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|--------|--|---|
| NF211A | <p align="center"><b>Health Information and Quality Authority</b><br/>Accidental or unintended exposure to ionising radiation*</p> |  <p>Health Information and Quality Authority<br/>An tÚdaráis Um Fhaisnéis agus Cáilíocht Sláinte</p> |
|--------|--|---|

This form allows you to notify us of a significant event as required by Regulation 17(1)(e). This form must be used when notifying HIQA of significant events involving **Dental, Radiology** or **Nuclear Medicine** (therapeutic and diagnostic). Significant events should be notified to HIQA within three working days of the discovery of the significant event.

| Undertaking and medical radiological installation details                    |  | For official use |
|--|--|------------------|
| Undertaking <b>name</b>  |  |                  |
| Undertaking <b>address</b> (include <b>Eircode</b> )                         |  |                  |
| Undertaking <b>email address</b>   |  |                  |
| Undertaking <b>contact number</b>  |  |                  |
| <b>Medical radiological installation name</b> where incident <b>occurred</b> |  |                  |
| <b>Address</b> incident <b>occurred</b> (include Eircode)                    |  |                  |
| Designated manager <b>name</b>   |  |                  |
| Designated manager <b>email address</b>                                      |  |                  |
| Designated manager <b>contact number</b>                                     |  |                  |

| Section 1. Significant event details   |        |        | For official use    |
|--|--------|--------|---------------------|
| <b>Exact location</b> incident <b>occurred</b> (area <b>or</b> department <b>or</b> room <b>or</b> unit) |        |        |                     |
| <b>Date</b> incident <b>occurred</b>   |        |        |                     |
| <b>Time</b> incident <b>occurred</b> (HH:MM)   |        |        |                     |
| <b>Date</b> incident <b>discovered</b>   |        |        |                     |
| <b>Multiple</b> service users affected   | Yes    | No     | Number <sup>†</sup> |
|  |        |        |                     |
| Service user <b>details</b>  | Gender |        | Age                 |
|  | Male   | Female |                     |

\* Please complete this form with HIQA's statutory notification guidance. You can download the guidance at [www.hiqa.ie](http://www.hiqa.ie).

† If multiple service users are affected, please contact HIQA at [radiationprotection@hiqa.ie](mailto:radiationprotection@hiqa.ie) for further advice

|   |     |  |    |  |  |
|---|-----|--|----|--|--|
| <p>Please provide <b>brief details</b> of the incident - no personally identifiable information (PII) should be submitted in line with General Data Protection Regulations (GDPR)</p> |     |  |    |  |  |
| <p>Have <b>appropriate actions</b> been taken to <b>mitigate</b> against immediate <b>recurrence</b> of this incident?</p>  | Yes |  | No |  |  |
| <p>Please provide <b>brief details</b> of the <b>initial actions</b> taken to <b>mitigate against immediate recurrence</b> of this incident</p>                                       |     |  |    |  |  |

| Significant event category   |  |  |
|--|--|--|
| Administered activity variation of 20% from intended dose during use of therapeutic nuclear medicine   |  |  |
| Administration of a Reference Point Air Kerma ( $K_{a,r}$ ) of 15 Gray (Gy) or greater as a result of a single interventional radiological procedure (including interventional cardiology) or a cumulative $K_{a,r}$ dose of 15 Gy arising from a series of interventional radiological procedures carried out over a six month period |  |  |
| Dose to a breastfed child greater than 1 millisievert (mSv)  |  |  |
| Dose given to comforters and carers greater than 3 millisievert (mSv) for adults under 60 years of age and 15 millisievert (mSv) for those over 60 years of age  |  |  |
| Inadvertent dose to a foetus greater than 1 milligray (mGy)  |  |  |
| Incorrect anatomy greater than 1 millisievert (mSv)  |  |  |
| Incorrect procedure greater than 1 millisievert (mSv)  |  |  |
| Incorrect radiopharmaceutical  |  |  |
| No dose intended/incorrect service user exposed to greater than 1 millisievert (mSv)   |  |  |
| Overexposure of a child of more than twice the exposure intended that leads to a dose that is greater than 3 millisievert (mSv) or 15 times the dose intended  |  |  |
| Overexposure of an adult of more than twice the exposure intended that leads to a dose that is greater than 10 millisievert (mSv) or 20 times the dose intended  |  |  |
| Therapeutic dose given instead of diagnostic dose, for example, in the use of radioiodine  |  |  |
| Tissue reactions (deterministic effects) as a result of interventional radiology/cardiology  |  |  |
| Any other radiation exposure incident considered to have serious service user safety implications, for example, multiple non-notifiable incidents of a similar nature  |  |  |

