Notes for guidance on the clinical administration of radiopharmaceuticals and use of sealed radioactive sources

Administration of Radioactive Substances Advisory Committee

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Preface

These notes for guidance have been prepared by members of the Administration of Radioactive Substances Advisory Committee (ARSAC) past and present.

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Contents

Introduction

1 The guidance given in these notes is not mandatory and does not have the force of statutory regulations: nevertheless, it is based on national and international recommendations and represents the advice of the Administration of Radioactive Substances Advisory Committee (ARSAC). These notes can be considered to be a guide to good clinical practice in the UK for nuclear medicine and have been updated from the previous revision.

2 ARSAC will review these notes annually. Additional information will be provided through guidance published on the website. Notification of changes or updates will be made using the email subscription bulletin. Please subscribe to the GovDelivery service to receive updates.

3 This document is uncontrolled when printed. The most up-to-date version of the notes is available on the website.

4 In this version of the notes there are the following notable updates:

- **(a)** updated guidance on the practice of authorising exposures under guidelines written by a practitioner in sections 3.5 to 3.7
- **(b)** clarification on the information required for therapeutic research trials sections 4.12 to 4.14
- **(c)** minimum requirements for therapeutic prescriptions in section 5.15
- **(d)** additional information on the administration of prescription only medicines as part of Nuclear Medicine procedures in section 5.19
- **(e)** updated guidance on using Table 6.1 for paediatric dose scaling
- **(f)** updated guidance on freezing breastmilk and decay storing post nuclear medicine administration in section 7.29
- **(g)** removal of guidance values for thyroid blocking in section 8.4
- **(h)** the nuclear medicine core curriculum is now included as appendix 1

Section 1

Licensing requirements of the Ionising Radiation (Medical Exposure) Regulations

Introduction

1.2 Article 28(a) of the EURATOM Basic Safety Standard Directive 2013 [1] (BSSD) requires licensing for the deliberate administration of radioactive substances to persons for the purposes of medical diagnosis, treatment or research.

1.3 The medical exposure aspects of the BSSD were transposed into the Ionising Radiation (Medical Exposure) Regulations 2017 [2] in Great Britain (GB) (IR(ME)R). In Northern Ireland these were transposed into the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 [3]. These regulations include the licensing requirements of article 28(a) relating to medical exposures.

Licensing authority

1.4 IR(ME)R requires employers and practitioners to hold a licence for the administration of radioactive substances for a specified purpose.

- **(a)** each employer is required to hold a licence at each medical radiological installation where radioactive substances are to be administered to humans
- **(b)** every practitioner is required to hold a licence in order to justify the administration of radioactive substances to humans

1.5 Licences are required for any administration of a radioactive substance that results in an effective dose greater than 1µSv. This precludes the need to apply for a licence for the administration of the majority of substances that contain only naturally occurring levels of radioactivity.

1.6 The licensing authority for employer licences is:

- **(a)** in England, the Secretary of State
- **(b)** in Scotland, the Scottish Ministers
- **(c)** in Wales, the Welsh Ministers
- **(d)** in Northern Ireland, the Department of Health (NI)

1.7 The licensing authority for practitioner licences is:

- **(a)** in GB, the Secretary of State
- **(b)** in NI, the Department of Health (NI)

1.8 ARSAC provides advice on the issue of licences to the relevant licensing authority. Applications are processed by the UK Health Security Agency (UKHSA).

1.9 The purpose for which each radioactive substance specified in a licence may be administered is defined as research, diagnosis or treatment.

1.10 A licence may be revoked or varied by the licensing authority at any time.

1.11 A licence is valid for the period specified on the licence. The majority of licences are issued for 5 years; however, licences with a shorter duration may be issued as appropriate. ARSAC will provide in writing the reasons for a decision to issue a licence for less than 5 years at the time of issue.

Review

1.12 Any applicant who is aggrieved by a decision of the licensing authority or conditions attached to a licence, may seek a review as specified in schedule 1 of IR(ME)R. This includes:

- **(a)** rejecting a licence application
- **(b)** issuing a short licence (less than 5 years)
- **(c)** revoking a licence

1.13 Reviews must be requested in writing within 28 days of the applicant receiving notice of the decision on an application. Requests for reviews should be sent to ARSAC stating the application reference and the reason the review is being requested from the list above.

1.14 All requests for review will be relayed to the licensing authority and a response will be provided in writing.

Processing and assessment of applications

1.15 Applications should be submitted as far in advance as possible of the date by which authorisation is required to allow sufficient time for processing and assessment.

1.16 When an application is submitted to ARSAC, it is first checked for completeness by the ARSAC support unit. Incomplete applications will be

returned to the applicant, with a request for provision of the missing information before consideration by ARSAC.

1.17 Complete applications are acknowledged and then sent to a subset of committee members for assessment. ARSAC does not meet to assess applications and no individual committee member approves any single application.

1.18 Committee members are assigned to assess applications based on the application type and member's expertise. The ARSAC support unit considers any potential conflicts of interest when applications are assigned for assessment. Committee members do not assess applications from practitioners who they may work with, or for medical radiological installations where they work.

1.19 UKHSA and ARSAC will aim to process all applications within 6 to 8 weeks of receipt of a complete application, however applications which require additional information or clarification can take longer to process.

1.20 If an application is referred back for additional information, it cannot be considered further until an appropriate reply is received from the applicant, for example, the practitioner or named individuals within the application for employer licences.

1.21 The chairman assesses any applications where further information was requested by members. The chairman's assessment supports the committee in maintaining a consistent position with respect to all applications received.

1.22 No information about an application will be provided to any other persons except those named on the application form.

Urgent applications – particular patient licence (PPL)

1.23 An application for a particular patient may be submitted for urgent referrals where the appropriate procedure code is not held on the relevant employer and/or practitioner licence. Whilst recognising the urgency in which a referral may be received, where possible a PPL should be submitted to ARSAC 48 hours prior to the date of administration. PPL applications cannot be accepted for research purposes. The committee would not normally approve PPL applications for novel procedures which have not been previously authorised by ARSAC. Advice about such applications, and other matters, can be sought from the ARSAC support unit.

1.24 Where more than one such administration is to be undertaken by an employer or practitioner, an amendment application must be submitted to add the procedure to the employer licence and the practitioner licence.

1.25 Employers who do not hold a licence at a medical radiological installation cannot submit a request for a PPL.

1.26 Practitioners who do not hold a licence cannot request a PPL. In cases of extreme urgency, the ARSAC support unit may be able to help such practitioners locate appropriate licence holders and advise on special circumstances when a standard referral to another medical radiological installation is inappropriate.

Research involving the administration of radioactive substances

1.27 Employer and practitioner licences issued under IR(ME)R for research are not trial specific.

1.28 A trial must receive confirmation of ARSAC approval prior to any administrations of radioactive substances taking place. The ARSAC research approval document will confirm the approved procedures within the trial. The trial sponsor must provide this to all relevant participating medical radiological installations. To take part in any ARSAC approved research trial, the employer and practitioner licences must include the specified procedure codes for the purpose of research.

Section 2

Applying for an employer licence

Initial application

2.1 An employer licence is required for each employer at each medical radiological installation at which administrations of radioactive substances may occur. Applications should be supported by the Medical Director or Chief Executive Officer (or other equivalent individuals) on behalf of the employer in conjunction with the supporting staff available at each medical radiological installation.

2.2 An application for an employer licence should be submitted as far in advance as possible, but at least 8 weeks before the expiry of the licence at a medical radiological installation to allow clinical services to continue.

2.3 Where services (for example, nuclear medicine and brachytherapy) are provided by the same IR(ME)R employer but split across buildings at the same hospital address, they should be included together in one application.

2.4 Where there are multiple employers based at a medical radiological installation, all employers will need a licence covering the scope of service for which they are responsible. If more than one employer has a shared responsibility for the management of a service, then it must be clear which employer is taking legal responsibility for each exposure, or aspect of each exposure. This may result in multiple employers holding a licence for the same procedure at the same medical radiological installation.

2.5 Details on how to apply and application forms are available on the ARSAC web page. Once completed application forms should be submitted using the online portal.

2.6 There are fees for employer applications, see the ARSAC web page. To complete an employer licence application, the following information is required:

- **(a)** address of the medical radiological installation
- **(b)** full legal name and address of the employer as it will appear on the licence
- **(c)** name of the accountable representative of the employer under IR(ME)R. For an NHS hospital, this is often the Chief Executive

Officer. For non-NHS organisations, an equivalent ‘board level’ individual accountable under IR(ME)R should be listed

(d) name of the Medical Director

(e) names and email addresses for the practitioners, Medical Physics Experts (MPEs) and relevant individuals responsible for radiopharmaceutical provision

(f) details of arrangements in place for support from practitioners and MPEs where relevant

(g) where appropriate, details of training of supporting staff

(h) procedures for which authorisation is sought and for which purpose. Diagnostic procedures may be requested by checking the appropriate functional groups (see Table 5.5)

(i) for procedures not listed in these notes, local diagnostic reference levels (DRLs) where appropriate and effective dose to include references

(j) equipment and facilities available to the employer. Details of any equipment replacement plans should be included and, for older equipment, confirmation of continued clinical utility should be provided.

(k) equipment based at a different site that is required for the procedures included within the application. For example, this would include sample counters for Glomerular Filtration Rate (GFR) studies and gamma probes for Sentinel Lymph Node Biopsy (SLNB) procedures where surgery is conducted elsewhere.

(l) summary of governance and management arrangements for IR(ME)R, including information on how IR(ME)R is implemented on site; how the employer delegates the role of carrying out duties to others and how the employer is assured that IR(ME)R procedures are complied with

(m) information relating to the radiopharmaceutical service provision

(n) any other information as may be specified on the application form or may be reasonably required for the assessment of the application

2.7 Applications for an employer licence for therapy procedures should detail the following:

(a) confirmation of training of the entire team (including support staff) in the treatment

(b) Details of the start-up of the service to include how the treatment is to be delivered on site, the proposed patient pathway and

arrangements for patient selection and ongoing patient management.

(c) appropriate facilities, equipment and trained staff to support all aspects of the procedure. Some procedures may require diagnostic facilities for verification of treatment delivery and individual planning of target doses (see section 5.16). Plans for imaging for treatment dosimetry or treatment verification. A summary of current guidance can be found in the internal dosimetry user group position statement on molecular radiotherapy [4].

(d) designated in-patient accommodation as appropriate (some treatments will require en-suite facilities and shielded rooms)

(e) number of procedures undertaken in the last 12 months and predicted numbers to be undertaken in the following 12 months. Guidance on appropriate numbers of procedures for sealed sources therapies has been released by NHS England [5].

Toxicological and pharmaceutical safety

2.8 Employer and practitioner licences may be granted for radiopharmaceuticals or other products which do not have marketing authorisations. In this case, the employer retains responsibility for all aspects of the safety, quality and efficacy of such products. This also applies to the use of licensed products outside the terms of their marketing authorisation.

2.9 The chief pharmacist (within NHS organisations) is corporately accountable for the delivery of pharmaceutical services including the safe use of radiopharmaceuticals. For non-NHS organisations, this responsibility should be held by an equivalent individual. The chief pharmacist's (or equivalent individuals') signature on the employer licence application form confirms they have satisfied themselves that sufficient and appropriate arrangements for safe use of radiopharmaceuticals are in place. The arrangements for safe use encompass procurement, manufacture, preparation (if appropriate), receipt, storage, handling, administration, supply and disposal, each of which are described in guidance from the UK Radiopharmacy Group (UKRG) [6].

Supporting staff and services

2.10 At a medical radiological installation where administrations of radioactive substances are undertaken, it is expected that there will be a multi-disciplinary team involved with service provision. This will include practitioners, MPEs, radiopharmacists (if appropriate), and other healthcare professionals (for example, radiographers, technologists, surgeons and nursing staff) with appropriate training and experience.

2.11 The team will be involved in practical aspects of medical exposures as defined within IR(ME)R. For the administration of radioactive substances, this includes, but is not limited to:

- **(a)** administering radioactive substances, for example, injecting radiopharmaceuticals
- **(b)** acquiring and processing images
- **(c)** calibration and assessment of technical performance of equipment
- **(d)** planning treatment target doses and estimation of tissue doses
- **(e)** providing personalised radiation protection advice to patients
- **(f)** manufacturing and drawing up radiopharmaceuticals for administration
- **(g)** performing surgical or interventional procedures

2.12 IR(ME)R requires that employers must ensure that suitable MPEs are appointed and involved in exposures involving the administration of radioactive substances. The MPE should advise the employer on compliance with IR(ME)R. Guidance from the Institute of Physics and Engineering in Medicine (IPEM) on what constitutes sufficient levels of MPE support has been supported by ARSAC [7]. This provides details of minimum amounts of whole time equivalent support required for services of different types. Multiple individual MPEs may be required dependant on the individual's training and the scope of service to be provided. Having more than one individual available will allow for robust support in case of absences.

2.13 While the role of the MPE is defined in IR(ME)R, ARSAC recognises that additional scientific support may be provided to a service from other support staff including clinical scientists, medical physicists and clinical technologists. Further detail is included on these roles in the IPEM guidance referenced above. Employers can include this information in their licence applications to inform the Committee about the wider scientific support available to the service.

2.14 The employer should ensure that there are suitable trained and entitled licensed practitioners available to support all the services that they wish to deliver. Most services will require at least 2 individuals to be entitled, to allow for cover to be provided over periods of absences such as leave and to maintain a stable long-term service.

2.15 As nuclear medicine techniques and services develop, new functions and processes are expected to be undertaken by staff within the nuclear medicine department and may be undertaken by staff in locations that are outside the department working under different management structures. It is important that the employer's procedures specify how all duty holders are entitled

following demonstration of competence through appropriate training and experience.

2.16 The adequacy of other supporting services will depend upon the nature and complexity of the work involved [8]. Factors to be considered for medical exposures include the suitability of:

- **(a)** equipment to undertake the procedure involved
- **(b)** working areas and related laboratory equipment
- **(c)** trained staff for the supervision, treatment and nursing of patients who have been administered with radioactive substances
- **(d)** trained surgical teams for procedures involving administration of a radioactive substance and interventional or surgical procedures

2.17 Demonstration of initial competence for supporting staff can be provided through formal theoretical training, supervised practical experience and mentored practical experience. Theoretical training can be achieved through attending conferences or training courses. Practical experience can be provided through formal visits to other centres with experience of a procedure, often acquired by involvement in early research applications. There are different ways to demonstrate sufficient training and experience and opportunities to gain experience remotely may also be available.

