

BNMS Nuclear Medicine Generic Quality Guidelines For The Provision of Radionuclide Diagnostic Services

Report March 2016



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Purpose

The purpose of these guidelines is to promote the provision of a high quality Nuclear Medicine service. This includes aspects of effectiveness, safety and timeliness.

Facilities

- 1.1 *Facilities in which Radionuclide investigations are performed will be covered by ARSAC certification and comply with all relevant legislation. (See paragraph 6.)
- 1.2 Facilities will be sufficient to support all studies performed on site, including, where relevant, the production and storage of radiopharmaceuticals and disposal of unused radiopharmaceuticals and radioactive waste in accordance with current legislation.
- 1.3 Equipment will be appropriate for the level of service supplied and will be maintained and serviced regularly, and conform to current performance criteria. Quality control and quality assurance procedures will be carried out regularly and the results recorded. (IPEM report no. 86 Quality Assurance in Gamma Camera Systems, Institute of Physics and Engineering in Medicine 2003; IPEM report 87 Basics of gamma camera PET, IPEM report 85 Radioactive Sample Counting Principles and Practice 2002)
- 1.4 *Staffing levels will be sufficient for the service provided and include an adequate mix of skills. A range of guidance is available from different professional bodies. For example the Royal College of Physicians (Consultant Physicians working with patients, Royal College of Physicians 2005), The Institute of Physics and Engineering in Medicine (Recommendations for support for PET-CT, IPEM 2008), The UK Radiopharmacy Group (A capacity planning toolkit for radiopharmacy services in the UK, UKRG, 2009). There will be ready access to doctors, technical staff, clinical scientists, radiopharmacists and nurses as required to ensure the quality of the service on a daily basis and in compliance with IR(ME)R. The clinical aspects of the service will be directed by an appropriate ARSAC certificate holder. A Medical Physics Expert (MPE) will be available to provide scientific support and advice to the service. A Radiation Protection Advisor will be available for radiation protection advice.
- 1.5 Departments will submit to regular external peer review, such as the BNMS Organisational Audit Programme, as well as participating in local audit programmes.
- 1.6 All staff will undergo annual appraisal and will maintain and demonstrate appropriate levels of competence in accordance with the recommendations of Royal Colleges and relevant professional bodies.
- 1.7 When 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.
- 1.8 A document management system will be in place to cover all relevant documents.

Patient Referral

- 2.1 *All referrals will be justified and authorised by the ARSAC certificate holder or a trained health professional to whom the task of authorisation has been properly delegated under the terms of IR(ME)R 2000 for appropriateness and level of urgency. The department must have personnel available for timely discussion of relevant clinical issues. (CPWP, 3rd Edition RCP, 2005)
- 2.2 Through a process of authorisation, the investigation will be assigned to an appropriate protocol, e.g. SPECT.
- 2.3 *Waiting times for Nuclear Medicine studies will be in line with national guidelines.
- 2.4 A list of appropriate referrers will be held in accordance with legislative requirements (IRMER 2000)
- 2.5 *Out patients will agree their appointment time with the department.
- 2.6 All patients will be offered suitable information about the investigation in a timely fashion. (Annual Health Check, Quality of Service Core Standards – C16 <http://www.qcqc.org.uk/guidanceforprofessionals/healthcare/nhsstaff/annualhealthcheck2008/09/qualityofservices.cfm>, NHSLA Risk Management Standards for Acute Trusts primary Care Trusts and Independent Sector Providers of NHS Care – Standard 4.2 - <http://www.nhs.uk/riskmanagement>, RR416 information to accompany patients undergoing nuclear medicine procedures www.hse.gov.uk/research.rrpdf/rr416pdf)

Performance of Study

- Departments will have local procedures to ensure that national guidelines on patient consent are followed.
- 3.1 Studies will be performed in accordance with written current site protocols and in accordance with legislative requirements.
 - 3.2 *Department protocols should be in place to ensure that pregnancy status and breastfeeding status are recorded for all female patients of child bearing age as appropriate.
 - 3.3 The results of all relevant imaging and other appropriate investigations will be accessible at the time of the patient's attendance.
 - 3.4 A suitably qualified person will be available during the study to check the results, request additional views and obtain additional relevant clinical information.
 - 3.5 Studies will routinely be performed in accordance with ARSAC Notes for Guidance and other best practice guidelines.
 - 3.6 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. A register

of competencies will be maintained and will record training and competences.

