
Guidelines for the provision of radiopharmacy support to nuclear medicine

Report of a Joint Working Group of the British Institute of Radiology, the British Nuclear Medicine Society and the UK Radiopharmacy Group, Autumn 2001

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1. Introduction and purpose of this report

1.1 This document gives guidance on levels of professional radiopharmacy support required for the provision of a safe, effective and responsive nuclear medicine service. It identifies the role of the radiopharmaceutical scientist in nuclear medicine and provides a clear statement of duties.

1.2 In 1997 the Royal College of Physicians (RCP) published guidelines on the levels of consultant medical staff time required for the provision of a safe and effective nuclear medicine service [1]. This was published to assist informed discussion between consultant medical staff and managers and to provide guidance to management to assist them in making provision for medical cover. The present document is intended to assist nuclear medicine staff and management in the planning and provision of appropriate radiopharmacy support to nuclear medicine.

2. The requirement for radiopharmacy support to nuclear medicine

2.1 Administration of radiopharmaceuticals can only be performed by an appropriately authorized doctor or dentist, or by an individual acting under his direction. The Administration of Radioactive Substances Advisory Committee (ARSAC) advises health ministers on the granting of certificates of authorization for this purpose to doctors and dentists. Statements from individuals responsible for the provision of both scientific and radiopharmacy support must accompany applications for approval.

2.2 Radiopharmaceuticals are medicinal products as defined by the Medicines Act 1968 [2]. The preparation of radiopharmaceuticals in hospitals is considered to be a manufacturing operation, and there are only two systems under which this can legally be performed. In the first instance, preparation takes place under the terms of a Manufacturing (Specials) Licence issued by the Medicines Control Agency of the Department of Health. It is necessary to identify a production manager, and a quality controller, and to adopt a system of quality management and good manufacturing practice. Alternatively, the manufacture can be performed by, or under the direct supervision of, a pharmacist operating under the exemption offered by Section 10 of the Medicines Act.

2.3 A requirement for radiopharmacy support to the provision of a nuclear medicine service is implicit in the following documents:

- The Ionising Radiations (Medical Exposures) Regulations 2000 [3],
- The Medicines (Administration of Radioactive Substances) Regulations 1978 [4],
- The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995 [5],
- The Ionising Radiations Regulations 1999 [6],

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- Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources [7],
- Rules and guidance for pharmaceutical manufacturers and distributors 1997 [8],
- The quality assurance of aseptic preparation services [9],
- Isolators for pharmaceutical applications [10].

3. Staffing requirements

Management of a basic radiopharmacy service requires staff to be of at least Grade D pharmacist or equivalent. Staffing levels would depend on the extent and complexity of the service provision, which is not necessarily dependent on the size or nature of the base hospital.

4. The role of the radiopharmaceutical scientist in nuclear medicine

4.1 A number of broad areas in nuclear medicine have been identified where radiopharmaceutical scientists are considered to have a distinct role. Within these areas, some tasks are, in part, associated with statutory requirements and can clearly be assigned to pharmacists. Other tasks, although frequently performed by pharmacists, may be undertaken by other staff groups.

4.2 The manufacturing and supply operations are the most important roles. The objective of any manufacturing operation is the production of a product that is effective and safe. The circumstances under which manufacture is permitted have been described above. The Consumer Protection Act 1987 [11] was designed to safeguard the general public from unsafe products. Radiopharmaceutical products are prescription only medicines, and it is essential to have systems in place to allow the proper supply of such materials. Performance of clinical procedures such as the radiolabelling of blood cells is an integral part of the supply operation in many hospitals.

4.3 Adoption of a comprehensive programme of quality assurance is essential to the provision of a radiopharmaceutical service. *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 1997* [8] defines quality assurance as a wide-ranging concept which covers all matters which individually or collectively influence the quality of a product. It is the sum total of all organized arrangements made with the object of ensuring that medicinal products are of the quality required for their intended use.

4.4 Procurement of products of an appropriate quality can have a marked influence on the quality of results produced in the nuclear medicine clinic.

4.5 Monitoring of adverse events such as adverse drug reactions, altered biodistributions or the effects of concomitant drug therapy, can be helpful in the interpretation of data produced in the clinic.

4.6 Teaching, training and research are important aspects of the radiopharmaceutical scientist's role. Appropriate training is essential to the requirements of the IR(ME) Regulations [3].

5. Duties of the radiopharmaceutical scientist in nuclear medicine

Duties have been grouped into essential (core) and non-core activities. Core activities are shown in Table 5.1, while non-core duties are shown in Table 5.2.

6. Assessment of the workload and staffing requirements

6.1 The extent of a radiopharmacy service and the level of commitment required is not necessarily related to the size of hospital in which it is based. Therefore emphasis has been placed on the range and complexity of procedures undertaken in the assessment of workload.

6.2 Minimum staffing levels do not take into account those operations defined as non-core.

6.3 Some duties are not dependent on the availability of support staff. Routine production duties require the presence of at least one supporting staff member for the purposes of conformity with good manufacturing practice.