Remote support for services

2.18 Some employers delivering nuclear medicine and PET/CT services may use third-party providers for some aspects of their services, for example, MPE support, radiopharmacy services or practitioner support. Further guidance for practitioners is available in section 3.44 to 3.46. The employer's procedures should consider the entitlement and scope of practice of any IR(ME)R duty holders from a third-party [9,10].

2.19 The availability and proximity of the MPE should bear a direct relation to the radiation risk involved with the procedures on the licence. There should be sufficient MPE support available based on the services provided. For example, an MPE for a diverse therapy service should be readily available, directly involved in treatments and normally employed at the medical radiological installation listed in the application. An MPE for an application including low dose procedures in a research laboratory could be based offsite and at some distance from the laboratory.

2.20 Where radiopharmacy services are provided by a third-party or radiopharmaceuticals are procured from an external provider, the chief pharmacist (or equivalent) must be satisfied that the arrangements for safe use of radiopharmaceuticals are appropriate [6].

2.21 There are many ways in which nuclear medicine services are delivered and supported across the UK. Employers should ensure that any changes that lead to an increase in remote support, consider the requirements for patient safety to ensure that appropriate standards of quality of care are maintained. The arrangements for remote support should be commensurate with the complexity of the service. These arrangements should be documented in the employer's procedures and in any relevant written agreements with third parties.

Renewal of licences

2.22 An employer licence may be renewed on expiry. It should be noted that it is the responsibility of the employer to hold a valid licence for the scope of service provided. Renewals should be submitted at least 8 weeks prior to the expiry of a licence to allow sufficient time for processing. There are fees for employer renewal applications, see the ARSAC web page.

2.23 Prior to submitting a renewal application via the ARSAC online portal, the existing licence should be reviewed to ensure the procedures listed encompass the scope of the whole service. Any procedures that are no longer performed may be withdrawn. Any additional procedures that are required can be included.

2.24 The ARSAC support unit will send a renewal reminder email 14 weeks before the expiry of a licence. It is the responsibility of each employer to be aware of the expiry date on their licences and to submit a renewal application for the procedures required prior to this expiry date.

2.25 The ARSAC support unit should be notified if the employer licence is no longer required.

Amendment to licences

2.26 An amendment to an employer licence should be submitted via the ARSAC online portal for the following circumstances:

- **(a)** addition of a procedure
- **(b)** change in purpose for a procedure (for example from research to diagnosis)
- **(c)** request for authorisation for an administered activity above the DRL or for a significantly greater administered activity than previously authorised for any procedures not in these notes

2.27 Applications for an amendment can be made whenever required within the duration of a valid licence. There are fees for employer amendment applications, see the ARSAC web page.

2.28 Where applications are made for a licence to include procedures that are significantly different from those already held, then further evidence of appropriate facilities and relevant training and experience of the supporting staff should be included in the application.

2.29 Some suppliers have developed training to support the introduction of new radiopharmaceuticals into the UK, where the use of the radiopharmaceutical requires expertise and skills not usually available within an existing nuclear medicine service. Reference to completion of this training in an amendment application may enable applications to be processed more quickly.

2.30 Alternative local methods of developing appropriate skills can always be used, but recognised training schemes may be preferable as these provide evidence of competence that might be more easily transferable. Where local training is developed, this should be equivalent to existing formal schemes. Within any application to ARSAC, greater detail will be required about local training schemes so that the committee can satisfy itself as to the competence of all staff involved.

2.31 Staff competence must be maintained and demonstrated through appraisal and similar mechanisms. The requirement for maintaining competence applies to all staff involved in service delivery including those outside the department management structure.

Notification of material changes to licences

2.32 A notification should be submitted via the ARSAC online portal prior to any material changes that may affect the validity of the licence. Applicants should extract the relevant section of the employer licence application form and complete this with the updated information. There is no fee for processing notifications. Such changes include, but are not limited to:

- **(a)** change in Chief Executive Officer or Medical Director*
- **(b)** change to administrative details (for example, legal name of hospital or trust)
- **(c)** replacement of existing equipment*
- **(d)** change in level of support including addition or removal of named:
  - (i) MPEs
  - (ii) supporting staff for radiopharmaceutical provision
  - (iii) practitioners
- **(e)** change in provision of radiopharmaceuticals*
- **(f)** closure of department/services*

(g) removal of a procedure from a licence

* Notification is required if changes will be implemented for 6 months or more

Fees

2.33 Employer applications can only be processed, and licences released, on the payment of the correct fee. Details of fees are available on the ARSAC webpage.

2.34 Full details of how to pay the fee will be provided once an application has been accepted. The default payment method is by credit card/debit card through a secure online portal. Payment may be invoiced for employers who are unable to pay by card and hold a credit account with UKHSA.

Section 3

Applying for a practitioner licence

Requirement for a practitioner licence

3.1 A practitioner licence may only be granted to the practitioner who is clinically responsible for the justification of administrations of radioactive substances. Justification is the process of weighing up the expected benefits of an exposure against the possible detriment of the associated radiation dose. Further guidance on justification is included in the RCR guide to understanding the implications of IR(ME)R [9,10].

3.2 Currently, ARSAC will only support applications from practitioners who are medically trained. It is expected that practitioners are on the specialist register and are appointed in a substantive consultant post at a UK installation. Where an individual in a locum post wishes to apply for a licence, specific justification must be provided in the application, however applications will only be considered in exceptional and well justified circumstances.

3.3 Every practitioner licence application must list all medical radiological installations where they are, or will be, entitled as a practitioner under IR(ME)R [2,3]. It is expected that the practitioner will review and approve all protocols used at all medical radiological installations where they are entitled.

3.4 A licensed practitioner may be entitled to work at a remote medical radiological installation where they can provide sufficient support as specified in paragraphs 3.43 to 3.45.

3.5 Authorisation is a process separate to justification and is the documentation confirming that the intellectual activity of justification has taken place. Where it is not practicable for the practitioner to authorise every exposure, they may issue written guidelines to allow appropriately trained and entitled operators to authorise these exposures. The review date and a single named practitioner responsible for each exposure included in the written authorisation guidelines should be clearly stated.

3.6 A practitioner licence is not required for individuals who authorise exposures according to written authorisation guidelines. Healthcare professionals who authorise exposures under such guidelines may need to review their entitlement in line with their employer's procedures. The licenced practitioner remains responsible for the justification of an exposure that an operator authorises following their authorisation guidelines. On instances where the information in the patient referral or patient related factors are outside of the criteria written in the authorisation guidelines, the licensed practitioner will be required to authorise the exposure. The employer's procedures should

include how the licensed practitioner should be contacted in such instances and how the authorisation should be documented.

3.7 A Practitioner licence is not required to perform other aspects of the exposure such as reporting. Reporting, or clinical evaluation of an exposure, is an operator task under IR(ME)R. This may be undertaken by appropriately trained and entitled operators.

3.8 Further guidance on the justification and authorisation process is included in the RCR guide to understanding the implications of IR(ME)R [9,10].

3.9 Clinicians under training may also authorise exposures under the supervision of a licensed practitioner. This should be as part of their training and involve oversight and mentorship by the licensed practitioner. In such scenarios the licensed practitioner remains responsible for the justification of the exposure. Once appropriately qualified and trained, such individuals should apply for their own licence to work independently to justify exposures and be entitled as a practitioner.

Initial applications

3.10 Details of how to apply and the practitioner application forms are available on the ARSAC web page.

3.11 Once completed, practitioner applications should be submitted via the ARSAC online portal. Applicants will need to set up an account to apply. Practitioner applications can be submitted by the practitioner or by someone else on their behalf. If an application has been submitted on behalf of the practitioner, it is the responsibility of the practitioner to set up an account password in order to get access to their application and any issued licences.

3.12 Further guidance on how to use the online portal is available.

3.13 There are no fees for practitioner applications. The following information is required in practitioner licence applications:

- **(a)** name, address, qualifications and appointment of the applicant
- **(b)** the medical radiological installations at which they are entitled including all NHS and private installations
- **(c)** procedures for which authorisation is sought and for which purpose. Diagnostic procedures may be requested individually or by selecting appropriate functional groups (see Table 5.5)
- **(d)** theoretical training relevant to the procedures applied for
- **(e)** practical experience relevant to the procedures applied for, to include confirmation of appropriate continuing medical education (CME) since training

(f) details of the licensed practitioner who has supervised or provided mentorship. An application may be strengthened by the provision of letter(s) of support from clinicians or physicists who are familiar with the applicant and their training and competence. The submission of such letter(s) with applications is encouraged.

(g) Details of appropriate multidisciplinary team meeting involvement

(h) any other information as may be specified on the application form or may be reasonably required for the assessment of the application

3.14 Applications for a practitioner licence to include therapy procedures should detail the following:

(a) specific recent training and experience in the procedures applied for to include:

(i) indicative numbers of cases

(ii) the applicant's level of involvement

(iii) whether experience was gained during formal training or under the mentorship of another practitioner

(iv) details of the licensed practitioner who has supervised or provided mentorship, including letters of support where appropriate

(v) training in the individual planning of doses, dosimetry (where relevant) and treatment verification for each procedure to include the assessment of organs at risk and dose limiting measures

(b) number of procedures undertaken in the last 12 months and predicted numbers to be undertaken in the following 12 months. Guidance on appropriate numbers of procedures for sealed sources therapies has been released by NHS England [5].

(c) details of how the administered activity is to be calculated, what the main organs at risk are and any dose limiting measures. Where available, references should be attached to the application.

(d) attendance at relevant training courses to include certificates and syllabus as appropriate

(e) details of involvement in relevant multidisciplinary team meetings for appropriate patient selection and onward management

Qualifications and experience of the practitioner

3.15 To hold a licence, it is essential to receive both theoretical and practical training in the procedures applied for. The degree of training required by a practitioner will vary with the nature of the procedures to be undertaken.

3.16 Practitioners who wish to apply for a licence to enable them to support a comprehensive diagnostic nuclear medicine imaging service should have satisfactorily completed a nuclear medicine training programme, a clinical radiology training programme with special interest training in radionuclide radiology or demonstrate an equivalent level of training.

3.17 Holders of a certificate of completion of training (CCT)or CESR(CP) (certificate of eligibility for specialist registration (combined programme)) in nuclear medicine, would normally expect to receive a licence including most of procedures in Table 5.1 and Table 5.3.

3.18 Those who have successfully completed clinical radiology training with a special interest in radionuclide radiology would normally expect to be licensed for most of those imaging procedures listed in Table 5.1.

3.19 Practitioners who wish to apply for a licence to support a therapy service should have completed a formal nuclear medicine training programme, a formal clinical oncology training programme or demonstrate an equivalent level of training and be on the GMC Specialist Register for the appropriate discipline. Specific experience and training in brachytherapy and/or molecular radiotherapy should be evidenced, as appropriate. This may include, for example, a clinical or research fellowship, or attendance at specialist meetings, or a greater than minimum clinical service commitment in these areas.

3.20 Applicants who have not undertaken a formal training programme are required to demonstrate equivalent training, experience and competence relevant to the procedures they wish to undertake.

3.21 Alternative local methods of developing appropriate skills can always be used, but recognised training schemes may be preferable as these provide evidence of competence that might be more easily transferable. Where local training is developed, this should be equivalent to existing formal schemes. Within any application to ARSAC, greater detail will be required about local training schemes so that the committee can satisfy itself as to the competence of all staff involved.

3.22 Some suppliers have developed training to support the introduction of new radiopharmaceuticals into the UK, where the use of the radiopharmaceutical requires expertise and skills not usually available within an existing nuclear medicine service. Reference to completion of this training in an amendment application may enable applications to be processed more quickly.

Additional requirements for positron emission tomography/ computed tomography (PET/CT) or positron emission tomography/ magnetic resonance imaging (PET/MRI)

3.23 Practitioners who wish to justify exposures as part of a PET/CT or PET/MRI service will require training and experience additional to that required for conventional nuclear medicine procedures. Such practitioners should already hold a licence for a comprehensive range of nuclear medicine procedures.

3.24 For those undertaking formal training programmes, a licence for routine diagnostic PET procedures will usually be granted on completion of the training grade.

3.25 For those who have not undergone formal training to include PET/CT and/or PET/MRI, additional information on post qualification training and experience will need to be provided to demonstrate adequate knowledge, experience, competence and skill. Specific details of practical experience required is detailed in section 3.39 to 3.42.

Theoretical training

3.26 Theoretical training can provide information on clinical indications, appropriate patient selection and reporting along with practical details on patient preparation, image acquisition and radiopharmaceutical considerations. There are different ways to demonstrate sufficient training and experience and opportunities to gain experience remotely may also be available. Examples of training opportunities include:

- **(a)** webinars
- **(b)** e-learning courses
- **(c)** conferences
- **(d)** scientific meetings
- **(e)** online training sessions
- **(f)** literature reviews

3.27 Several courses on PET/CT are available in the UK, Europe and North America and these will provide sufficient theoretical knowledge for the applicant, when considered in conjunction with an existing broad knowledge of nuclear medicine.

3.28 The theoretical training in the core curriculum in Appendix 1 is intended as a guide for applicants who have not completed formal training programmes. It should be noted that this does not address the comprehensive medical knowledge required for the management of patients. The time taken to cover

the relevant areas in Appendix 1 will vary depending on the scope of the application. Sections that are not relevant to the application may be omitted.

3.29 The core curriculum is intended to provide sufficient detail so that the licence holder has an appreciation of all aspects of the procedures applied for but cannot provide the same depth of understanding that other professionals within the specialty will bring to the subject, for example radiopharmacists and physicists.

3.30 Within any application, details should be provided of the training opportunity participated in, the date of attendance, and a short summary of how it is relevant to the procedures applied for. Training certificates can be attached to the application in the online portal.

Practical experience

3.31 The amount of appropriately supervised practical experience needed for a licence will vary depending on the procedures applied for, whether this is a first application or an amendment to an existing licence. Information provided can be restricted to those procedures which have been applied for.

