BNMS Nuclear Medicine Generic Quality Guidelines for the Provision of Diagnostic Nuclear Medicine Services

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BNMS
BRITISH NUCLEAR MEDICINE SOCIETY

Science & Technology Facilities Council

Updated by:

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Purpose

The provision of Nuclear Medicine services is challenging due to the highly complex regulatory environment the service has to work within due to its use of ionising radiation. The purpose of these guidelines is to promote adoption of best practice and establishment of high quality Nuclear Medicine services and cover aspects of effectiveness, safety and timeliness. To help manage this complexity, the introduction and use of formal quality systems to oversee the delivery of nuclear medicine services, can only be encouraged and these guidelines embrace some basic principles of quality systems.

1 Management

1.1 The service should define its operational procedures and the required staffing levels and skill mix to deliver the range of services provided.

1.2 Well-defined governance arrangements must be in place to ensure safe and effective delivery of the service.

- CQC Guidance - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 17

1.3 Quality assurance arrangements will be defined for all aspects of the service.

1.4 The service will identify, assess, mitigate and monitor risks to the service delivery.

1.5 A process will be in place for the introduction of new procedures to assess regulatory and other risks and manage capacity and training issues.

1.6 A document management system will be in place to cover all relevant documents.

1.7 A policy on the management of medicines used in nuclear medicine should be in place.

1.8 Departments must routinely audit the clinical and regulatory compliance of their services and should submit to regular external peer review, such as the BNMS Organisational Audit Programme.

1.9 Systems for continuous improvement of the service should be in place incorporating audit/review outputs and patient and staff feedback.

1.10 Where more than one partner is involved in the provision of a service, the responsibilities for, and the management structures of, the individual partners must be formally agreed and documented to ensure a cohesive service with appropriate governance.

2 Facilities/Equipment

2.1 Facilities will be suitable to support all studies performed on site, including the storage, preparation, use of radiopharmaceuticals and management of radioactive waste in line with regulatory requirements and should take account of national best practice.

2.2 Compliance of the fabric of the facilities with regulatory requirements should be audited at regular intervals.

2.3 The MPE will be involved in equipment selection and all new equipment will be commissioned before use.

2.4 Equipment will be appropriate for the level of service provided and will be maintained and serviced regularly and conform to acceptable performance criteria.

2.5 Quality control and quality assurance procedures will be carried out regularly on key equipment in line with national guidance with the results recorded and trended.

IPEM have produced several relevant reports:

- Report 111 Quality Control of Gamma Cameras and Nuclear Medicine Computer Systems
- Report 108 Quality Assurance of PET and PET/CT Systems
- Report 85 Radioactive Sample Counting - Principles and Practice (under review)
- Report 91 Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Systems

2.6 There should be a planned replacement programme for key equipment

3 Staffing/Training

3.1 Sufficient numbers of suitably qualified, competent, skilled and experienced staff must be available to deliver a safe service.

A range of guidance is available from different stakeholders -

- Royal College of Physicians - Consultant Physicians working with patients, Royal College of Physicians 2013
- BNMS - Generic Guidelines
- IPEM - Recommendations for support for PET-CT 2008);
- UK Radiopharmacy Group - (A capacity planning toolkit for radiopharmacy services in the UK 2018).
- CQC Guidance - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 18

3.2 Training requirements, particularly for IRMER roles, should be well defined including initial training, competency assessment and ongoing training needed to maintain competence. Detailed records of training, competence and entitlement will be kept.

3.3 All staff will undergo annual appraisal and will maintain records of CME/ CPD.

3.4 Suitably experienced and certificated regulatory experts will be available and appointed in writing (MPE, RPA, RWA).

3.5 Staff using hybrid imaging equipment in the service (eg SPECT/CT) should be adequately trained in all elements of the hybrid technology.

4 Patient Referral

4.1 Referrers to the service must be defined and referral guidelines for all studies, which also detail the referrer's legal responsibilities under IRMER, must be made available to them.

4.2 All referrals must be justified by a practitioner and authorised by suitably trained and entitled staff.

4.3 Personnel must be available for timely discussion of relevant clinical issues.

4.4 Out patients will agree their appointment time with the department.

4.5 Waiting times for Nuclear Medicine studies should be in line with national guidelines.

4.6 Patients and their carers will be given timely and appropriate information about the NM study they are to undergo. This will include radiation risks, radiation protection requirements and include a contact point.

- HSE advice - RR416 Information to accompany patients undergoing nuclear medicine procedures 2006
- SCoR - Communicating Radiation Benefit and Risk to Individuals under IRMER 2019
- CQC Guidance - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12

5 Performance of Studies

5.1 Policies and procedures for obtaining consent to care must be in place and reflect current legislation and guidance, and staff must follow them at all times.

