and Reporting of Assessments ACC-PR-07-01, Sampling during Assessment and Internal Audits ACC-PR-03-01, Policy for Management of Extraordinary Events PL-13-01, Policy for dealing with objection of assessors/experts PL-30-01 and the relevant ILAC Mandatory Documents. Accreditation shall be on the basis of demonstrated competence of the diagnostic imaging services in accordance with the requirements of ISO 15189.

1.4 Roles and Responsibilities

Role	Responsibility
Medical Department KENAS	Process owner
Manager Medical KENAS	Reviewer
Chief Manager Testing KENAS	Recommender

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Role	Responsibility
Chief Executive Officer	Approval
Medical Diagnostic Imaging Service Providers	Compliance

2 Terms and Definitions

For the purpose of this guidance document, the following terms and definitions shall apply in addition to those given in ISO 15189, ISO/IEC 17000 and the Kenya Accreditation Service Act 2019.

2.1 Acronyms and Abbreviations

CME	Continuing Medical Education
CPR	Cardiopulmonary resuscitation
EMCA	Environmental Management and Co-ordination Act
KENAS	Kenya Accreditation Service
KNRA	Kenya Nuclear Regulatory Authority
KMPDC	Kenya Medical Practitioners and Dentists Council
KW	Kilowatt
MHz	Megahertz
MRI	Magnetic resonance imaging
NM	Nuclear Medicine
OHSAS	Occupational Health and Safety Assessment Series
POCUS	Point of Care Ultrasound
PET	Positron Emission Tomography
RMI	Risk of Malignancy Index
RPNSD	Radiation Protection and Nuclear Science Department
RSO	Radiation Safety Officer
SPECT	Single Photon Emission Computed Tomography

2.2 Definition of Terms

2.2.1 Accreditation

Third-party attestation related to a conformity assessment body conveying a formal demonstration of its competence to carry out specific conformity assessment tasks.

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2.2.2 Scope of Accreditation

The specific conformity assessment services for which accreditation is sought or has been granted.

2.2.3 Imaging

The action or process of producing an image especially of a part of the body by medical imaging techniques.

2.2.4 Technical area

This is an area characterized by similar activities, products or services and the related environmental aspects.

2.2.5 Technical Competence

Documented ability to apply knowledge and skills for medical diagnostic imaging.

2.2.6 Radiologist

Specialist medical doctors diagnose, treat and prevent illness, disease, injury and other physical and mental impairments using specialized testing, diagnostic, medical , surgical, physical and psychiatric techniques, through application of the principles and procedures of modern medicine. They plan supervise and evaluate the implementation of care and treatment plans by other healthcare providers. They specialize in certain disease categories, types of patient or methods of treatment, and may conduct medical education and research activities in their chosen areas of specialization.

2.2.7 Radiographer

Medical imaging and therapeutic equipment technicians test and operate radiographic, ultrasound and other medical imaging equipment to produce images of body structures for the diagnosis and treatment of injury, disease and other impairments. They may administer radiation treatments and monitor patients' conditions under the supervision of a radiologist or other health professional.

2.2.8 Radiation Safety Officer

This is a designated individual responsible for ensuring the safe use and management of radiofrequency (RF) radiation and other non-ionizing radiation sources within an organization.

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3 Criteria

3.1 General Requirements

All assessments are done in accordance with ISO 15189 requirements. Applicable KENAS documents are accessible on the KENAS Website.

3.2 Personnel

3.2.1 The personnel in medical diagnostic facilities shall include but not be limited to:

a) Radiologist
b) Radiographer
c) Radiation Safety Officer

3.2.2 The examinations shall be performed under the supervision of one of the following, as required in the Health Act of 2017, Kenya Medical Practitioners and Dentists Act (Cap 253) and Radiographers Act (Cap 28) of 2022

a) The supervising specialist in charge of the facility shall be identified.
b) The supervising specialist shall be a medical practitioner registered with the KMPDC as a specialist in the field of diagnostic radiology as recognized by the Ministry of Health.
c) The supervising specialist shall demonstrate competency in radiology services by having completed one of the following:
    i) Completed a radiology training programme which included a specific curriculum in radiology services (MMed. Master of medicine),
    ii) Completed at least 12 months of radiology working under supervision by a qualified radiologist,
    iii) Demonstrated clinical experience in supervision and interpretation of images.
d) As evidence of continuing competence in the interpretation and reporting of these examinations, the supervising practitioner should have CPD in accordance with KMPDC.

3.2.3 Medical Imaging Facilities are to comply with the Medical Practitioners and Dentists Act (Cap 253) and Radiographers Act (Cap 28) of 2022, Kenya Nuclear Regulatory Authority Act No 29 of 2019 the subsidiary regulations.

