

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.

Ms K Adamson	Dr N Hartman
Ms S Aldridge	Dr N Hujairi
Dr C Beadsmoore	Dr P Julyan
Professor K Bradley (Chairman)	Dr D Levine
Dr M Cooper	Professor I Lyburn
Dr C Coyle	Mrs C Moody
Dr A Craig	Dr G Petrides
Dr J Dickson	Dr S Rasul
Dr K Dixon	Dr N Singh
Dr R Ganatra	Dr T Szyszko
Dr M Gaze	Professor S Vinjamuri
Mr D Graham	Professor J Wadsley

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For further information, contact:

Tel: 01235 825006

Email:arsac@phe.gov.uk

Website:www.gov.uk/arsac

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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 January 2022 version of the notes there are the following notable updates:
 - (a)** updates to replace Public Health England with the UK Health Security Agency
 - (b)** changes to reflect the online application process for employer licence applications
 - (c)** additional guidance on medical physics expert support for employers
 - (d)** additional guidance on practitioner support for employers
 - (e)** clarification on the requirements and details required in a practitioner licence application
 - (f)** update to the documentation required for the research approval process
 - (g)** changes to routine procedures in Tables: [5.1](#), [5.3](#), [5.4](#) and [5.5](#).

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. IR(ME)R repeals the Medicines (Administration of Radioactive Substances) Regulations 1978 [4] (MARS regulations) which transposed previous requirements.

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 1 μ Sv. 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.

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 by email to ARSAC@phe.gov.uk 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 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. 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.

Transitional arrangements

- 1.27** Any valid ARSAC certificates after 6 February 2018 (when IR(ME)R came into force) are deemed:
- (a) to be considered as legally equivalent to a licence until its expiry date
 - (b) to licence the employer at the medical radiological installation for the same scope and purpose (diagnosis, treatment or research)
 - (c) to licence the practitioner at the specified medical radiological installation for the same scope and purpose
- 1.28** There is nothing in IR(ME)R to prohibit employers and practitioners from applying for licences at any time. This may result in a combination of licences and certificates being valid at an installation for any given exposure. A licence does not invalidate any existing certificates. Written procedures used locally should clearly state which authorisation method (a licence or certificate) is being used by the employer and practitioner to comply with the legal requirement for licensing.
- 1.29** Applications for licences should be submitted as far in advance as possible and at least 8 weeks before the expiry of a certificate to allow sufficient time for processing. Once a certificate expires, then employers and practitioners will no longer legally be allowed to administer the specified radioactive substances until appropriate licences have been issued.

Research involving the administration of radioactive substances

- 1.30** Employer and practitioner licences issued under IR(ME)R for research are not trial specific.
- 1.31** 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.
- 1.32** Any valid research certificate is considered as legally equivalent to a licence for the practitioner and the employer at the radiological installation, to

administer radioactive substances in accordance with the research trial detailed on the certificate until it expires.

- 1.33** Research certificates issued under the MARS regulations are trial specific and cannot be used for other research trials.

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 last certificate or licence at a medical radiological installation for a required procedure 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 [section 2.32](#). 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 contact details 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 GFR (Glomerular Filtration Rate) studies and gamma probes for SLNB (Sentinel Lymph Node Biopsy) 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) start-up discussions for procedures new to the medical radiological installation
- (b) patient selection and onward management (for example, multidisciplinary team meetings)
- (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 5.15](#))

- (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. [IPEM has published guidance](#) on what constitutes sufficient levels of MPE support which has been supported by ARSAC. 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** 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 two 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.
- 2.14** 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.
- 2.15** The adequacy of other supporting services will depend upon the nature and complexity of the work involved [7]. 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
- 2.16** 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

- 2.17** 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 3.41 to 3.43. The employer's procedures should consider the entitlement and scope of practice of any IR(ME)R duty holders from a third-party [8,9].
- 2.18** 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.
- 2.19** 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.
- 2.23** The ARSAC Support Unit should be notified if the employer licence is no longer required.

Amendment to licences

- 2.24** An amendment to an employer licence should be submitted 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
- 2.25** Applications for an amendment can be made whenever required within the duration of a valid licence. There are fees for employer amendment applications, see [section 2.32](#).
- 2.26** 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.
- 2.27** 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.
- 2.28** 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.
- 2.29** This 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

- 2.30** A notification should be emailed to the ARSAC Support Unit 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

Fees

2.31 Applications can only be processed, and licences released, on the payment of the correct fee.

2.32 Details of fees are as follows:

- (a) new licence application: £250
- (b) amendment to existing licence: £200
- (c) renewal of an existing licence: £200

2.33 Full details of how to pay the fee will be provided once an application has been accepted. Standard payment method is using a debit or credit card through a secure online portal. Alternative payment methods using Bacs (Bankers Automated Clearing System) and invoices are available.

