Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

QUALITY ASSURANCE AND VERIFICATION DIVISION

HEALTHCARE AUDIT

Tús Áite do Shábháilteacht Othar
Patient Safety First

SUMMARY REPORT

Title	**Audit of incident reporting and learning in radiotherapy as outlined in section 3 of the Medical Exposure Radiation Unit's (MERU) Patient Radiation Protection Manual**	
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Timeframe	June – October 2016	
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Source of Evidence	**Type**	**Date**
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	Site Visits: Mid Western Radiation Oncology Centre (MWROC) UPMC Whitfield Cancer Centre (WCC) University Hospital Galway (UHG) St. Luke's Hospital (SLH)	 09 August 2016 23 August 2016 30 August 2016 06 September 2016
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1. BACKGROUND / RATIONALE

The Medical Exposure Radiation Unit (MERU) of the Health Service Executive regulates patient radiation protection practices in radiological facilities, both private and public, and receives advice from the National Radiation Safety Committee. In 2010, the National Radiation Safety Committee guidelines recommended that all service providers keep a patient radiation protection manual on site. In 2013, MERU produced the 'Template for developing a Patient Radiation Protection Manual for facilities using medical ionising radiation' (hereafter referred to as the radiation protection manual). The radiation protection manual was developed to support the practical application of Statutory Instrument 478 for the safe and optimal use of medical ionising radiation. By adapting and using the radiation protection manual, the service provider has an assurance that they have arrangements in place to comply with the legislative obligations of Statutory Instruments 478/303/459 and to inform continuous improvement and ensure patient safety.

Facilities using medical ionising radiation are required to report all notifiable incidents upon discovery and all non-notifiable incidents and near misses to MERU on an annual basis. Section 3 of the radiation protection manual provides the detail with regard to defining and managing all patient radiation incidents in conjunction with reporting documentation and the key performance indicators that should be in place.

The rationale for choosing section 3 of the radiation protection manual for audit was based on the low number of patient radiotherapy incidents reported from radiotherapy services to MERU for the years 2013 – 2015. Additionally, the audit examined the governance arrangements in selected locations as detailed in section 1 of the radiation protection manual.

2. AIM AND OBJECTIVES

The aim of this audit was to assess the level of compliance with section 1 and section 3 of the radiation protection manual for a sample of locations providing radiotherapy services.

The objectives of this audit were to:

1. Confirm that selected locations have adapted the radiation protection manual locally.
2. Confirm that selected locations comply with the governance key performance indicators from section 1 of the radiation protection manual.
3. Confirm that selected locations are using the incident reporting documentation as set out in section 3 of the radiation protection manual.
4. Evaluate the implementation of key performance indicators as outlined in section 3 of the radiation protection manual.

3. KEY FINDINGS

Objective 1: Confirm that selected locations have a radiation protection manual adapted locally.

Based on the evidence reviewed, the audit team can confirm that the selected locations had a radiation protection manual adapted locally. A shortfall was identified in all locations regarding the absence of a specific reference to the radiation protection manual at induction/training for staff.

Objective 2: Confirm that selected locations comply with the governance key performance indicators from section 1 of the radiation protection manual.

Governance: Section 1 refers to the governance structures which holders of medical ionising radiation equipment should have in place according to Statutory Instruments 478/303/459. The audit team found reasonable evidence that appropriate governance structures regarding incident reporting were in place in the selected locations.

All locations had active radiation safety committees established in line with the National Radiation Safety Committee guidelines and demonstrated that patient radiation incidents were regularly

reviewed. Terms of reference for the radiation safety committees reflected multidisciplinary, allied hospital and interdepartmental working in all locations. A review of the agendas and minutes of the committee meetings found that incident reporting was a standing item and incidents were discussed and evaluated.

In relation to radiotherapy services, it is recommended that committee meetings are held quarterly and in two locations this criterion was met. All four locations had additional committee(s) in place where incidents/near misses were also discussed.

Radiation safety procedures - local rules: Reference to incident reporting was found in various sections of each of the local rules reviewed. However, none of the local rules had included a specific reference to their local policy on the management of incidents involving radiation, and only two had included a specific reference to the radiation protection manual.

