Statutory Notification of Accidental and Unintended Exposures

Guidance for Providers of IR(ME)R Regulated Services

Introduction

This document has been produced for Employers and duty holders of Ionising Radiation (Medical Exposure) Regulations, known as IR(ME)R services which are regulated by the Regulation and Quality Improvement Authority (RQIA), to provide guidance on the requirement to report accidental and unintended exposures affecting service users to RQIA.

The aim of this document is to promote:

- awareness of statutory reporting requirements
- awareness of the procedure of reporting notifiable events to RQIA
- improvement in the quality of information submitted to RQIA in relation to notifiable events
- improvement in service provision through the monitoring and reporting of adverse events

The document does so by answering the following questions:

It is the intention of RQIA to enable the statutory notification of accidental and unintended exposures via the web portal and we will contact you once this function becomes available.

Why am I required to notify RQIA?

Regulation 8(4) (ii) of The Ionising Radiation (Medical Exposures) Regulations (Northern Ireland) 2018 states Employers must in relation accidental and unintended exposures "immediately notify the relevant enforcing authority."

All Regulations in relation to IR(ME)R services regulated by RQIA make provision for this reporting of accidental and unintended exposures. All services are therefore required to make formal notifications to RQIA.

Although individual service providers have primary responsibility for investigation and risk management in relation to any accidental or unintended exposures, RQIA has responsibility to ensure that effective systems are in place to safeguard and promote the wellbeing of patients.

Robust reporting mechanisms and data definitions furthermore enable RQIA to identify trends which assist to assure and improve the overall quality of health and social care provided within Northern Ireland.

What do I need to Report?

Accidental and unintended exposures must be reported to RQIA in accordance to Significant Accidental and Unintended Exposures Guidance, June 2019 (Appendix 1)

How do I report a Notifiable Event?

All notifications are to be submitted on the appropriate Notification Form with a copy of the medical physics expert (MPE) report (or immediately when available).

To ensure that notifications are made in a timely and cost effective manner, notifications should be by email.

The relevant notification forms can be located on the RQIA website. The link is provided below:

IR(ME)R Form (1a) - Notification of accidental or unintended exposure form
IR(ME)R Form (2) - Notification of accidental or unintended exposure form

Confidentiality

It is the duty of the providers to comply with the General Data Protection Regulations 2018 (GDPR) by not sending confidential personal information electronically or on hard copy. The notifications therefore must **NOT** contain names or personal details of patients, staff or other persons involved in the incident. Providers are required to allocate a unique Identifier for any patient in relation to which a report was made. The identifier has to be unique to the patient and should be used for all future incidents relating to this patient. It is the responsibility of the provider to ensure that the patients can be identified if necessary.

What happens after I have reported an event?

It is the responsibility of the service provider to ensure that incidents are followed up and that any necessary actions following the occurrence of a notifiable event are taken to ensure the safety and wellbeing of patients. Confirmation is required that all recommendations made the MPE have been implemented.

If required, an Inspector will contact the service to ensure that the incident is dealt with appropriately. They will aim to do so within one week of the incident having been reported. The inspector may also request additional information or confirmation that other agencies have been notified of the event and you may be asked to submit a notification follow up Form 2.

Inspectors will review the occurrence of any incidents in relation to the service as part of inspection planning and incidents will be reviewed as part of the inspection process.

Records retention

All statutory notifications received as electronic records are retained on file, archived or destroyed according to RQIA's Records Management Policy and Procedure and Retention and Disposal Schedule.

Service providers, as the originators of the document, are required to retain the original record of the notifications made in line with their Records Management Policy and Procedure.

Any additional records relating to the notifiable event should also be retained as further details may be requested during subsequent inspections.

How do I complete the reporting templates?

The templates and this guidance document are not intended to replace the professional judgement of the designated person reporting the incident.

Please complete all shaded sections on the form (if information available) and follow the guidance given on the form.

Concise and precise description of the surrounding circumstances

In order to comply with the GDRP personal information should be sent electronically or on hard copy, the description of the incident therefore must not contain names or personal details of patients, staff or other persons involved in the incident.

The standard notification template is provided to support consistency in information provided and it is essential that all notifications are an accurate account of the incident or event. Completion of the template needs to be:

- concise, clear and avoid jargon
- objective and realistic
- open about what has happened and should detail what measures have been taken to avoid a re-occurrence

When do I need to notify the RQIA?

Incidents should be reported to the RQIA in line with the legislative requirement **without delay** of the event taking place (see Appendix 1).

Whom do I notify within the RQIA?