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.
- 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. 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 work at a remote medical radiological installation where they are also entitled to act as a practitioner and can provide sufficient support as specified in paragraphs 3.41 to 3.43.
- 3.5** Where it is not possible for the practitioner to authorise every exposure, they may issue guidelines to allow appropriately trained and entitled operators to authorise these exposures. A practitioner licence is not required for individuals who authorise exposures according to authorisation guidelines or who perform other aspects of the exposure such as reporting. Further guidance on the justification and authorisation process is included in the RCR guide to understanding the implications of IR(ME)R [8,9]. Doctors who authorise exposures under such guidelines may need to review their entitlement in line with their employer's procedures.
- 3.6** 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 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

3.7 Details of how to apply and the practitioner application forms are available on our [the ARSAC web page](#).

3.8 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.

3.9 [Further guidance](#) on how to use the online portal is available.

3.10 There are no fees for practitioner applications. To complete a practitioner licence application form and submit it on the ARSAC online portal, the following information is required:

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

3.11 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

- 3.12** 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.
- 3.13** 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.
- 3.14** Holders of a CCT (certificate of completion of training) 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 5.3.
- 3.15** Those who have successfully completed training in radionuclide radiology would normally expect to be licensed for most of those imaging procedures listed in table 5.1.

- 3.16** Practitioners who wish to apply for a licence to support a therapy service should have completed a nuclear medicine training programme, a clinical oncology training programme or demonstrate an equivalent level of training. It will strengthen the application if the individual is able to give evidence of additional experience and training in brachytherapy and/or molecular radiotherapy, 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.
- 3.17** 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.
- 3.18** 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.
- 3.19** 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)

- 3.20** 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.
- 3.21** For those undertaking formal training programmes, a licence for routine diagnostic PET procedures will usually be granted on completion of the training grade.
- 3.22** 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 3.36 to 3.40](#).

Theoretical training

- 3.23** 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
- 3.24** 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.
- 3.25** The theoretical training in the core curriculum in [table 3.1](#) 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 [table 3.1](#) will vary depending on the scope of the application. Sections that are not relevant to the application may be omitted.
- 3.26** 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.
- 3.27** 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.

Table 3.1: 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 MIRL (Medical Internal Radiation Dose) concepts for calculating whole body, organ and tumour doses
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

Table 3.1: Full nuclear medicine service core curriculum

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
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

Table 3.1: Full nuclear medicine service core curriculum

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
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

Table 3.1: Full nuclear medicine service core curriculum

2.8 Computing	<p>Electronic image data storage, native and standard file formats (Interfile, DICOM (Digital Imaging and Communications in Medicine))</p> <p>Structure of digital images and determination of image file sizes</p> <p>Anonymisation of image data</p> <p>Archiving of image data including Radiology Information Systems (RIS), PACS (Picture Archiving and Communication System) and vendor neutral archives (VNA)</p> <p>Major considerations regarding processing and review systems – hardware, performance and operating systems</p> <p>Image processing applications software</p> <p>Computing for tomography, requirements for data reconstruction and corrections</p> <p>Fusion, registration and visualisation of tomographic image datasets</p> <p>Acceptance testing and QA of processing and review systems</p>
2.9 Therapy equipment	<p>Design safety</p> <p>Control of administration including automated infusion devices</p> <p>Management of radioactive waste from administration and the patient</p>
2.10 Positron emission tomography (required for PET licences)	<p>Principles of tomography</p> <p>Principles of positron emission tomography</p> <p>Design of PET/CT or PET/MR systems – PET detectors, detector block architecture and performance</p> <p>Time of flight (TOF)</p> <p>Noise equivalent count rate (NECR) and optimised data acquisition protocols</p> <p>PET image formation, sinograms and data blocks, from 2D to 3D geometries</p> <p>PET image reconstruction, FBP and iterative reconstruction techniques</p> <p>PET/CT – appropriate CT protocols, registration and fusion of PET and CT data</p> <p>Use of CT for attenuation correction and anatomical fusion, CT artefacts and use of CT contrast</p> <p>Reconstruction with CTAC and scatter correction</p> <p>Quantification – requirements for calibration of PET systems</p> <p>PET quantification of radiopharmaceutical uptake, distribution and kinetics and SUV analysis</p> <p>Acceptance testing, QA programmes and QC testing for PET/CT or PET/MR</p> <p>QA and standardisation of protocols for clinical trials imaging</p>
2.11 Computed tomography (required for licences including SPECT/CT or PET/CT)	<p>Construction, function and operation of a contemporary multislice CT scanner</p> <p>CT image reconstruction, FBP and iterative reconstruction techniques</p> <p>Factors controlling CT image quality</p> <p>Factors controlling CT radiation dose to patients</p> <p>Optimising CT radiation dose to patients</p> <p>Dose metrics for CT – DAP, DLP, CT dose indices (CTDI), effective dose, local and national DRLS and dose investigation levels (DIL)</p> <p>Radiation safety in CT</p> <p>Acceptance testing, QA programmes and QC testing for CT</p>

Table 3.1: Full nuclear medicine service core curriculum

3 Calibration techniques	
3.1 Preparation of calibration sources and phantoms	Preparing calibration sources and phantoms
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