3.32 The experience gained should be enough to justify the procedures included in the application, support the day-to-day running of the service, and respond to any patient management problems that may arise.

3.33 For diagnostic applications, experience should not be limited to just reporting. The applicant should be able to demonstrate active involvement in protocol development, participation in patient selection, patient preparation, justification, participation in multidisciplinary team (MDT) meetings, clinical evaluation and, within the nuclear medicine facility, day-to-day running of the service.

3.34 Practical experience is usually obtained from supervised working or visits to centres that are already undertaking procedures. Where it is not possible to visit an external site, experience in some practical elements can be gained remotely. Within an application, details should be included of both face to face and remote training. For the range of procedures within the application, include approximate number of cases, level of involvement and the name of the practitioner under whose mentorship or supervision experience has been gained.

3.35 Examples of practical experience opportunities include:

- **(a)** take part in local protocol development
- **(b)** discuss requirements with experts from other centres
- **(c)** MDT meetings (virtual or in person)
- **(d)** virtual or in person mentoring from another licensed practitioner

(e) remote or in person consultations with patients

3.36 As a guide, applicants should have experience of supervising and reporting a number of procedures consistent with the Joint Royal Colleges of Physicians Training Board (JRCPTB) Nuclear Medicine 2021 curriculum [11] or the curriculum of the European Board of Nuclear Medicine (EBNM) [12] ,

3.37 Applicants for a comprehensive diagnostic licence are expected to have experience of approximately 3,000 procedures. This level of experience will enable a practitioner to justify, perform, and develop the protocols for those procedures included within the issued licence.

3.38 For hybrid imaging, licences do not confirm the holder's knowledge, experience, competence and skill in relation to any use of CT as this is outside the scope of licence. The use of CT in nuclear medicine procedures is subject to clinical governance considerations [13].

3.39 Practical experience in PET/CT (or PET/MR) should be obtained through attendance at an established clinical PET installation. Mobile PET/CT facilities may contribute to the experience of an individual but are not sufficient to be recognised as the sole source of training.

3.40 Applicants who wish to justify ^{18}F-FDG-based oncology procedures, should be able to demonstrate active involvement in approximately 600 cases typically over a period of about one year. This should be achieved in blocks rather than through sessional involvement and it is recommended that the blocks should be of no less than 4 weeks duration. Experience gained in this way should ensure a representative patient case-mix.

3.41 For non-^{18}F-FDG PET/CT procedures, ARSAC would normally expect applicants to demonstrate practical experience specific to each procedure applied for. For neurological PET/CT this should include the mentored review of approximately 50 cases (including library cases) for each indication. For cardiac PET/CT this should include the mentored review of approximately 100 cases (including library cases).

3.42 Practitioners who wish to justify cerebral amyloid PET/CT procedures need to include the following information within their applications:

(a) confirmation of participation in, or feedback from, the relevant MDT and referring dementia experts

(b) knowledge, experience, and authorisation for ^{18}F-FDG imaging for differential diagnosis of dementia

(c) specific understanding of brain amyloid imaging in dementia, following attendance at a reader training programme or equivalent

(d) practical experience in the procedure requested to include mentored review of at least 50 cases

Remote supervision of services

3.43 ARSAC does not encourage remote practitioners. The committee considers that remote working makes it more difficult to ensure that the requirements for patient safety and appropriate standards of quality of care are maintained. Under exceptional circumstances there may be changes in the way in which practitioners are delivering and supporting nuclear medicine and PET/CT services. ARSAC is of the view that wherever possible, the practitioner should regularly attend at each medical radiological installation for which they are providing support. The frequency of attendance and level of supervision should be commensurate with the complexity of the service. For example, for the administration of a non-standard therapy, the practitioner would be expected to be available on site.

3.44 It is the professional responsibility of all licensed practitioners to ensure that they are providing adequate supervision for the appropriate justification of exposures and management of protocols. As a broad principle, the committee consider that a practitioner should not be based so far away from a site that it is not practicable for them to ever visit.

3.45 Where a licensed practitioner is looking to extend support to additional medical radiological installations, the following should be considered:

- **(a)** practitioners should be entitled as a practitioner and as an operator for any other practical aspects that they undertake according to the employer's procedures
- **(b)** practitioners should hold a contract with the employer
- **(c)** the practitioner should review their licence to ensure that all procedures licensed at the medical radiological installation are included for the purpose specified
- **(d)** the practitioner should spend time on site providing supervision, the level of supervision should be commensurate with the complexity of the procedures performed
- **(e)** when the practitioner is not based on site, they should be contactable to provide support when the procedures are being undertaken
- **(f)** the practitioner should approve and provide support for the ongoing review of all protocols
- **(g)** the practitioner should review the employer's procedures under IR(ME)R to ensure they can comply with them
- **(h)** if it is not practicable for the practitioner to authorise every exposure, the practitioner should issue written guidelines to allow the authorisation of exposures by appropriately entitled operators. Further guidance is available in section 3.5 to 3.6

(i) the practitioner should assess the arrangements to ensure that there are appropriate supporting staff available to them. This is particularly important where operators will be authorising referrals under their guidelines

Renewal of licences

3.46 A practitioner licence may be renewed on expiry. It should be noted that it is the responsibility of the practitioner to ensure that they hold a valid licence. Renewals should be submitted at least 8 weeks prior to the expiry of a licence to allow enough time for processing.

3.47 Maintenance of competence is a clinical governance issue and an essential part of modern clinical practice. Practitioners are expected to undertake appropriate CME associated with the procedures on their licence as part of the appraisal and revalidation processes and to confirm this at the time of renewal.

3.48 Prior to submitting a renewal application via the ARSAC online portal, the existing licence should be reviewed to ensure the procedures listed encompass the practitioner's current scope of practice. Any procedures that are no longer performed may be withdrawn. Any additional procedures that are required can be included.

3.49 The ARSAC support unit will send a renewal reminder email 14 weeks before the expiry of a licence. It is the responsibility of each licensed practitioner to be aware of the expiry date on their licence and to submit a renewal application for the procedures required in good time prior to this expiry date.

3.50 The ARSAC support unit should be notified if the licence is no longer required.

Amendments to licences

3.51 An amendment to a practitioner licence should be submitted for the following changes:

(a) addition of a procedure

(b) change in purpose for an existing authorised procedure (for example, research to diagnosis)

3.52 Applications for amendments can be added within the duration of a valid licence. These should be submitted as and when required. Details of the how to apply and the practitioner amendment form are available on the ARSAC web page.

3.53 Completed practitioner amendment applications should be submitted via the ARSAC online portal. Evidence of appropriate training and experience specific to the procedures requested should be included in the amendment application.

3.54 Applicants will need to set up an account to apply. Practitioner amendment applications can be submitted by the practitioner or by someone else on their behalf.

Notification of material changes to licences

3.55 A notification should be submitted via the ARSAC online portal, prior to any material change in circumstances that may affect the validity of the licence.

3.56 Applicants should extract the relevant section of the new practitioner licence application form and complete this with the updated information. Such changes include, but are not limited to:

(a) change in appointment

(b) addition or removal of medical radiological installations where the licence holder is entitled as practitioner

(c) retirement or reduction in hours

(d) change of contact details (for example, email address)

(e) removal of a procedure from a licence

Section 4

Applying for research authorisation

Introduction

4.1 IR(ME)R [2,3] addresses the exposure of individuals as part of biomedical and medical research. The principles of justification and optimisation also apply to research exposures. IR(ME)R requires the employer to establish either a dose constraint or target levels of dose for each research trial.

4.2 Regulation 11(1)(d) of IR(ME)R states that a person must not administer a radioactive substance in the course of a research trial unless it has been approved by an expert committee. ARSAC is this expert committee. It also requires such research trials to be approved by a recognised research ethics committee (REC).

4.3 Under IR(ME)R, employers and practitioners wishing to take part in any ARSAC approved research trial, must ensure the specified procedure codes are included on their licences for the purpose of research.

4.4 Practitioners should be appropriately notified of the research protocol by the research sponsor during the setup of the research trial and prior to any administrations taking place at each radiological installation.

4.5 Further information on approvals for research trials by other bodies may be obtained from the Health Research Authority (HRA).

Applying for a research approval

4.6 ARSAC research approval must be obtained by the trial sponsor for all research trials as follows:

- **(a)** where the protocol requires the administration of radioactive substances regardless of whether this is considered standard care
- **(b)** where the protocol specifies the frequency, administration or processing for an exposure involving radioactive substances that would otherwise always be considered standard care

4.7 ARSAC research approval is not required for research trials where:

- **(a)** the protocol does not specify any administrations of radioactive substances

(b) the only administration of a radioactive substance mentioned in the protocol is an inclusion criterion that would be received by all participants as part of clinical care outside of the trial and prior to giving consent to take part (for example, a trial where all participants must have received prior radioiodine therapy to be considered eligible or a trial involving the retrospective review of imaging data)

4.8 The HRA has produced further guidance to aid sponsors in determining if the exposures within a trial are research exposures.

4.9 Submissions to ARSAC should be made at the same time as ethical approval is sought. Submissions should be made via the ARSAC online portal. Applicants will need to set up an account to submit an application. Further guidance on how to use the online portal is available.

4.10 An ARSAC application form can be generated for research trials which involve the administration of radioactive substances on the research application system (IRAS). The sponsor (or someone on their behalf) should submit the forms to the ARSAC support unit via the online portal with any relevant participant information sheets (PIS) and supplementary documentation.

4.11 ARSAC does not routinely require the research protocol to be provided except for studies involving the administration of therapeutic radioactive substances.

4.12 For novel therapeutic radiopharmaceuticals, ARSAC would expect that full dosimetry and treatment verification is included in the trial protocol. For radioisotopes where imaging and direct measurements are impossible, applications should describe how the treatment delivery will be verified and absorbed doses are to be calculated. Examples of such novel therapeutic radiopharmaceuticals include but are not limited to:

(a) Therapeutic radiopharmaceuticals in first in human trials

(b) Therapeutic radiopharmaceuticals that have never been used in the UK before and where insufficient international data is available

(c) Therapeutic radiopharmaceuticals that have been used in UK trials but where comprehensive dosimetry has not been determined

(d) Therapeutic radiopharmaceuticals that have been used in the UK but are being investigated for a different indication or population

4.13 For therapeutic radiopharmaceuticals which have been used extensively in research before, the dosimetry method chosen may be adapted based on previous trial data and the level of dose to organs at risk. This rationale should be fully described in the information submitted to ARSAC. This does not preclude the requirement for appropriate verification of treatment delivery. Additional information of dosimetry can be included in the research protocol or supplied in a separate document attached to the application on the online portal.

4.14 For therapeutic administrations, ARSAC recommends that the Clinical Radiation Expert (CRE) assessing the study should hold a practitioner licence for relevant therapeutic procedures. For novel or non-standard diagnostic administrations, the CRE should hold an appropriate diagnostic practitioner licence. Where multiple CREs are involved, an appropriate licensed practitioner should be consulted when preparing the clinical assessment of the research exposures.

4.15 There are fees for research approvals, see the ARSAC web page.

4.16 A trial must receive confirmation of ARSAC approval prior to any administrations of radioactive substances taking place. The ARSAC research approval document will confirm the approved procedures within the trial. The trial sponsor must provide this to all relevant participating medical radiological installations.

Research amendments

4.17 If a research trial is amended after approval, ARSAC should be notified of any changes concerning the administration of radioactive substances as this may affect the approval granted. Such changes normally meet the criteria for notifying substantial amendments to the REC and include, but are not limited to:

- **(a)** changes to the number of administrations of radioactive substances as indicated on the original application
- **(b)** addition or removal of a procedure involving the administration of radioactive substances
- **(c)** addition of a new population with a different clinical condition (including changing the age range for participants)
- **(d)** addition of healthy volunteers receiving administrations of radioactive substances
- **(e)** changes to the radiation risk information in the PIS following a change to the protocol for the administration of radioactive substances

4.18 ARSAC does not need to be notified of amendments due to other changes to the research study unrelated to the administration of radioactive substances for example, changes to CT scans. Advice on whether a change constitutes an amendment can be sought by contacting the ARSAC Support Unit.

4.19 Research sponsors should submit a research amendment application on the ARSAC online portal with the following attachments:

- **(a)** notice of the substantial amendment

(b) updated ARSAC application form if there are changes to the number of administrations or procedures involving radioactive substances

(c) any other relevant documents (for example, updated PIS to include any tracked changes)

4.20 Applicants will need to set up an account to submit an application. Further guidance on how to use the online portal is available. ARSAC will contact the applicant through the online portal if any further information is required to process the amendment. There are fees for research amendments, see the ARSAC web page.

4.21 Submission of an amendment does not affect the original approval of the research study by ARSAC. Administrations can continue; as indicated in the approved application form, while the amendment is being assessed.

4.22 Once approved, an updated research approval document will be provided to confirm approval of the amendment. The trial sponsor must provide this to all relevant participating medical radiological installations.

Research notifications

4.23 ARSAC should be notified of changes to the research trial title to ensure the approval remains valid. Notification should be submitted via the ARSAC online portal. Once approved, an updated research approval document will be provided. The trial sponsor must provide this to all relevant participating medical radiological installations.

4.24 Notifications are not subject to a fee.

Issues considered by ARSAC when assessing research trials

4.25 ARSAC has primary responsibility for assessing whether the proposed administration of radioactive substances in a research trial is appropriate. This includes consideration of:

(a) whether the administration of radioactive substances is appropriate to the trial objectives, considering international and UK guidelines

(b) the effective or target tissue dose per administration and per participant

(c) for therapeutic administrations, whether the protocol ensures that appropriate verification of treatment delivery is performed including, where relevant, tumour and normal tissue dosimetry

(d) the risks to participants from these administrations in combination with other ionising radiation to be administered, taking into account the age, diagnosis and other characteristics of the research cohort

(e) measures to minimise the risks, in particular for individuals with child-bearing potential

(f) information in the PIS regarding the administration of radioactive substances and the risks

Activity administered and effective dose

4.26 The activity administered to individuals should be the minimum consistent with obtaining adequate information, especially for administrations to individuals who are not expected to benefit directly. Research involving high radiation doses may be approved if specific justification is provided. The justification must apply to the individual recipient as well as to the population as a whole. All unnecessary administrations should be avoided.