3.2.4 The requirements pertaining to personnel working in different modalities within diagnostic medical imaging are as below:

3.2.4.1 Mammography

a) **Supervising Specialists** – Is a radiologist or a breast imaging specialist as licensed by KMPDC, and requisite competence as demonstrated by annual peer review of the mammographic images and reports.

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b) **Radiographer/ Mammography technologist** – All Radiographers/ Mammography technologists shall have completed a training programme approved by the Head of Department or supervising specialist. The Radiographer / Mammograph technologist should participate in yearly Continuing Medical Education relevant and appropriate to mammography examinations. (refer to Mammography quality standards) by SER/ ACR.

3.2.4.2 Ultrasound

a) **Supervising Specialists** – Is a radiologist licensed by KMPDC and requisite competence as demonstrated by annual peer review of the ultrasound images and reports.
b) **Ultrasonographer / Sonographer** – All Ultrasonographers /Sonographers shall complete a training programme possess an advanced diploma or higher qualification in Ultrasound. The Ultrasonographer / Sonographer should participate in yearly Continuing Medical Education relevant and appropriate to Ultrasound imaging.

3.2.4.3 MR Imaging

a) **Supervising Specialists** – Is a radiologist licensed by KMPDC and requisite competence as demonstrated by annual peer review of the MR images and reports.
b) **MR Radiographer** – All MR Radiographers shall have completed a minimum of 6 months on the job training programme or possess an MSc in MRI or cross-sectional imaging. The MR Radiographer should participate in yearly continuing medical education relevant or appropriate to MRI. MRI safety training shall be provided for all staff accessing the MRI area.

3.2.4.4 CT Scanning

a) **Supervising Specialists** - Is a radiologist licensed by KMPDC and requisite competence as demonstrated by annual peer review of the CT images and reports.
b) **CT Radiographer** – All CT Radiographers shall complete a minimum of 6 months training programme or possess an MSc in CT or cross-sectional imaging. He/she shall also possess a valid License according to the Act. The MR Radiographer shall participate in continuing medical education with at least 10 hours relevant or appropriate to CT imaging.

3.2.4.5 Nuclear Medicine

a) **Supervising Nuclear Medicine Specialist** - The supervising Nuclear Medicine Specialist shall be certified and licensed by the Kenya Medical Practitioners and Dentists Council.

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b) **Nuclear Medicine Radiographer** - Nuclear Medicine Radiographers shall complete a minimum of 6 months training programme in nuclear medicine after completion of a diploma or degree in radiography or possess a degree in Nuclear Medicine or a Master of Science in Nuclear medicine. He/she shall be licensed to practise by KNRA. The Nuclear Medicine Radiographer should participate in continuing medical education with at least 10 hours relevant or appropriate to Nuclear Medicine.

3.2.4.6 General Radiography

a) **Supervising Specialist** - Is a radiologist licensed by KMPDC and requisite competence as demonstrated by annual peer review of the radiographic images and reports.
b) **Radiographer** - All radiographers shall possess a recognised diploma or degree in radiography. Radiographers shall participate in continuing medical education with at least 10 hours per relevant or appropriate to this field.

3.2.5 The following details are the requirements of other personnel working in a radiology service as applicable:

a) **Nurses**: Nurses working in the radiology department of the facilities shall hold current license with the Kenya Nursing Council.
b) **Anaesthesiologist /Anaesthetist**: Staff administering general anaesthesia shall have the relevant current licenses from the respective licensing body.
c) **Health information officer**: Shall have the relevant qualification to manage patient information.
d) **Medical physicist**: Shall have the relevant qualification.
e) **Biomedical Engineer**: Shall have relevant qualification.

3.2.6 Each facility should exercise supervision of the staff for compliance with the ISO 15189 requirements. In general, the supervision entails the following:

a) Each facility must have one or more supervising radiologists whose overall responsibility shall be:
   i) Running the facility,
   ii) Supervising the staff, and
   iii) Setting standards within the facility, including ensuring that the examinations are performed by suitably qualified radiographers, and assuring the quality of the images and reports.
b) All radiologists must have the responsibility for:
   i) Reviewing clinical indications for examinations (justification),
   ii) Specifying the use and dosage of contrast agents, specifying the imaging protocol for the procedure.
   iii) Ensuring the quality of both the images and interpretations.
c) All radiographers must have the responsibility for:

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i) Implementation of the protocols and appropriate dosage of contrast agents.
ii) Ensuring the optimization of the imaging examinations.

