**Amend or renew employer licence application form**

This is an application form to amend or renew an employer licence to administer radioactive substances as required under:

* Ionising Radiation (Medical Exposure) Regulations 2017
* Ionising Radiation (Medical Exposure) (Northern Ireland) Regulations 2018

Amendment and renewal applications are subject to a fee, see the [ARSAC website](https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee) for details. Once the application has been accepted, details of how and when to pay will be provided.

Please submit this form with any supporting information onto the [online portal](https://jira.collab.test-and-trace.nhs.uk/servicedesk/customer/portal/212). Forms can be electronically signed.  **Please do not delete any sections of this form when completing.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Form completed by: | Click here to enter text. | |
|  | Full legal name of medical radiological installation (site) | Click here to enter text. | |
|  | Full legal name of employer | Click here to enter text. | |
|  | Accountable representative of the employer under IR(ME)R who has responsibility for the services included in this application (usually the Chief Executive Officer or equivalent person) | | |
|  | Name and title | Choose an item. | Click here to enter text. |
|  | Job title | Click here to enter text. | |
|  | Email address | Click here to enter text. | |
|  | Senior Medical Director (or equivalent individual at board level) responsible for the services included in this application | | |
|  | Name and title | Choose an item. | Click here to enter text. |
|  | Job title | Click here to enter text. | |
|  | Email address | Click here to enter text. | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Application type  (tick all that apply) | Remove procedure(s) | |  |
| Add procedure(s) | |  |
| Change of purpose of procedure (for example from research to routine) | |  |
| Request increased activity (above the NDRL) | |  |
| Renew licence (please fill in Q7 and Q12 to Q43) | |  |
|  | **Existing procedures** | | | |
|  | Do you wish to continue to be authorised for all current procedures on your licence? | | Yes / no | |
|  | If no, please list the procedure codes to be removed from your licence. | |  | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Additional diagnostic procedures** | | | | | | | | | |
|  | Please enter the additional diagnostic procedure codes from the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  (Enter one procedure code per line. To add more procedures, insert rows into the table and if desired copy the relevant drop-down box to the new row.) | | | | | | | | | |
|  | Select diagnostic procedures | | | | | | | | | |
|  | Select PET procedures | | | | | | | | | |
|  | Click here to enter text. | | | | | | | | | |
|  | Functional groups – please check the relevant boxes to add **all** the procedures within a functional group to your licence. The procedures included in each functional group are set out in the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  If only some of the procedures within a functional group are required, please list in Q8a individually. | | | | | | | | | |
| Imaging | | | | | | Non- Imaging | | | |
| 1 – Cardiac | |  | 8 – Genito-urinary | |  | 20 – Absorption | | |  |
| 2 – Vascular | |  | 9 – Infection/Inflammation | |  | 22 – Haematology | | |  |
| 3 – Lung | |  | 10 – Haematology | |  | 23 – Endocrine | | |  |
| 4 – Brain | |  | 11 – Endocrine | |  | 24 – Gastrointestinal | | |  |
| 5 – Bone/joint | |  | 13 – Lacrimal | |  | 25 – Genito-Urinary | | |  |
| 6 – Gastrointestinal | |  | 14 – Tumour | |  |  | | |  |
| 7 – Hepatobiliary | |  | 15 – Sentinel Node | |  |  | | |  |
|  | Please enter details of additional diagnostic procedures that are **not** included in the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  (Please enter one procedure per line, to apply for additional procedures insert more rows into the table and include any references for effective doses listed.)  If you know the relevant procedure code, you can include this with the indication, but it is not mandatory. | | | | | | | | | |
| Radio-nuclide | Pharmaceutical or chemical form | | | Indication | | Route | Activity (MBq) | ED (mSv) | |
|  |  | | |  | |  |  |  | |
|  |  | | |  | |  |  |  | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Additional sealed source therapy** | | | | | |
|  | Please enter the additional sealed source therapy procedure codes from the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  (Enter one procedure per line. To add more procedures, insert rows into the table and if desired copy the relevant drop-down box to the new row.) | | | | | |
| Procedure code | | Number performed in last 12 months (if applicable) | | Predicted number performed in next 12 months | |
| Choose an item. | |  | |  | |
| Choose an item. | |  | |  | |
|  | Please enter details of the additional sealed source therapy procedures that are **not** included in the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  Enter one procedure per line. To add more procedures, insert rows into the table.  If you know the relevant procedure code, you can include this with the indication, but it is not mandatory. | | | | | |
|  | Radionuclide | Appliance or device | | Indication | Number performed in last 12 months (if applicable) | Predicted number performed in next 12 months |
|  |  | |  |  |  |
|  |  | |  |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Additional unsealed source therapy** | | | | | | |
|  | Please enter the additional unsealed source therapy procedure codes from the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  (Enter one procedure per line. To add more procedures, insert rows into the table and if desired copy the relevant drop-down box to the new row.) | | | | | | |
| Procedure code | | Number performed in last 12 months (if applicable) | | | Predicted number performed in next 12 months | |
| Select a procedure code | |  | | |  | |
| Select a procedure code | |  | | |  | |