4.27 ARSAC expects that when an application for a research trial involving novel diagnostic radiopharmaceuticals is submitted, estimates of effective dose will be based on the best information available at the time. Where such estimates are not possible from similar existing human studies, data from animal dosimetry studies, or where practicable from human studies involving extremely low radiation doses, should be submitted as part of the application. References to published works should be included on the application form and attached to the online portal with the application or, where this is not available; any unpublished data should be provided.

4.28 More accurate information on dosimetry may be available once the trial commences. To help ARSAC in its task of reviewing future applications, updated dosimetry estimates can be sent to the ARSAC Support Unit.

Age

4.29 Consideration must be given to the age of the subjects proposed for investigation. Persons under 16 years of age should not be involved except where problems specific to their age group are under investigation. Special justification would be required for the inclusion of children and young persons in research trials.

4.30 Whenever possible, healthy volunteers should be aged over 50 years [14]. If the trial requires subjects below the age of 50 years, then explicit justification for the age range required should be included by the CRE within their assessment in the application. Upper age limits do not need to be stated in the application.

Multiple trials

4.31 Consideration should be given to the risks to an individual who is involved in several research trials. It is unacceptable that an individual should repeatedly take part in research trials leading to a substantial cumulated radiation dose. This is particularly relevant for healthy volunteers where an annual dose constraint of 10mSv from all research exposures (including those from non-nuclear medicine procedures) should be applied.

4.32 Investigators should always review the previous radiation exposure of the proposed participants. In the case of healthy volunteers, previous exposures as part of their clinical diagnosis or treatment should not be included as part of the proposed annual dose constraint of 10mSv.

Pregnancy

4.33 The possibility of early pregnancy should always be borne in mind in connection with the use of individuals of childbearing potential as research subjects.

4.34 Individuals who are pregnant or breastfeeding must not be involved in any trial, except where problems related to their condition are under investigation and alternative techniques that do not involve ionising radiation have been considered and rejected.

Communicating risk to research ethics committees, patients and research subjects

4.35 IR(ME)R includes a requirement for all research subjects to receive prior information on the risk of any exposures they may receive as part of a research trial. Knowledge and communication of risk to patients and research subjects form an essential element of modern medical practice and, without it; informed consent cannot truly be obtained.

4.36 When communicating risk, it is normal to discuss risk in terms of numbers. Care should be taken to ensure that the risks are not compared with practices that are unfamiliar or considered unacceptable. Comparing the risk associated with a paediatric procedure with that of smoking cigarettes or using internationally derived comparisons, such as drinking half a bottle of red wine a day, may give a false impression or trivialise the risk.

4.37 As the level of risk becomes greater, quoting risks in numerical terms may be helpful. At moderate levels of risk, it is likely that only in exceptional circumstances would a properly informed individual volunteer without a balancing individual benefit.

4.38 Where discussing the risk of a single administration the dose can be compared with the average dose to which people are exposed in a year in the UK (approximately 2.7mSv [15]). It would not be appropriate to compare the risk in a trial to an excessive number of years of background radiation.

4.39 ICRP Publication 62 [16] provides general guidance for assessing research proposals against radiation risk. When designing research trials, consideration should be given as to whether the extra information gained from the trial warrants the risk involved.

4.40 The HRA have also published guidance [17] on representing risk to patients and research subjects.

Fees

4.41 Research sponsor applications can only be processed on the payment of the correct fee. Details are available on the ARSAC web page.

4.42 Full details of how to pay the fee will be provided once an application has been accepted. The default payment method is by credit card/debit card through a secure online portal. Payment may be invoiced for research sponsors who are unable to pay by card and hold a credit account with UKHSA.

Section 5

Routine procedures

Introduction

5.1 These notes contain information regarding a subset of procedures undertaken routinely in the UK using radioactive substances. This is intended to be neither exhaustive nor exclusive. Omission of a particular procedure does not imply that ARSAC will not approve an application for its use or that it is in any way unsatisfactory. ARSAC reviews and updates the procedure details within these notes periodically.

Considerations for diagnostic procedures

5.2 It is important that the administered activity for each individual exposure is optimised such that appropriate diagnostic information is obtained with the lowest practicable dose to the patient. This is the principle underlying optimisation.

5.3 IR(ME)R [2,3] requires that employers regularly review and have available to operators DRLs. All procedures should be undertaken in accordance with departmental written protocols. Local DRLs should be specified in the written protocols.

5.4 The values for administered activity listed in these notes are to be considered as the national DRLs (NDRL) for investigations in adult patients of standard size, for example, 70kg. These levels, while not a maximum limit, are not expected to be consistently exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied.

5.5 In many cases, it will be possible to administer activities less than the NDRL. This is encouraged in line with the optimisation principles above.

5.6 NDRL for CT exposures used as part of SPECT/CT and PET/CT procedures have been published.

5.7 The NDRL are to be regarded as guidelines and should be exceeded only in individual patients where clinical circumstances make it necessary, for example, patients who are very much overweight or unable to tolerate standard acquisition times. The guiding principle, however, remains that the activity administered should be the minimum consistent with acquiring adequate information from the investigation concerned.

5.8 Where administered activity is increased on the basis of an individual patient's weight or other clinical consideration, it is unnecessary to inform ARSAC. If such increased activities are used infrequently, they should be justified, and details documented within the patient record by the licensed practitioner. The requirement for this should be included in the employer's procedures. The actual activity administered must be recorded in the patient's medical or departmental records.

5.9 Where this becomes a regular process, but is still assessed for each individual patient, for example, where a fixed activity per kg body weight is administered, this should be included in local protocols. This can then be applied by staff other than the licensed practitioner but the requirement to record the actual administered activity and the reason for the increase remains.

5.10 If, within the context of local circumstances (for example, all patients for bone scans at the radiological installation have confirmed cancer and severe bone pain), all patients at a medical radiological installation will require a standard activity for a procedure higher than the NDRL, an amendment to the employer licence should be made to ARSAC, giving the justification for the increased activity. If agreed, this should be included within local written protocols

5.11 Many employers written protocols calculate the administered activity for radiopharmaceuticals dependant on the patient weight. ARSAC supports this, particularly for PET radiopharmaceuticals where patient specific administered activities are more common. ARSAC will accept applications with proposed administered activities indicated by weight, for example MBq/kg. Values used should be based on published data and adapted for the capabilities of local equipment. This should be detailed in local protocols with the activity calculated for a 70kg person being less or equal to the NDRL stated in these notes.

5.12 Where applications are made for procedures by reference to functional groups or specific procedure codes within these notes, then the activities administered to patients should be those quoted in these notes or lower.

5.13 ARSAC expects routine audits to be performed on the administered activity. Persistent administration of activities larger than those contained in these notes, without documented justification, would be cause for concern.

Considerations for therapeutic procedures

5.14 For treatments using unsealed sources, ARSAC considers the total activity administered to be a matter of clinical judgement by the responsible licensed practitioner. Where available, clinical guidelines should be taken into consideration.

5.15 The treatment prescription is frequently used by clinical providers as evidence that the justification of treatment has been completed. ARSAC advises that the prescription for treatments involving unsealed sources should as a minimum include the following information:

- **(a)** unique patient identification
- **(b)** clinical indication and any other relevant radiation protection information (for example incontinence, requirement for carers and comforters or return to non-domestic premises such as residential home)
- **(c)** pregnancy or breastfeeding status
- **(d)** radiopharmaceutical and any other associated pharmaceuticals required (for example thyroid blocking or renal protection)
- **(e)** prescribed activity to be administered (to include weight based or alternative scaling method where applicable)
- **(f)** method of administration (IV/oral etc)
- **(g)** Fractionation regime if relevant to include fraction number (for example 1 of 6)
- **(h)** identity of the licensed practitioner (including signature or electronic authorisation)
- **(i)** date prescription completed

5.16 IR(ME)R requires that practitioners ensure that exposures of target volumes are individually planned and their delivery appropriately verified taking into account that doses to non-target volumes and tissues must be as low as reasonably practicable and consistent with the intended radiotherapeutic purpose of the exposure. ARSAC recommends that:

- **(a)** in cancer treatments with radioactive substances, the absorbed dose to the tumour, and to non-target volumes and tissues, following each administration should be measured and recorded, to permit subsequent optimisation of total doses
- **(b)** for treatment of benign conditions or, where direct measurements are impossible, absorbed doses should be calculated or estimated and recorded

5.17 Applications for therapy administrations both in routine clinical practice and research, are therefore expected to specify what dosimetry will be performed, per course, on an individual patient basis. Employers should ensure that appropriate resources are available.

5.18 For treatments using sealed sources, where available, clinical guidelines should be taken into consideration for determining the prescription.

Administration of Prescription Only Medicines as part of diagnostic and therapeutic procedures

5.19 As stated in the RCR Guidance [9,10] there is provision in Regulation 240 of the Human Medicines Regulations 2012 [18] for IR(ME)R operators to administer prescription only medicines (POM) required as part of nuclear medicine procedures. For example this would include thyroid blocking agents as part of diagnostic thyroid investigations (see section 8) and diuretics administered as part of a renogram. In order for this to apply certain conditions need to be met as follows:

(a) The POM is administered by an operator in accordance with the protocol

(b) The exposure is authorised by a practitioner or an operator following authorisation guidelines

(c) The practitioner holds a licence for the administration of the radioactive substance

(d) The POM is not a product subject to special medical prescription

(e) The administration of the POM is included in the protocol.

General techniques for dose reduction

5.20 Several simple techniques can be used to reduce radiation dose. For example, many radiopharmaceuticals are excreted by the kidneys. Bladder doses can be minimised by drinking plenty of fluid and frequent bladder emptying.

5.21 Advice on the use of thyroid blocking agents is given in section 8.

5.22 Where different imaging investigations give equivalent information and are available to the patient within the time frame of their clinical management then, on radiation protection grounds, the investigation resulting in the lower dose should be selected.

5.23 In some cases, if the patient is healthy and cooperative, administered activity can be reduced and scan times increased. However, it is important that the diagnostic information produced is not compromised by any reduction in administered activity. An example might include lung scans for pregnant women.

5.24 Software programs (for example, resolution recovery) that improve image quality may allow for a reduction in the administered activity while maintaining the required levels of diagnostic information. Where available, such programs should be used and optimised in local protocols.

5.25 When equipment is upgraded or replaced, consideration should be given to technology which will allow further reductions in administered activity. When the equipment is installed, the protocols and set up should be optimised to ensure adequate image quality is maintained.

Effective dose (ED)

5.26 The effective doses given in these notes have been calculated from the corresponding DRL using the methodology described in ICRP Publication 128 [19], using weighting factors from ICRP Publication 60 [20]. Revised weighting factors have been published in ICRP Publication 103 [21], but have yet to be applied to the ICRP models.

5.27 Although the concept of effective whole-body dose was originally only intended for occupational risks, it provides a useful index when used in connection with radiopharmaceuticals.

5.28 The effective doses are based on clinically normal subjects and may vary considerably in pathological states. Caution should therefore be exercised in conditions where the abnormal retention of the radiopharmaceutical can result in a substantially higher absorbed radiation dose.

5.29 Information on radiation doses to patients from radiopharmaceuticals is provided in ICRP Publication 53 [22] and its addendums [23 to 25] and summarised in ICRP Publication 128. For those procedures not covered in ICRP publications, other published dosimetry estimates have been used [26 to 37].

5.30 Estimates of the dose to the uterus may be used as an indicative dose to the foetus in cases where pregnancy is known or suspected. Figures are derived from the literature, mostly from ICRP Publication 128. It should be noted that these figures do not include a component of dose from the cross-placental transfer of radiopharmaceuticals which may need to be considered for higher risk foetal exposures. IR(ME)R requires practitioners to consider whether the exposure could be delayed until it is confirmed whether the individual is pregnant, or the exposure can wait until the baby is born.

Functional groups

5.31 To simplify the application process, some of the procedures in Table 5.1 have been organised into ‘functional groups’, relevant to patient pathology and physiology. Where all procedures within a functional group are required on a licence, the applicant can specify the functional group instead of listing individual procedures.

5.32 Procedures within the functional groups are listed in Table 5.5 for imaging procedures and Table 5.6 for non-imaging procedures.