d) Nuclear medicine physician (NMP) shall be responsible for all components of nuclear medicine service including:
   i) Determining the appropriateness of and monitoring the quality of the procedures,
   ii) Ensuring all procedures are performed as per protocol including dosimetry and acquisition parameters
   iii) Maintain all necessary licenses for the use and storage of each radionuclide,
   iv) Ensuring all nuclear medicine equipment are in good working condition through performance of requisite QCs and PMs.
   v) Supervise maintenance of necessary logs of radiopharmaceuticals and nuclear medicine equipment
   vi) Assessing and influencing the outcome of the procedures, and
   vii) Providing a final scan report.
   viii) Determining appropriateness and administering radionuclide therapy
e) Nuclear medicine technologists shall be responsible for the following:
   i) Preparing the radiopharmaceuticals and administering them to patients for imaging or treatment under the guidance of the NMP
   ii) Implementation of the protocols and appropriate dosage of radiopharmaceuticals.
   iii) Ensuring the optimization of the imaging examinations in conjunction with the nuclear medicine physician and medical physicists.
   iv) Perform required Quality control tests in nuclear medicine equipment
   v) Maintain appropriate radiation safety measures
f) Radiation Safety Officer: Each facility shall appoint a Radiation Safety Officer (RSO). The RSO is responsible for ensuring radiation safety and compliance with National regulations and conditions of the license.
   i) Radiation monitoring of all radiation workers and maintaining records to ensure radiation safety in the workplace,
   ii) Ensuring the facility is complying with applicable regulatory requirements.
   iii) Initiate process of investigating any radiation incidents & accidents involving either patient(s) or staff and notify the authorities.
   iv) Ensure appropriate sourcing, storage, use and disposal of radiation materials.

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3.2.7 Supervision of Trainees as applicable

a) A qualified specialist shall be available to provide appropriate on-site supervision of trainees at all times in-hours and be available to provide advice and backup at all times out-of-hours.
b) The facility shall retain documentation of all trainees including but not limited to identification badges, engagement record, qualification, training and radiation monitoring records.

3.3 Accommodation and Environmental Conditions

3.3.1 All medical imaging facilities shall provide for at least the following areas where applicable:

a) Patient waiting area/ reception,
b) Patient education/ preparation areas,
c) Screened patient changing area/ cubicle(s) with access control,
d) Signage in all rooms in the facility with specified signage for restricted areas (radiation/ MRI),
e) Equipment console and operating areas,
f) Facilities for the performance of administrative duties,
g) Film viewing and reporting areas,
h) Temperature and humidity control,
i) Resuscitation and Revival Equipment,
j) Facilities for data storage,
k) Areas for storage of equipment accessories and consumables,
l) Provision for the safe emergency exit, and

3.3.2 Radiology Safety:

3.3.2.1 Legislation Pertaining to Radiation Safety

Practices shall comply with applicable national, regional and international safety standards and legislation: Nuclear regulatory Act No.29 of 2019, (SSG-46), IAEA safety standards etc

3.3.2.2 As a minimum, the diagnostic imaging facility shall demonstrate the following:

a) Valid license from Kenya Nuclear Regulatory Authority
b) Radiation shielding and protection of patients, staff, public and premises,
c) Installation of warning lights and appropriate signage,
d) Use of protective and monitoring devices,
e) Adherence to dose and exposure limits for radiation workers, staff and members of the public with appropriate documentation.

3.3.3 The facility shall have documented safety policies and/or procedures.

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3.3.4 Specific Requirement for Magnetic Resonance Imaging:

3.3.4.1 As a minimum the facility shall:

a) Demonstrate exclusion of the general population outside the 5 Gauss line
b) Have appropriate warning signs (MRI safety signs), and
c) Have patient changing area/cubicles with access control,
d) Have an MRI checklist and consent form
e) Document policies/procedures to handle MRI accidents and incidents.
f) Have an intercom system.

3.3.4.2 All equipment in the MRI imaging facility shall be MRI-compatible.

3.3.5 Specific Requirement for Nuclear Medicine:

3.3.5.1 As a minimum the facility shall have:

a) Appropriate procedures and resources for handling accidents involving radioactive materials and for subsequent decontamination must be available.
b) Radiation monitoring equipment for the detection of contamination and radiation exposure levels must be available.
c) Materials presenting a hazard of airborne transport should be handled in fume hoods.
d) Provisions for emergency eyewash should be available, clearly identified and appropriately labelled.
e) Suitable protective clothing/ equipment such as eye protective devices, impervious aprons should be available.

3.3.5.2 There should be provisions for flushing materials from the skin rapidly in the event of accidental splashing.

3.3.5.3 Nuclear Medicine facility will be expected to adequately provide for at least the following specialist items/facilities relevant to the accommodation of NM imaging equipment:

a) Radioisotope preparation and storage (“hot laboratory”) facilities,
b) Personnel decontamination facilities,
c) Radioactive waste disposal facilities,
d) Controlled access to the hot lab and imaging room with appropriate signage,
e) Communication with the patient being examined, and
f) Sedation and general anaesthesia facilities where indicated.