|  | Please enter details of the required unsealed source therapy procedures that are **not** included in the [notes for guidance](https://www.gov.uk/government/publications/arsac-notes-for-guidance).  (Enter one procedure per line. To add more procedures, insert rows into the table.)  If you know the relevant procedure code, you can include this with the indication, but it is not mandatory. | | | | | | |
| Radio-nuclide | Pharmaceutical or chemical form | Indication | Route | Number performed in last 12 months  (if applicable) | | Predicted number performed in next 12 months |
|  |  |  |  |  | |  |
|  |  |  |  |  | |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Additional research** | | | | | | | |
|  | Would you like to apply to administer all routine diagnostic procedures listed in Q8 for research? | | | | | |  | |
|  | Would you like to apply to administer all sealed source therapy procedures listed in Q9 for research? | | | | | |  | |
|  | Would you like to apply to administer all unsealed source therapy procedures listed in Q10 for research? | | | | | |  | |
|  | Please enter details of additional procedures required for **research only** that are not included in a, b or c above.  Enter one procedure per line and include relevant references for effective dose. To add more procedures, insert rows into the table. Where the procedure code is not known, please enter the IRAS ID of the research trial in the indication column to allow cross referencing. | | | | | | | |
| Procedure code | Radio-nuclide | Pharmaceutical or chemical form | Indication (as per research study) | Route | Activity (MBq) | | ED (mSv) (or target dose for therapy) |
|  |  |  |  |  |  | |  |
|  |  |  |  |  |  | |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Service information**  (Please answer questions 12 to 26 for the whole service provided at this site.) | | | |
|  | How many days per week does this service run? | | |  |
|  | Please provide details of the scope of the service, for example, approximate department workload, planned expansion to service if relevant. | | | |
|  | | | |
|  | Do you perform administrations to paediatric patients? | | |  |
|  | If yes, do you have procedures to scale administered activity for all procedures on paediatric patients? | | |  |
| Please provide details: | | | |
|  | | | |
|  | Please provide a 1-page summary of governance arrangements for IR(ME)R at this installation (Please include details of 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. This can be attached to the application in the [online portal](https://jira.collab.test-and-trace.nhs.uk/servicedesk/customer/portal/212) as a separate document or entered below.) | | | |
|  | | | |
|  | Do you have a clinical audit programme in place? | | |  |
|  | Do you contribute to national audit programmes for specific procedures? | | |  |
|  | Please provide details of local clinical audits and national audit programmes | | | |
|  | | | |
|  | Please confirm whether multi-disciplinary team meetings are set up for appropriate patient selection and management for the procedures in this application? | | |  |
| Please provide details: | | | |
|  | | | |
|  | Are procedures in place to reduce the likelihood of accidental and unintended medical exposures? | | |  |
|  | How are these procedures available to staff? | | |  |
|  | If other, please provide details: | | | |
|  | | | |
|  | **Medical physics expert (MPE) support**  (Only one lead MPE should sign the form authorisation at A1) | | | |
|  | How many individuals are entitled as MPEs at this installation?  (Please specify how many MPEs support the administration of radioactive substances at this site, not just for the procedures included in this amendment.) | Diagnostic nuclear medicine |  | |
| Unsealed source therapy |  | |
| Sealed source therapy |  | |
|  | How much whole-time equivalent (WTE) support do these individuals provide to this service?  (If an individual’s role covers diagnostic and unsealed source therapy, please give an approximate split of WTE support.) | Diagnostic nuclear medicine |  | |
| Unsealed source therapy |  | |
| Sealed source therapy |  | |
|  | Please confirm how MPE advice is provided. If any support is provided remotely please provide details of arrangements in place for ensuring that adequate support can be provided. | | | |
|  |  | | | |
| 21. | Please provide details of the wider scientific support available (for example, clinical scientists, technologists) and how they provide support to this service for the scope of procedures applied for. | | | |
|  |  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Entitled licenced practitioner support** | | |
|  | How many individual practitioners are entitled at this installation?  (Please specify how many practitioners support the administration of radioactive substances at this site, not just for the procedures included in this amendment.) | Diagnostic nuclear medicine |  |
| Unsealed source therapy |  |
| Sealed source therapy |  |
|  | How much WTE support do these individuals provide to this service?  (Please specify how much WTE support there is for the administration of radioactive substances at this site, not just for the procedures included in this amendment.) | Diagnostic nuclear medicine |  |
| Unsealed source therapy |  |
| Sealed source therapy |  |
|  | Please confirm how practitioner support is provided. If any support is provided remotely, please provide details of arrangements in place for ensuring that adequate supervision can be provided. | | |
|  |  | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Equipment**  Please enter one piece of medical radiological equipment per line. To add more equipment, insert rows into the table and if desired copy the drop-down box into the new row. | | | | | |
|  | Type | Manufacturer | | Model number | Serial number | Year of installation |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  |  | |  |  |  |
|  | Please list any equipment available at other hospitals or sites required for the requested procedures (for example, sample counters for GFR or gamma probes used for surgery for sentinel lymph node biopsy). | | | | | |
| Type of equipment | | Site | | | |
|  | |  | | | |
|  |  | |  | | | |