In 2010, the National Radiation Safety Committee[1] issued guidance to holders of medical ionising radiation equipment to highlight the legislative responsibilities of the licence holder, the practitioner in charge, the practitioner, the prescriber, and the radiographer according to Statutory Instrument 478. In three of the local rules reviewed, while roles and responsibilities were included, a duty in relation to incident reporting and management for key personnel was not found. For example, in some cases this related to the licence holder, the practitioner in charge, the radiation protection advisor[2] and the medical physics expert. In the remaining location roles and responsibilities were absent entirely.

Objective 3: Confirm that selected locations have implemented local incident reporting documentation in line with section 3 of the radiation protection manual.

Incident reporting systems and documentation: Section 3 of the radiation protection manual refers to the National Radiation Safety Committee guidelines to defining and managing all radiation incidents, i.e., all patient radiation incidents should be managed through the normal risk management route within the organisation and tabled on the radiation safety committee agenda. In line with the guidelines, all four locations demonstrated that patient radiotherapy incidents were integrated into the existing local electronic incident reporting systems and incident review was included on the local radiation safety committee agenda. The audit team can confirm that the incident reporting systems in place were adequate and fit for purpose.

Section 3 of the radiation protection manual recommends that facilities should have local incident protocols and templates in place and the audit team can confirm that all locations demonstrated that appropriate local documentation was in place (policies, procedures protocols and forms). Shortfalls were identified in some locations as follows:

- Three locations did not make specific reference to the local incident reporting policies/protocols/procedures in their local rules.
- Two locations did not make reference to the definitions of notifiable and non-notifiable patient radiation incidents as outlined in section 3 of the radiation protection manual.
- Two locations did not reference the requirements to report incidents/near misses to MERU in local incident reporting policies.

[1] Guidance on Responsibilities in European Communities (Medical Ionising Radiation Protection) Regulations (Statutory Instrument (SI) 478 of 2002), as amended by the European Communities (Medical Ionising Radiation Protection) (Amendment) Regulations (SI 303 of 2007). HSE March 2010.

[2] The similar qualifications and training of a Radiation Protection Adviser (RPA) and Medical Physics Expert (MPE) can lead to confusion between the two roles. Facilities are required to appoint an approved RPA as set out in SI 125 of 2000, which is primarily concerned with protection of the public and staff. SI 478 (2002) places a further requirement on equipment checking by MPEs and is concerned with radiation protection of the patient. However, an appointed RPA may also act as the MPE where eligible and fulfil the MPE responsibilities under SI 478 as well as existing responsibilities under SI 125.

Objective 4: Evaluate key performance indicators as outlined in section 3 of the radiation protection manual.

Annual record kept of patient radiation incidents reported: All locations stated that they promote an open culture of patient radiation incident reporting, however the system is wholly self-reporting and entirely reliant upon professional integrity.

In the Republic of Ireland there are 12 facilities providing radiotherapy and all were listed on the MERU incident database. In 2015, the total number of incidents reported was 805 (14 notifiable, 522 non notifiable and 269 near misses).

The following table provides an overview of the approximate number of radiotherapy fractions delivered at the four locations audited and the number of incidents reported in 2015. One location did not notify MERU of any incidents related to radiotherapy and returned data on radiology related incidents only on the required annual template.

Site	Approximate total number of radiotherapy fractions delivered	Radiotherapy Incidents reported to MERU				Total as a % of all fractions
		Notifiable	Non-Notifiable	Near Miss	Total	
1	15,000	0	29	8	37	0.0025%
2	15,934	0	1	1	2	0.0001%
3	26,123	0	0	0	0	0.0000%
4	28,433	0	58	91	149	0.0052%

No notifiable incidents were reported from the four locations audited to MERU in 2015 and it would appear that the total number of non-notifiable incidents reported was comparatively low given the number of radiotherapy fractions delivered.

Currently, non-notifiable incidents are reported to MERU using the 'Annual Template to record Patient Radiation Incidents' contained within section 3 of the radiation protection manual. In some locations there appeared to be confusion over what incidents/near misses were considered as non-notifiable. The audit team was of the opinion that this may have contributed to the lower number of incidents/near misses reported on the annual template. The reason for this may be found in the wording of section 3 which outlines the definition of non-notifiable incidents and contains the following wording in parenthesis "(no report required for MERU) but documented at location". This wording could be understood to mean that incidents identified as non-notifiable do not require reporting to MERU at all but that details are to be kept locally.

