

HEALTH SERVICE EXECUTIVE



REPORT OF THE NATIONAL RADIATION PROTECTION COMMITTEE 2019

NATIONAL RADIATION PROTECTION OFFICE

EXECUTIVE SUMMARY

Introduction

This report details the work undertaken by the newly established National Radiation Protection Committee (NRPC) of the Health Service Executive (HSE) in promoting radiation protection for patients and staff across public hospital and community healthcare locations. It acknowledges the hard work, dedication and commitment of all stakeholders in promoting robust governance, collaboration and safe practice.

The national framework for radiation protection changed considerably in 2019 with the enactment of new legislation and subsequent changes to regulatory requirements. A strong collaborative relationship was established between the NRPC, the Health Information and Quality Authority (HIQA) and the Environmental Protection Agency (EPA) which supported the transition process and maintained continuity for radiological services.

All hospitals and Community Healthcare Organisations (CHOs) providing a medical ionising radiation service to patients were registered with HIQA.

NRPC work programme for 2019

The Terms of Reference for the NRPC was finalised and approved by the National Directors of Acute Operations and Community Operations respectively. The roles and responsibilities of the NRPC and its secretariat, the National Radiation Protection Office (NRPO), are outlined in the following pages. A comprehensive programme of work for the NRPC based on radiation protection priorities, was consolidated and initiated. These priorities included:

- Governance of radiation protection
- Analysis of incidents
- Education and training initiatives
- Patient, staff and population dosimetry
- Communication plan
- Best practice guidelines for referrers and practitioners

In late 2019, the NRPO met with the HSE Health and Wellbeing Unit to discuss the development of

a policy to manage routine occupational radiation exposures which may meet Category A status under the new legislation.

Radiation safety incidents

Proactive risk management is fundamental to promoting the safe administration of medical ionising radiation and the welfare of staff and patients. This requires staff to report all adverse events candidly on the National Incident Management System (NIMS), to review incidents in line with the HSE Incident Management Framework (IMF) and to share any learning from an event promptly in order to improve practice and reduce the likelihood of recurrence.

All radiation safety incidents must be reported on the NIMS and managed in accordance with the HSE Incident Management Framework.

In addition to reporting on NIMS, radiation safety incidents involving staff or members of the public exceeding a dose of 1 millisevert must be reported to the EPA. And radiation incidents involving patients that meet notifiable criteria established by regulator must be reported to HIQA and include an investigation report and evidence of quality improvement, within the specified timeframe.

This year saw the introduction of the online HIQA portal which enabled locations to submit radiation safety data, including incident notifications, investigation reports and relevant governance information directly to HIQA.

The NRPO undertook a review of radiation safety incidents reported on the NIMS in 2019 and the main themes identified from the analysis were as follows:

- Inappropriate referrals for diagnostic procedures
- Incomplete or inadequate documentation
- Patient identification issues
- Equipment failure issues
- Poor communication

It was noted from the analysis that some of the

radiotherapy centres did not consistently report incidents on the NIMS. To understand how these locations managed incidents, the NRPO initiated a survey in late 2019 and this is expected be completed in early 2020. In addition, the NRPO adapted the incident guidance template formally developed by the Medical Exposure Radiation Unit to assist locations in identifying and managing incidents. This template will be submitted to the HSE for inclusion in the forthcoming revision of the Incident Management Framework in 2020.

The NRPO proposes to convene a workshop in 2020 to promote incident management in radiotherapy and to highlight the requirement to report all incidents on the NIMS.

Radiation equipment

Radiation protection legislation requires the undertaking to maintain a database of radiation equipment, implement an appropriate quality assurance programme and ensure there is a replacement policy in operation. In addition, the equipment must have the capability of recording the radiation dose delivered to the patient and this dose must inform the medical report.

A review of radiology and radiotherapy equipment was commenced in 2019 by the NRPO with support from the EPA and is expected to be completed in 2020. This review will result in the generation of a national database of radiation equipment which lists the make, model, dose tracking capability, year of commission, scheduled replacement date and purpose of use. The NRPO will update the information on an annual basis thereafter.

