NF211C	**Health Information and Quality Authority** Accidental or unintended exposure to ionising radiation*	Health Information and Quality Authority An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

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 medical exposures **other** than Dental, Radiology, Radiotherapy 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 **name**		
Undertaking **address** (include **Eircode**)		
Undertaking **email address**		
Undertaking **contact number**		
Medical radiological installation name where incident **occurred**		
Address incident **occurred** (include Eircode)		
Designated manager **name**		
Designated manager **email address**		
Designated manager **contact number**		

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

* Please complete this form with HIQA's statutory notification guidance. You can download the guidance at www.hiqa.ie.
† If multiple service users are affected, please contact HIQA at radiationprotection@hiqa.ie for further advice

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

Significant event categories		
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 patient 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	☐	
Radiotherapy dose or volume variation of 10% or greater from the total prescribed	☐	
Radiotherapy dose or volume variation of 20% or greater from the fraction prescribed	☐	
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	☐	
Unexpected tissue reactions (deterministic effects) as a result of radiotherapy treatment	☐	
Any other radiation exposure incident considered to have serious patient safety implications, for example, multiple non-notifiable incidents of a similar nature	☐	

Type of procedure **or** treatment involved in the **incident**		
Other, please specify:		

Section 2. Dental / Radiology / Nuclear Medicine incident details			For official use
Radiology, diagnostic nuclear medicine and interventional procedures Please provide an **initial estimated dose**	1 to 5 mSv	☐	
	Over 5 to 10 mSv	☐	
	Over 10 to 15 mSv	☐	
	Over 15 to 20 mSv	☐	
	Greater than 20 mSv	☐	
	Other, **please specify**:		
Therapeutic nuclear medicine procedures Please provide an **initial estimated radiation dose variation**	Greater than 20% total dose, **please specify**:		
Type of incident	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. Radiotherapy incident details			For official use
Process step where the incident **occurred**	Imaging for radiotherapy planning	☐	
	On-treatment quality management	☐	
	Post-treatment completion	☐	
	Pre-treatment review and verification	☐	
	Service user assessment/consultation	☐	

		Treatment delivery brachytherapy		☐	
		Treatment delivery external beam radiotherapy		☐	
		Treatment planning		☐	
		Other, **please specify:**			
Treatment **intent**		Radical	☐	Palliative ☐	
Radiotherapy treatment delivery Please provide an **initial estimated radiation dose variation**		Greater than 10% variation total dose, **please specify**:			
		Greater than 20% variation in a fractionated dose, **please specify:**			
Other radiotherapy incidents		Please provide an **initial estimated effective dose** in millisievert (mSv)			
Type of incident	**Dose** error	Calculation error		☐	
		Calibration error		☐	
		Excess imaging dose		☐	
		Treatment plan not physically deliverable		☐	
		Wrong plan dose		☐	
		Wrong prescription dose		☐	
	Hardware/software error	Ancillary equipment		☐	
		Medical radiological equipment		☐	
	Volume error	Service user movement		☐	
		Wrong anatomical site		☐	
		Wrong service user		☐	
		Wrong service user setup		☐	
		Wrong shift from setup point		☐	
		Wrong side (laterality)		☐	
		Wrong target or organs at risk contours, or planning margins		☐	
		Wrong treatment accessories		☐	
	Other errors	Inappropriate or poorly informed decision to treat or plan		☐	
		Scheduling error		☐	
		Service user related circumstance		☐	
	Other, **please specify**:				

Section 4. Open Disclosure				For official use
Was the incident that occurred considered to be a **clinically significant** unintended or accidental exposure?		Yes ☐	No ☐	
Did you **inform** the following individuals of this incident?	Service user/service user representative	Yes ☐	No ☐	
	Referrer	Yes ☐	No ☐	
	Practitioner	Yes ☐	No ☐	

Section 5. Notification of stakeholders				For official use
Please indicate, **where applicable**, if the following **stakeholders** have been **notified** 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, **please list if applicable**:				

Section 6. 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 7. 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 (**print**)		
Job Title		
Contact number		
Signed		
	Type your name in the signature field	
Date		

- **Email** form to: radiationprotection@hiqa.ie
- **Telephone**: 01 8286750.