6.4 Table 6.1 gives the recommended requirements for staffing levels, in terms of workload. As previously described, more emphasis is placed on the range and complexity of the service provided, rather than on the size of hospital in which the service is based. However, for guidance, a small service might produce of the order of 2000 doses per year, whereas a large teaching hospital may require 10,000 doses or more per year.

6.5 In all cases, the figures in Table 6.1 assume that technical support is provided by trained staff, and that equivalent cover is provided during periods of study and annual leave.

Table 1. Core activities of the radiopharmaceutical scientist.

<i>Duties</i>	<i>Examples</i>
Manufacturing and supply	Acting as production manager or supervising pharmacist Drawing up standard operating procedures Writing of procedure manuals and site master files
Quality assurance	Acting as quality controller Environmental monitoring and product testing Operator protection monitoring (for biological hazards associated with blood-cell labelling) Record keeping and documentation Audit Maintaining a complaints and product recall system
Procurement	Purchase of products of appropriate quality Maintaining knowledge of Product License status of products Maintaining systems for purchase of non-licensed products Maintaining awareness of new product development Procuring drugs for interventional studies Maintaining suitable storage conditions for procured items
Monitoring adverse events	Maintaining vigilance for adverse events, unusual biodistributions, drug interactions and mis-administration or maladministrations Reporting incidents
Education and training	Training staff in the requirements of good manufacturing practice Provision of pharmaceutical training as required under IR(ME)R [5] *CPD
Provision of clinical and professional advice	Liaison with other professional groups Information on PL status Preparation of patients' information leaflets Use of drugs in interventional procedures
Support for ARSAC applications	Provision of support as the individual responsible for the supply of radiopharmaceuticals
Radiation protection	Development of safe procedures for the production and manipulation of radioactive pharmaceutical products

APPENDICES

Standards of delivery of a nuclear medicine service

The British Nuclear Medicine Society offers purchasers of nuclear medicine services the following policy statement on standards for the safe practice of nuclear medicine [12]. (Items marked with an asterisk are a statutory requirement.)

Appendix A: Medical standards

1* The clinical nuclear medicine service shall be delivered under the responsibility of one or more clinicians holding the relevant ARSAC certificates for that site.

- 2 The number of dedicated consultant sessions shall be appropriate for the workload.
- 3 Consultants responsible for the delivery of the clinical nuclear medicine service shall be trained to an appropriate standard, usually that defined by the specialist professional body.
- 4 Medical reports shall be the responsibility of one or more consultants with appropriate experience and training. A medical opinion can only be given by a medically qualified individual.
- 5 Adequate arrangements for consultant cover shall be in place at all times.
- 6 Adequate provision for study leave and/or continuing education for clinical staff shall be identified in the documents relating to the terms and conditions of service.

Table 2. Non-core activities of the radiopharmaceutical scientist.

<i>Duties</i>	<i>Examples</i>
Participation in clinical trials	Procurement, custody and storage of clinical trial supplies Development of systems of good manufacturing practice for the preparation of materials for clinical trials Documentation of receipt, storage, dispensing, administration and destruction of supplies used in clinical trials
Research and development	Undertaking projects Participation in interdisciplinary projects Provision of scientific and technical support to other research studies within the hospital or academic environment
Audit	Multidisciplinary clinical audit and external audit (e.g., Health and Safety Executive, Environment Agency).
Professional activities/ committee work	Involvement in hospital committees (including radiation safety) and activities associated with relevant professional societies
Education and training	Education and training of other NHS staff groups (e.g., medical, nursing)
Staff meetings	Clinical meetings, hospital management briefings and departmental meetings

Appendix B: Scientific and technical standards

- 1* Scientific and technical support shall be provided through dedicated medical physicists and technologists in accordance with the recommendations of the IPEM, BNMS, HSG(95)3 [13] and relevant current legislation. Such staff shall be trained to an appropriate standard as defined by the appropriate professional bodies.
- 2 The service of a radiation protection adviser shall be available for the provision of advice on relevant current legislation and other radiation protection matters.
- 3 A radiation protection supervisor shall be appointed by the provider unit.
- 4 Adequate provision for study leave and/or continuing education for scientific and technical staff shall be identified in the documents relating to the terms and conditions of service.

Appendix C: Organizational standards

- 1 The nuclear medicine service shall be managed by a suitable person with the organizational and administrative authority to deliver a safe service.
- 2* Radiopharmaceuticals shall be made available through qualified staff in an approved environment. Written procedures for the preparation, dispensing

and administration of such agents shall be accessible and reviewed at regular intervals.