National audit of radiation protection in cardiac catheterisation laboratories

It is known that imaging procedures which routinely deliver a high dose of radiation, such as those performed in the speciality of interventional cardiology, present a risk to patients and staff. A national audit of radiation protection practices in cardiac catheterisation laboratories was commissioned by the NRPO and commenced by the HSE Healthcare Audit Team in late 2019. This is the first time a national review of radiation protection practices in interventional cardiology has been commissioned and it is anticipated that this audit will be completed in early 2020.

Communication

Finally a communications plan was proposed to inform and engage all stakeholders in the important work of the NRPC. This will necessitate the development of a web-based platform which will include portal access and subscription to a mailing list for the sharing of radiation protection information and guidance, NRPO surveys, incident trending data and other such relevant reports. Work is on-going between the NRPO, HSE Acute Hospital Operations Division and HSE Communications Division in this regard.

In the interim, information pertaining to the work of the NRPO and NRPC is available by contacting the NRPO directly at radiation.protection@hse.ie.

Conclusion

In conclusion, the work of the NRPC builds on previous achievements in radiation protection made by the HSE both nationally and at the point of service delivery. To enhance these achievements going forward, NRPC endeavours to reflect the principles of radiation safety which can be applied universally across all medical specialities in its priorities identified for 2020.

Focussing on these tenets will go some way to providing reasonable assurance to the regulators, all staff and most importantly, to our patients, that medical radiation exposure is maintained at optimum levels and that safe practice is prioritised.

FOREWORD FROM THE CHAIR

As co-chairs of the newly established National Radiation Protection Committee (NRPC), it is with great pleasure that we present to you this inaugural report detailing the good work in promoting radiation safety undertaken by our colleagues throughout 2019. The success of this committee in bringing radiation protection to the forefront is attributed to the tireless support of frontline staff who engage with our patients on a daily basis and without whom this important work would not have been achieved.

Five meetings of the NRPC were convened in 2019 and we would like to take this opportunity to thank the members of the committee for their positivity, commitment and enthusiasm throughout the year. We would also like to acknowledge the support of the National Radiation Protection Office (NRPO) which has proven instrumental in achieving our objectives.

This year brought considerable change to the Irish regulatory landscape for radiation protection with transposition of the European Basic Safety Standard Directive 2013/59/EURATOM and promulgation of Statutory Instrument (SI) 256 (2018) and SI 30 (2019). The Environmental Protection Agency (EPA) remained the regulator and competent authority for protection of workers and the public under SI 30 (2019). However, a new approach to regulation was instigated whereby locations must hold an EPA authorisation, as required. That is, authorisation by either registration or licensing, depending on the exposure risk associated with the practice for workers and members of the public.

SI 256 (2018) identified the Health Information and Quality Authority (HIQA) as the competent authority and regulator for patient radiation protection. This was the first time that a regulator for patient radiation protection had been delegated inspection and enforcement powers and it necessitated the establishment of a new regime for monitoring patient radiation protection practices.

The Health Service Executive (HSE) as a provider of medical radiological services was considered an undertaking under SI 256 (2018) and as a consequence, had clearly defined responsibilities and obligations. The NRPO was allocated the onerous task of registering with HIQA all radiology and radiotherapy locations providing a service under the auspices of the HSE. This included providing the name and contact details of designated managers in all locations whom HIQA would engage with on subsequent inspections.

The NRPO, on behalf of the NRPC, worked closely with both the EPA and HIQA throughout the year to ensure a smooth regulatory transition, continuity in supporting and advising frontline staff of the progress being made and collaboration in the promotion of safe practice and positive outcomes for patients.

A detailed programme of work based on numerous radiation safety priorities identified by the NRPC was developed and approved by the HSE senior management team. This plan was informed by the guidance received from the National Radiation Safety Committee which had been stood down in early 2019, the NRPO analysis of incident reports on the National Incident Management System (NIMS) and the extensive regulatory requirements outlined in the new legislation.