|  |  |  |
| --- | --- | --- |
|  | Please provide details of any replacement plans in place for the equipment listed above which may be due for replacement | |
|  |  | |
|  | Has the employer ensured that a quality assurance schedule is in place for all equipment in Q24? |  |
| Please provide details: | |
|  | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Radiopharmaceutical service provision** | | | | | | |
|  | How many radiopharmaceutical service providers do you have to provide the procedures on your licence and the additional procedures in Q8, Q10 and Q11 at this installation? (Please do not include licenced providers who only provide products with Marketing Authorisation (MA) or short term providers used for emergencies.) | | | | |  | |
|  | Does the employer making this application operate a radiopharmaceutical manufacturing facility? | | | | |  | |
|  | Is this based at this installation? | | | | |  | |
|  | Under what authorisation does this facility operate? Please indicate all that apply and provide the licence number(s) where relevant. | | Manufacturers Specials licence (MS) | | |  | |
| Manufactures or importers licence (MIA) | | |  | |
| Manufactures licence for Investigational Medicinal Products (IMP) | | |  | |
| Section 10 exemption  (under the supervision of a pharmacist) | | |  | |
|  | Do you procure radiopharmaceuticals which have an MA licence from external providers? | | | | |  | |
|  | Do you procure radiopharmaceuticals which do not have an MA licence from external providers? | | | | |  | |
|  | Please provide the contact details of the person taking responsibility for the safe use of any procured radioactive substances. (This person should sign the form authorisation at A2)  (In the NHS this will always be the Chief Pharmacist. For non-NHS organisations this should be an individual with the equivalent responsibility.) | | | | | | |
|  | Name and title | | |  |  | | |
|  | Job title | | |  | | | |
|  | Email address | | |  | | | |
|  | Base site or location | | |  | | | |
|  | Registration number | | |  | | | |
|  | If radiopharmaceuticals are provided from a radiopharmaceutical manufacturing facility operated by the employer making this application (that is, the answer to Q28 was yes) please complete Q32a-c.  (Where multiple licence types are held (MS/MIA/IMP), please copy Q32a-c for each licence.) | | | | | | |
|  | Please provide a brief outline of the manufacturing facility sufficient to show capability for the scope of licence, for example, separate facility for labelled blood cells, cyclotron for PET. Include a statement to confirm there is sufficient capacity to supply products and that staff are appropriately trained to perform the tasks required by this licence application. | | | | | | |
|  | | | | | | |
|  | Please provide the contact details of either:   * the named person on the MS/MIA licence being responsible for quality control * the quality manager (for an IMP licence) * the QP (for an IMP licence) * the Accountable Pharmacist (for those operating under Section 10 exemption)   (This person should sign the form authorisation at A3.) | | | | | | |
| Name and title | | |  | | | |
| Job title | | |  | | | |
| Base site or location | | |  | | | |
| Email address | | |  | | | |
| Qualification | | |  | | | |
| Professional registration (if applicable) | | |  | | | |
|  | For those operating under a section 10 exemption, does the person named above supervise the preparation of radiopharmaceuticals as defined in NHS Pharmaceutical Quality Assurance Committee (PQAC) (2014)? | | | | | |  |
|  | Please provide details of all external radiopharmaceutical service providers used to procure radiopharmaceuticals which do not hold an MA licence.  (Please copy Q33a-d for each provider. There is no requirement to list short term emergency arrangements or external providers which only provide radiopharmaceuticals with an MA licence.) | | | | | | |
|  | Name |  | | | | | |
|  | Email address |  | | | | | |
|  | Has the employer ensured that the provider named above has the facilities, capacity and appropriately trained staff to provide the scope of the procured radiopharmaceuticals required at this installation? | | | | | |  |
|  | Please provide a brief outline of the external provider sufficient to show capability for the scope of procured radiopharmaceuticals required in this licence application, for example, separate facility for labelled blood cells. | | | | | | |
|  | | | | | | |