3.3.5.4 For facilities offering radionuclide therapy, in addition to above, they should have:

a) Clear protocols on radionuclide treatment including indications, dose, mode of administration and patient follow-up

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b) Guidelines on radiation safety to ensure minimisation of radiation exposure to health workers and the public
c) For out-patient treatment, guidelines on permissible maximum dose to be administered as an out-patient
d) For in-patient treatment of high dose therapy, a therapy room meeting all radiation safety requirements and licenced by KNRA

3.3.6 Specific Requirement for Interventional Radiology:

3.3.6.1 As a minimum the facility shall have:

a) Have appropriate warning signs (radiation safety signs) as applicable
b) Have patient changing area/cubicles with access control,
c) Have a time out checklist and consent form. The time out checklist shall include patient identifiers, the procedure to be carried out, signed consent form, site of the procedure, operator identification as a minimum.
d) Document policies/procedures to handle emergencies.

3.4 Equipment

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

a) Purchase, usage, and replacement.
b) An inventory;
c) Appropriate checks before use;
d) Quality control;
e) Maintenance, particularly with respect to safety and infection control;
f) Data protection and backup.

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

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

a) Imaging equipment and modalities;
b) Software and hardware for digital imaging and teleradiology;
c) Auxiliary imaging equipment such as viewing devices and contrast pumps;
d) Quality assurance phantoms and dosimetry equipment;

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3.4.4 The replacement of imaging equipment shall be consistent with the appropriate regulatory requirements for radiation safety.

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

a) Medical support equipment such as wheelchairs and trolleys.
b) Medical equipment for resuscitation, anaesthesia and sedation, and monitoring.
c) Administrative equipment such as computers, printers, and software.

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

a) Plain radiography;
b) Fluoroscopy;
c) Image guided interventional procedures.
d) Mammography;
e) Computed tomography;
f) Dental radiography;
g) Ultrasonography;
h) Magnetic resonance imaging;
i) Dual energy X ray absorptiometry (DXA).
j) Screen–film systems and cassettes

3.4.7 Equipment inventory

3.4.7.1 All types of facility equipment should be recorded in a comprehensive equipment inventory. Recorded information for each piece of equipment shall include (as applicable):

a) Name, manufacturer, and serial number or other identifier;
b) Dates of acquisition and installation;
c) Instruction manual;
d) Acceptance performance or validation documentation;
e) Maintenance contract, and maintenance and safety testing records;
f) Quality control, calibration and corrective action records;
g) Service records;
h) Manufacturer’s specification and any modifications.

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

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3.4.8 Quality assurance processes for imaging equipment

3.4.8.1 Selection of equipment

a) The first step in good QC of equipment is the selection of high-quality equipment appropriate for the required clinical imaging procedure.
b) Selection of equipment shall be undertaken by a team of senior staff, including a specialist radiological medical practitioner, a senior radiographer and a medical physicist. This process shall involve the drafting of equipment specifications, a tender process and evaluation of the resulting tenders.
c) Fundamental considerations for equipment specifications shall include:
    i) Site requirements and room design;
    ii) Radiation shielding (or magnetic and radiofrequency shielding for MRI units);
    iii) Technical specifications for equipment performance;
    iv) Image quality requirements;
    v) Patient dose implications;
    vi) Equipment ergonomics;
    vii) Economic considerations, including the cost of purchase and installation, and the ongoing costs for maintenance and supplies;
    viii) Availability and quality of service and maintenance;
    ix) Integration into a digital environment;

3.4.9 Acceptance testing and the setting of baseline values.

3.4.9.1 Acceptance testing assures the purchaser that new equipment meets the standards specified before purchase.

3.4.9.2 Acceptance testing will be done by the medical physicist and/or by the vendor engineers under the supervision of the medical physicist, as appropriate.

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

3.4.9.4 The establishment of baseline values as part of equipment commissioning ensures that effective standards are established for QC testing of the equipment. There shall be a documented protocol for acceptance testing and baseline measurements, and each piece of equipment shall have an acceptance and commissioning report that is available for the life of the equipment.

3.4.10 Routine quality control testing

Each equipment modality and piece of associated auxiliary equipment shall have an appropriate QC system in place that evaluates equipment performance, stability and safety, as well as image quality. Quality control tests shall be carried out regularly, after major repair

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or maintenance procedures, and whenever a change of performance is suspected. These systems shall be documented in a written protocol and include the following elements:

a) The persons responsible for performing and evaluating tests;
b) The required QC test equipment;
c) The minimum frequency of regular QC tests;
d) The test procedures:
    i) Equipment QC tests,
    ii) Reject analysis,
    iii) Review of radiographic technique.

3.4.11 Routine quality control testing

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

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

3.4.12 Equipment replacement policy

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

3.4.12.2 Severely defective equipment must be put out of service. If only a limited number of components of the equipment are defective, the equipment may be allowed to operate in a limited capacity, provided that the overall performance of the equipment is not impaired.