Table 5.1: Diagnostic procedures

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin*	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	FG
111In-107-58	^{111}In	leucocytes	infection/inflammation imaging	IV	20	7.2	2.4	9
111In-131-132	^{111}In	pentetreotide	somatostatin receptor imaging	IV	110	5.9	4.3	14
					220 SPECT	11.9	8.6	
111In-140-139	^{111}In	platelets	thrombus imaging	IV	20	7.8	1.9	10
111In-41-92	^{111}In	DTPA with non-absorbable compounds	oesophageal/gastric/intestinal motility studies	oral	12	3.8	2.0	6
123I-117-136	^{123}I	mIBG	sympathetic innervation imaging of the heart	IV	370	4.8 [1]	3.7	1
123I-117-167	^{123}I	mIBG	tumour imaging	IV	400	5.2 [1]	4.0	14
123I-93-142	^{123}I	iodide	thyroid imaging/uptake	oral or IV	2 uptake	0.6	0.02	23
					20 imaging	6.1	0.17	11
123I-93-143	^{123}I	iodide	thyroid metastases imaging (after ablation)	oral	400	10 [2]	4.8	14
				or IV	400	7.8 [2]	4.8	
123I-96-15	^{123}I	ioflupane	brain imaging	IV	185	4.6 [1]	2.6	4
125I-84-101	^{125}I	human albumin	plasma volume	IV	0.2	0.04 [1]	0.04	22

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin*	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	FG
131I-93-142	^{131}I	iodide	thyroid imaging/uptake	oral	0.2	5.8	0.008	23
131I-93-143	^{131}I	iodide	thyroid metastases imaging (after ablation)	oral	400 [3]	68 [2]	18	14
				or IV	400 [3]	52 [2]	18	
14C-166-51	^{14}C	urea	H Pylori detection	oral	0.2	0.006	0.005	24
14C-79-19	^{14}C	glycocholic acid	breath tests	oral	0.4	0.14	0.06	24
201Tl-157-83	^{201}Tl	thallous chloride	myocardial imaging	IV	80	11.2	4.0	1
51Cr-44-46	^{51}Cr	EDTA	GFR measurement	IV	3	0.006	0.008	25
51Cr-48-109	^{51}Cr	erythrocytes	red cell kinetics	IV	4	0.7	0.3	22
51Cr-48-48	^{51}Cr	erythrocytes	GI bleeding	IV	4	0.7	0.3	24
75Se-1-7	^{75}Se	23-seleno-25-homotaurocholic acid (SeHCAT)	bile salt absorption	oral	0.4	0.3	0.3	20
81mKr-74-75	^{81m}Kr	Gas	lung ventilation imaging	inhalation	6,000	0.2	0.001	3
99mTc-113-113	^{99m}Tc	MAG 3	renal imaging/renography	IV	100	0.7	1.2	8
99mTc-125-92	^{99m}Tc	non-absorbable compounds	oesophageal/gastric/intestinal motility studies	oral	40	0.9	0.6	6
99mTc-132-117	^{99m}Tc	pertechnetate	salivary gland imaging	IV	80	1.0	0.6	6

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin*	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	FG
99mTc-132-142	^{99m}Tc	pertechnetate	thyroid imaging/uptake	IV	80 imaging	1.0	0.6	23
					40 uptake	0.5	0.3	11
99mTc-132-39	^{99m}Tc	pertechnetate	ectopic gastric mucosa imaging (Meckel's)	IV	400	5.2	3	6
99mTc-132-42	^{99m}Tc	pertechnetate	first pass blood flow imaging	IV	800	10.4	6.5	1
						3 [1]	5.1 [1]	
99mTc-132-61	^{99m}Tc	pertechnetate	lacrimal drainage	eye drops	4 per eye	0.05	–	13
99mTc-137-11	^{99m}Tc	phosphonates and phosphates	bone imaging	IV	600	2.9	3.7	5
					800 SPECT	3.9	5.0	
99mTc-150-167	^{99m}Tc	sestamibi	tumour imaging	IV	900	8.1	7.0	14
99mTc-150-83	^{99m}Tc	sestamibi	myocardial imaging	IV	800 [4] rest	7.2	6.2	1
					800 [4] stress	6.3	5.8	
99mTc-150-95	^{99m}Tc	sestamibi	parathyroid imaging and/or probe studies	IV	900	8.1	7.0	11
99mTc-154-75	^{99m}Tc	technegas	lung ventilation imaging	inhalation	40	0.6	0.01	3
99mTc-156-83	^{99m}Tc	tetrofosmin	myocardial imaging	IV	800 [4] rest	6.4	6.2	1
					800 [4] stress	5.5	5.6	
99mTc-24-12	^{99m}Tc	colloid	bone marrow imaging	IV	400	3.6	0.4	5

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin*	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	FG
99mTc-24-121	^{99m}Tc	colloid	sentinel node (breast) probe studies with or without imaging	interstitial/ peri-tumoural	20 [5]	0.02	0.001	15
					40	0.08 [6]	0.003	
99mTc-24-125	^{99m}Tc	colloid	sentinel node (melanoma) imaging and probe studies	Interstitial/ peri-tumoural	40 [5]	0.18	0.002	15
99mTc-24-48	^{99m}Tc	colloid	GI bleeding	IV	400	3.6	0.4	6
99mTc-24-61	^{99m}Tc	colloid	lacrimal drainage	eye drops	4 per eye	0.04	–	13
99mTc-24-64	^{99m}Tc	colloid	liver and spleen imaging	IV	80	0.7	0.1	7
					200 SPECT	1.8	0.2	
99mTc-24-76	^{99m}Tc	colloid	lymphoscintigraphy	interstitial	20 per limb	0.09	0.001	2
99mTc-24-92	^{99m}Tc	colloid	oesophageal/gastric/intestinal motility studies	Oral	40	0.9	0.6	6
99mTc-30-133	^{99m}Tc	denatured erythrocytes	spleen imaging	IV	100	0.2	0.14	10
99mTc-33-112	^{99m}Tc	DMSA(III)	renal imaging	IV	80	0.7	0.4	8
99mTc-39-22	^{99m}Tc	DPD	cardiac amyloid imaging	IV	700	5.6	4.4	-
99mTc-40-113	^{99m}Tc	DTPA	renal imaging/renography	IV	300	1.5	2.4	8
99mTc-40-42	^{99m}Tc	DTPA	first pass blood flow studies	IV	800	3.9	6.3	4
99mTc-40-46	^{99m}Tc	DTPA	GFR measurement	IV	10	0.05	0.08	25

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin*	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	FG
99mTc-40-75	^{99m}Tc	DTPA	lung ventilation imaging	aerosol inhalation	80	0.5	0.5	3
99mTc-43-15	^{99m}Tc	ECD	brain imaging	IV	750	5.8	6.9	4
99mTc-48-10	^{99m}Tc	erythrocytes	blood pool imaging (MUGA) /probe studies	IV	800	5.6	3.1	1
99mTc-48-48	^{99m}Tc	erythrocytes	GI bleeding	IV	400	2.8	1.6	6
99mTc-48-111	^{99m}Tc	erythrocytes	Red cell volume	IV	2	0.02	0.01	22
99mTc-50-15	^{99m}Tc	exametazime	brain imaging	IV	750	7.0	5.0	4
99mTc-51-58	^{99m}Tc	exametazime labelled leucocytes	infection/inflammation imaging	IV	200	2.2	0.7	9
99mTc-5-70	^{99m}Tc	albumin macro-aggregates or microspheres	lung perfusion imaging	IV	100	1.1	0.2	3
					200 SPECT	2.2	0.4	
99mTc-5-71	^{99m}Tc	albumin macro-aggregates or microspheres	lung perfusion imaging with venography	IV	160	1.8	0.4	3
99mTc-5-73	^{99m}Tc	albumin macro-aggregates or microspheres	lung shunt assessment	IV / IA	150	1.6	0.3	3

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin*	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	FG
99mTc-88-132	^{99m}Tc	HYNIC-Ty3-octreotide	somatostatin receptor imaging	IV	740	3.7	3.0	14
99mTc-91-44	^{99m}Tc	iminodiacetate	functional biliary system imaging	IV	150	2.4	1.7	7

Notes

[1] With the thyroid blocked.

[2] Effective dose calculated without contribution from thyroid.

[3] Activities of ^{131}I greater than 30MBq should be considered as therapy administration for radiation protection purposes.

[4] For combined rest–stress protocols carried out on a single day the total activity administered should not exceed 1,600MBq. Two-day protocols are recommended based on superior image quality, but it is recognised that these may not be practicable.

[5] The administered activity should be adjusted to give a retained activity of approximately 10MBq at the time of surgery if probe studies, with or without imaging, are to be undertaken on the day following administration.

[6] The effective dose should not be scaled linearly. An administration of 40MBq will give an effective dose of 0.08mSv based on an 18-hour gap between injection and surgery.

Abbreviations: IV (intra-venous), IA (intra-arterial) and FG (functional group)

Table 5.2: Diagnostic procedures – positron emission tomography

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	Activity by weight [1] (MBq/kg)	ED (mSv)	Dose to uterus (mGy)
11C-20-52	^{11}C	choline chloride	hepatocellular cancer imaging	IV	370		1.6	0.7
11C-20-105	^{11}C	choline chloride	prostate cancer imaging	IV	370		1.6	N/A
11C-111-17	^{11}C	L-methyl-methionine	brain tumour imaging	IV	400		3.3	2.7
11C-111-96	^{11}C	L-methyl-methionine	parathyroid tumour imaging	IV	740		6.1	5.0
13N-6-83	^{13}N	ammonia	myocardial imaging	IV	550		2.0	1.4
18F-19-52	^{18}F	choline	hepatocellular cancer imaging	IV	370	4.0	7.4	5.6
18F-19-94	^{18}F	choline	parathyroid imaging	IV	300	3.0	6.0	4.5
18F-19-105	^{18}F	choline	prostate cancer imaging	IV	370	4.0	7.4	N/A
18F-57-17	^{18}F	FDG	brain tumour imaging	IV	250		4.8	4.5
18F-57-37	^{18}F	FDG	differential diagnosis of dementia	IV	250		4.8	4.5
18F-57-43	^{18}F	FDG	focal epilepsy	IV	250		4.8	4.5
18F-57-58	^{18}F	FDG	infection/inflammation imaging (includes cardiac sarcoidosis)	IV	400	4.5 [2]	7.6	7.2
18F-57-83	^{18}F	FDG	myocardial imaging [3]	IV	400		7.6	7.2
18F-57-169	^{18}F	FDG	whole body tumour imaging	IV	400	4.5 [2]	7.6	7.2
18F-61-27	^{18}F	florbetaben	cerebral amyloid assessment	IV	300		5.8	4.9

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	Activity by weight [1] (MBq/kg)	ED (mSv)	Dose to uterus (mGy)
18F-62-27	^{18}F	florbetapir	cerebral amyloid assessment	IV	370		6.9	5.8
18F-64-167	^{18}F	fluciclovine	tumour imaging	IV	370		8.2	16.7
18F-66-11	^{18}F	fluoride	bone imaging	IV	250		4.3	3.3
18F-67-17	^{18}F	fluoroethyltyrosine	brain tumour imaging	IV	370		5.9	6.3
18F-68-87	^{18}F	fluoro-L-DOPA	neuroendocrine tumour imaging	IV	280	4.0	7.0	7.8
18F-68-135	^{18}F	fluoro-L-DOPA	suspected congenital hyperinsulinism	IV	280	4.0	7.0	7.8
18F-71-27	^{18}F	flutemetamol	cerebral amyloid assessment	IV	185		5.9	4.6
18F-141-105	^{18}F	PSMA	prostate cancer imaging	IV	280	4.0	6.2	N/A
68Ga-37-132	^{68}Ga	DOTATATE / DOTATOC / DOTANOC	somatostatin receptor imaging	IV	250		6.4 TATE 5.8 TOC 4.2 NOC	3.7
68Ga-141-105	^{68}Ga	PSMA	prostate cancer imaging	IV	200		4.6	N/A
82Rb-18-83	^{82}Rb	chloride	myocardial imaging	IV	2,220		2.4	2.2

Notes

[1] These values should be used as a guide only, with the administered activity optimised locally based on availability of equipment and software. Using this value should allow for administrations at levels below the DRL at most centres for most patients. Further guidance on administering by weight is provided in section 5.8 to 5.11.

[2] For systems that apply a PET bed overlap of ≤30 %, the minimum recommended administered activity is calculated as follows:

FDG (MBq) = 14 (MBq·min·bed^{-1}·kg^{-1}) × patient weight (kg)/emission acquisition duration per bed position (min·bed^{-1})
for systems that apply a PET bed overlap of >30 %, the minimum FDG administered activity is calculated as follows:
FDG (MBq) = 7 (MBq·min·bed^{-1}·kg^{-1}) × patient weight (kg)/emission acquisition duration per bed position (min·bed^{-1}) [38]

[3] Procedure 18F-57-83 is for the detection of hibernating myocardium. The imaging of cardiac sarcoidosis should be authorised under 18F-57-58 for infection/inflammation imaging.

Table 5.3: Therapeutic procedures with unsealed sources

Procedure code	Radionuclide	Chemical form	Indication	Route of admin
131I-117-156	^{131}I	mIBG	treatment of malignancy	IV
131I-93-145	^{131}I	iodide	treatment of benign thyroid disease	IV or oral
131I-93-150	^{131}I	iodide	treatment of carcinoma of thyroid	IV or oral
153Sm-46-146	^{153}Sm	EDTMP	treatment of bone metastases	IV
169Er-24-144	^{169}Er	colloid	treatment of arthritis	intra-articular
177Lu-141-164	^{177}Lu	PSMA [1]	treatment of prostate cancer	IV
177Lu-37-157	^{177}Lu	DOTATATE / DOTATOC / DOTANOC	treatment of neuroendocrine malignancy	IV
186Re-24-144	^{186}Re	colloid	treatment of arthritis	intra-articular
186Re-82-146	^{186}Re	HEDP	treatment of bone metastases	IV
223Ra-32-147	^{223}Ra	dichloride	treatment of bone metastases in castration resistant prostate cancer	IV
32P-136-163	^{32}P	phosphate	treatment of polycythemia vera and related disorders	IV or oral
89Sr-18-146	^{89}Sr	chloride	treatment of bone metastases	IV
90Y-27-144	^{90}Y	colloidal silicate/citrate	treatment of arthritis	intra-articular

Procedure code	Radionuclide	Chemical form	Indication	Route of admin
90Y-37-157	^{90}Y	DOTATATE / DOTATOC / DOTANOC	treatment of neuroendocrine malignancy	IV
90Y-89-155	^{90}Y	ibritumomab tiuxetan (Zevalin)	treatment of lymphoma	IV
90Y-118-153	^{90}Y	microspheres	treatment of hepatic malignancy	intra-arterial

Notes

The activity per administration is a matter for clinical judgement; caution is advised in treatments for non-malignant disease especially in young patients.

[1] For novel variants of PSMA, advice should be sought from ARSAC on whether this can be authorised under the existing procedure code.

Table 5.4: Procedures with sealed sources

Procedure code	Radionuclide	Physical form	Indication
106Ru-52-151	^{106}Ru	eye plaque	treatment of eye diseases
125I-148-164	^{125}I	seeds	treatment of prostate cancer
125I-148-67	^{125}I	seeds	localisation of tumours [1]
192Ir-169-148	^{192}Ir	wire/appliances	treatment of breast cancer
192Ir-169-154	^{192}Ir	wire/appliances	treatment of lung cancer
192Ir-169-159	^{192}Ir	wire/appliances	treatment of oesophageal cancer
192Ir-169-165	^{192}Ir	wire/appliances	treatment of rectal cancer
192Ir-169-166	^{192}Ir	wire/appliances	treatment of skin cancers and benign skin diseases
192Ir-7-152	^{192}Ir	appliances	treatment of gynaecological cancers
192Ir-7-164	^{192}Ir	appliances	treatment of prostate cancer
90Sr-7-151	^{90}Sr	appliances	treatment of eye diseases

Notes

The target volume dose and dose rate are a matter for clinical judgement for therapeutic procedures.

