

NF211B

Health Information and Quality Authority

Accidental or unintended exposure to ionising radiation*



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 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 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		

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

Section 2. 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		
	Other errors	Wrong treatment accessories		
		Inappropriate or poorly informed decision to treat or plan		
		Service user related circumstance		
	Scheduling error			
	Other, please specify:			

Section 3. 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 4. 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 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 (print)		
Job Title		
Contact number		
Signed		
	Type your name in the signature field	
Date		

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