3.4.12.3 Equipment with minor defects may be used for a limited period until repair is possible, as long as its use does not significantly degrade image quality or create a significant hazard to patients or staff.

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

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3.4.13 Instrumentation and calibration

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

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

3.4.13.3 The facility should have a calibration policy and a record of equipment calibration and equipment cross-checks.

3.5 Standard Operating Procedures (SOPs)

3.5.1 The diagnostic imaging facilities shall have documented SOPs for all procedures in the facility

3.5.1.1 Pre- Examination activities include:

a) Examination request form by Registered Healthcare Professionals. The facility shall define the procedures for handling all requests (oral, written, electronic, On presentation, patient identification and details shall be verified. Discrepancies on the request/ referral forms must be shall and a record kept of the outcome shall be maintained)
b) Patient identification
c) Justification
d) Consent can be oral or written as applicable. At a minimum, consenting shall include;
    i) The procedure
    ii) Previous contrast reaction if any
    iii) Allergies
    iv) Last menstrual period
    v) Specialized procedures refer on additional requirements
    vi) Potential risks

3.5.1.2 Examination

3.5.1.3 Post examination including discharge procedures

3.5.1.4 Infection Control

3.5.1.5 Medication management

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3.5.1.6 Patient Identification

a) There shall be procedures to ensure that every report and image are correctly identified with patient's name, age, date of examination, hospital or x-ray number at a minimum.
b) All records relating to any given patient shall be correctly identified through all stages of the procedure. Such records shall include worksheets, checklists, films, consent forms etc.

3.5.1.7 Patient Needs Assessment

3.5.1.7.1 The written or electronic request, originated from attending medical practitioner or licensed healthcare professional involved in patient clinical management shall provide adequate clinical information to show the necessity of the examination and enable appropriate interpretation of result.

3.5.1.7.2 Information relevant to the studies may include allergies, pregnancy status and previous studies. Additional specific information shall be obtained and recorded prior to patients undergoing special examinations such as MRI, angiography, interventional procedures – Check pre- examination activities

3.5.1.8 Patient Infection Control

3.5.1.8.1 The use of multi-dose vials of contrast media or radiopharmaceuticals is acceptable if the following procedures are used:

a) Withdrawal of contrast media or radiopharmaceuticals under strict aseptic conditions,
b) Use of new needles and syringes for re-entering vials even for the same patient's use
c) Discarding of any contrast media or radiopharmaceuticals beyond their expiration time.
d) Date and time of first use is clearly indicated on the bottle/vial.

3.5.1.9 Patient Preparation for Interventional Radiology

3.5.1.9.1 Adequate provision must be made for patient preparation and observation post-procedure. This may be within the radiology department, a short stay unit or in the hospital wards.

3.5.1.9.2 Personnel, equipment and facilities shall be available for emergency resuscitation.

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3.5.1.10 Patient Safety

3.5.1.10.1 Female patients of childbearing age shall be asked if they are pregnant. If they are pregnant, the specialist shall decide whether to proceed with the procedure. If the specialist decides to proceed, the patient shall be advised of the risk involved, consent given, and documented evidence shall be available.

If the patient is suspected to be pregnant, the pregnancy status should be confirmed either by a serum pregnancy test and/or pelvic ultrasound examination.

3.5.1.10.2 Diagnostic Mammography

The average glandular dose as determined by the supervising specialist must not exceed 2mGys (200mrads) per view, using the RMI-156 phantom or another equivalent constitution-specific dose.

3.5.1.10.3 Fluoroscopy

A log of screening times and radiation dose for all fluoroscopic examinations shall be kept.

3.5.1.10.4 MRI

a) All personnel in the MRI suite shall be trained in MRI safety procedures and administration of the MRI checklist
   All patients, their attendants and healthcare professionals shall be screened prior to accessing the MRI suite.
b) An appropriately equipped MRI-compliant emergency cart shall be immediately available to treat serious adverse reactions and for resuscitation in case of respiratory or cardiac arrest within the MRI suite.

3.5.1.10.5 Nuclear Medicine

a) Instructions shall be given to the patient and their attendants regarding the radiation doses, half-life of the radiopharmaceutical and radiation safety, safe disposal of any radioactive physiological body effusions such as breast milk, urine and excreta for all radiopharmaceuticals used either for diagnosis or therapeutic purposes. Special wards, waiting rooms and toilets shall be provided as appropriate after administration of the radiopharmaceutical.
b) Appropriate procedures regarding pregnant and breastfeeding patients shall be observed, including warning signs, verbal enquiry and the issue of special instructions to the patient when required.

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3.5.1.11 Patient preparation:

3.5.1.11.1 All procedures must reflect best and safe practice.

3.5.1.11.2 Aseptic techniques shall be followed.

3.5.1.11.3 When a procedure is modified in the best interests of a patient, the modification must be approved by the supervising specialist and documented noted in the patient's record and in the report.