Table 3.1: Full nuclear medicine service core curriculum

5 Management and radiation protection of the patient	
5.1 Patient selection	<p>Disease process and other investigations relevant to the disease</p> <p>Patient preparation and consent (as appropriate)</p> <p>Food and drug interactions</p> <p>Arrangements for radioactive patients in the hospital and home</p> <p>Administration of radioactivity – techniques and procedures, and apparatus</p> <p>Preparation and disposal of syringes and needles</p> <p>Documentation – for procedural requirements, clinical governance and regulatory compliance</p> <p>Hygiene in relation to radioactivity</p> <p>Reporting procedures (including accidents, adverse reactions, errors in preparation and administration)</p> <p>Non-medical imaging</p> <p>Special groups and contraindications:</p> <ul style="list-style-type: none"> • pregnancy • breastfeeding • infants and children • the seriously ill
5.2 Therapy aspects	<p>Planning of investigations including the selection of appropriate tests and imaging techniques for the diagnosis of malignant disease</p> <p>Formal consent for therapy administrations</p> <p>Interaction with other pharmaceuticals, foods and clinical investigations</p> <p>Criteria for discharge of the inpatient</p> <p>Radiation safety issues in public areas, the workplace and at home</p> <p>Possible toxicity of the therapy, both early and late</p> <p>Follow up, assessment of efficacy and retreatment</p>
6 Statutory and advisory publications and general radiation protection	
6.1 Statutory and advisory aspects	<p>Underpinning concepts of radiation protection:</p> <ul style="list-style-type: none"> • justification, optimisation and limitation • application of the 'As Low As Reasonably Practicable' (ALARP) principle to practices • UK regulatory framework for radiation protection <p>National and international regulatory requirements relevant to the practice of nuclear medicine</p> <p>National and international guidance on nuclear medicine</p>

Table 3.1: 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: <ul style="list-style-type: none">• 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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Practical experience

- 3.29** 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.
- 3.30** 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.
- 3.31** 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.
- 3.32** 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.
- 3.33** 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
- 3.34** 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 [13] or the curriculum of the European Board of Nuclear Medicine (EBNM) [12] ,
- 3.35** 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.

- 3.36** 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 [14].
- 3.37** Practical experience in PET/CT should be obtained through attendance at an established clinical PET/CT 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.
- 3.38** Applicants who wish to justify ¹⁸F-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.
- 3.39** For non-¹⁸F-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).
- 3.40** 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 ¹⁸F-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

- 3.41** 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.

3.42 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.

3.43 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 possible for the practitioner to authorise every exposure, the practitioner should issue guidelines to allow the authorisation of exposures by appropriately entitled operators
- (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

3.44 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.

- 3.45** 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.
- 3.46** The ARSAC Support Unit should be notified if the licence is no longer required.

Amendments to licences

- 3.47** 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)
- 3.48** 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](#).
- 3.49** 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.
- 3.50** Applicants will need to set up an [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

- 3.51** A notification should be emailed to the ARSAC Support Unit, prior to any material change in circumstances that may affect the validity of the licence.
- 3.52** 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
- (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 programme.
- 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 programme unless it has been approved by an expert committee. ARSAC is this expert committee. It also requires such research programmes 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 standard care (for example, a trial where all participants must have received prior radioiodine therapy to be considered eligible)
- 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 The research approval process is undergoing significant changes. Details of the current process to submit a research study to ARSAC is available on our website.
- 4.11 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.
- 4.12 ARSAC does not routinely require the research protocol to be provided except for studies involving the administration of therapeutic radioactive substances. Where the trial involves novel radiopharmaceuticals, references or estimates of effective doses should be submitted (see [section 4.27](#)).
- 4.13 For therapeutic administrations and novel or non-standard diagnostic administrations, ARSAC recommends that the Clinical Radiation Expert (CRE) assessing the study should hold an appropriate practitioner licence. Where multiple CREs are involved, a licensed practitioner should be consulted when preparing the clinical assessment of the research exposures.
- 4.14 There are fees for research approvals, see [section 4.42](#).
- 4.15 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

- 4.16 Occasionally, a research trial may change after a trial has been approved. 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
- 4.17** ARSAC does not need to be notified of amendments due to other changes to the research study unrelated to the administration of radioactive substances e.g. changes to CT scans.
- 4.18** 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)
- 4.19** 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 sponsor through the online portal if any further information is required to process the amendment. There are fees for research amendments, see [section 4.42](#).
- 4.20** 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.
- 4.21** 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

- 4.22** ARSAC should be notified of changes to research trial title to ensure the approval remains valid.
- 4.23** Notifications can be made to the ARSAC Support Unit by email and are not subject to a fee.
- 4.24** Advice on whether a change constitutes an amendment can be sought by contacting the ARSAC Support Unit.

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 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. For novel therapeutic radiopharmaceuticals, the protocol should allow for appropriate verification of treatment delivery where practicable.