Based on the evidence reviewed, the audit team can confirm that all locations maintained local annual records of reported patient radiotherapy incidents.

All notifiable incidents are appropriately investigated and acted upon: Locations stated that they had no notifiable incidents during 2015, however three locations confirmed that one incident at each of the sites was currently under review and may be reported retrospectively. During the site visit, the context expert advised that if there was any doubt regarding incidents they should be submitted to MERU for clarification.

All locations identified serious events which did not meet the criteria of notifiable incidents and conducted investigations as appropriate. Following a review of incident details during the site visits the audit team can confirm that one location did not report any radiotherapy incidents (notifiable and non notifiable) externally for 2015. The context expert was of the opinion that three incidents at this particular location met the criteria for a notifiable incident and therefore should have been notified to MERU within the specified time frame. It was also found that this location did not report any of these incidents to the National Incident Management System.

Based on the evidence reviewed, the audit team can confirm that three locations investigated incidents appropriately with follow up actions. In the remaining location, the audit team was satisfied that incidents were reported, investigated and acted upon locally, however incidents that satisfied the criteria for a notifiable incident were not reported externally to MERU or to the National Incident Management System.

Evidence of improvements made resulting from incident investigations: All locations provided sufficient evidence to demonstrate learning had resulted from incident investigations and that actions had been implemented to prevent reoccurrence.

Evidence of staff awareness of incident procedures: Based on the evidence reviewed, the audit team can confirm that staff at all four locations were made aware of incident reporting procedures. In addition, the definition of what constitutes a notifiable incident appeared to be understood across the locations. Nevertheless, confusion was evident at three sites as they were reconsidering whether one incident in each location should have been notified to MERU. Sites reported that the majority of these particular incidents involved a treatment error. As radiotherapy treatment is delivered over several weeks, it is possible that the dosages given maybe adjusted if necessary to ensure that the patient receives the full prescribed radiation dose.

Based on all of the evidence gathered against the KPIs above, precise clarity with regard to the definition of notifiable and non-notifiable incidents is now critical and timely as MERU are currently conducting a review of the patient radiation protection manual.

Pregnancy Consent: Although outside the scope of the objectives, the audit team was informed of different practices in relation to patient pregnancy consent. The legislation (Statutory Instrument 478) requires, that female patients of childbearing age must be asked if they are or maybe pregnant and the answer recorded in writing. Pregnancy consent in radiotherapy treatment is extremely important as the amount of radiation prescribed is significant, and all locations confirmed that they did ask the pregnancy question at the beginning of the radiotherapy treatment. Radiotherapy treatment is delivered over several weeks; a female patient who confirmed she was not pregnant at the beginning of her treatment could potentially become pregnant during the radiotherapy treatment episode. Analysis of notifiable radiotherapy incidents to MERU in 2015 found that two incidents of inadvertent dose to the foetus had been reported. In order to ensure that radiotherapy departments are meeting their legislative pregnancy consent requirements, special consideration should be given to reviewing the current pregnancy consent protocols in radiotherapy.

4. CONCLUSION

Based on the documentary evidence reviewed and discussion undertaken with radiotherapy staff, the audit team can provide reasonable assurance that the four locations have implemented a MERU radiation protection manual locally and have complied with the key performance indicators of section 1 of the radiation protection manual. In addition, all four locations demonstrated that they had implemented appropriate policies/protocols/procedures and templates.

In relation to the four key performance indicators in section 3 of the radiation protection manual, all locations demonstrated that they kept annual records of radiotherapy incidents reported. Evidence reviewed showed that all locations had made improvements as a result of incidents investigated and that staff were aware of local incident procedures. In one location the audit team found that patient radiotherapy incidents were not being reported externally but were being reported, investigated and acted upon locally. Therefore, in this site reasonable assurance could not be provided with regard to notifiable incidents being appropriately acted upon as this would include external reporting. In the remaining locations and based on the evidence submitted and reviewed, reasonable assurance can be provided that all notifiable incidents were appropriately investigated and acted upon.

5. RECOMMENDATIONS

Finalised reports containing site specific findings and recommendations were issued to the locations (see Appendix A for list of recommendations issued).

The following recommendations identify actions that MERU must implement in order to ensure that locations comply with the patient incident reporting requirements as outlined in section 3 of the radiation protection manual.