[1] This procedure involves the insertion and later removal of a seed for diagnostic purposes. The dose delivered will vary dependant on the activity of the seed, the number of seeds inserted, the time to removal and the volume of tissue excised. This procedure should be applied for under the diagnostic section of the application forms to include details of the local protocol and associated dose estimates.

Table 5.5: Imaging groups

Group 1 I – cardiac

99mTc-48-10	^{99m}Tc	erythrocytes	blood pool imaging (MUGA)/probe studies
99mTc-132-42	^{99m}Tc	pertechnetate	first pass blood flow imaging
99mTc-150-83	^{99m}Tc	sestamibi	myocardial imaging
99mTc-156-83	^{99m}Tc	tetrofosmin	myocardial imaging
123I-117-136	^{123}I	mIBG	sympathetic innervation imaging of the heart
201Tl-157-83	^{201}Tl	thallous chloride	myocardial imaging

Group 2 I – vascular

99mTc-24-76	^{99m}Tc	colloid	lymphoscintigraphy

Group 3 I – lung

81mKr-74-75	^{81m}Kr	gas	lung ventilation imaging
99mTc-5-70	^{99m}Tc	albumin macro-aggregates or microspheres	lung perfusion imaging
99mTc-5-71	^{99m}Tc	albumin macro-aggregates or microspheres	lung perfusion imaging with venography
99mTc-5-73	^{99m}Tc	albumin macro-aggregates or microspheres	lung shunt assessment
99mTc-40-75	^{99m}Tc	DTPA	lung ventilation imaging
99mTc-154-75	^{99m}Tc	technegas	lung ventilation imaging

Group 4 I – brain

99mTc-40-42	^{99m}Tc	DTPA	first pass blood flow studies
99mTc-43-15	^{99m}Tc	ECD	brain imaging
99mTc-50-15	^{99m}Tc	exametazime	brain imaging
123I-96-15	^{123}I	ioflupane	brain imaging

Group 5 I – bone/joint

99mTc-24-12	^{99m}Tc	colloid	bone marrow imaging
99mTc-137-11	^{99m}Tc	phosphonates and phosphates	bone imaging

Group 6 I – gastrointestinal

99mTc-24-48	^{99m}Tc	colloid	GI bleeding
99mTc-24-92	^{99m}Tc	colloid	oesophageal/gastric/intestinal motility studies
99mTc-48-48	^{99m}Tc	erythrocytes	GI bleeding
99mTc-125-92	^{99m}Tc	non-absorbable compounds	oesophageal/gastric/intestinal motility studies
99mTc-132-39	^{99m}Tc	pertechnetate	ectopic gastric mucosa imaging (Meckel's)
99mTc-132-117	^{99m}Tc	pertechnetate	salivary gland imaging
111In-41-92	^{111}In	DTPA with non-absorbable compounds	oesophageal/gastric/intestinal motility studies

Group 7 I – hepatobiliary

99mTc-24-64	^{99m}Tc	colloid	liver and spleen imaging
99mTc-91-44	^{99m}Tc	iminodiacetate	functional biliary system imaging

Group 8 I – genitourinary

99mTc-33-112	^{99m}Tc	DMSA(III)	renal imaging
99mTc-40-113	^{99m}Tc	DTPA	renal imaging/renography
99mTc-113-113	^{99m}Tc	MAG3	renal imaging/renography

Group 9 I – infection/inflammation

99mTc-51-58	^{99m}Tc	exametazime labelled leucocytes	infection/inflammation imaging
111In-107-58	^{111}In	leucocytes	infection/inflammation imaging

Group 10 I – haematology

99mTc-30-133	^{99m}Tc	denatured erythrocytes	spleen imaging
111In-140-139	^{111}In	platelets	thrombus imaging

Group 11 I – endocrine

99mTc-132-142	^{99m}Tc	pertechnetate	thyroid imaging/uptake
99mTc-150-95	^{99m}Tc	sestamibi	parathyroid imaging and/or probe studies
123I-93-142	^{123}I	iodide	thyroid imaging/uptake

Group 13 I – lacrimal

99mTc-24-61	^{99m}Tc	colloid	lacrimal drainage
99mTc-132-61	^{99m}Tc	pertechnetate	lacrimal drainage

Group 14 I – tumour

99mTc-88-132	^{99m}Tc	HYNIC-Ty3-octreotide	somatostatin receptor imaging
99mTc-150-167	^{99m}Tc	sestamibi	tumour imaging
111In-131-132	^{111}In	pentetreotide	somatostatin receptor imaging
123I-93-143	^{123}I	iodide	thyroid metastases imaging (after ablation)
123I-117-167	^{123}I	mIBG	tumour imaging
131I-93-143	^{131}I	iodide	thyroid metastases imaging (after ablation)

Group 15 I – sentinel node

99mTc-24-121	^{99m}Tc	colloid	sentinel node (breast) probe studies with or without imaging
99mTc-24-125	^{99m}Tc	colloid	sentinel node (melanoma) imaging and probe studies

Table 5.6: Non-imaging groups

Group 20 NI – absorption

75Se-1-7	^{75}Se	23-seleno-25-homo-tauro-cholate (SeHCAT)	bile salt absorption

Group 22 NI – haematology

51Cr-48-109	^{51}Cr	erythrocytes	red cell kinetics
99mTc-48-11	^{99m}Tc	erythrocytes	red cell volume
125I-84-101	^{125}I	human albumin	plasma volume

Group 23 NI – endocrine

99mTc-132-142	^{99m}Tc	pertechnetate	thyroid imaging/uptake
123I-93-142	^{123}I	iodide	thyroid imaging/uptake
131I-93-142	^{131}I	iodide	thyroid imaging/uptake

Group 24 NI – gastrointestinal

14C-79-19	^{14}C	glycocholic acid	breath tests
14C-166-51	^{14}C	urea	H pylori detection
51Cr-48-48	^{51}Cr	erythrocytes	GI bleeding

Group 25 NI – genitourinary

51Cr-44-46	^{51}Cr	EDTA	GFR measurement
99mTc-40-46	^{99m}Tc	DTPA	GFR measurement

Section 6

Investigations in children and young persons

Introduction

6.1 In diagnostic investigations in children, particular care must be exercised to ensure that the most appropriate investigation is chosen to answer the clinical problems. When considering the choice of investigation, factors which should be considered are risk/benefit ratios, economic cost, invasiveness, and radiation dose.

6.2 The radiation dose from the administration of radioactive substances, when used in the appropriate clinical situation, is justifiable assuming the information gained cannot be obtained using diagnostic procedures with either a lower or no radiation exposure and/or a less invasive procedure. Where appropriate and practical, an investigation which does not involve ionising radiation should be chosen, assuming access to such procedures is available within a timeframe appropriate to the clinical management of the patient.

6.3 Nuclear medicine departments designed for adults often provide a poor environment for children. Successful nuclear medicine procedures for children require some simple modifications to the environment and normal procedures. Comprehensive practical information can be found on the EANM website under each specific examination. Consideration should be given as to whether it would be more appropriate to refer the child to a specialist centre.

6.4 Procedures involving children always take longer than the equivalent adult procedure. Children tend to be less predictable and more varied in their response than adults. It is advisable to schedule at least 50% extra time for paediatric procedures.

6.5 All staff involved in paediatric procedures should be familiar with local arrangements. Delay in carrying out parts of the procedure can often lead to the child being less cooperative. This can in turn lead to an increase in the time taken for the procedure or in some cases the procedure may not be successful.

6.6 The parent/guardian of the child should be fully informed about the procedure in advance of the imaging appointment. Leaflets providing full information on the particular examination should be given to the parent/guardian at the time of the appointment. On the day of the examination the entire procedure should be explained to the child and accompanying adult.

Activity administered

6.7 The activity administered should be the minimum consistent with obtaining a diagnostic result. As this is the same principle applied to adults, the normal activity administered to adults should be used as a baseline for the calculation of activity to be administered to children weighing less than 70kg. Advice has been provided by the Paediatric Task Group of the EANM [39]. This is presented in Table 6.1. An update to the EANM guidance was released in the form of a new paediatric dosage card in 2007 [40] and further amended in 2014 [41] to provide weight-independent scaling factors dependent on the class of investigation. This was supported by further guidance detailing scaling information for ^{18}F-FDG PET imaging [42].

6.8 It is recommended by ARSAC that for children or young persons, body weight should always be measured. Except for PET imaging, the adult administered activity should then be scaled down as shown in Table 6.1. This will produce an image quality and an imaging time comparable with that expected for adults by maintaining the same image count density. The resulting effective dose by weight when compared to an adult will be higher. ARSAC advises that the employer's procedures state clearly how the fraction of adult administered activity is applied to children and young persons whose body weight lie in between the presented weight (kg) categories in Table 6.1.

Table 6.1 Scaling of adult administered activity for children or young persons by body weight.

Weight (kg)	Fraction of adult administered activity	Weight (kg)	Fraction of adult administered activity	Weight (kg)	Fraction of adult administered activity
3	0.10	22	0.50	42	0.78
4	0.14	24	0.53	44	0.80
6	0.19	26	0.56	46	0.82
8	0.23	28	0.58	48	0.85
10	0.27	30	0.62	50	0.88
12	0.32	32	0.65	52-54	0.90
14	0.36	34	0.68	56-58	0.92
16	0.40	36	0.71	60-62	0.96
18	0.44	38	0.73	64-66	0.98
20	0.46	40	0.76	68	0.99

6.9 Centres using PET for paediatric patients, while being cognisant of the most recent guidance from the EANM, should optimise the administered activity locally based on equipment settings and clinical reporting preferences. For ^{18}F-FDG whole body tumour imaging it is recommended to scale by body weight with the same scheme as used for adults. ARSAC is of the view that this area requires further research as technology and techniques are evolving.

6.10 As a general guide, activities less than 10% of the value of the equivalent adult activity should not be administered. For most purposes this simple approach will be adequate. For a number of procedures, however, if adequate image quality is to be achieved, the administered activity should be not less than that set out in Table 6.2.

Table 6.2 Recommended minimum administered activity for children.

Radiopharmaceutical	Investigation	Minimum activity (MBq)
^{99m}Tc-DTPA	renal imaging/renography	20
^{99m}Tc-DMSA(III)	renal imaging	15
^{99m}Tc-MAG3	renal imaging/renography	15
^{99m}Tc-phosphonates and phosphates	bone imaging	40
^{99m}Tc-colloid	liver and spleen imaging	15
^{99m}Tc-colloid	bone marrow imaging	20
^{99m}Tc-colloid	oesophageal/gastric/intestinal motility studies	10
^{99m}Tc-denatured erythrocytes	spleen imaging	20
^{99m}Tc-normal erythrocytes	blood pool imaging/probe studies	80
^{99m}Tc-pertechnetate	first pass blood flow imaging	80
^{99m}Tc-pertechnetate	ectopic gastric mucosa imaging (Meckel's)	20
^{99m}Tc-pertechnetate	thyroid imaging/uptake	10
^{99m}Tc albumin macroaggregates or microspheres	lung perfusion imaging	10
^{99m}Tc exametazime	brain imaging	100
^{99m}Tc exametazime labelled leucocytes	infection/inflammation imaging	40
^{99m}Tc-iminodiacetate	functional biliary system imaging	20

Radiopharmaceutical	Investigation	Minimum activity (MBq)
^{99m}Tc-tetrofosmin	myocardial imaging	50
^{99m}Tc-sestamibi	myocardial imaging	50
^{123}I-iodide	thyroid imaging/uptake	3
^{123}I mIBG	tumour imaging	70

Imaging technique

6.11 There should be specific protocols in place for imaging children in nuclear medicine departments. These should include the choice of collimator, imaging parameters and views for the various examinations. For example, in a bone scan, it is essential that the limbs should be imaged separately from the torso unless a whole-body scan protocol is used. In this case, specific localised views of the knees and any abnormal focal areas are essential.

Sedation

6.12 A cooperative child will not normally require sedation or general anaesthetic [43] Sedation may be required for long examinations when movement should not occur. Before sedating the child, consideration should be given to the effect that sedation may have on function. This applies especially to SPECT studies, PET/CT and pinhole views of the hips in the young child.

6.13 Sedation or general anaesthetic may, in some cases, be considered necessary, but this should be based on an individual assessment. Children in pain require analgesia and, if this is adequate, sedation may not be required.

Radiation protection

6.14 When a radiopharmaceutical is administered that is excreted by the kidneys, simple protective measures such as encouraging a high fluid intake, active bladder emptying or frequent nappy changing will enhance the process of elimination of the radiopharmaceutical and reduce gonadal and bladder doses. Additionally, the appropriate choice of radiopharmaceutical can result in a major reduction in radiation dose.

6.15 Where appropriate, thyroid blocking agents should be administered. Further information is provided in section 8.

Therapeutic procedures

6.16 Administration of radioactive substances for the treatment of cancer in children should only be undertaken in facilities which are appropriately staffed and resourced for the treatment of children. This relates not simply to facilities for associated imaging for treatment verification but also to accommodation of children in paediatric facilities with round the clock paediatric medical and nursing staff for the duration of the inpatient stay. General anaesthesia, if required to perform sequential post administration imaging studies for dosimetry, must be available.

6.17 For unsealed source therapeutic procedures in children, the need for patient specific dosimetry (see section 5.16) is just as applicable as it is in adults. In fact, given the greater vulnerability of children to the adverse effects of radiation exposure, and the longer potential survival duration if cured, accurate tumour and normal organ dosimetry becomes more important. While recognising the increased logistic challenges of performing dosimetry in young children, ARSAC nonetheless regards this as an essential component of good practice.

Section 7

Pregnancy, conception, and breastfeeding

Pregnancy

7.1 When it is necessary to administer radioactive substances to an individual of childbearing potential, the radiation exposure should be the minimum required to answer the clinical question, whether or not the individual is known to be pregnant. Alternative techniques which do not involve ionising radiation should always be considered. Such consideration as part of the justification process, is particularly important when using radionuclides with long half-lives due to the potential effective doses involved.

7.2 Only investigations which are necessary should be conducted during pregnancy. Investigations carried out on pregnant patients result in radiation doses to both the patient and the foetus.

