Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

# RADIATION SAFETY INCIDENTS REPORTED ON THE NATIONAL INCIDENT MANAGEMENT SYSTEM IN 2017 AND 2018


**NATIONAL RADIATION PROTECTION OFFICE**
**QUALITY ASSURANCE AND VERIFICATION DIVISION**
**HEALTH SERVICE EXECUTIVE**

# RADIATION SAFETY INCIDENTS REPORTED ON THE NATIONAL INCIDENT MANAGEMENT SYSTEM IN 2017 AND 2018

**NATIONAL RADIATION PROTECTION OFFICE**
**QUALITY ASSURANCE AND VERIFICATION DIVISION**
**HEALTH SERVICE EXECUTIVE**

## EXECUTIVE SUMMARY

Patient safety is the first priority of all staff working with medical ionising radiation. Radiation protection is dependent upon robust risk management processes which promote a proactive approach to identifying threats, prompt management of adverse situations and action plans to mitigate risks before a serious incident occurs. Supporting staff in this process and sharing learning from unfortunate mistakes is crucial, together with collecting, collating and analysing information on all incidents and near miss events in order to identify emergent trends.

This report provides a synopsis of the radiation safety incidents reported on the National Incident Management System (NIMS) in 2017 and 2018 and highlights a number of themes in relation to patient safety:

- The justification process
- Poor referral practices
- Patient identification issues
- Managing the pregnant patient
- Equipment failure and software issues

The measures taken to address the issues are described in the following pages.

The risks associated with medical ionising radiation can never be eliminated but can, in most instances, be managed appropriately to optimise safety and ensure the best outcomes for patients.

## INTRODUCTION

Patient safety is the first priority of all staff working with medical ionising radiation. Fundamental to this is the operation of a risk management process which promotes an open, transparent culture where adverse events are identified by staff, reported locally and dealt with appropriately. Identifying trends and raising alerts are essential to mitigating potentially catastrophic events involving medical ionising radiation. Therefore, fear of reproach must not be a consideration in reporting incidents or near miss events and any learning to be gained from managing an incident or near miss event should be shared nationally to encourage this safety culture.

The State Claims Agency has governance over the NIMS and works closely with the Quality Assurance and Verification (QAV) division of the Health Service Executive (HSE) to ensure that all staff are trained in reporting and managing adverse events in line with the HSE Integrated Risk Management Policy (HSE, 2017a).

This trending report presents an analysis on the radiation safety incidents reported on the NIMS in 2017 and 2018 and details the measures taken to mitigate emergent risks.

## INCIDENTS REPORTED ON THE NIMS IN 2017 AND 2018

In 2016, the State Claims Agency worked closely with the HSE QAV division to ensure that the important information in relation to patient radiation protection was routinely captured on the NIMS. In November 2016, the first report detailing all radiology and radiotherapy incidents reported by public hospitals on the NIMS was generated by the QAV division for analysis and this review continued on a monthly basis thereafter. The analysis allowed the QAV team to capture incident information nationally from public hospitals and facilitated an in depth study of minor incidents and near miss events in radiology and radiotherapy. The process supported existing HSE risk management structures established locally to manage patient safety events.

Details of the radiation safety incidents reported on the NIMS in 2017 and 2018 are presented hereunder. Adverse events in radiology departments related to peripheral vascular catheters, magnetic resonance imaging and ultrasound have not been included in the analysis as they do not involve radiation exposure.

**Figure 1: Category of radiation safety event**

| Category of radiation safety event | | |
|---|---|---|
| | **2017** | **2018** |
| **Actual incident** | 522 | 751 |
| **Near miss event** | 274 | 432 |
| **Total number of reports** | 796 | 1183 |

The increased reporting of incidents in 2018, especially in regards near miss events, compared to 2017, is evidence of a positive radiation safety culture and is reflective of increased levels of reporting on the NIMS overall.

**Figure 2: Category of person affected by the radiation safety event**

| Category of person affected by the radiation safety event | | |
|---|---|---|
| | **2017** | **2018** |
| **Adult patients / service users** | 735 | 1096 |
| **Paediatrics and adolescents** | 41 | 46 |
| **Neonates** | 3 | 10 |
| **Staff members inadvertently exposed to radiation** | 17 | 31 |

The causes of events reported on the NIMS in 2018 and 2017 are detailed in Figures 3 and 4 on the next page.