MERU to:

1. Amend the wording of section 3 of the patient radiation protection manual in order to provide precise clarity regarding the definition of notifiable and non-notifiable patient radiation incidents that are required to be reported to MERU immediately and/or annually.
2. Actively pursue locations that do not report patient radiotherapy incidents/near misses whether these are notifiable incidents requiring immediate notification and/or non-notifiable incidents for inclusion in the annual returns.
3. Initiate a discussion with all radiotherapy locations to ensure that local protocol practices regarding pregnancy consent meet legislative requirements.

Acknowledgements:

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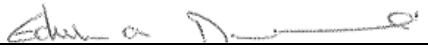
Signature	
Date	04 November 2016

APPENDIX A: RECOMMENDATIONS ISSUED TO THE LOCATIONS	
Hospital	**Recommendation**
MWROC	1. Amend the appropriate section(s) of the Local Rules to include the following: • Section 7.2.4 must make reference to all patient radiotherapy incidents that require investigation as identified in Section 3 of the radiation protection manual. • The role and responsibilities of the licence holder and the practitioner in charge and to include their duties in relation to the governance of incident reporting/management. • The duty of the medical physics expert in relation to patient incident reporting. • Reference to the incident reporting templates detailed in section 3 of the radiation protection manual. • Reference the local 'Policy for the Reporting of Radiological Incidents and Near Misses' and appropriate forms. 2. Increase the number of Radiation Safety Committee meetings to four annually and ensure all reported incidents are discussed to meet the requirements of the National Radiation Safety Committee guidelines. 3. Amend the local Procedure in the Event of a Level 1 Radiotherapy Incident to include the requirement to complete the Radiotherapy Patient Radiation Incident Form as recommended in section 3 of the radiation protection manual. 4. Amend the local Procedure for the Reporting of Radiation Errors/Incidents and the form for Incident Investigation to clearly indicate the requirement to report patient incidents to MERU. 5. Ensure the inclusion of the MERU radiation protection manual as part of induction and training activities for new/existing staff in the radiotherapy department.
WCC	1. Amend the appropriate section of the local rules to include the following: • The role and responsibilities of the radiation safety officer and the medical physics expert to include their duty in relation to incident reporting/management. • Reference to WCC incident reporting policies, procedures and forms. 2. Increase the number of Radiation Safety Committee meetings to four annually and ensure all reported incidents are discussed to meet the requirements of the National Radiation Safety Committee guidelines. 3. Amend the Policy and Procedure on the Reporting of Radiation Incidents to include the requirement to report to MERU all notifiable incidents/near misses upon discovery and to include other incidents/near misses on the annual template returns. 4. Ensure the inclusion of the MERU radiation protection manual as part of induction and training activities for new staff in the radiotherapy department.

UHG	1. Amend the appropriate section(s) of the local rules to include the following: • The role and responsibilities of the licence holder, the practitioner in charge, radiation safety officer and radiation protection adviser to include their duty in relation to incident reporting/management. • The duty of the medical physics expert in relation to incident reporting. • Amend section 3 of the local rules to clearly state the necessity to report notifiable incidents upon discovery and to include other incidents/near misses on the annual template returns. 2. Amend the terms of reference of the Radiation Safety Committee to include the monitoring and management of incidents/near misses. 3. Amend the standard operating procedure on Incident Reporting to include an issue and review date. 4. Ensure that the template for recording incidents in section 3 of the MERU radiation protection manual is used going forward. 5. Ensure that all notifiable incidents are identified and acted upon and reported to MERU within the specified time frame. 6. Ensure the inclusion of all non-notifiable incidents on the MERU annual template. 7. Ensure that all incidents/near misses in radiotherapy are reviewed in line with the HSE Safety Incident Management Policy and are reported to the National Incident Management System when required. 8. Ensure the inclusion of the MERU radiation protection manual as part of induction and training activities for staff in the radiotherapy department.
SLH	1. Amend the appropriate section(s) of the local rules to include the following: • The role and responsibilities of the radiation safety officer and the medical physics expert to include their duty in relation to incident reporting. • Reference to the local 'Policy on Radiotherapy Risk through Incident Learning'. 2. Ensure the electronic links in section 1 and 3 of the radiation protection manual are operational. 3. Ensure the inclusion of the MERU radiation protection manual as part of induction and training activities for staff in SLH.