3.5.1.11.4 Policies shall be in place, documented and approved by the supervising specialist.

3.5.1.12 Administration of Radionuclides:

3.5.1.12.1 The activity of the radioactive material to be dispensed for administration to patients shall be calculated according to an established protocol.

3.5.1.12.2 The activity of radioactive material to be administered to each patient shall be measured just prior to administration.

3.5.1.12.3 The standard activity of radioactive material administrated for each procedure must be established and recorded in the procedure manual.

3.5.1.13 Handling of Radioactive Substances:

3.5.1.13.1 Appropriate procedures must be maintained for the identification of radiation areas and the receipt, storage and disposal of radioactive substances.

3.5.1.13.2 The facility must possess radiation safety and radioactive waste manuals, which stipulates the proper use, handling and disposal of radioactive substances.

3.5.1.14 Requirements on Radiopharmaceuticals:

3.5.1.14.1 Onsite refers to the preparation of radiopharmaceuticals at the facility. Off-site refers to sites where radiopharmaceuticals are utilised only.

3.5.1.14.2 For radiopharmaceuticals prepared on-site:

a) The volume and quantity of radioactivity eluted from the generator/vial must be measured and recorded with suitable precautions taken to minimise personnel exposure during such measurements,
b) Each batch of the generator must be checked for the breakthrough of the parent nuclei,
c) Preparations must be prepared according to product labelling or documented procedures established in-house,
d) Aseptic procedures must be used when handling all components and preparations for potential parenteral or ophthalmic administration,

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e) Radiopharmaceutical purity and labelling efficiency must be checked routinely,
f) Reagent kits and prepared radiopharmaceuticals must be stored according to established criteria or according to instructions specified by the kit insert (e.g. product labelling).

3.5.1.14.3 Patient identification must be verified prior to onsite or off-site administration of radiopharmaceuticals.

3.5.1.14.4 Appropriate records must be maintained of the following:

a) Radiopharmaceutical receipt,
b) Radiopharmaceutical preparation,
c) Radiopharmaceutical disposal,
d) Adverse reactions to radiopharmaceuticals,
e) Misadministration and other recordable events, and
f) Actions taken in response to problems identified in any areas

3.5.1.15 Blood Products:

3.5.1.15.1 For radionuclide tagging of blood and blood products performed on-site

a) Only one patient's blood shall be processed at a time,
b) Only one specimen shall be handled at a time to avoid the hazards associated with handling blood and the risk of swapping samples,
c) Blood shall be processed in aseptic conditions,
d) Tagging procedures shall be standardised in-house, documented and followed,
e) Tagging efficiency and other quality control criteria including stability shall be established
f) Tagged products shall satisfy the required standard before being administered to patients unless otherwise determined by the supervising specialist.

3.5.1.15.2 There may be instances where standard protocols/ procedures will need to be amended to accommodate to presenting features and/ or clinical details. In such cases, these amended practices shall be approved by the specialist, and facilities must keep a record of the approval to deviate from the standard documented protocols and the changes adopted.

3.5.1.15.3 Any changes adopted should offer benefit to the patient over those currently in use.

3.5.1.15.4 Appropriate records must be maintained of the following

a) Tagging of patient blood and blood products,
b) Adverse reactions to tagged product,

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c) Misadministration and incidence, and
d) Actions taken in response to any problems identified.

3.6 Examination procedures

3.6.1 Medical Imaging protocols shall be documented describing the performance of all procedures performed by the practice. These protocols shall include all necessary information including that for:

a) Patient education and management,
b) Imaging procedures appropriate to specific clinical indications,
c) Deviations from standard imaging protocols,
d) Operation of equipment,
e) Quality control procedures,
f) Necessary remedial action e.g. adverse event management,
g) Record-keeping
h) Safety issues/ Precautionary issues.

3.6.2 Manuals and documents shall be maintained for all Medical Imaging procedures. The procedure manual should include each procedure performed:

a) A summary of patient conditions that may affect the interpretation of the imaging procedure (e.g. Posture, time and content of previous drug dosage, diet, time of day),
b) A description of any special quality assurance measures specific to the particular procedure, and
c) A definition of quality control limits, if appropriate and instructions on any preliminary actions to be taken in case of deviation from the acceptable limits before referring the problem to the supervising specialist

3.6.3 All medical imaging services shall hold, have direct access to, a comprehensive range of current specialist text books, scientific journals and other reference literature appropriate and relevant to the scope of activities of the facility in either hard or soft copy formats.

3.6.4 All images, raw data and quality control data shall be stored for a minimum of 5 years.

3.6.5 A daily log or equivalent record of all patients' studies must be retained according to the appropriate statutory requirements or for a minimum of 3 years whichever is longer.