**Figure 3: Causes of incidents reported on the NIMS in 2018**

| Causes of incidents reported on the NIMS in 2018 | | | | | | |
|---|---|---|---|---|---|---|
| **Process** | **Severity Rating** | | | | | **Total** |
| | **Extreme** | **Major** | **Moderate** | **Minor** | **Negligible** | |
| Checking patient identification | | | | | 71 | 71 |
| Clinical details on referral | | | | | 166 | 166 |
| Incomplete documentation | | | | 1 | 247 | 253 |
| Communication / consent issues | | | | 2 | 56 | 59 |
| Equipment failure | | | | | 100 | 100 |
| Performing procedure | 1 | 1 | 18 | 6 | 425 | 451 |
| Pregnancy status | | | | | 2 | 2 |
| Not applicable / unknown | | | 2 | 1 | 78 | 81 |

**Comments on Figure 3:**

- The extreme and major events refer to clinical complications incurred during procedures.
- The 'not applicable/ unknown' category refers to adverse events which were either not captured by the categories listed on NIMS or they involved a combination of multiple categories. This number of incidents listed under this category **increased by 29%** in 2018 compared to 2017 which suggests that perhaps a review of NIMS categorisation would be beneficial.

**Figure 4: Causes of incidents reported on the NIMS in 2017**

| Causes of incidents reported on the NIMS in 2017 | | | | | |
|---|---|---|---|---|---|
| **Process** | **Severity Rating** | | | | **Total** |
| | **Extreme** | **Moderate** | **Minor** | **Negligible** | |
| Checking patient identification | | | | 48 | 48 |
| Clinical details on referral | | 1 | | 109 | 110 |
| Incomplete documentation | | 2 | 1 | 167 | 170 |
| Communication / consent issues | | 1 | | 57 | 58 |
| Equipment failure | | | 2 | 61 | 63 |
| Performing | 1 | 7 | 7 | 258 | 273 |

| | | | | | |
|---|---|---|---|---|---|
| procedure | | | | | |
| Pregnancy status | | | | 11 | 11 |
| Not applicable / unknown | 1 | 1 | 2 | 59 | 63 |

**Comments on Table 4:**

- The extreme incident which occurred whilst performing a procedure concerned the administration of a radiotherapy dose variation greater than 20% of the prescribed dose which had significant consequences for the patient.
- The extreme incident categorised as 'unknown' concerned a clinical issue unrelated to radiation exposure.
- There was no 'major' category listed in NIMS in 2017.

The NIMS data was used by the HSE QAV division to identify trends and inform radiation safety priorities.

## Discussion / Analysis

The threat of danger from medical ionising radiation can never be eliminated. However monitoring incidents and near miss events nationally, identifying trends and emerging risks, and disseminating that information to all locations, will inform local mitigation plans and help to promote a safety culture for all concerned. It will also contribute to national initiatives to protect the patient from the harmful effects of radiation exposure.

The aim of any risk management framework is to identify trends and promote actions which mitigate risks before a patient safety event occurs. Therefore, this data, whilst providing evidence of good practice in relation to the notification of incidents, cannot be viewed in isolation. To be of real value, it must be considered in combination with the learning to be gained from the analysis of subsequent incident investigation reports. It is planned that investigation reports will be made available on the NIMS in 2019.

The information reported on the NIMS in 2017 and 2018 highlighted a number of themes in relation to patient safety, as follows:

- The justification process
- Poor referral practices
- Patient identification issues
- Managing the pregnant patient
- Equipment failure and software issues
- Communication and consent issues

These themes are described below together with the measures taken to mitigate risks.

### *The justification process*

Inappropriate referrals for diagnostic procedures are known to contribute to unnecessary patient radiation exposure and incidents related to this were prevalent throughout the period under review.

The Heads of European Radiological Competent Authorities (HERCA) identified this issue as a risk throughout Europe and commenced a review of justification practices across all member states. Ireland's contribution was a national audit of the justification process in diagnostic imaging departments in 2017 (HSE, 2017b) which found inconsistencies in how diagnostic referrals were made by referrers and assessed by practitioners. The audit indicated that poor referral practices were a major consideration in the justification of procedures and recommended the development of a national justification process to standardise practice, thereby reducing risks to patients.