- 4.28** More accurate information on dosimetry may be available once the trial commences. To help ARSAC in its task of reviewing future applications, such information should be made available to the ARSAC Support Unit as soon as possible.

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 [15]. 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 [16]). 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 [17] 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 [18] 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.
- 4.42** Details of fees are as follows:
- (a) new multi-centre research trial: £350
 - (b) new single-centre research trial: £300
 - (c) new low dose research trial (<1mSv total participant dose): £200
 - (d) research amendment (>1mSv total participant dose): £250
 - (e) research amendment (<1mSv total participant dose): £200
- 4.43** Full details of how to pay the fee will be provided once an application has been accepted. Standard payment method is using a debit or credit card through a secure online portal. Alternative payment methods via Bacs (Bankers Automated Clearing System) and invoice are available.

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 may review and update 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 are expected not 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** 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
- 5.16** 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.
- 5.17** For treatments using sealed sources, where available, clinical guidelines should be taken into consideration for determining the prescription.

General techniques for dose reduction

- 5.18** 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.
- 5.19** Advice on the use of thyroid blocking agents is given in [section 8](#).
- 5.20** 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.
- 5.21** In some cases, if the patient is healthy and cooperative, administered activity might 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.
- 5.22** 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.

Effective dose (ED)

- 5.23** 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.
- 5.24** 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.
- 5.25** 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.
- 5.26** 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 38].
- 5.27** 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. 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

- 5.28** 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.
- 5.29** 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)	Functional group	Old serials
111In-107-58	¹¹¹ In	leucocytes	infection/inflammation imaging	IV	20	7.2	2.4	9	49a3
111In-131-132	¹¹¹ In	pentetreotide	somatostatin receptor imaging	IV	110	5.9	4.3	14	49a61i
					220 SPECT	11.9	8.6		
111In-140-139	¹¹¹ In	platelets	thrombus imaging	IV	20	7.8	1.9	10	49a5ii
111In-41-92	¹¹¹ In	DTPA with non-absorbable compounds	oesophageal/gastric/intestinal motility studies	oral	12	3.8	2.0	6	49a1vii 49a6
123I-117-136	¹²³ I	mIBG	sympathetic innervation imaging of the heart	IV	370	4.8 [1]	3.7	1	53a5iv
123I-117-167	¹²³ I	mIBG	tumour imaging	IV	400	5.2 [1]	4.0	14	53a5iii
123I-93-142	¹²³ I	iodide	thyroid imaging/uptake	oral or IV	2	0.6	0.02	23	53a1i
					20	6.1	0.17	11	53a1ii
123I-93-143	¹²³ I	iodide	thyroid metastases imaging (after ablation)	oral	400	10 [2]	4.8	14	53a1iii
				or IV	400	7.8 [2]	4.8		
123I-96-15	¹²³ I	ioflupane	brain imaging	IV	185	4.6 [1]	2.6	4	53a71i
125I-84-101	¹²⁵ I	human albumin	plasma volume	IV	0.2	0.04 [1]	0.04	22	53b4iii
131I-93-142	¹³¹ I	iodide	thyroid imaging/uptake	oral	0.2	5.8	0.008	23	53c6i
131I-93-143	¹³¹ I	iodide	thyroid metastases imaging (after ablation)	oral	400 [3]	68 [2]	18	14	53c6ii
				or IV	400 [3]	52 [2]	18		
14C-166-51	¹⁴ C	urea	H Pylori detection	oral	0.2	0.006	0.005	24	6a50

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	Functional group	Old serials
14C-79-19	¹⁴ C	glycocholic acid	breath tests	oral	0.4	0.14	0.06	24	6a 1
201TI-157-83	²⁰¹ Tl	thallous chloride	myocardial imaging	IV	80	11.2	4.0	1	81a1iv
51Cr-44-46	⁵¹ Cr	EDTA	GFR measurement	IV	3	0.006	0.008	25	24a4
51Cr-48-109	⁵¹ Cr	erythrocytes	red cell kinetics	IV	4	0.7	0.3	22	24a 1i 24a 1ii 24a 1iii
51Cr-48-48	⁵¹ Cr	erythrocytes	GI bleeding	IV	4	0.7	0.3	24	24a 1iv
75Se-1-7	⁷⁵ Se	23-seleno-25-homotaurocholic acid (SeHCA)	bile salt absorption	oral	0.4	0.3	0.3	20	34a 3
81mKr-74-75	^{81m} Kr	Gas	lung ventilation imaging	inhalation	6,000	0.2	0.001	3	36a 1
99mTc-113-113	^{99m} Tc	MAG 3	renal imaging/renography	IV	100	0.7	1.2	8	43a13i
99mTc-125-92	^{99m} Tc	non-absorbable compounds	oesophageal/gastric/intestinal motility studies	oral	40	0.9	0.6	6	43a11i 43a11ii
99mTc-132-117	^{99m} Tc	pertechnetate	salivary gland imaging	IV	80	1.0	0.6	6	43a1iii
99mTc-132-142	^{99m} Tc	pertechnetate	thyroid imaging/uptake	IV	80 imaging	1.0	0.6	23	43a 1i
					40 uptake	0.5	0.3	11	43a 1ii
99mTc-132-39	^{99m} Tc	pertechnetate	ectopic gastric mucosa imaging (Meckel's)	IV	400	5.2	3	6	43a1iv
99mTc-132-42	^{99m} Tc	pertechnetate	first pass blood flow imaging	IV	800	10.4	6.5	1	43a1xvi
						3 [1]	5.1 [1]		

