

**APPLICATION FOR CERTIFICATE
TO ADMINISTER RADIOACTIVE MEDICINAL PRODUCTS**

Medicines (Administration of Radioactive Substances) Regulations 1978 (SI 1978 No 1006)

Medicines (Radioactive Substances) Order 1978 (SI 1978 No 1004)

Medicines (Administration of Radioactive Substances) Amendment Regulations 1995 (SI 1995 No 2147)

- i. Applications should be made by those practitioners who have responsibility for administration of radioactive medicinal products and carrying out procedures, rather than by those requesting them.
- ii. Before completing this form please read carefully the ARSAC Notes for Guidance.
- iii. Please complete in typescript or black ink and send to:

**ARSAC Support Unit,
Health Protection Agency, Centre for Radiation, Chemical and Environmental Hazards
Radiation Protection Division, Chilton, Didcot, Oxon OX11 0RQ.
Telephone: 01235-832421/822772 (administration) 01235-822887 (scientific)
Fax Number: 01235-834925**

- iv. If you wish to add procedures (for diagnosis or treatment) to an existing ARSAC certificate, the additions form should be used.
- v. All applicants must complete Parts A and C, and the appropriate section(s) of Part B.
- vi. All signatures must be originals – photocopied signature are not acceptable
- vii. Exemption for very low doses - It is **not** necessary to apply for a certificate in cases where the patient or subject will receive an effective dose of less than or equal to 1 micro sievert (0.001 mSv).

PART A: APPLICANT

A

1. Surname
2. Forenames
3. Post/Position and title
4. Date of Appointment
5. Speciality
6. Address for Correspondence

7. Telephone Number and Extension
8. Fax Number
9. Name and address of Employer at the site for which the certificate is issued. This should be consistent with Part B paras 1.1, 2.1 and 3.1 and/or 4.1 and Part C para 1.

10. Qualifications:
 - (a) Medical and Dental Qualifications with dates

 - (b) Other qualifications relevant to administration of radioactive medicinal products with dates

11. Training and Experience

For guidance in the amount of training and experience required for an ARSAC certificate to be issued, please see Section 2 and Appendix IV of the Notes for Guidance revision 2006.

(a) Training

Please state supervised training with reference to Appendix IV of the Notes for Guidance stating scope (e.g. A1., A2), name of institution (e.g. NHS Trust) and period of training (e.g.1987-1991)

Scope of Training	Name of institution	Period of training

(b) Experience

Please state supervised experience with reference to Appendix IV of the Notes for Guidance. Please state Whole Time Equivalent. **NB** Para 11(b) - Total whole-time-equivalent practical experience is not the time spent in imaging/therapy but the time actually spent in the use of radioactive medicinal products.

You may find it helpful to state the number of sessions in nuclear medicine/radiotherapy undertaken per week.

Total whole-time-equivalent _____ years _____ months

Number of sessions per week

Scope of Experience	Name of institution	Period of training/Number of Procedures

12. Do you hold, or have you previously held an ARSAC certificate? If so, please give the reference number of the certificate most relevant to this application.

RPC

If you do not hold an ARSAC certificate, please attach any documentation or supporting statements indicating that you have been trained in radiation protection relating to the patient and others as appropriate, consistent with schedule 2 of the Ionising Radiation (Medical Exposure) Regulations 2000.

I apply for a certificate to administer the radioactive medicinal products listed in Part B of this form. I have available to me the supporting services indicated in Part C of the form.

Signature _____ Date

NB: This signature must be an original

Part B: ITEMS FOR WHICH AUTHORISATION IS SOUGHT

- the use of an appropriate radioactive surface marker will be assumed as appropriate.

Please complete at least one of the following:

- Part B1 - Diagnostic
- and/or
- Part B2 - Therapy
- and/or
- Part B3 – Functional Groups
- OR**
- Part B4 - Research

B1. DIAGNOSIS - Please see Section 3 of the Notes for Guidance

B1

1.1 The name and address of the site where the procedures will be undertaken: -

NB: A separate form should be submitted for each site where the procedures will be undertaken

1.2 Please specify the individual serial numbers of the investigations listed in Appendix I Parts A and/or B of the ARSAC Notes for Guidance for which authorisation is sought (e.g.: 43a7ii), or complete Part B3 of this form for functional groups

1.3 For investigations using sources not listed in Appendix I Parts A and/or B of the ARSAC Notes for Guidance please specify: -

Radio-Nuclide	Chemical Form	Nature of Investigation	Route of Administration	Usual activity per test (MBq)	ED per test*

*Effective Dose, in mSv, estimated as in Appendix II of the Notes for Guidance, giving references or attaching a summary of calculation.