To address this, an awareness campaign to highlight the risks to patients associated with the justification of referrals was proposed by HERCA. The HSE QAV division initiated this campaign in 2018 on behalf of the Department of Health and targeted general practitioners who are the main source of diagnostic referrals in Ireland. HIQA, as the new competent authority, assumed responsibility for this campaign when statutory instrument 256 (2018) was enacted in January 2019.

### *Poor referral practices*

A review of minor incidents reported by public hospitals on the NIMS highlighted poor referral practices nationwide. These incidents included incorrect or missing information on referral forms, referrals not being signed by the referrer and incomplete documentation required to support a referral. As mentioned above, referral practices inform the justification process and are recognised as a risk throughout Europe.

Evidence suggested that referral tools, such as the *iRefer Guidelines* developed by the British Royal College of Radiologists, were not being used by referrers, despite being endorsed by the Faculty of Radiology and the HSE. Referral tools are known to standardise practice, reduce unnecessary diagnostic interventions and optimise outcomes for patients. A national survey on the use of referral guidelines was undertaken by the QAV division in 2017 (MERU, 2018) and the outcome supported the findings from the NIMS review and the aforementioned justification audit. This survey recommended the initiation of a national awareness campaign by the HSE to highlight the availability of referral guidelines and the importance of using them. The survey also informed the justification campaign targeting general practitioners.

### *Patient identification*

A considerable number of incidents and near miss events were due to an incorrect patient receiving an unnecessary exposure to radiation. Indeed, there was a **48% increase** in these incidents in 2018 compared to 2017.

The patient identification errors occurred at multiple points in the patient pathway, for example, at administrative check-in, when being called into the procedure room or when being collected from an inpatient ward for a procedure. This issue was highlighted by the QAV division in a presentation delivered at the Irish Ergonomics Society (IES) National Conference in May 2018 and in the subsequent article published in the IES Annual Review 2018, entitled '*Understanding of human factors – ergonomics issues in incidents of medical exposure to radiation'* (Wynne and Lindsay, 2018).

All hospitals have local policies in place to ensure the correct patient is being treated and typically, in radiology and radiotherapy departments, this involves what is termed a 'triple identification check'.

The patient is asked by the member of staff to confirm their name, date of birth and address before any radiation is delivered. Despite the number of adverse events related to this process, good practice in this regard must be acknowledged which includes local initiatives introduced by staff to mitigate risks. An example of this is the '*Safety Pause'* introduced in Beaumont Hospital which encouraged staff to stop and review the situation to ensure the patient is safe before proceeding. This initiative was led by the radiation safety officer and adapted from the '*Paused and Checked*' campaign of the Society and College of Radiographers in the United Kingdom. A poster from the Beaumont Hospital campaign can be found in the appendix.

It must be noted, however, that there is no national policy on patient identification and given the high number of incidents and near miss events associated with the identification process, it is unlikely that staff are always compliant with their local policy. Thus, it is recommended that the Acute Hospital Services develop a national policy to standardise practice across all public hospitals and this should be supported by an awareness campaign to highlight the risks associated with non-compliance.

### *Managing the pregnant patient*

Incidents concerning pregnant patients receiving radiotherapy treatment led to the QAV division commissioning the HSE healthcare audit team to undertake a national audit of patient pregnancy protocols. This audit was completed in late 2015 and identified inconsistencies in how pregnant patients in radiology and radiotherapy departments were managed (HSE, 2015). In early 2016, with support from the QAV division, a multidisciplinary group of professionals came together to review practices across radiotherapy and radiology department. The outcome of this group was the development and successful ratification of the *National policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures* (Faculty of Radiology, 2017).

This policy was adopted nationally by all locations in 2018 and the **82% reduction** in pregnancy related radiation safety incidents reported on the NIMS in 2018 compared to 2017 suggests that implementation of the policy has been a success.

### *Equipment failure and software issues*

Analysis of the equipment failure and software related issues pertaining to radiology and radiotherapy recorded on the NIMS indicated an emerging risk to patient safety. The number of incidents linked to this category **increased by 26%** in 2018 compared to 2017.

In 2017, following one serious reportable event which had catastrophic consequences for the patient, a letter was issued by the National Radiation Safety Committee to all locations emphasising the risks associated with equipment malfunction and software incompatibilities and the necessity to be vigilant in this regard.