- DHSC guidance - Consent for examination or treatment 2009

5.2 Patients' privacy, dignity and security must be maintained at all times during examinations and procedures.

- CQC Guidance - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 10

5.3 Compliance with legislation and guidance on patient confidentiality must be fully observed.

- Gov.uk - Data Protection Act /Data Protection Regulations 2018
- DHSC Guidance - Access to Health Records Requests 2010
- DHSC Guidance - Confidentiality: NHS Code of Practice 2003

5.4 Department protocols should be in place to ensure that pregnancy and breastfeeding status enquiries are made and recorded for all relevant patients.

5.5 Studies will be performed in accordance with written protocols taking account of national guidance.

5.6 Separate protocols should be available for paediatric studies.

5.7 The results of all relevant imaging and other appropriate investigations will be accessible at the time of the patient's attendance.

5.8 The study will be performed by staff appropriately trained and competent in the use of that equipment and in the performance of that study with support and advice from appropriately trained scientific staff.

5.9 A suitably qualified person will be available during the study to check the results, request additional views and obtain additional relevant clinical information.

5.10 Soft copy display and summary images of study output sent to PACS must be labelled with patient's name, identifier, date of study and radiopharmaceutical used. Laterality and other relevant information must also be clearly displayed.

5.11 Quantification software used in the measurement of clinically significant parameters will be validated and will have reproducible results between clinical systems used by the service.

5.12 Adverse occurrences will be reported in accordance with local incident procedures and investigated. If necessary, these should be reported to the appropriate bodies – Care Quality Commission, Health & Safety Executive, Medicines & Healthcare products Regulatory Agency. Root cause analysis should be performed for serious incidents.

6 Reporting

6.1 Reporting is an operator task under IRMER and all reporters will be suitably trained and entitled by the Employer.

6.2 An image reporting policy should be in place, which covers the format of reports, turnaround times and the management of unexpected diagnoses and indications of potential medical emergencies in accordance with national guidelines.

- RCR - Standards for interpretation and reporting of imaging investigations 2018

6.3 An MPE and the technologist undertaking the study will be available for consultation with the person issuing the report.

6.4 Additional diagnostic investigations will be instigated as appropriate according to local protocols.

6.5 Study output (images and reports) will be available to referrers.

6.6 Study data will be retained as appropriate.

6.7 The report will be retained as a record of the examination in accordance with national guidance.

- NHS - Records Management Code of Practice 2021

6.8 Appropriate records of the radiopharmaceutical and administered activity must be kept.

6.9 Studies will normally be reported within 1 working day of completion of study and the report will be available within two working days following completion of the study.

6.10 Reporters should be available for discussion of the study output and should attend relevant Multidisciplinary Team meetings.

7 Regulatory Compliance

A list of regulations is included as Appendix 1 - Note that this list is not exhaustive and includes legislation that was in force at the last revision date.

The service will be compliant with national regulations relating to the use of ionising radiation and will conduct regular audits to demonstrate this. Liaison with the relevant regulatory expert is essential. Some key aspects of the main legislation are listed below -

7.1 Ionising Radiations (Medical Exposure) Regulations - (Expert – MPE)

a) Employers IRMER procedures are in place

b) ARSAC Licences (Employer and Practitioner) exist for all studies performed at the site

c) Staff are trained, competent and entitled

d) Diagnostic Reference Levels are in place
e) Imaging protocols are optimised
f) A policy and risk assessment for Serious Accidental/Unintended Exposures is in place
g) Clinical and IRMER audits are performed
h) MPE appointed

7.2 Ionising Radiation Regulations – (Expert – RPA)

a) HSE Authorisation
b) Radiation Protection Policy is signed off at the highest levels
c) Radiation protection training
d) Radiation Risk Assessments
e) Local Rules
f) Dose Records
g) Contamination Monitoring
h) RPA appointed
i) Suitable numbers of RPS's trained and appointed

7.3 Environmental Permitting Regulations (Expert – RWA)

a) Environmental Permits
b) Best Available Techniques
c) Radioactive Waste Management
d) Delivery & Receipt of Radioactive Materials
e) Security of Radioactive Sources
f) RWA appointed

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Revised	April 2001	
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Revised	March 2005	
Revised	April 2016	Nicola Mulholland King George Hospital, London
Last Revised	September 2021	Paul Hinton, Royal Surrey County Hospital, Guildford

Appendix 1

Relevant Regulations

Note: this list is not exhaustive and includes legislation that was in force at the last revision date.

1. Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER)
2. Environmental Permitting (England and Wales) Regulations 2016 (EPR) & Environmental Authorisations (Scotland) Regulations 2018 (EASR)
3. Ionising Radiations Regulations 2017 (IRR)
4. Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG) and amendments
5. Human Medicines Regulations 2012 (HMR)
6. Medicines for Human Use (Clinical Trials) Regulations 2004 (MHUCTR)
7. Management of Health and Safety at Work Regulations 1999 (MHSWR)
8. Radiation (Emergency, Preparedness and Public Information) Regulations 2019 (REPPIR)
9. Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)
10. Personal Protective Equipment Regulations 2002 (PPER)
11. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014