


<b>NF211B</b>	<b>Health Information and Quality Authority</b> Accidental or unintended exposure to ionising radiation*	 <small>An tUdaráis Um Fhaisnéis agus Cálíocht Sláinte</small>
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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 **Radiotherapy**. 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	<b>Yes</b>	<b>No</b>	<b>Number</b> <sup>†</sup>
Service user <b>details</b>	<b>Gender</b>		<b>Age</b>
	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.

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)				
Have <b>appropriate actions</b> been taken to <b>mitigate</b> against immediate <b>recurrence</b> of this incident?		Yes		No
Please provide <b>brief details</b> of the <b>initial actions</b> taken to <b>mitigate against immediate recurrence</b> of this incident				

Significant event category		
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)		
No dose intended/incorrect patient exposed to greater than 1 millisievert (mSv)		
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		
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		

<b>Type</b> of procedure <b>or</b> treatment involved in the <b>incident</b> (if other please submit NF211C)	
Radiotherapy	

Section 2. Radiotherapy incident details			For official use
Process step where the incident <b>occurred</b>	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, <b>please specify:</b>					
<b>Treatment intent</b>		Radical		Palliative			
<b>Radiotherapy treatment delivery</b>  Please provide an <b>initial estimated radiation dose variation</b>		Greater than 10% variation total dose, <b>please specify:</b>					
		Greater than 20% variation in a fractionated dose, <b>please specify:</b>					
<b>Other radiotherapy incidents</b>		Please provide an <b>initial estimated effective dose</b> in millisievert (mSv)					
<b>Type of incident</b>		<b>Dose error</b>		Calculation error			
				Calibration error			
				Excess imaging dose			
				Treatment plan not physically deliverable			
				Wrong plan dose			
				Wrong prescription dose			
		<b>Hardware/software error</b>		Ancillary equipment			
				Medical radiological equipment			
		<b>Volume error</b>		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			
		<b>Other errors</b>		Inappropriate or poorly informed decision to treat or plan			
				Service user related circumstance			
				Scheduling error			
		<b>Other, please specify:</b>					

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@hiqa.ie](mailto:radiationprotection@hiqa.ie)
- **Telephone**: 01 8286750.