|  |  |  |
| --- | --- | --- |
|  | **Sealed source provision** | |
|  | Please provide details of the person responsible for the measurement and/or calibration of sealed sources administered at this installation. (This person should sign the form authorisation at A4) | |
|  | Name and title |  |
|  | Job title |  |
|  | Base site or location |  |
|  | Email address |  |
|  | Registration number |  |

|  |  |  |
| --- | --- | --- |
|  | **Facilities for the administration of radioactive substances** | |
|  | Please confirm that you have appropriate arrangements in place for the storage of radiopharmaceuticals |  |
| Please provide details: | |
|  | |
|  | How is radiopharmaceutical stock managed? | |
|  | |
|  | Is drawing up performed in line with the UKRG guidance note: Safe drawing up of radiopharmaceuticals in nuclear medicine departments? |  |
| Please provide details. If no, please provide confirmation that the method used for drawing up has been risk assessed and approved by the Chief Pharmacist or Responsible Person identified in Q31 or Q32b above and provide details of any action plan in place to improve compliance. | |
|  | |
|  | Where are diagnostic administrations performed? | |
|  |  | |
|  | Please confirm that there is a procedure in place for administrations covering each location |  |
|  | Where are therapeutic administrations performed? | |
|  | |
|  | Please confirm that there is a procedure in place for administrations covering each location |  |
|  | Are in-patient therapies performed? |  |
| Please provide details of any shielded rooms or other facilities for in-patient therapies | |
|  | |
| Have ward staff received training on radiation protection measures? |  |

|  |  |
| --- | --- |
|  | **Supporting information** |
|  | Please provide any other information to support this application. For example:   * if a shorter licence was issued – details of improvements as recommended by ARSAC * experience of surgical teams or other supporting staff * arrangements for staff outside the department * details of the start-up of new services * rationale for the application |
|  |  |

|  |  |  |
| --- | --- | --- |
|  | **Form authorisations**  This section can be signed electronically | |
| A1 | The Lead Medical Physics Expert should authorise the application below to indicate that all the information in this application is correct, that they are aware of their responsibilities under IR(ME)R to give advice, that they contribute to matters specified in the regulations for this application, that the radiation risk estimate associated with this application is accurate, reasonable and that the entire scope of this application can be delivered at this radiological installation along with the intended clinical outcomes. | |
| Name |  |
| Job title |  |
| Date |  |
| Signature |  |
| A2 | The Chief Pharmacist or alternative responsible staff member named in Q31 for procured radiopharmaceuticals should authorise the application below to indicate all the relevant pharmaceutical information in this application is correct, that the relevant scope of this application can be delivered at this radiological installation and that they are satisfied with the quality and arrangements for the radiopharmaceuticals to be administered. | |
| Name |  |
| Job title |  |
| Date |  |
| Signature |  |
| A3 | The responsible staff member for the radiopharmaceutical manufacturing facility detailed in Q32b should authorise the application below to indicate all the relevant information in this application is correct, that the relevant scope of this application can be delivered at this radiological installation and that they are satisfied with the quality of the radiopharmaceuticals to be administered.  (please leave this section blank if the employer does not operate a radiopharmaceutical manufacturing facility) | |
| Name |  |
| Job title |  |
| Date |  |
| Signature |  |
| A4 | The responsible staff member for the measurement and/or calibration of sealed sources named in Q34 should authorise the application below to indicate that all the relevant information in this application is correct, and that appropriate arrangements are in place for the use of sealed radioactive substances at this radiological installation.  (Please leave this section blank if sealed sources are not included in this application) | |
| Name |  |
| Job title |  |
| Date |  |
| Signature |  |
| A5 | The individual named in Q4 (for example, Chief Executive Officer) or the individual named in Q5 (for example, Medical Director) should authorise the application below on behalf of the employer. This is to indicate that all the information in this application is correct, that the entire scope of this application can be delivered at this radiological installation and that they are aware of their responsibilities under IR(ME)R with regard to the administration of radioactive substances. | |
| Name |  |
| Job title |  |
| Date |  |
| Signature |  |