B2. TREATMENT - Please see Section 4 of the Notes for Guidance

B2

The use of radio-labelled antibodies for treatment is recognised but, with a few exceptions, is not currently considered as routine. Applicants should review the evidence for their intended use and where appropriate submit a research application by completing Part B4.

2.1 Name and address of the site where treatment is to be undertaken: -

NB: A separate form should be submitted for each site where the procedures will be undertaken

2.2 Please specify the serial numbers of therapeutic procedures listed in Appendix I Parts C and/or D of the Notes for Guidance for which authorisation is sought (e.g.: 0C 5):

2.3 For treatment using unsealed sources **not listed** in Appendix I, Part C of the Notes for Guidance please specify:-

Radio-nuclide	Chemical form	For treatment of	Route of administration	Usual activity per administration (MBq)

2.4 For sealed source treatments using (a) surface or ophthalmic applicators (b) interstitial or intracavitary devices (other than teletherapy apparatus or cardiac pacemakers) please specify: -

Radionuclide	Appliance/Device

B3. FUNCTIONAL GROUPS - Please see Appendix I Section E of the Notes for Guidance **B3**

3.1 Name and address of site where the procedures will be undertaken: -

NB: A separate form should be submitted for each site where this facility is required

3.2 Please specify the functional groups for which authorisation is now sought. Following authorisation, your certificate(s) will be updated and new copies of the certificate(s) will be forwarded to you as appropriate. In future when any new radioactive medicinal products are allocated to these groups your certificate(s) will be automatically updated.

NB The group(s) requested should be consistent with the training and experience indicated in Part A para 11.

3.2.1 Imaging Groups
please tick the relevant groups

✓	Group No.	Group Name
	1	I – Cardiac
	2	I – Vascular
	3	I – Lung
	4	I – Brain
	5	I – Bone/Joint
	6	I – Gut
	7	I – Hepatobiliary

✓	Group No.	Group Name
	8	I – Genito-Urinary
	9	I – Infection/Inflammation
	10	I – Haematology
	11	I – Endocrine
	13	I – Lacrimal
	14	I – Tumour
	15	I – Sentinel Node

3.2.2 Non-Imaging Groups
please tick the relevant groups

✓	Group No.	Group Name
	20	NI – Absorption
	22	NI – Haematology
	23	NI – Endocrine

✓	Group No.	Group Name
	24	NI – Gastrointestinal
	25	NI – Genito-Urinary
	28	NI – Sentinel Node

B4. RESEARCH - Please see Section 5 of the Notes for Guidance

4.1 The name and address of the site where the study is to be undertaken: -

4.2 The names and qualifications of other participating practitioners: -

4.3 The name and address of the primary Research Ethics Committee (COREC/MREC/LREC etc) as appropriate.

4.4 **ATTACH A ONE PAGE SUMMARY** of the research ethics submission to include the title and aims of the study and justification for the radionuclide procedures in research studies. [Failure to provide this will delay the application]. Include the radiation dose (and equivalence to other sources of radiation if stated) as in this submission.

4.5 Is the study part of a multi centre trial? If yes, state:-

- (i) title (if known) / number of study
- (ii) study co-ordinator's name
- (iii) RPC number of study when already certificated at another site

4.6 Details of the radionuclide(s) to be administered: -

Radio-nuclide	Chemical form	Route of administration	Proposed activity (MBq)	Number of administrations per subject	ED* per administration

* Effective Dose, in mSv, estimated as in Appendix II of the Notes for Guidance, giving references or attaching a summary of calculation.

4.7 If it is proposed to administer rare or unusual substances the following information is required (please use a separate sheet): -

- a. the formula of the substance and the site of its label;
- b. a summary of the animal (and any human) experiments and the bio-distribution data obtained;
- c. the effective dose, with a description of the method used in estimation.

4.8 Details of PATIENTS to be studied: -

Number**	Age Range	Sex	Clinical condition	Total ED per individual*

4.9 Details of any NORMAL VOLUNTEERS to be studied (see Section 5 of the Notes for Guidance): -

Number**	Age Range	Sex	Total ED per individual*

* Effective Dose, in mSv, estimated as in Appendix II of the Notes for Guidance, giving references or attaching a summary of calculation.

** For multi centre trials please provide total number to be included in the study as a whole, as well as the number to be studied at your site.

4.10 If pregnant women or breast-feeding mothers are to be studied give reasons and details of special radiation protection measures to be taken.

4.11 If patients or normal volunteers are also exposed to external ionising radiation (e.g. radiological investigations) as part of the research project, the following information should be given on a separate sheet: -

- a. the nature of the procedure(s);
- b. the number of exposures;
- c. an estimate of effective dose per exposure;
- d. an estimate of total effective dose per subject (from radioactive medicinal products plus other ionising radiation).

**PART C: STAFF, FACILITIES & EQUIPMENT
AVAILABLE TO THE APPLICANT**

C

All applicants must ensure that Part C is completed.