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	Functional group	Old serials
99mTc-132-61	^{99m} Tc	pertechnetate	lacrima drainage	eye drops	4 (each eye)	0.05	–	13	
99mTc-137-11	^{99m} Tc	phosphonates and phosphates	bone imaging	IV	600	2.9	3.7	5	43a4ii
					800 SPECT	3.9	5.0		
99mTc-150-167	^{99m} Tc	sestamibi	tumour imaging	IV	900	8.1	7.0	14	43a15iv 43a15vi
99mTc-150-83	^{99m} Tc	sestamibi	myocardial imaging	IV	800 [4] rest	7.2	6.2	1	43a15vi i
					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	43a15i
99mTc-152-58	^{99m} Tc	sulesomab	infection/inflammation imaging	IV	750	6.0	4.4	9	43a18
99mTc-154-75	^{99m} Tc	technegas	lung ventilation imaging	inhalation	40	0.6	0.01	3	43a55
99mTc-156-83	^{99m} Tc	tetrofosmin	myocardial imaging	IV	800 [4] rest	6.4	6.2	1	43w46v
					800 [4] stress	5.5	5.6		
99mTc-24-12	^{99m} Tc	colloid	bone marrow imaging	IV	400	3.6	0.4	5	43a7ii
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	43a7xi
					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	43a7xiii
99mTc-24-48	^{99m} Tc	colloid	GI bleeding	IV	400	3.6	0.4	6	43a7iv

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	Functional group	Old serials
99mTc-24-61	^{99m} Tc	colloid	lacrima drainage	eye drops	4 (each eye)	0.04	–	13	43a7vi
99mTc-24-64	^{99m} Tc	colloid	liver and spleen imaging	IV	80	0.7	0.1	7	43a7i
					200 SPECT	1.8	0.2		
99mTc-24-76	^{99m} Tc	colloid	lymph node (lymphoedema) imaging	interstitial	20 (each limb)	0.09	0.001	2	43a7xvii
99mTc-24-92	^{99m} Tc	colloid	oesophageal/gastric/intestinal motility studies	Oral	40	0.9	0.6	6	43a7v
99mTc-30-133	^{99m} Tc	denatured erythrocytes	spleen imaging	IV	100	0.2	0.14	10	43a9
99mTc-33-112	^{99m} Tc	DMSA(III)	renal imaging	IV	80	0.7	0.4	8	43a6iii
99mTc-39-22	^{99m} Tc	DPD	cardiac amyloid imaging	IV	700	5.6	4.4	-	43a4vii
99mTc-40-113	^{99m} Tc	DTPA	renal imaging/renography	IV	300	1.5	2.4	8	43a5i
99mTc-40-42	^{99m} Tc	DTPA	first pass blood flow studies	IV	800	3.9	6.3	4	43a5iii
99mTc-40-46	^{99m} Tc	DTPA	GFR measurement	IV	10	0.05	0.08	25	43a5xi
99mTc-40-75	^{99m} Tc	DTPA	lung ventilation imaging	aerosol inhalation	80	0.5	0.5	3	43a5xix
99mTc-43-15	^{99m} Tc	ECD	brain imaging	IV	750	5.8	6.9	4	43w49
99mTc-48-10	^{99m} Tc	erythrocytes	blood pool imaging (MUGA) /probe studies	IV	800	5.6	3.1	1	43a10iv
99mTc-48-48	^{99m} Tc	erythrocytes	GI bleeding	IV	400	2.8	1.6	6	43a10iii
99mTc-50-15	^{99m} Tc	exametazime	brain imaging	IV	750	7.0	5.0	4	43a17

Procedure code	Radio-nuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	ED (mSv)	Dose to uterus (mGy)	Functional group	Old serials
99mTc-51-58	^{99m} Tc	exametazime labelled leucocytes	infection/inflammation imaging	IV	200	2.2	0.7	9	43a14
99mTc-5-70	^{99m} Tc	albumin macro-aggregates or microspheres	lung perfusion imaging	IV	100	1.1	0.2	3	43a3i
					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	43a3ii
99mTc-5-73	^{99m} Tc	albumin macro-aggregates or microspheres	lung shunt assessment	IV / IA	150	1.6	0.3	3	43a3xiv
99mTc-88-132	^{99m} Tc	HYNIC-Ty3-octreotide	somatostatin receptor imaging	IV	740	3.7	3.0	14	43w70
99mTc-91-44	^{99m} Tc	iminodiacetate	functional biliary system imaging	IV	150	2.4	1.7	7	43a8

Notes

- [1] With the thyroid blocked.
- [2] Effective dose calculated without contribution from thyroid.
- [3] Activities of ¹³¹I 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 increased 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.