There were a number of key ventures initiated in 2019 and included, for example, the analysis of incidents reported on the NIMS and the sharing of learning nationally; a review of radiotherapy incident management; the development of a dedicated radiation protection website to enhance communication with stakeholders; and the generation of a national inventory of radiology and radiotherapy equipment. In addition, an audit of radiation protection practices in cardiac catheterisation laboratories was commissioned and commenced in late 2019.

Finally, this report outlines the key themes hereunder, which are not exclusive, for the NRPC to focus on going forward into 2020:

- Governance of radiation protection
- Education and training of staff
- Promoting best practice
- Communication with stakeholders
- Quality assurance of equipment
- Incident monitoring and sharing the learning
- Patient and staff dosimetry

Promoting safe, efficient and evidence based practice in the best interest of the patient is the aim of all those who work with medical ionising radiation. For this to manifest, we need robust governance with clear lines of accountability; an open culture that promotes a proactive approach to risk management; a system in which staff are appropriately trained and competent to undertake the role to which they are assigned; and most importantly, the continued support and positive engagement of all stakeholders in promoting and prioritising safe radiation protection practices for all who work in the field and avail of the service.

We are proud to confirm that the strong collaborative relationship established between

the HSE, EPA and HIQA during this difficult and often confusing transition period has proven very successful and we are confident that this positive engagement will continue in 2020. We are also in no doubt that going forward the important work initiated by the NRPC will continue to be endorsed by local radiation safety committees and supported by our frontline colleagues who work tirelessly to provide safe radiology and radiotherapy services in hospitals and community locations nationwide.

In conclusion, we are mindful of the NRPCs duty to provide reasonable assurance that medical radiation exposure is maintained at optimum levels and that staff and patient safety are prioritised.

Dr. Ciaran Browne, Co-chair HSE National Radiation Protection Committee

Mr. Jonathon Paul Nolan, Co-chair HSE National Radiation Protection Committee

INTRODUCTION

This report details the establishment of the National Radiation Protection Committee (NRPC) by the Health Service Executive (HSE) in 2019 and the work undertaken by this committee to promote radiation safety for patients and staff in public hospitals and Community Healthcare Organisations (CHOs). It acknowledges the hard work, commitment and dedication of all stakeholders in prioritising radiation safety and outlines the priorities for the NRPC going forward into 2020.

1. CHANGES IN THE REGULATORY LANDSCAPE FOR RADIATION PROTECTION

This year brought considerable change for radiation protection practices in Ireland through the transposition of the European Basic Safety Standard (BSS) Directive 2013/59/EURATOM with enactment of Statutory Instrument (SI) 256 (2018) and SI 30 (2019) (herein known as IRR19).

IRR19 repealed SI 125 (2000) which regulated for the protection of workers and the general public from radiation exposure. IRR19 maintained the Environmental Protection Agency (EPA) as the regulator and introduced several changes, for example, a new registration and licensing regime, new dose constraint levels for practitioners and regulation of non-medical imaging procedures.

SI 256 (2018) regulates radiation safety of patients which was formerly governed by SI 478 (2002). Under the previous regime, the National Radiation Safety Committee (NRSC) and the HSE Medical Exposure Radiation Unit (MERU) provided advice and guidance, and undertook radiation safety initiatives across public and private locations, and worked in the interest of best practice and patient safety. With ratification of SI 256 (2018) in January 2019, the NRSC and MERU were stood down.

SI 256 (2018) delegates the roles of competent authority and regulator for patient radiation protection to the Health Information and Quality Authority (HIQA) and provides HIQA with inspection and enforcement powers. The HSE as a provider of medical ionising radiation services is considered an undertaking under SI 256 (2018).