3.6.6 The following must be recorded either in one consolidated patient record or practice records:

a) Patient's name, Identification number and any other satisfactory identifiers
b) Requesting practitioner's name,

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c) Type of imaging procedure performed as identified in the practice procedure manual and, where necessary, an explanation of any modification to the procedure,
d) Type, activity, route of any substance (such as contrast agents, radiopharmaceutical) administered to the patient,
e) Name of technologist and specialists performing the procedure,
f) Date of procedure,
g) Description of findings,
h) Identification of the responsible specialist.

3.6.7 Where technical data applicable to a group of patients' studies is not recorded in individual patients' records, there must be sufficient cross-referencing to enable that data to be retrieved for a specific patient study if required.

3.6.8 Drugs used for sedation and further management shall be recorded in the patient's medical record, along with times of administration and details of any adverse reaction.

3.6.9 All studies shall have representative images recorded which shall be available to the referring doctor. The records shall have patient identification, the date and, where necessary, time of the study and the practice name (and preferably the site) imprinted on them. The identity of the person who performed the study must be available either on the image or other associated records such as the worksheet, request form, etc.

3.6.10 The labelling of medical images must be sufficiently comprehensive to ensure that they be unequivocally traced to the patient and to enable their interpretation. Films must be labelled with a permanent identification label, preferably a "flash" label, rather then a stick-on label which details:

a) Practice name,
b) Site name,
c) Patient's full name,
d) Patient identification, and
e) Examination date.

3.6.11 Documented policies and practices must follow all radiation safety policies and procedures according to appropriate legislation, which aims to minimize radiation exposure. Documented policies and procedures must be available for the safe use of radionuclides and ionising radiation for medical imaging.

3.6.12 Policies and procedures for all infection control issues including sterilization/disinfection must be documented.

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3.6.13 Documented policies and procedures must be available for the safe disposal of contaminated/ medical and radioactive waste which must be in accordance with relevant regulations.

3.6.13.1 Specific Documentation Requirement for Mammography

3.6.13.1.1 Radiopaque markers indicating laterality (R/L) and projection/ view (MLO/CC):

a) Placed near the aspect of the breast closest to the axilla,
b) Placed on the cassette so they can be read from overhead, and
c) Large enough to be clearly readable without being distracting.

3.6.13.1.2 Cassette/ screen must be uniquely identified on screen to identify screens with artefacts or defects.

3.6.13.1.3 With the exception of the markers indicating laterally and view, all labels must be placed as far from the breast as possible.

3.6.13.2 Specific Documentation Requirement for Nuclear Medicine

3.6.13.2.1 For Nuclear Medicine, the following information shall be included for Anger-type gamma cameras and PET/CT scanners (unless the following information is described in the procedure manual):

a) Camera identification,
b) Collimator type,
c) Window settings for each radionuclide imaged, Patient orientation (e.g. Supine, sitting, etc),
d) View obtained, including orientation of detector, if relevant, and number of heads used for multi-head cameras,
e) Total image counts, and
f) time required to record image.

3.6.13.2.2 For other instruments such as multi-head cameras, thyroid uptake probes etc. appropriate data analogous to those described for single-crystal cameras.

3.6.14 A documented policy must be available for the wearing of proper radiology attire that includes lab coats, footwear, scrubs, requirements for Operating Theatre (OT), angiography, etc.

3.6.15 Provision of resources shall be listed for devices that are MRI compatible.

3.7 Ensuring quality of examination results

3.7.1 At the time of installation (as part of the commissioning procedure) and after major maintenance or software upgrades, quality control procedures shall be performed.

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3.7.2 Quality control procedures shall be performed regularly in accordance with manufacturer's recommendations.

3.7.3 Criteria used for the assessment of quality control results and the action to take in the event of unacceptable results shall be documented.

3.7.4 A record shall be kept of corrective action taken in response to unacceptable quality control results and shall include;

a) Equipment evaluation,
b) Suspension of patient measures, and
c) Reanalysis of quality control data.

3.7.5 Digital radiographic devices shall provide images that conform to the DICOM standard.

3.7.6 Details of image acquisition such as kVp, mAs, Patient ID, radiology facility, site, side of study and exposure indicators should be recorded in the DICOM. Exposure indicators should be monitored in a regular basis.

3.7.7 As a minimum quality check, a test image such as AAPM TG18-QC test pattern should be captured, transmitted, archived, retrieved and displayed at appropriate intervals.

3.7.8 As a test of display fidelity, TG18-QC pattern data files sized to occupy the full area used to display images on the monitor should be displayed. As a dynamic range test, both the 5% and 95% areas should be seen as distinct from the respective adjacent 0% and 100% areas.