Table 5.2: Diagnostic procedures – positron emission tomography

Procedure code	Radionuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	Activity by weight [1] (MBq/kg)	ED (mSv)	Dose to uterus (mGy)	Old serial
11C-20-52	¹¹ C	choline chloride	hepatocellular cancer imaging	IV	370		1.6	0.7	6b74i
11C-20-105	¹¹ C	choline chloride	prostate cancer imaging	IV	370		1.6	N/A	6b74
11C-111-17	¹¹ C	L-methyl-methionine	brain tumour imaging	IV	400		3.3	2.7	6b2i
11C-111-96	¹¹ C	L-methyl-methionine	parathyroid tumour imaging	IV	740		6.1	5.0	6b2ii
13N-6-83	¹³ N	ammonia	myocardial imaging	IV	550		2.0	1.4	7a22i
18F-19-52	¹⁸ F	choline	hepatocellular cancer imaging	IV	370	4.0	7.4	5.6	9a44ii
18F-19-94	¹⁸ F	choline	parathyroid imaging	IV	300	3.0	6.0	4.5	9a44vii
18F-19-105	¹⁸ F	choline	prostate cancer imaging	IV	370	4.0	7.4	N/A	9a44
18F-57-17	¹⁸ F	FDG	brain tumour imaging	IV	250		4.8	4.5	9a21iii
18F-57-37	¹⁸ F	FDG	differential diagnosis of dementia	IV	250		4.8	4.5	9a21v
18F-57-43	¹⁸ F	FDG	focal epilepsy	IV	250		4.8	4.5	9a21vi
18F-57-58	¹⁸ F	FDG	infection/inflammation imaging	IV	400	4.5 [2]	7.6	7.2	9a21iv
18F-57-83	¹⁸ F	FDG	myocardial imaging [3]	IV	400		7.6	7.2	9a21vii
18F-57-169	¹⁸ F	FDG	whole body tumour imaging	IV	400	4.5 [2]	7.6	7.2	9a21i
18F-61-27	¹⁸ F	florbetaben	cerebral amyloid assessment	IV	300		5.8	4.9	9a59
18F-62-27	¹⁸ F	florbetapir	cerebral amyloid assessment	IV	370		6.9	5.8	9a40
18F-64-167	¹⁸ F	fluciclovine	tumour imaging	IV	370		8.2	16.7	9a62

Procedure code	Radionuclide	Chemical form	Investigation	Route of admin	DRL (MBq)	Activity by weight [1] (MBq/kg)	ED (mSv)	Dose to uterus (mGy)	Old serial
18F-66-11	¹⁸ F	fluoride	bone imaging	IV	250		4.3	3.3	9a23i
18F-67-17	¹⁸ F	fluoroethyltyrosine	brain tumour imaging	IV	370		5.9	6.3	9a52
18F-68-87	¹⁸ F	fluoro-L-DOPA	neuroendocrine tumour imaging	IV	280	4.0	7.0	7.8	9a22iii
18F-68-135	¹⁸ F	fluoro-L-DOPA	suspected congenital hyperinsulinism	IV	280	4.0	7.0	7.8	9a22i
18F-71-27	¹⁸ F	flutemetamol	cerebral amyloid assessment	IV	185		5.9	4.6	9a42
18F-141-105	¹⁸ F	PSMA	prostate cancer imaging	IV	280	4.0	5.5	N/A	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	31b29
68Ga-141-105	⁶⁸ Ga	PSMA	prostate cancer imaging	IV	200		4.6	N/A	31b33
82Rb-18-83	⁸² Rb	chloride	myocardial imaging	IV	2,220		2.4	2.2	37a20i