The framework for radiation protection in Ireland is legislative based, incorporating various Irish laws and European Directives, including the following:

European Basic Safety Standard Directive 2013/59/EURATOM – This directive establishes radiation safety standards across Europe for patients, workers and the public.

https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:013:0001:0073:EN:PDF

It was transposed into Irish law in January 2019 through ratification of the following statutes:

SI 256 (2018) – This SI regulates the radiation exposure of patients, appoints HIQA as the competent authority and regulator and provides enforcement powers.

http://www.irishstatutebook.ie/eli/2018/si/256/made/en/pdf

IRR19 – This SI regulates the radiation exposure of workers and the public, appoints the EPA as the competent authority and regulator and maintains the enforcement powers from previous legislation.

http://www.irishstatutebook.ie/eli/2019/si/30/made/en/pdf

2. REQUIREMENTS OF THE REGULATORS

HIQA

The HSE, as a provider of radiological services, was required to register with HIQA as the legal undertaking in accordance with SI 256 (2018). The NRPO was tasked with co-ordinating this registration process on behalf of the HSE undertaking representative, Ms. Anne O'Connor, Deputy Director General.

In early 2019, with support from hospitals and the nine CHOs, all locations administering medical ionising radiation to patients under the auspices of the HSE were identified by the NRPO and formally registered with HIQA. These locations consisted of 37 HSE hospitals, the National Breastcheck Screening Service, 14 diagnostic community facilities and 230 dental surgeries.

Voluntary hospitals, although they receive funding from the HSE, are separate legal entities and as such, were required to individually register with HIQA and nominate their own undertaking representative.

HIQA required the nomination of a named designated manager in each location who was of appropriate seniority and could facilitate site visits. The designated managers were also required to ensure that operational plans were implemented to address any recommendations made following an inspection. The designated managers for HSE locations were identified as the chief officers in each CHO area and general managers, or equivalent, in each hospital location.

EPA

The regulatory framework established under IRR19 is different to SI 256 (2018).

For the purpose of IRR 19, each individual hospital or CHO is defined as an undertaking. This means that all hospitals (HSE or voluntary) and each relevant CHO must hold an EPA authorisation, as required. The EPA requires either registration or licensing depending on the exposure risk associated with the practice for workers and members of the public. EPA registrations are issued on an indefinite basis while licences must be renewed every 10 years.

3. GOVERNANCE OF RADIATION PROTECTION

Both IRR19 and SI 256 (2018) require a clearly documented line of accountability from the designated manager to frontline staff who work directly with medical ionising radiation and deliver a radiation dose to the patient. Therefore the designated manager must sub-delegate authority in writing to the relevant professionals and must ensure that these people are appropriately trained and competent. All staff working with ionising radiation must ensure they have a clear understanding of their roles and responsibilities in regards radiation safety for both patients and their colleagues, including what to do in the event of an incident.

A local radiation safety committee must be established by all locations to maintain oversight of radiation protection practices and promote quality and safety in all aspects of radiation exposure. This forum supports existing governance structures within the location; provides guidance on best practice for radiation safety; ensures referrers and practitioners have the necessary supports available to them and a clearly defined scope of practice; and it provides assurance to management, patients and the public that radiation exposures are delivered in a safe, effective and appropriate manner.

The HSE National Director of Acute Hospital Operations issued guidance in relation to the governance of radiation protection and the new regulatory requirements in late 2019.

A diagram of radiation protection governance in the HSE can be found in Appendix 2.

HSE NATIONAL RADIATION PROTECTION COMMITTEE

The HSE established the NRPC in March 2019 to provide national oversight of radiation protection practices and support the work of the local committees in both CHO and acute hospital services. The committee is co-chaired by Dr. Ciaran Browne, Acute Hospital Operations and Mr. Jonathon Paul Nolan, Community Operations.

The NRPC consists of no more than 19 members, appointed by the National Directors of Acute Hospital Operations and Community Operations respectively, for a period not exceeding three years. The NRPC was convened five times in 2019.

Please see Appendix 1 for details of the NRPC membership.