This part should be completed by the persons responsible for the scientific aspects of the work (who may or may not include the applicant).

For the site specified in Part B of this form (the place where diagnosis, treatment or research is to be carried out) please specify: -

1. The name and address of the site: -

2. Equipment

	Brief details of equipment (e.g. make, model)	QA Programme
Radionuclide dose calibrators		Yes/No
Imaging systems (where appropriate)		Yes/No
a. <u>gamma cameras</u>		Yes/No
b. <u>computers</u>		Yes/No
<u>sample counters</u> (where appropriate)		Yes/No
Other relevant major equipment		Yes/No

3. Facilities

	Brief details of facility
Radionuclide storage	
Stock control	
Dispensing	
Administration of treatment (where appropriate)	
Ward care of patients given treatment (where appropriate)	

4. The Radiation Protection Adviser should sign below to indicate that he/she is satisfied with the arrangements for radiation safety.

Name and Address

Signature

Date

5. The Medical Physics Expert should sign below to indicate that he/she is satisfied with the arrangements for patient dosimetry

Name and Address

Signature

Date

6. The scientist(s) responsible for the provision of radioactive medicinal products should sign below to indicate that he/she is satisfied with the arrangements for which he/she is responsible. **NB** - please refer to para 10 of the attached notes regarding this section.

Name
Qualifications
Post and site
Relevant experience

Name
Qualifications
Post and site
Relevant experience

Signature

Date

Signature

Date

7. The scientist responsible locally for the other scientific support facilities should sign below to indicate that he/she is satisfied with the arrangements for which he/she is responsible.

Name	Post
Qualifications	
Relevant experience	

Signature	Date
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NB: All the above signatures must be originals – photocopies are not acceptable

NOTES ON THE COMPLETION OF THE APPLICATION FORM TO ADMINISTER RADIOACTIVE MEDICINAL PRODUCTS - FULL FORM

Your application for a certificate to administer radioactive medicinal products will be dealt with more quickly if all the information requested is given accurately and completely at the time of application. Some common problem areas which lead to delay are noted below.

PART A

1. Signatures - the applicant must sign and date the application form. Photocopied signatures are not acceptable.
2. Para 11 - Training - Please see Appendix IV of the ARSAC Notes for Guidance 2006. FULL DETAILS must be given including experience of radiopharmacy, physics, radiation protection and clinical experience - these must be relevant to the products requested in Part B of the form. It is insufficient to present a list of institutions where you have worked. You may wish to attach a separate page covering these details.
3. **NB** - FRCR alone is an insufficient qualification for a certificate.
4. Para 12 - Failure to provide documentation or supporting statements indicating that you have been trained in radiation protection relating to the patient and others as appropriate, on the first application for a certificate will result in the application form being returned. Enclosing documentation, which is not relevant to the application e.g. a diagnostic X-ray training course certificate would not be acceptable.

PART B

5. Para 1.2 - Please quote serial numbers of those procedures in the latest version of the ARSAC Notes for Guidance - Parts A and/or B. If the activity required on a routine basis is greater than that in Notes for Guidance, complete para 1.3 giving a full justification. For the procedures not listed in Notes for Guidance complete para 1.3.
6. Para 1.3 - Failure to complete the ED section will result in a request for further information (except for therapy and therapy research applications)
7. Para 4.4 - A one page summary of the full REC submission is required. ARSAC does not want to see the full submission and enclosing this can, in itself delay an application. **NB** - the summary should clearly cover the relevance of the procedure using radioactive medicinal products to the research study.
8. You should note the following general issues: -
 - a) pregnant women, women who may be pregnant, or breast-feeding mothers. Researchers may find it better to include a statement about excluding such women from their project. ARSAC are likely to query any project where it appears that such women may not be excluded. Full justification must be given if such women are to be included - see para 4.10. See Section 7 of the Notes for Guidance.
 - b) age - ARSAC policy is to restrict research, wherever possible, to patients and normal volunteers aged 50 and over. Full justification should be given at the outset if persons aged under 50 are to be studied e.g. the condition being researched is only found in younger patients. See Section 5 of the Notes for Guidance.
 - c) multiple studies - all steps should be taken to exclude persons from repeated studies. See Section 5 of the Notes for Guidance.

PART C

9. Signatures - the persons who sign Part C must be properly qualified and have sufficient experience. See Section 2 of the Notes for Guidance. For example nurses and/or clinical assistants would not be acceptable as signatories to Part C. Full details of qualifications and relevant experience must be given. Photocopied signatures are not acceptable.
10. If radioactive medicinal products are supplied from another hospital, please ask the local scientist responsible for the provision of these radioactive medicinal products at that hospital to sign Section 6, as well as the local scientist who is responsible for acceptance of radioactive medicinal products at your own site.