- 3 UK licensed products shall be used except when written authorization on an individual patient basis is provided by the clinician holding the relevant ARSAC certificate.
- 4* The provider site shall hold a certificate of registration for the keeping and use of radioactive materials and be appropriately authorized to accumulate and dispose of radioactive waste in accordance with relevant current legislation, unless exempt from so doing.
- 5* Procedures shall be in place to ensure that the transport of radioactive materials meets relevant current legislation.
- 6* Measures to monitor and control the radiation exposure of patients, staff and members of the public must satisfy the requirements of relevant current legislation.
- 7 The policies, procedures and delivery of the service shall be subject to organizational audit at agreed intervals.
- 8 All investigations or therapies shall be performed only on receipt of forms signed by a medical practitioner and these forms shall be made available by the provider unit.
- 9 Audit standards for the delivery of the service shall be agreed to include the range of services to be supplied, interval between request, appointment and report and other quality measures.

Table 3. Recommended staffing levels: provision of services essential to the following activities (hours per week).

Service	1	2	3	4
Manufacture	7.5	10	15	15
Quality assurance	5	7.5	5	10
Cell labelling	N/A	5	N/A	20
Documentation	2.5	3	3.75	5
Record keeping	2.5	3	3.75	5
Monitoring	3.75	3.75	3.75	3.75
Audit	1.25	1.25	2.5	2.5
Procedures	1	2	2	2
Radiation protection	1.25	1.25	1.25	1.25
Management	1	2	2	3
Administration	1.25	2.5	2.5	3.75
ARSAC support	1	1	2	2
CPD	1	1	1	1
Professional activities	1.25	2.5	2.5	2.5
Education and training	1	2	2	3
Staff meetings	1	2	2	2
Total hours	32.25	49.75	51	81.75
Total sessions*	9	14	15	23

Column 1: Supply of kit-based or 'dilution-only' radiopharmaceuticals for use within the hospital.

Column 2: Supply of complex products and/or provision of services for labelling blood cells within the hospital.

Column 3: Extended supply of kit based or 'dilution only' products.

Column 4: Extended supply of complex products and/or provision of services for labelling blood cells.

*Assuming 3.5 hours per session and 10 sessions per week. Additional hours will be required to cover for study and annual leave.

N/A, not applicable.

10 An adequate staff mix for the safe delivery of the service and appropriate patient care shall be in place. There shall be compliance as appropriate with the Patients' Charter and the Children's Charter.

11 Services shall be provided in an environment that is conducive to good patient care, with particular emphasis on cleanliness, timeliness, pleasant attitude and appearance of staff. Patient privacy, dignity and ethnic origin shall be respected.

12* All research procedures shall be performed in accordance with the terms of the local research ethics committee and the ARSAC certificate specific to that project.

Appendix D: Equipment and facilities

- 1 The service shall be delivered through safe equipment that meets current accepted standards of performance.
- 2 The performance of equipment, in particular gamma cameras and dose calibrators, shall be assessed at

suitable intervals. Records shall be maintained and be available on request.

- 3 Radiation monitoring, imaging, counting and data processing facilities appropriate to the level of service shall be available.

ABBREVIATIONS USED IN THIS REPORT

ARSAC Administration of Radioactive Substances Advisory Committee of the Department of Health set up under the Medicines (Administration of Radioactive Substances) Regulations 1978 (SI 1978 No. 1006) and the Medicines (Radioactive Substances) Order 1978 (SI No. 1004).

BIR British Institute of Radiology

BNMS British Nuclear Medicine Society

CPD continuing professional development

IPEM Institute of Physics and Engineering in Medicine

NHS National Health Service

PL Product License

RCP Royal College of Physicians.

References

1. Royal College of Physicians of London. Nuclear medicine: guidelines for the provision of a clinical service. London: RCP, 1997.
2. The Medicines Act 1968. London: HMSO, 1968.
3. The Ionising Radiations (Medical Exposures) Regulations 2000. (SI 2000 No. 1059) London: The Stationery Office Ltd, 2000.
4. The Medicines (Administration of Radioactive Substances) Regulations 1978. (SI 1978 No. 1006). London: HMSO, 1978.
5. The Medicines (Administration of Radioactive Substances) Amendment Regulations 1995. (SI 1995 No. 2147). London: HMSO, 1995.
6. The Ionising Radiations Regulations 1999 (SI 1999 No. 3232). London: The Stationery Office, Ltd, 1999.
7. Administration of Radioactive Substances Advisory Committee. Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources. Chilton, Oxon, UK: National Radiological Protection Board, 1998.
8. Rules and Guidance for pharmaceutical manufacturers and distributors. London: The Stationery Office Ltd, 1997.
9. Beaney A, ed. Quality assurance of aseptic preparation services, 3rd edn. London: The Pharmaceutical Press, 2001.
10. The UK Pharmaceutical Isolator Group. Isolators for pharmaceutical applications. London: HMSO, 1994.
11. Consumer Protection Act 1987 (Part I: Product Liability). London: HMSO.
12. Nuclear medicine standards for purchasers and trusts. London: British Nuclear Medicine Society, 1997.
13. Health service guidelines: health service use of ionising radiations. HSG(95)3. London: NHS Executive, 1995.