The roles of the NRPC include, for example:

- To provide assurance to all stakeholders that best practice in relation to radiation protection is promoted and adhered to; and that radiological locations are compliant with SI 256 (2018) and IRR19.
- To develop and disseminate relevant policies, protocols and guidelines on radiation protection practices which support legislative requirements.
- To monitor, track and report on population dose and cumulative exposure to workers.
- To act as the principle interface for issues pertaining to radiation protection between the HSE and various regulators, external agencies and professional bodies.
- To work with the relevant professional bodies to develop a range of radiation safety training material which will be made available through the HSE online training platform and tailored to specific cohorts of staff, depending on their exposure risk.
- To develop and implement a national communication plan to ensure patients and relevant stakeholders are informed of the risks associated with radiation exposure, the latest research to promote best practice and relevant initiatives that champion radiation safety.
- To monitor incidents reported to HIQA and on the NIMS in order to identify trends and inform action plans to mitigate risks.
- To develop and communicate key performance indicators to services and generate periodic reports on these nationally.
- To gather data on radiological equipment and provide an assurance that each item is recorded as being maintained and safe to operate.
- To monitor and report on radiation dose diagnostic reference levels as established by HIQA.
- To support HSE emergency management planning initiatives.

The NRPC is an advisory committee only and operational responsibility for the implementation of radiation safety recommendations lies with both the National Director of Acute Hospital Operations and National Director of Community Operations.

HSE NATIONAL RADIATION PROTECTION OFFICE

The National Radiation Protection Office (NRPO) was established in 2019 to support the work of the NRPC in promoting best practice in radiation protection for patients and staff.

The NRPO team consists of Dr. Ciaran Browne, National Office of Acute Hospital Operations, Ms. Janet Wynne, manager and Ms. Rose Lindsay, senior administrator.

The office falls under the remit of the HSE Acute Hospital Operations Division and has many functions, for example:

- Support and manage the work of the NRPC.
- Develop and provide guidance for locations on their legislative responsibilities.
- Review, analyse and report on incident data recorded on the NIMS and reported to HIQA for trending purposes.
- Share best practice initiatives nationally and share learning from incidents.
- Maintain an up-to-date repository of contact details of all relevant staff working in radiation protection to ensure that information being circulated reaches the correct people and that a valuable resource of experienced staff is available to assist the NRPO with its endeavours.
- Ensure that the HSE is registered with HIQA as the undertaking for radiological locations which operate under its remit. And that information pertinent to this registration is maintained as accurate and up-to-date as possible.
- Maintain a national inventory of equipment in operation across all radiology and radiotherapy locations.

The NRPC and NRPO build on previous work in radiation protection undertaken by the aforementioned NRSC and MERU which were stood down in early 2019 with promulgation of the new legislation.

RADIATION SAFETY INITIATIVES UNDERTAKEN IN 2019

To support the transition process, a comprehensive report detailing radiation protection priorities for safe practice was presented to the committee by the Chair of the NRSC when that committee was stood down. This report, together with the new regulatory requirements and on-going incident trending analysis undertaken by the NRPO, informed the NRPC work objectives for 2019.

The programme of work identified named individuals on the committee who were delegated responsibility for leading on specific actions related to the five domains outlined hereunder:

- Governance of radiation protection
- Education and training initiatives
- Patient, staff and population dosimetry
- Communication Plan
- Best practice guidelines for referrers and practitioners

This programme of work is on-going and the information herein outlines the progress made to date.

1. RADIATION SAFETY INCIDENTS REPORTED ON THE NATIONAL INCIDENT MANAGEMENT SYSTEM IN 2019

A fundamental factor to facilitating safe practice in the management of medical ionising radiation is the prompt reporting and analysis of incidents and near miss events. All adverse events must be reported on the NIMS and managed in accordance with the HSE Incident Management Framework http://13.94.105.41/eng/about/qavd/incidentmanagement/hse-2018-incident-managementframework-guidance-stories.pdf. In addition, it is a statutory requirement to report radiation safety incidents to the respective regulator.