| Type of procedure or treatment involved in the incident |  |                                 |  |  |
|---|--|---------------------------------|--|--|
| Computed Tomography (CT)                                |  | Interventional radiology        |  |  |
| Dental  |  | Mammography                     |  |  |
| Dual-energy X-ray absorptiometry (DXA)                  |  | Nuclear medicine                |  |  |
| Fluoroscopy   |  | Positron Emission Tomography/CT |  |  |
| Interventional cardiology                               |  | Radiology - general             |  |  |

| Section 2. Dental/Radiology/Nuclear Medicine incident details  |   |  |  | For official use |
|--|---|--|--|------------------|
| <b>Radiology, diagnostic nuclear medicine and interventional procedures</b><br>Please provide an <b>initial estimated dose</b> | 1 to 5 mSv  |  |  |                  |
|  | Over 5 to 10 mSv                                    |  |  |                  |
|  | Over 10 to 15 mSv                                   |  |  |                  |
|  | Over 15 to 20 mSv                                   |  |  |                  |
|  | Greater than 20 mSv                                 |  |  |                  |
|  | Other, <b>please specify:</b>                       |  |  |                  |
| <b>Therapeutic nuclear medicine procedures</b><br>Please provide an <b>initial estimated radiation dose variation</b>          | Greater than 20% total dose, <b>please specify:</b> |  |  |                  |
| <b>Type of incident</b>  | Hardware/software - Ancillary equipment             |  |  |                  |
|  | Hardware/software - Medical radiological equipment  |  |  |                  |
|  | Inappropriate or incorrect justification            |  |  |                  |
|  | Incorrect protocol selection                        |  |  |                  |
|  | Optimisation error (practical aspects)              |  |  |                  |
|  | Quality assurance error                             |  |  |                  |
|  | Referral error - wrong patient                      |  |  |                  |
|  | Referral error - wrong procedure                    |  |  |                  |
|  | Scheduling error                                    |  |  |                  |
|  | Service user movement                               |  |  |                  |
|  | Service user related circumstance                   |  |  |                  |
|  | Wrong anatomical site                               |  |  |                  |
|  | Wrong service user                                  |  |  |                  |
|  | Wrong service user setup                            |  |  |                  |
|  | Wrong side (laterality)                             |  |  |                  |
| Other, please specify:   |   |  |  |                  |

| Section 3. Open Disclosure   |  |     |    | For official use |
|--|--|-----|----|------------------|
| Was the incident that occurred considered to be a <b>clinically significant</b> unintended or accidental exposure? |  | Yes | No |                  |
| Did you <b>inform</b> the following individuals of this incident?  | Service user/service user representative | Yes | No |                  |
|  | Referrer                                 | Yes | No |                  |
|  | Practitioner                             | Yes | No |                  |

| Section 4. Notification of stakeholders  |  |  |  | For official use |
|--|--|--|--|------------------|
| Please indicate, <b>where applicable</b> , if the following <b>stakeholders</b> have been <b>notified</b> of the incident: |  |  |  |                  |
| Medical Physics Expert   |  | Radiation Therapy Services Manager       |  |                  |
| Practitioner   |  | Radiography Services Manager             |  |                  |
| Risk Manager   |  | Referrer                                 |  |                  |
| Radiation Safety Officer   |  | Radiation Safety Committee or equivalent |  |                  |
| Undertaking  |  |  |  |                  |
| Other regulatory agencies where necessary, <b>please list if applicable:</b>   |  |  |  |                  |

| Section 5. Follow-up documentation  |
|---|
| The results of the investigation into the significant event and corrective measures to avoid such events must be submitted within the next 120 calendar days. |

| Section 6. Declaration  |  | For official use |
|---|--|------------------|
| By submitting, I declare that the information I have provided in this form is true to the best of my knowledge and belief. The undertaking is aware that I am making this submission on its behalf. |  |                  |
| Name ( <b>print</b> )   |  |                  |
| Job Title   |  |                  |
| Contact number  |  |                  |
| Signed  |  |                  |
|   | <b>Type</b> your name in the signature field |                  |
| Date  |  |                  |

- **Email** form to: [radiationprotection@hqa.ie](mailto:radiationprotection@hqa.ie)
- **Telephone**: 01 8286750.