- 3.7 Adverse occurrences will be reported to the appropriate bodies (www.bnms.org.uk) as well as local reporting in accordance with local incidents.
- 3.8 *Study output/hard/soft copy display must be labelled with patient's name, identifier, date of study and radiopharmaceutical used. Laterality and other relevant information must also be clearly displayed.
- 3.9 Compliance with guidance and legislation on patient confidentiality must be fully observed. (Data Protection Act 1998, Access to Health Records 1990, Access to Medical Reports Act 1988, DoH Guidance Confidentiality NHS Code of Practice.)
- 3.10 Compliance with guidance and legislation on patient dignity must be fully observed. (Dignity in Care Healthcare Commission Report September 2007.)

Reporting Study

- 4.1 *All studies will be reported by an appropriately trained medical practitioner who must be a holder of a relevant ARSAC certificate, or the suitably trained delegate of such. It is the responsibility of the person issuing the report to be available for further consultation with the referrer. This is also important in the context of multidisciplinary meetings "MDM's"), when appropriate Nuclear Medicine expertise must be available for discussion of the implications of the report in the full clinical context.
- 4.2 An MPE and the technologist undertaking a study will be available for consultation with the person issuing the report.
- 4.3 The report will contain elements of description, indications and clinical interpretation. The goal is to provide a timely answer to the clinical question within the limits of the test.
- 4.4 Additional diagnostic investigations will be instigated as appropriate according to local protocols.
- 4.5 Study output will be available to referrers.
- 4.6 Study data will be retained as appropriate.
- 4.7 *The report will be retained as a record of the examination in accordance with NHS guidelines.
- 4.8 *Appropriate records of the radiopharmaceutical administered and activity must be kept.
- 4.9 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.

- 4.10 Urgent and or unexpected results will be notified to the referring clinician. There will be a department written procedure for this in accordance with national guidelines.

Relevant Legislation

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

- Ionising Radiations Regulations 1999 (SI 1999 No 3232) London, HMSO
- Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000 No 1059) London,
- HMSO
- The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, SI
- 2006/2523 London. HMSO.
- Medicines (Administration of Radioactive Substances) Regulations 1978 (SI 1978 No
- 1006) London, HMSO
- Medicines (Administration of Radioactive Substances) Amendment Regulations 1995
- (SI 1995 No 2147) London, HMSO
- Medicines (Administration of Radioactive Substances) Amendment Regulations 2006
- (SI 2006 No 2806) London, HMSO
- Environmental Permitting Regulations 2010 London, HMSO
- Radioactive Substances (Hospitals) Exemptions Order 1990 (SI 1990 No 2512) and
- amendment order 1995 (SI 1995 No 2395) London, HMSO
- Medicines Act 1968, London, HMSO
- Radioactive Substances (Testing Instruments) (England and Wales) Exemption
- Order 2006 (SI 2006 No 1500) London, HMSO
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment
- Regulations 2007 (SI 2007 No 3236)
- The Justification of Practices involving Ionising Radiation Regulations 2004 (SI 2004
- No 1769) London, HMSO

Review

Date for review/Update March 2021

Comment	Date	Version	Reviewer
Initial draft first posted	July 1999	V1	
Revised	April 2001	V2	
Revised	February 2003	V3	
Revised	March 2005	V4	
Revised	April 2010	V5	
Last revised	March 2016	V6	Nicola Mulholland
Revision due	March 2021		

These guidelines do not constitute a formal protocol but highlight the aspects of a study where variation in practice may significantly affect the quality of outcome of the study.

*auditable points