It is the ethos of the HSE to support both staff and patients when an adverse event occurs, thereby promoting an open, transparent, non-punitive approach to reporting and managing failures in care.

ALL INCIDENTS AND NEAR MISS EVENTS MUST BE REPORTED ON THE NIMS AND MANAGED IN ACCORDANCE WITH THE HSE INCIDENT MANAGEMENT FRAMEWORK.

In addition, incidents must be reported to the relevant regulators, as follows:

• Adverse events of clinical significance involving patients are reported to the Health Information and Quality Authority.

https://www.hiqa.ie/

• Adverse events involving staff and members of the public are reported to the Environmental Protection Agency

https://www.epa.ie/

• Adverse events involving equipment failure are reported to the Health Products Regulatory Authority https://www.hpra.ie/ This year, HIQA introduced an online portal which enabled locations to submit radiation safety data, including incident notifications, investigation reports and relevant governance information directly to the regulator. The NRPO was granted access to this portal for the purpose of generating national reports on locations working under the auspices of the HSE.

Analysis of incidents reported on the NIMS throughout 2019 by all HSE and voluntary locations enabled the NRPO to identify trends in radiation safety, highlight emerging risks and subsequently use this information to inform NRPC priorities.

ANALYSIS OF NIMS REPORTS

The information provided in the tables herein details the radiation safety incidents reported on the NIMS from January to December 2019 by both HSE and voluntary locations. The figures listed do not include incidents related to ultrasound, magnetic resonance imaging or issues pertaining to the administration of contrast via peripheral vascular catheters.

1. Category of radiation safety incident

Category of incident	Radiology	Radiotherapy
Actual incidents	396	88
Near miss events	371	252
Total number of reports	766	340

In total, there were 1106 adverse events involving medical ionising radiation reported on the NIMS in 2019.

The majority of actual incidents were considered minor or negligible, the details of which are provided in the tables hereunder and as such, did not cause harm to patients or staff. The relatively high number of near miss events recorded on the NIMS is considered a positive finding and indicative of a strong culture of radiation safety. Identifying trends when processes fail and putting in place measures to mitigate risks in a timely fashion is paramount to protecting patients and staff from the harmful effects of radiation exposure.

2. Category of person affected by the radiation safety incident

Category of person	Radiology	Radiotherapy
Adult patient / service user	696	340
Paediatrics	27	0
Neonates	18	0
Member of staff or member of the public	25	0

The majority of medical ionising radiation services are provided in the adult hospital setting therefore it is no surprise that most of the incidents reported on the NIMS involved adult service users.

The use of ionising radiation is expanding across many specialities, including for example, interventional cardiology, orthopaedics, renal and endoscopy. However this is not reflected in the NIMS reports as the majority of incidents recorded in 2019 occurred in radiology and radiotherapy departments. This suggests that, whilst there is clearly a focus on radiation protection in radiology and radiotherapy departments, there is a need to promote this ethos across all specialities which use ionising radiation. The inadvertent exposure of staff to radiation is managed locally in accordance with the HSE IMF and reported to the EPA, as required. Even though the risk to staff from an individual exposure may be low, the damage sustained from radiation exposure is cumulative and may appear over the duration of employment. The regulations regarding staff exposure, in particular the monitoring requirements for Category A workers and dose limits to eye exposure, were changed in 2019. It is anticipated that the EPA will publish new guidance in 2020 to address these changes and in preparation the NRPO has commenced engagement with the HSE Occupational Health Department to support the development of a policy for managing risks to Category A workers.

