

# DEPARTMENT OF HEALTH

(ADDITIONS FORM)

## APPLICATION FOR AN ADDITION TO A CURRENT 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. Before completing this form please read carefully the ARSAC Notes for Guidance.
- ii. 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**

- iii. If you wish to add items for diagnosis to an existing ARSAC certificate, you must complete pages 1, 2 and 4. For treatment items please complete pages 1, 3 and 4.
- iv. Please use this form **only to request the addition of further diagnostic or therapy procedures** to a current certificate. Research applications require the full ARSAC form to be completed.
- v. This application form should not be used for additions involving Functional Groups (see Appendix I Section E of the Notes for Guidance).

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### 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 and/or 2.1
10. Please give the REFERENCE NUMBER of the diagnostic or therapy certificate issued you to be amended

**RPC**

**PART B: ADDITIONAL ITEMS FOR WHICH AUTHORISATION IS SOUGHT**

**B**

**B1. DIAGNOSIS** – please see section 3 of the Notes for Guidance

1.1 Name and address of 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 **now** sought (e.g.: 43a7ii), or complete the functional groups application form for functional groups

1.3 For investigations 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.

1.4 Please specify details of training and experience relevant to your application if the additional items require vastly different techniques from those already demonstrated for the issue of your current certificate.

**B2. TREATMENT** - please see section 4 of the Notes for Guidance

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 the full form.

2.1 Name and address of the site where the 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 those therapeutic serials listed in Appendix I Parts C and/or D of the ARSAC Notes for Guidance for which authorisation is **now** sought: -

2.3 For treatments using unsealed sources not listed in Appendix I Parts C and/or D of the ARSAC 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 treatment using (a) surface or ophthalmic applicators (b) interstitial or intracavitary devices (other than teletherapy apparatus or cardiac pacemakers) please specify: -

Radionuclide	Appliance/Device

2.5 Please specify details of training and experience relevant to your application if the additional items require vastly different techniques from those already demonstrated for the issue of your current certificate.

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

**C**

Please indicate any changes in scientific staff, facilities and equipment since your last full application was approved for the site.

**This application must have the agreement of the signatories to Part C of your last full application. If any of those signatories are no longer appropriate, a new Part C should be submitted in full with this form.**

Signature of applicant: \_\_\_\_\_ Date:

**NB: This signature must be an original**