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 provide **brief details** of the incident - no personally identifiable information (PII) should be submitted in line with General Data Protection Regulations (GDPR)				

* 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

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	
	Service user/service user representative	Yes	No	
	Referrer	Yes	No	

Did you **inform** the following individuals of this incident?	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.