A review of the age and functionality of all radiological equipment operated under the auspices in the HSE is planned for 2019.

### *Communication and consent issues*

Incidents recorded on the NIMS pertaining to communication with the patient and consent for radiological procedures in 2018 presented a similar pattern to 2017 records. It is recommended that all radiation protection information provided to patients is made readily available and delivered in a manner that is unhurried, easy to comprehend and where possible, supported by appropriate literature.

## RADIATION SAFETY INCIDENT MANAGEMENT GOING FORWARD

Radiation safety incidents are reported on the NIMS and managed locally by hospitals in accordance with the HSE Integrated Risk Management Framework (HSE, 2017a). To support local governance and provide national oversight, in February 2019 the HSE established the National Radiation Protection Committee to supervise radiation protection practices nationally. The National Radiation Protection Office supports the work of this committee and undertakes the analysis of radiology and radiotherapy incidents reported on the NIMS.

The recurrent themes identified in this report are inherent risks to all radiology and radiotherapy locations and will continue to pose a threat to patient safety, despite the efforts taken by the HSE to mitigate risks. The positive and proactive engagement by all locations with the National Radiation Protection Office has proven beneficial for identifying and managing the risks associated with radiation exposure, however there is no room for complacency. Radiation is always dangerous and exposure has the potential for catastrophic outcomes if managed inappropriately. Therefore, vigilance must be maintained and the monitoring of incidents reported on the NIMS must continue in order to ensure that risks are identified and a safety culture prevails.

## CONCLUSION

The dangers associated with medical ionising radiation may never be eliminated but can be dealt with appropriately when robust risk management processes are in place. This requires promoting a proactive approach to the reporting of incidents and near miss events; the identification and monitoring of incident trends; and the activation of a prompt response, both locally and nationally, to address concerns and mitigate risks before a serious event occurs. For this to be successful, all staff must be supported in reporting and managing adverse events and encouraged to share any learning from unfortunate failures in order to champion a culture of patient safety.

The themes identified in this report are indicative of poor compliance with local policies and procedures or in some cases, the absence of a policy or guideline to standardise practice. Whilst measures were taken to address the deficits and to proactively manage the risks identified from the review of incident data, the risks associated with radiation exposure and the threat to patient safety prevails. Staff working with medical ionising radiation must remain vigilant and be supported to take prompt action to mitigate risks when required.

The NIMS data is a fundamental tool to support the risk management process. However, despite HSE achievements to date, there is still considerable work to be done to ensure that best practice in radiation protection is maintained and that our patients are managed safely.

## REFERENCES

Faculty of Radiology (2017) '*National policy for the protection of the unborn child arising from ionising radiation received during medical diagnostic or therapeutic procedures'* A joint publication between the Faculty of Radiology, Irish Institute of Radiographers and Radiation Therapists and the Irish Association of Physics in Medicine. http://www.radiology.ie/practice/policy-and-procedure-documents/

HSE (2015) '*Audit of patient pregnancy protocols and diagnostic reference levels as outlined in the Medical Exposure Radiation Unit's (MERU)Patient Radiation Protection Manual'* Health Service Executive. https://www.hse.ie/eng/about/qavd/audit-service/medicalexposure.pdf

HSE (2017a) '*HSE Integrated Risk Management Policy*' Health Service Executive. https://www.hse.ie/eng/about/qavd/riskmanagement/risk-management-documentation/hse%20integrated%20risk%20management%20policy%202017.pdf

HSE (2017b) '*Audit of the Justification Process in Diagnostic Radiology'* Health Service Executive. https://www.hse.ie/eng/about/qavd/audit-service/audit-of-the-justification-process-in-diagnostic-radiology.pdf

MERU (2018) '*National Survey to Establish the Efficacy of iRefer Guidelines for Referrers'* Medical Exposure Radiation Unit, Health Service Executive.

Wynne, J. and Lindsay, R. (2018) '*Understanding of human factors – ergonomics issues in incidents of medical exposure to radiation'* Irish Ergonomics Society Annual Review - Proceedings of the Irish Ergonomics Society Annual Conference 2018 , pg.17-22. http://www.irishergonomics.org/wp-content/uploads/2018/08/Irish-Ergonomics-Review-2018.pdf

**APPENDIX : POSTER FROM THE BEAUMONT HOSPITAL' *PAUSE AND CHECK*' CAMPAIGN**