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 5.8 to 5.11.
- [2] For systems that apply a PET bed overlap of $\leq 30\%$, the minimum recommended administered activity is calculated as follows:
 $FDG (MBq) = 14 (MBq \cdot min \cdot bed^{-1} \cdot kg^{-1}) \times patient\ weight (kg) / emission\ acquisition\ duration\ per\ bed\ position (min \cdot bed^{-1})$
for systems that apply a PET bed overlap of $> 30\%$, the minimum FDG administered activity is calculated as follows:
 $FDG (MBq) = 7 (MBq \cdot min \cdot bed^{-1} \cdot kg^{-1}) \times patient\ weight (kg) / emission\ acquisition\ duration\ per\ bed\ position (min \cdot bed^{-1})$ [39]
- [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	For treatment of	Route of admin	Old serial
131I-117-156	¹³¹ I	mIBG	treatment of malignancy	IV	0C10
131I-93-145	¹³¹ I	iodide	treatment of benign thyroid disease	IV or oral	0C 2 / 0C 3
131I-93-150	¹³¹ I	iodide	treatment of carcinoma of thyroid	IV or oral	0C 4
153Sm-46-146	¹⁵³ Sm	EDTMP	treatment of bone metastases	IV	0C38
169Er-24-144	¹⁶⁹ Er	colloid	treatment of arthritis	intra-articular	0C 8
177Lu-141-164	¹⁷⁷ Lu	PSMA [1]	treatment of prostate cancer	IV	N/A
177Lu-37-157	¹⁷⁷ Lu	DOTATATE / DOTATOC / DOTANOC	treatment of neuroendocrine malignancy	IV	0C65
186Re-24-144	¹⁸⁶ Re	colloid	treatment of arthritis	intra-articular	0C21
186Re-82-146	¹⁸⁶ Re	HEDP	treatment of bone metastases	IV	0C39
223Ra-32-147	²²³ Ra	dichloride	treatment of bone metastases in castration resistant prostate cancer	IV	0C54
32P-136-163	³² P	phosphate	treatment of polycythemia vera and related disorders	IV or oral	0C 5
89Sr-18-146	⁸⁹ Sr	chloride	treatment of bone metastases	IV	0C 9
90Y-27-144	⁹⁰ Y	colloidal silicate/citrate	treatment of arthritis	intra-articular	0C 6
90Y-37-157	⁹⁰ Y	DOTATATE / DOTATOC / DOTANOC	treatment of neuroendocrine malignancy	IV	0C66
90Y-89-155	⁹⁰ Y	ibritumomab tiuxetan (Zevalin)	treatment of lymphoma	IV	0C53
90Y-118-153	⁹⁰ Y	microspheres	treatment of hepatic malignancy	intra-arterial	0C35

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	Old serial
106Ru-52-151	¹⁰⁶ Ru	eye plaque	treatment of eye diseases	0T30
125I-148-164	¹²⁵ I	seeds	treatment of prostate cancer	0T29
125I-148-67	¹²⁵ I	seeds	localisation of tumours [1]	N/A
192Ir-169-148	¹⁹² Ir	wire/appliances	treatment of breast cancer	0T25
192Ir-169-154	¹⁹² Ir	wire/appliances	treatment of lung cancer	0T25
192Ir-169-159	¹⁹² Ir	wire/appliances	treatment of oesophageal cancer	0T25
192Ir-169-165	¹⁹² Ir	wire/appliances	treatment of rectal cancer	0T25
192Ir-169-166	¹⁹² Ir	wire/appliances	treatment of skin cancers and benign skin diseases	0T25
192Ir-7-152	¹⁹² Ir	appliances	treatment of gynaecological cancers	0T25
192Ir-7-164	¹⁹² Ir	appliances	treatment of prostate cancer	0T25
90Sr-7-151	⁹⁰ Sr	appliances	treatment of eye diseases	0T24

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-84-10	^{99m} Tc	human albumin	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	lymph node (lymphoedema) imaging
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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
99mTc-152-58	^{99m} Tc	sulesomab	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
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Group 22 NI – haematology

51Cr-48-109	⁵¹ Cr	erythrocytes	red cell kinetics
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 [40]. This is presented in [table 6.1](#). An update to this guidance was released in the form of a new paediatric dosage card in 2007 [41] and further amended in 2014 [42] to provide weight-independent scaling factors dependent on the class of investigation. This was supported by further guidance detailing scaling information for ¹⁸F-FDG PET imaging [43].
- 6.8** It is recommended 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.
- 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 ¹⁸F-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 rapidly evolving.

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

6.10 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 human 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
^{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 [44] 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 [45] 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.

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 consistent with acquiring the desired clinical information, whether the individual is known to be pregnant. Alternative techniques which do not involve ionising radiation should always be considered. Such consideration is particularly important when using radionuclides with long half-lives.
- 7.2** Only investigations which are imperative should be conducted during pregnancy. Investigations carried out on pregnant patients result in radiation doses to both the patient and the foetus.
- 7.3** Any individual of childbearing potential undergoing procedures involving radiopharmaceuticals should be asked whether they are or might be pregnant. The employer's procedures 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). Further information is available in the RCR guidance for understanding the implications of IR(ME)R [\[8,9\]](#)
- 7.4** If the possibility of pregnancy cannot be excluded, the patient should be asked whether their menstrual period is overdue. Low dose procedures, in which the foetal dose is likely to be below 10mGy, can continue to be undertaken, provided that the period is not overdue. For procedures resulting in higher foetal doses, exceeding 10mGy, the procedure should only be undertaken during the first 10 days of the menstrual cycle [\[46\]](#). If necessary, a pregnancy test can be performed to confirm the patient is not pregnant in accordance with the employer's procedure.
- 7.5** 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.
- 7.6** 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.

- 7.7** The response to pregnancy enquires should be documented as evidence that the employer's procedure has been followed.
- 7.8** 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.
- 7.9** 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 [47] suggests that the risk of an adverse effect (for example, childhood cancer) from a dose of 1mGy is about 1 in 17,000.
- 7.10** Further information regarding biological effects after prenatal irradiation has been published by the ICRP [48].