7.3 IR(ME)R requires employers to have a written procedure to establish pregnancy and breastfeeding status of individuals of childbearing potential undergoing exposures involving radiopharmaceuticals. The employer's procedure should describe when and how pregnancy enquires should be made and specify the age range of individuals who should be asked (for example, 12 to 55 years old). The employer's procedure should be inclusive and consider the diversity of the gender spectrum in the local population. Further information is available in the RCR guidance for understanding the implications of IR(ME)R [9,10] and comprehensive inclusive pregnancy status guidelines for ionising radiation are available from the SoR [44].

7.4 Within the employer's written procedure there should be consideration for a range of methods to establish pregnancy status, proportionate to the risk of an exposure to a foetus. When writing the employer's procedure, clinical conditions that may affect the menstrual cycle should be taken into account. The following graded approach could be incorporated in the employer's procedure for diagnostic administrations:

(a) For administrations resulting in foetal doses of less than 0.1mGy, the employer's procedure could specify that the operator must ask the patient whether they are or might be pregnant

(b) For administrations involving foetal doses between 0.1mGy and 10mGy, additional assurances may be required, for example, the patient could be asked whether their menstrual period is overdue. Exposures where the foetal dose is likely to be below 10mGy, can continue to be undertaken, provided that the period is not overdue

(c) For administrations resulting in higher foetal doses, exceeding 10mGy, the exposure should only be undertaken during the first 10 days of the menstrual cycle [45]. The employer's procedure should describe situations where pregnancy testing is required for example, where it is not possible to confirm menstrual history, or exclude pregnancy from patient history (such as, previous hysterectomy)

7.5 For therapeutic procedures, the exclusion of pregnancy is of paramount importance given the potential consequences of foetal exposure. The confirmation of menstrual history alone is not considered adequate to exclude pregnancy. Therefore, the appropriate choice of pregnancy test should be described in the employer's procedure along with the information to be recorded in the patient's record. The employer's procedure should also consider reasonable exceptions for some localised therapeutic procedures, for example, intra-articular treatments for arthritis.

7.6 Where a patient is probably or definitely pregnant, the justification for the exposure should be considered by the practitioner following consultation with the multidisciplinary team responsible for the patient. It should be noted that a procedure of clinical benefit to the pregnant patient may be of indirect benefit to the foetus.

7.7 If the practitioner decides that the procedure should be undertaken in a pregnant patient, the exposure to both the patient and foetus must be optimised. Any reduction in administered activity must not impact on the likelihood of achieving a diagnostic outcome.

7.8 The response to pregnancy enquires should be documented as evidence that the employer's procedure has been followed.

7.9 Estimates of dose to the uterus are included in Tables 5.1 and 5.2, for risk assessment purposes. No component of dose from cross-placental transfer of radiopharmaceuticals is included in these values. These dose estimates refer to early pregnancy, before organogenesis has proceeded far enough for there to be concentrations of radioactivity in particular foetal organs.

7.10 ARSAC recommends that where foetal doses exceed 1mGy, the practitioner should pay particular attention to the justification of these exposures. A dose up to 1mGy corresponds to a level of risk comparable to that due to variations in natural background radiation. The available evidence [46] suggests that the risk of an adverse effect (for example, childhood cancer) from a dose of 1mGy is about 1 in 17,000.

7.11 Further information regarding biological effects after prenatal irradiation has been published by the ICRP [47].

Conception

7.12 There is no evidence that pre-conceptual irradiation of an individual can cause any abnormality in their offspring [46]. ARSAC does not consider that advice needs to be given concerning avoidance of conception for the majority of routine diagnostic administrations of radioactive substances.

7.13 The foetal thyroid gland is known to concentrate radioiodine avidly during the second and third trimesters of pregnancy; during this period the quantity of radioactivity within the pregnant patient should not exceed 0.1MBq of ^{125}I or 0.03MBq of ^{131}I. Consideration of the diagnostic procedure 125I-84-101 (0.2MBq ^{125}I human albumin) has shown that this will decrease to below 0.1MBq in 15 days: it is, therefore, unnecessary to issue any advice to delay pregnancy following this procedure.

7.14 Of the diagnostic imaging procedures listed in Table 5.1, only 131I-93-143 (^{131}I-iodide, thyroid metastases imaging after ablation) requires advice to delay pregnancy. Any administered activity of ^{131}I greater than 30MBq should be considered as a 'therapy' administration for radiation protection purposes; advice on pregnancy in Table 7.1 should be followed.

Table 7.1 Period following therapy administration for which individuals should be advised to avoid pregnancy.

Radioactive substance	For treatment of	All activities up to (MBq)	Avoid pregnancy (months)
^{32}P-phosphate	polycythaemia and related disorders	200	3
^{89}Sr-chloride	bone metastases	150	24
^{90}Y-colloid	arthritis	400	0
^{131}I-iodide	benign thyroid disease	800	6 to 12
^{131}I-iodide	thyroid cancer	6,000	6 to 12
^{131}I mIBG	malignancy	7,500	3
^{153}Sm-colloid	bone metastases	2,600	1
^{169}Er-colloid	arthritis	400	0

7.15 In some circumstances it will be necessary to advise patients to avoid conceiving for a period following the administration of long-lived radioactive substances.

7.16 The administration of therapeutic doses of ionic forms of longer-lived radionuclides is, however, a possible source of concern because of the appearance of larger quantities of such radionuclides in ejaculate and in sperm [48]. Following the therapeutic administration of ^{131}I-iodide, ^{32}P-

phosphate, or ^{89}Sr-chloride it is advisable to instruct individuals to avoid conception for 4 months as this is greater than the lifecycle of a sperm cell.

7.17 Individuals should be advised to avoid becoming pregnant for a period following therapy administration as given in Table 7.1. The administration of activities smaller than those indicated in Table 7.1 does not imply that the advisory period specified may be reduced.

Diagnostic administrations to individuals who are breastfeeding or lactating

7.18 Before administering a radioactive substance to a patient who is lactating (for example, breastfeeding, or expressing milk), consideration should be given as to whether:

(a) the test could reasonably be delayed

(b) the most appropriate choice of radiopharmaceutical has been made, bearing in mind the secretion of radioactivity in breast milk

(c) appropriate quality control measurements have been made (see 7.21)

7.19 Where the patient is breastfeeding, specific written instructions must be given, and these instructions should be recorded in their medical records.

7.20 Information on secretion of radioactivity into human breast milk is limited, and for most radiopharmaceuticals the advice given here is based on small numbers of measurements. Sites which undertake such measurements are encouraged to forward any data to the ARSAC support unit to facilitate future guidance updates.

7.21 The presence of radionuclide impurities or free ions, such as pertechnetate or iodide, will incur additional radiation dose. ^{123}I should not be administered to breastfeeding patients unless it is pure (containing no ^{124}I or ^{125}I).

7.22 In addition to any potential radiation dose to the infant from ingestion of breastmilk, the external exposure from close contact with the patient for prolonged periods of time during feeding should also be considered.

7.23 Advice is given in the Medical and Dental Guidance Notes [49] that special precautions or restrictions are only required when patients have been administered more than 30MBq of ^{131}I, 120MBq of ^{111}In-pentetreotide, 150MBq of ^{201}Tl-thallous chloride, or 800MBq of ^{99m}Tc myocardial perfusion agents, such as sestamibi or tetrofosmin. Advice is also given for administrations of more than 10MBq of ^{111}In-labelled leucocytes; however, it is not recommended to administer greater than 10MBq to breastfeeding patients. Precautions may also be necessary after administration of positron emitting radionuclides.

7.24 Precautions should be taken to minimise the radiation dose to the breastfed infant from external and internal sources. A dose constraint of 1mSv is recommended.

7.25 Table 7.2 lists breastfeeding interruption times for a limited range of radiopharmaceuticals. For those radiopharmaceuticals not listed, feeding should be interrupted until measurements on milk samples demonstrate that it is safe to recommence and that the dose to the infant will not exceed the dose constraint.

7.26 The interruption times include an assessment of the dose to the infant from ingestion and external irradiation. The interruption time is calculated such that the dose to the infant should be less than 1mSv from a single administration. The annual dose to the infant should also be less than 1mSv and consideration of extending the interruption times should be given if multiple exposures are expected.

7.27 Breastfeeding may be restarted immediately after the interruption time has elapsed since administration of the radiopharmaceutical. In many cases this time is zero, and no interruption of feeding is strictly necessary. The principle of 'as low as reasonably practicable' (ALARP), however, indicates that even where no interruption time is recommended, it is usually appropriate to express the milk completely once and discard it.

7.28 For some radiopharmaceuticals the required interruption time would be so long that the patient should be advised to stop breastfeeding altogether.

7.29 Specific advice should be given as follows:

(a) wherever possible, at least one feed should be expressed and appropriately stored in advance of the administration

(b) the infant should be breastfed just before the administration

(c) at the time of the next feed or 3 hours post administration (whichever is soonest), the breastfeeding patient should express as much milk as possible. This milk should be discarded or frozen and decay stored appropriately with alternatives used instead.

(d) breastfeeding should not resume until after a total period of interruption as given in Table 7.2, or as calculated from measured samples. During the period of interruption, milk should be regularly expressed as completely as possible and discarded or, frozen and decay stored appropriately.

(e) breastfeeding can be undertaken following subsequent pregnancies

7.30 The interruption times in Table 7.2 do not apply during the period of early lactation when colostrum is being secreted. During that period, feeding should be interrupted until measurements on milk samples demonstrate that it is safe to recommence.

7.31 The dose to the infant may be estimated by measuring the radioactive concentration in a sample (or in successive samples) of the breast milk.

7.32 ICRP Publication 72 [50] details a method for the calculation of dose following the ingestion of radioactivity that can be used to provide an estimate of the dose to infants.

Table 7.2 Breastfeeding interruption time by radioactive substance administered.

Radioactive substance	Activity administered to mother (MBq)	Feeding interruption time (hours)
^{32}P phosphate	Any	STOP
^{18}F FDG	400	1
^{51}Cr EDTA	3	0
^{81m}Kr gas	6,000	0
^{99m}Tc-pertechnetate	80	30
	800	57
^{99m}Tc albumin macroaggregates or microspheres	100	13
	200	20
^{99m}Tc normal erythrocytes[1]	800	20
^{99m}Tc DTPA	300	0
	800	5
^{99m}Tc DMSA(III)	80	0
^{99m}Tc-iminodiacetate	150	0
^{99m}Tc exametazime	500	0
^{99m}Tc-sulesomab	750	11
^{99m}Tc MAG3	100	0
	200	2
^{99m}Tc colloid [2]	80	0
^{99m}Tc sestamibi	400	0
	900	3
^{99m}Tc phosphates and phosphonates	800	0
^{111}In leucocytes	10	0
^{111}In pentetreotide	220	60
^{123}I iodide	20	42

Radioactive substance	Activity administered to mother (MBq)	Feeding interruption time (hours)
^{123}I mIBG	400	25
^{125}I human albumin	Any	STOP
^{131}I-iodide	Any	STOP
^{201}Tl-thallous chloride	80	10

Notes
[1] For labelled normal erythrocytes the figures will be sensitive to changes in the labelling efficiency, which can vary substantially.
[2] This value only applies to the intravenous administration of colloid.

7.33 External measurements of dose rate at 0.1m from the patient's torso may be used to estimate the external component of the exposure. The effective dose from the administration without any restriction on close contact may be calculated by multiplying the maximum external dose rate by the effective exposure time [51,52].

7.34 Values of effective exposure time from commonly used radioactive substances are listed in Table 7.3. The effective exposure time assumes a total contact time of 9 hours in a 24 hour period [53] consisting of 35 minutes in close contact at the start of each hour for the first 8 hours after radioactive substance administration, 35 minutes at the start of each fourth hour for the next 12 hours (modelling feeding times overnight), and 35 minutes at the start of each hour for the remaining 4 hours.

Table 7.3 Effective exposure time by radioactive substances administered.

Radioactive substance	Effective exposure time (h)
^{18}F FDG	1.8
^{51}Cr EDTA	2.4
^{99m}Tc (all compounds)	3.9
^{111}In leucocytes	35.9
^{111}In-pentetreotide	10.9
^{123}I iodide (euthyroid)	4.2
^{123}I iodide (hyperthyroid)	5.5
^{123}I mIBG	4.4
^{131}I iodide (euthyroid)	27.4
^{131}I iodide (hyperthyroid)	32.2
^{201}Tl thallous chloride	30.2

7.35 As the dose rate from the patient reduces over time through physical decay and biological excretion, the effective dose to the infant will also reduce. Estimates of interruption times based on physical decay will remove the need for repeated dose rate measurements from the patient.

7.36 Restrictions may be relevant for patients who are bottle feeding infants, where no dose is expected from ingestion.

7.37 The internal component of the effective dose(x) can be calculated using the following formula [51] which assumes a mono-exponential decrease of activity concentration with time:

$$x = \frac{D_{max}}{e^{\left\{\ln 2 \cdot \left(\frac{P - t_c}{t_{½max}}\right)\right\}}}$$

Where:

D_{max} = maximum value of effective dose to the infant (mSv) [51,54,55] (corrected for ARSAC DRL)

P = breastfeeding interruption time (hours)

t_c = time of first feed following administration of radioactive substance assuming no interruption (set at 3 hours, using a feeding interval of 4 hours and a feed one hour prior to administration)

$t_{½max}$ = maximum value of effective half-life (hours)

7.38 Table 7.4. summarises values of maximum effective half-life taken from published data [56 to 60] that may be used in this calculation.

Table 7.4 Maximum effective half-life by radioactive substance administered

Radioactive substance	Maximum effective half-life (h)
^{18}F FDG	0.89
^{51}Cr EDTA	11
^{99m}Tc pertechnetate	8.26
^{99m}Tc human albumin macroaggregates or microspheres	7.01
^{99m}Tc phosphonates	6.83
^{99m}Tc DTPA	5
^{99m}Tc DMSA (III)	5.9
^{99m}Tc colloid	8.3
^{99m}Tc iminodiacetate	9.14
^{99m}Tc erythrocytes	9.5
^{99m}Tc MAG3	5
^{99m}Tc sestamibi	6.73

Radioactive substance	Maximum effective half-life (h)
^{99m}Tc exametazime	3.77
^{99m}Tc sulesomab	3.14
^{111}In leucocytes	134
^{111}In pentetreotide	10.05
^{123}I iodide	10.4
^{123}I mIBG	8.56
^{131}I iodide	11.1
^{201}Tl chloride	43

Therapeutic administration to individuals who are breastfeeding or lactating

7.39 Whilst breastfeeding is completely contraindicated for therapeutic procedures using radionuclides which are excreted in breast milk (for example, ^{I31}I for treatment of thyrotoxicosis or thyroid cancer), unusually there may be instances where, despite cessation of breastfeeding, continued lactation may result in significant dose to breast tissue. In the example of ^{131}I, ICRP Publication 95 [61] gives the equivalent dose to the breast tissue (in the euthyroid case) as 1.3 x10^{-9}Sv.Bq^{-1} for the lactating breast - an increase by a factor of approximately 20 compared to the non-lactating organ.