Completed notification forms should be returned by:

Email: registration@rqia.org.uk

This guidance should be read in conjunction with Significant Accidental and Unintended Exposures Guidance June 2019 (Appendix 1)

Appendix 1

Please click on the link below to access this guidance:

Significant Accidental and Unintended Exposures under IR(ME)R - Guidance for Employers and Duty Holder, June 2019

Appendix 2

Regulatory Framework

IR(ME)R 2018, Regulation 8 and 9

Employer's duties: accidental or unintended exposure

8(1) The employer's procedures must provide that the referrer, the practitioner, and the individual exposed or their representative (if there is one) are informed of the occurrence of a clinically significant unintended or accidental exposure and of the outcome of the analysis of this exposure.

(a) The employer's quality assurance programme must, in respect of radiotherapeutic practices, include a study of the risk of accidental or unintended exposure.

(b) The employer must establish a system for recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice.

(c) Where the employer knows or has reason to believe that an accident or unintended exposure has or may have occurred in which a person, while undergoing any exposure, was or could have been exposed to levels of ionising radiation significantly greater than those generally considered to be proportionate in the circumstances; a radiotherapeutic exposure was or could have been exposed to levels of ionising radiation significantly lower than those generally considered to be proportionate in the circumstances, the employer must undertake an immediate preliminary investigation of the incident; unless that investigation shows beyond reasonable doubt that no such exposure has occurred, immediately notify the relevant enforcing authority; conduct or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received; and notify the relevant enforcing authority, within the time period specified by the relevant enforcing authority, of the outcome of the investigation and any corrective measures adopted.

Relevant enforcing authority's duties: accidental or unintended exposure

The relevant enforcing authority must put in place mechanisms enabling the timely dissemination of information, relevant to radiation protection in respect of medical exposures, regarding lessons learned from significant events.

APPENDIX 3

The Regulation and Quality Improvement Authority

Form (1a) - Notification of accidental or unintended exposure form

(Please complete all relevant sections)

Part 1: Service Details

Name of organisation/hospital/site:	
Modality Type:	
Local incident reference number:	

Part 2: Details of Service Users affected

Unique Identifier *(Please Do Not Use Name)*	**Year of Birth** *(yyyy)*	**Gender** *(male/female)*

(if more than 2 service users are affected please list details of remaining individuals in Part 4 of this form)

Part 3: Information about the Event

Date: *(dd/mm/yyy)* **Time:** *(24 hour clock)*

Please select one of the following:

- ☐ **Wrong patient exposed**
- ☐ **Wrong radioactive substance administered(NM)**
- ☐ **Unintended planning or verification exposure (RT)**
- ☐ **Wrong examination including body part or modality**
- ☐ **Failure to follow procedure regarding pregnancy or breast feeding enquiries**
- ☐ **Timing errors when an additional unintended exposure is undertaken**
- ☐ **Incident involving several individuals to an extent significantly greater or lower than considered proportionate (but less then the guidance factors)**
- ☐ **Equipment malfunction**
- ☐ **Unintended foetal exposure where there was no failure to follow procedures**
- ☐ **All other cases at the Employer's discretion**

Any duty holder/relevant parties informed:

Duty holder		**Date** *(dd/mm/yy)*
• Referrer		
• Practitioner		
• Employer		
• Patient/patient representative		
• Medical physics expert		
Others: *(e.g. NIAIC)*		

Part 4 Concise description of surrounding circumstances

Details of the event *(Provide details of what happened, anatomical site or system affected, known contributory factors leading to the incident)*	
Any immediate action taken following the event	
Any action taken to minimise recurrence and lessons learnt (*where appropriate) (include confirmation that MPE recommendations have been fully addressed)*	

Please submit the medical physics expert (MPE) report of this incident with the notification form (or immediately when available)

☐ MPE report attached

☐ MPE report to be forwarded when available

Part 5: Form Completed by:

Name	***Job Role***	**Date** *(dd/mm/yy)*

The Regulation and Quality Improvement Authority

Form (2) - Notification of accidental or unintended exposure form

(Please complete all relevant sections)

Part 1: Service Details

Name of organisation/hospital/site:	
Modality Type:	
Local incident reference number:	

Part 2: Details of Service User affected

Unique Identifier *(Please Do Not Use Name)*	**Year of Birth** *(yyyy)*	**Gender** *(male/female)*	**Date of Admission** *(dd/mm/yy)*

Part 3: Information about the Event

	Date *(dd/mm/yy)*	**Time** *(hh:mm)*	
Timing of Event:			*(Insert original date of event when reported)*

Part 4: Detail of Follow up action:

Summary of incident follow up *(include confirmation that MPE recommendations have been fully addressed)*	
Lessons learned	
Training needs identified	

Part 5: Form Completed by:

Name	**Job Role**	**Date**