3.7.9 Hardcopy imager accuracy and stability testing should also be performed and documented.

3.8 Post-examination Processes

3.8.1 The facility shall have a written policy and procedure on record retention.

3.8.2 Written policy and procedures shall be in place to ensure continuity of care, include internal redundancy systems, backup telecommunication links, disaster recovery and business continuity plane.

3.8.3 When reports and images are stored electronically, the facility shall have mechanism to ensure the image medium is readable at all ages and labelled with the necessary patient information. Media, such as CD, DVD, USB media, shall be stored in a way to maintain its integrity throughout the retention period.

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3.8.4 It is desirable to have mechanism for secure image sharing over the internet. Procedures shall also be in place for importing images and associated information in standard DICOM from physical media and from internet.

3.8.5 Waste management and occupational safety

a) The practice is to comply with the Radiation Protection Act & Radiation Protection Regulations.
b) Regarding waste management, the practice is recommended to refer to EMCA
c) Regarding Occupational Safety, the practice is recommended to refer to OHSAS

3.9 Reporting of Results

3.9.1 Imaging service shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval.

3.9.2 Reports shall be legible, without mistakes in transcription and reported to persons authorized to receive and use medical information. The report shall also include, but not be limited to, the following:

a) clear, unambiguous identification of the examination;
b) the identification of the radiology service that issued the report;
c) name or another unique identifier of the requester and the requester's address;
d) unique identification and location of the patient, where possible, and destination of the report;
e) details of the patient and indications for examination; identification of the modality and equipment used as relevant;
f) date and time of performance of the examination of the patient by the radiology service;
g) a summary of any contrast media doses or other relevant medication used during the taking of the images reported upon;
h) findings of the examination;
i) prior examination findings where relevant;
j) interpretation of results, where appropriate;
k) other comments (e.g. condition of the patient which may have compromised the result, findings/interpretations from subcontractor radiology services);
l) date and time of release of report, which, if not on the report, shall be readily accessible when needed;
m) identification of the person authorizing the release of the report;
n) Signature or authorization of the person checking or releasing the report, where possible.

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3.9.3 The radiology service shall have procedures for immediate notification of a physician (or other clinical personnel responsible for patient care) when examination results fulfil established ‘alert’ or ‘critical’ parameters. This includes results received on patients sent to a subcontractor radiology service for examination.

3.9.4 In order that local clinical needs can be served, the radiology service shall determine their ‘alert/critical’ criteria, in agreement with the clinicians using the radiology service.

3.9.5 Records of actions taken in response to reports that fulfil ‘alert/critical’ criteria shall be maintained. These shall include date, time, responsible radiology service staff member, and person notified. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.

3.9.6 Radiology service management, in consultation with the requesters, shall establish turnaround times for each of its examinations. A turnaround time shall reflect clinical needs.

3.9.7 There shall be a policy for notifying the requester when an examination is delayed. Turnaround times as well as any feedback from clinicians in relation to them shall be monitored, recorded and reviewed by radiology service management. Corrective action shall be taken to address any problems so identified.

3.9.8 This does not mean that the clinical personnel are to be notified of all delays in an examination, but only in those situations where the delay could compromise patient care. This procedure should be developed in collaboration between clinical and radiology service personnel.

3.9.9 When examination results from a subcontracted radiology service need to be transcribed by the referring radiology service, procedures for verifying the correctness of all transcriptions shall be in place.

3.9.10 The radiology service shall have clearly documented procedures for the release of examination reports, including details of who may release reports and to whom. The procedures shall also include guidelines for the release of findings and reports directly to patients and third parties.

3.9.11 The radiology service shall establish policies and practices for ensuring that reports distributed by telephone or other electronic means reach only authorized receivers. Reports provided verbally shall be followed by a properly recorded report.

3.9.12 The radiology service shall have written policies and procedures regarding the alteration of reports. When altered, the record must show the time, date and name of the person responsible for the change. Original entries shall remain legible when alterations are made.

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3.9.13 Original electronic records shall be retained and alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.

3.10 Imaging Information systems

3.10.1 The facility shall ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care.

3.10.2 The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information shall be:

a) Validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation;
b) Documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users;
c) Protected from unauthorized access;
d) Safeguarded against tampering or loss;
e) Operated in an environment that complies with supplier specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription;
f) Maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions;
g) In compliance with national or international requirements regarding data protection.

3.11 Use of KENAS accreditation symbol on examination reports

The rules of the use of KENAS symbol are set in the *PL-54 Policy on the Use of KENAS Marks, Combined Marks and Reference to Accredited Status".*

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO 15189:2022	Medical laboratories- Requirements for quality and competence
2.	ISO 15190:2003	Medical Laboratories- Requirements for Safety
3.	N/A	Implementing The New Zealand Code of Radiology Management Practice:2011

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5 Revision/Amendment Records

Date	Version	Revised by	Reason for Revision
24/10/2024	01	SDE	Newly developed document

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