Conception

- 7.11** There is no evidence that pre-conceptual irradiation of an individual can cause any abnormality in their offspring [47]. ARSAC does not consider that advice needs to be given concerning avoidance of conception for the majority of routine diagnostic administrations of radioactive substances.
- 7.12** 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 ¹²⁵I or 0.03MBq of ¹³¹I. Consideration of the diagnostic procedure 125I-84-101 (0.2MBq ¹²⁵I 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.
- 7.13** Of the diagnostic imaging procedures listed in table 5.1, only 131I-93-143 (¹³¹I-iodide, thyroid metastases imaging after ablation) requires advice to delay pregnancy. Any administered activity of ¹³¹I greater than 30MBq should be considered as a 'therapy' administration for radiation protection purposes; advice on pregnancy in table 7.1 should be followed.
- 7.14** In some circumstances it will be necessary to advise patients to avoid conceiving for a period following the administration of long-lived radioactive substances.
- 7.15** 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 [49]. Following the therapeutic administration of ¹³¹I-iodide, ³²P-

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.

- 7.16** 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.

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 (at least)
^{131}I -iodide	thyroid cancer	6,000	6 (at least)
^{131}I mIBG	malignancy	7,500	3
^{153}Sm -colloid	bone metastases	2,600	1
^{169}Er -colloid	arthritis	400	0

Diagnostic administrations to individuals who are breastfeeding or lactating

- 7.17** 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 7.20)
- 7.18** Where the patient is breastfeeding, specific written instructions must be given, and these instructions should be recorded in their medical records.
- 7.19** 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.

- 7.20** 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).
- 7.21** 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.
- 7.22** Advice is given in the Medical and Dental Guidance Notes [50] 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 $^{99\text{m}}\text{Tc}$ 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.
- 7.23** 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.
- 7.24** 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.
- 7.25** 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.
- 7.26** 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.
- 7.27** For some radiopharmaceuticals the required interruption time would be so long that the patient should be advised to stop breastfeeding altogether.
- 7.28** 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) 3 to 4 hours after the administration, the breastfeeding patient should express as much milk as possible - this milk should be discarded and 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
- (e) breastfeeding can be undertaken following subsequent pregnancies

7.29 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.

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

7.31 ICRP Publication 72 [\[51\]](#) 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 human 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

Radioactive substance	Activity administered to mother (MBq)	Feeding interruption time (hours)
^{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 pentetretotide	220	60
¹²³ I iodide	20	42
¹²³ I mIBG	400	25
¹²⁵ I human albumin	Any	STOP
¹³¹ I-iodide	Any	STOP
²⁰¹ Tl-thallos chloride	80	10
Notes	<p>[1] for labelled normal erythrocytes the figures will be sensitive to changes in the labelling efficiency, which can vary substantially</p> <p>[2] this value only applies to the intravenous administration of colloid</p>	

- 7.32** 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 [52,53].
- 7.33** 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 [54] 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 thallos chloride	30.2

- 7.34** 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.
- 7.35** Restrictions may be relevant for patients who are bottle feeding infants, where no dose is expected from ingestion.
- 7.36** The internal component of the effective dose(x) can be calculated using the following formula [52] which assumes a mono-exponential decrease of activity concentration with time:

$$x = \frac{D_{max}}{e^{\left\{ \ln 2 \cdot \left(\frac{P-t_c}{t_{1/2max}} \right) \right\}}}$$

Where:

- D_{max} = maximum value of effective dose to the infant (mSv) [52,55,56] (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)
- $t_{1/2max}$ = maximum value of effective half-life (hours)

- 7.37** Table 7.4. summarises values of maximum effective half-life taken from published data [57 to 61] 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
^{99m} Tc exametazime	3.77
^{99m} Tc sulesomab	3.14
¹¹¹ In leucocytes	134
¹¹¹ In pentetretotide	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

- 7.38** Whilst breastfeeding is completely contraindicated for therapeutic procedures using radionuclides which are excreted in breast milk (for example, ¹³¹I 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 ¹³¹I, ICRP Publication 95 [62] gives the equivalent dose to the breast tissue (in the euthyroid case) as $1.3 \times 10^{-9} \text{Sv.Bq}^{-1}$ for the lactating breast - an increase by a factor of approximately 20 compared to the non-lactating organ.
- 7.39** 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 [63]. 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 ^{123}I , ^{125}I or ^{131}I 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. Assuming full metabolism of the labelled compound and uptake of 25% of the released radioiodine by the thyroid, guidance values which will give this dose are:

^{123}I	15MBq
^{125}I	0.2MBq
^{131}I	0.1MBq

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 if the administered activity will be greater than the values in [section 8.4](#).

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 [64]

85mg potassium iodate contains 50mg iodine [65]

1ml of aqueous iodine oral solution BP (Lugol's Iodine) contains 130mg iodine [66]

- 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 [67]. The use of a blocking protocol using a combination of iodine and perchlorate could be considered in this situation [68].

- 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 8.4.

- 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 [69].

- 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 [70] 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 $10\text{mg}\cdot\text{kg}^{-1}$. 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.

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