7.40 Advice from a lactation consultant is recommended and a balance should be struck between delaying treatment until lactation and the associated increased uptake reduces naturally (which may take over 6 weeks) versus side effects caused by medications which inhibit lactation.

Section 8

Thyroid blocking

Introduction

8.1 Thyroid blocking is used to reduce radiation dose [62]. Of the radionuclides commonly used in nuclear medicine, only technetium and iodine are concentrated by the thyroid.

Technetium-99m

8.2 ARSAC considers it unnecessary to use blocking agents to reduce the radiation dose to the thyroid following administration of most radioactive substances containing ^{99m}Tc.

Radioiodine

8.3 When 123I, 125I or 131I is administered as iodine-labelled compounds, with or without iodide as a radiochemical impurity, a substantial part of the effective dose stems from irradiation of the thyroid. Thyroid blocking is recommended for all iodine-labelled compounds not intended for thyroid imaging or therapy.

8.4 Blocking will reduce the absorbed dose to the thyroid when radioiodine is administered as mIBG, albumin or as other labelled compounds. It should be performed if the absorbed dose to the unblocked thyroid will be greater than 50mGy.

8.5 Before administering a radioiodine compound which is metabolised to iodide or which contains radioiodine impurities, consideration should be given to blocking the thyroid.

Blocking agent equivalents

8.6 Various formulations of iodide and iodate are available for oral and intravenous administration. The iodine contents of commonly used blocking agents are:

65mg potassium iodide contains 50mg iodine [63]

85mg potassium iodate contains 50mg iodine [64]

1ml of aqueous iodine oral solution BP (Lugol's Iodine) contains 130mg iodine [65]

8.7 If iodine is contraindicated, thyroid blockade can be carried out with potassium perchlorate (200mg adult dose). It should be noted that currently potassium perchlorate is not licensed in the UK. Sodium perchlorate (2ml vials containing 200mg for intravenous use) may also be available.

Blocking protocols

8.8 An oral dose equivalent to approximately 100mg iodine will reduce thyroid uptake to less than 1% of normal. This should be administered the day before the investigation and then daily for one (^{123}I) and 5 (^{131}I) days, respectively. In patients receiving ^{131}I-based treatments, even a prolonged protection protocol may not avoid a substantial likelihood of subsequent hypothyroidism [66]. The use of a blocking protocol using a combination of iodine and perchlorate could be considered in this situation [67].

8.9 If potassium perchlorate is used it should be given one hour prior to the procedure and repeated at 8 hourly intervals until the estimated radioiodine levels have fallen to the levels shown in 8.3.

8.10 Where individuals have forgotten to take their thyroid blockade medication then the dose should be given to them at least one hour prior to the procedure. Use of potassium iodide 2 hours after exposure to ^{131}I still offers a 'protective effect' of 80% but blocking more than 8 hours after exposure is unlikely to be effective [68].

8.11 When thyroid blocking agents are administered to children, consideration should be given to reducing the dosage. This should be broadly consistent with advice [69] given in relation to the use of thyroid blocking in the event of a nuclear accident:

children of 3 to 12 years old	50% of adult dose
children of one month to 3 years old	25% of adult dose
neonates (birth to under one month old)	12.5% of adult dose

8.12 In children, the dosage of potassium perchlorate required is 10mg.kg^{-1}. The maximum total dosage should be 500mg and the minimum total dosage is 50mg. Potassium perchlorate should be administered 30 to 60 minutes prior to administration of the radioactive substance. A second dose can be given as late as possible on the same day. If the thyroid gland is seen at the time of scanning the following day, then the child should be given another (third) dose of potassium perchlorate.

Appendix 1

Full nuclear medicine service core curriculum

Full nuclear medicine service core curriculum	
1 Fundamental physics of radionuclides	
1.1 Atomic structure	Mass, atomic and neutron number Energy levels – nuclear and electronic
1.2 Radioactivity	Radionuclides Units of radioactivity Specific activity Physical half-life Decay constant Poisson (count) statistics
1.3 Radioactive decay	Mechanism of alpha, beta and gamma emission Electron capture and X-ray emission Isomeric transition, internal conversion Auger electrons Positron emission and annihilation
1.4 Properties of radiation	Excitation and ionisation Attenuation of X-rays and gamma rays Scattering and absorption Bremsstrahlung radiation
1.5 Radionuclide production	Production methods Isotope generators Cyclotron and nuclear reactors
1.6 Radiation hazards and dosimetry	Biological effects of radiation Risks and benefits of radiation Cellular radiobiology Biological and effective half-lives Absorbed dose, equivalent dose, effective dose and their units Application of MIRD (Medical Internal Radiation Dose) concepts for calculating whole body, organ and tumour doses

Full nuclear medicine service core curriculum	
1.7 Radiobiology aspects for therapy	Uptake ratios Cell cycles Cell killing Total lethal dose Radiosensitisation Tissue homogeneity
1.8 Dosimetry for therapy	Dose rate Fractionation Biological effective dose, dose volume histogram, tumour control probability Microdosimetry – residence and clearance Mass estimations
2 Principles of radiation detection, instrumentation and equipment	
2.1 Detection of radiation	Geiger-Müller detectors, proportional counters and ionisation chambers Scintillation and solid state detectors Spatial discrimination, collimators, basic design and function Energy discrimination, multichannel analysers and pulse height analysers Temporal discrimination, count-rate (dead-time) effects and corrections
2.2 Detection systems – general	Radionuclide assay calibrators Quality assurance (QA)programmes and quality control (QC) testing for radionuclide calibrators, and requirements for traceability Personal and Environmental contamination monitors Personal whole body and extremity dosimeters and dose rate meters Gamma sample counters; counting geometry and establishing protocols for counting External probe systems including intra-operative probes

Full nuclear medicine service core curriculum	
2.3 Detection systems – gamma camera	Gamma camera detectors, camera systems and associated equipment Construction and function of main components Care of scintillation crystals Principles of collimation, and main designs Output signals – *X* and *Y* position signals, *Z* energy signal Digitisation of event data, formation of digital images and optimal selection of discrete matrices Spatial resolution, information density and noise Energy resolution Energy, linearity and uniformity (sensitivity) corrections Anatomical markers Static, dynamic, electrocardiogram-gated and scanned (whole body) imaging Planar quantification of radiopharmaceutical uptake, distribution and kinetics Image processing techniques, region of interest analysis and time–activity curve generation Techniques for background correction, motion correction, attenuation correction, scatter correction and partial volume correction QA programmes and QC testing for planar gamma camera imaging
2.4 Associated electronic equipment	Photomultiplier tubes and photodiodes Power supplies (high and low voltage) and amplifiers Analogue to digital conversion
2.5 Single photon emission computed tomography (SPECT)	Principles of single photon emission computed tomography Requirements for performing SPECT on a gamma camera system Centre of rotation correction Energy, linearity and uniformity (sensitivity) corrections SPECT/CT – appropriate CT protocols, registration and fusion of SPECT and CT data Reconstruction of projection datasets Filtered back projection and iterative reconstruction techniques Attenuation correction, scatter correction and partial volume correction Algorithms for reconstruction with resolution recovery SPECT quantification of radiopharmaceutical uptake, distribution and kinetics Acceptance testing, QA programmes and QC testing for SPECT and SPECT/CT systems

Full nuclear medicine service core curriculum	
2.6 Image formation and quality	Image quality – noise, contrast resolution and spatial resolution Image artefacts Optimisation of image quality and radiation dose Optimisation of image display, including windowing, thresholding, saturation and the use of grayscale and colour lookup tables Acceptance testing, QA programmes and QC testing of display devices Administered activity and DRLs Investigation time Counting statistics and 'information density' Choice of collimator (design and specifications – energy range, sensitivity and resolution) Acquisition protocols for dynamic study (spatial and temporal resolution) Acquisition protocols for SPECT (collimation, angular sampling, image matrix and projection time)
2.7 Analysis of data	Manipulation of data Image processing techniques, region of interest analysis and time–activity curve generation Correction techniques, background correction, decay correction and motion correction Quantification of uptake, retention, clearance and distribution Kinetic analysis, compartmental analysis and deconvolution Algorithms Physiological basis of models

Full nuclear medicine service core curriculum	
2.8 Computing	Electronic image data storage, native and standard file formats (Interfile, DICOM (Digital Imaging and Communications in Medicine)) Structure of digital images and determination of image file sizes Anonymisation of image data Archiving of image data including Radiology Information Systems (RIS), PACS (Picture Archiving and Communication System) and vendor neutral archives (VNA) Major considerations regarding processing and review systems – hardware, performance and operating systems Image processing applications software Computing for tomography, requirements for data reconstruction and corrections Fusion, registration and visualisation of tomographic image datasets Acceptance testing and QA of processing and review systems
2.9 Therapy equipment	Design safety Control of administration including automated infusion devices Management of radioactive waste from administration and the patient

Full nuclear medicine service core curriculum	
2.10 Positron emission tomography (required for PET licences)	Principles of tomography Principles of positron emission tomography Design of PET/CT or PET/MR systems – PET detectors, detector block architecture and performance Time of flight (TOF) Noise equivalent count rate (NECR) and optimised data acquisition protocols PET image formation, sinograms and data blocks, from 2D to 3D geometries PET image reconstruction, FBP and iterative reconstruction techniques PET/CT – appropriate CT protocols, registration and fusion of PET and CT data Use of CT for attenuation correction and anatomical fusion, CT artefacts and use of CT contrast Reconstruction with CTAC and scatter correction Quantification – requirements for calibration of PET systems PET quantification of radiopharmaceutical uptake, distribution and kinetics and SUV analysis Acceptance testing, QA programmes and QC testing for PET/CT or PET/MR QA and standardisation of protocols for clinical trials imaging
2.11 Computed tomography (required for licences including SPECT/CT or PET/CT)	Construction, function and operation of a contemporary multislice CT scanner CT image reconstruction, FBP and iterative reconstruction techniques Factors controlling CT image quality Factors controlling CT radiation dose to patients Optimising CT radiation dose to patients Dose metrics for CT – DAP, DLP, CT dose indices (CTDI), effective dose, local and national DRLS and dose investigation levels (DIL) Radiation safety in CT Acceptance testing, QA programmes and QC testing for CT
3 Calibration techniques	
3.1 Preparation of calibration sources and phantoms	Preparing calibration sources and phantoms

Full nuclear medicine service core curriculum		
3.2	**Quality assurance**	Pulse height and window selection Uniformity of field Spatial linearity Spatial resolution – intrinsic and at depth, point and line spread functions Count rate performance Sensitivity Collimator performance Image processing
3.3	**Routine quality control checks**	Standard tests, applicability, frequency of testing, action and remedial thresholds
3.4	**Calibration of therapy sources**	Calibrating therapy sources
4	**Radiopharmaceuticals**	
4.1	**Chemistry of relevant radiopharmaceuticals**	Principles of their localisation
4.2	**Tracer principles and techniques**	Kinetics of radioactive tracers used in nuclear medicine Use of principles of kinetics and modelling techniques applied to radionuclide investigations Physiological principles of tracer techniques Errors associated with quantitative measurement
4.3	**Preparation of radiopharmaceuticals**	Radiopharmacy and working practices in respect of radiation safety and microbiological safety Principles of labelling blood products Individual dose preparation Identification of prepared products Quality control – radiochemical, sterility and pyrogens Documentation – packaging and transport of radiopharmaceuticals, Monitoring of work areas and waste disposal Use of kits, dilution and transfer of activity Principles of pharmaceutical good manufacturing practice (GMP) Regulation of radiopharmaceutical production
4.4	**Generators**	Safe handling of generators Elution of generators

Full nuclear medicine service core curriculum	
5 Management and radiation protection of the patient	
5.1 Patient selection	Disease process and other investigations relevant to the disease Patient preparation and consent (as appropriate) Food and drug interactions Arrangements for radioactive patients in the hospital and home Administration of radioactivity – techniques and procedures, and apparatus Preparation and disposal of syringes and needles Documentation – for procedural requirements, clinical governance and regulatory compliance Hygiene in relation to radioactivity Reporting procedures (including accidents, adverse reactions, errors in preparation and administration) Non-medical imaging Special groups and contraindications: • pregnancy • breastfeeding • infants and children • the seriously ill
5.2 Therapy aspects	Planning of investigations including the selection of appropriate tests and imaging techniques for the diagnosis of malignant disease Formal consent for therapy administrations Interaction with other pharmaceuticals, foods and clinical investigations Criteria for discharge of the inpatient Radiation safety issues in public areas, the workplace and at home Possible toxicity of the therapy, both early and late Follow up, assessment of efficacy and retreatment
6 Statutory and advisory publications and general radiation protection	
6.1 Statutory and advisory aspects	Underpinning concepts of radiation protection: • justification, optimisation and limitation • application of the 'As Low As Reasonably Practicable' (ALARP) principle to practices • UK regulatory framework for radiation protection National and international regulatory requirements relevant to the practice of nuclear medicine National and international guidance on nuclear medicine

Full nuclear medicine service core curriculum	
6.2 General radiation protection	Regulatory duty holders and their training and responsibilities: Radiation protection, with particular emphasis on: • shielding, preparation, dispensing and administration of doses • minimising radiation dose to staff, including pregnant and breastfeeding staff • prior risk assessment, restriction of exposure and dose monitoring • use of time, distance and shielding to reduce radiation dose • use of personal protective equipment to reduce exposure • environmental contamination monitoring of working areas • personal contamination monitoring of staff • decontamination procedures in dealing with spills • security, transportation and storage of radioactive substances • storage and disposal of radioactive waste • protection of the patient, their contacts and the wider public, and their comforters and carers

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