Radiology incidents reported on the NIMS in 2019						
Process	Severity Rating				Total	
	Extreme	Major	Moderate	Minor	Negligible	
Checking patient identification					65	65
Clinical details on referral				1	250	251
Documentation/medical records issues		1	3		132	136
Communication/consent issues					46	46
Equipment failure			1	1	93	95
Performing procedure		1	3	3	119	126
Pregnancy status					9	9
*Not Applicable/Other		1		1	45	47

3. Details of the process involved in the incidents

The category 'Not applicable /Other' refers to incidents which did not fit a single listed category on the NIMS and include:

- Inadvertent staff exposures
- Incorrect treatment protocols being followed which necessitated repeat procedures
- Unjustified referrals

The combination of inappropriate or inadequate clinical details recorded on referrals, poor documentation and other medical record issues account for the majority of incidents reported in 2019.

The HSE made available to all hospitals and general practitioners the Royal College of Radiologists iRefer Guidelines which is an online tool to support the referral process and aims to reduce inappropriate and unnecessary radiation exposures. A survey of referral practices conducted in 2017 found that these guidelines were not used regularly and it would appear from this analysis that referrers continued to ignore them in 2019. A campaign to raise awareness of the iRefer Guidelines in 2020 is to be considered.

Issues with equipment failing to initiate or freezing mid procedure persisted in 2019 and a NRPO initiative to identify the status of radiation equipment nationally is detailed in the following pages.

Incidents where the wrong patient was identified for a diagnostic procedure were common in 2019 and a campaign to highlight the importance of applying an identification policy in radiology departments is proposed for 2020.

Radiotherapy incidents reported on the NIMS in 2019						
Process	Severity Rating				Total	
	Extreme	Major	Moderate	Minor	Negligible	
Checking patient identification					1	1
Documentation / records					111	111
Communication / consent issues					22	22
Equipment failure					14	14
Performing procedure					188	188
Pregnancy status					2	2
*Not applicable / Other					2	2

*The two 'not applicable / other' reports concern an incident where a patient missed their radiotherapy treatment in another hospital because there was no transport available; and a near miss event where the protocol for managing a radiotherapy patient with a pacemaker in situ was not followed.

The number and details of radiotherapy incidents reported on the NIMS throughout 2019 is indicative of a strong safety culture, however, most reports were made by the St. Luke's Radiation Oncology Network only. This will be discussed in the following section. The majority of incidents concerned the performing of a procedure, failures in documentation and record keeping issues. The two pregnancy related incidents pertained to patients who were scheduled for treatment and subsequently informed staff that they were pregnant.

The analysis of NIMS reports for 2019 identified ongoing national risks in radiation safety and indicated that more work is required both locally and nationally to raise awareness around these issues.

SHARING THE LEARNING FROM INCIDENTS

In 2019, the NRPO published a comparative analysis of radiation safety incidents recorded on the NIMS in a report entitled *Radiation safety incidents reported on the National Incident Management System in 2017 and 2018*. This report provided a synopsis of the incidents reported on the NIMS and identified a number of themes in relation to patient safety, notably justification processes, poor referral practices, patient identification issues, managing the pregnant patient and equipment failure. It also detailed the quality improvement measures taken to mitigate risks. The report was presented by the NRPO in poster format at the National Patient Safety Conference in November.

A copy of the report is available upon request at radiation.protection@hse.ie

2. RADIOTHERAPY INCIDENT CLASSIFICATION

Radiotherapy is a high risk medical speciality in relation to radiation exposure where typically, the intention is to administer as much radiation as possible to a patient in order to kill a tumour whilst minimising the damage sustained by surrounding tissue. Patients' treatment regimes are individually tailored and usually targeted at specific areas of the anatomy. Thus, the experience and expertise of the staff delivering the treatment is crucial to a promoting a successful outcome for the patient.

A failure in process in radiotherapy can potentially have extreme consequences and for that reason, reporting and monitoring incidents and near miss events is critical to enabling a safe environment for patients and staff. However, a review of the NIMS data for 2019 indicated that only the St. Luke's Radiation Oncology Network (St. Luke's Hospital, St. James's Hospital and Beaumont Hospital) demonstrated a consistent approach to incident reporting and hence, a strong safety culture.

When asked to consider this, the NRPC suggested that there were perhaps a number of factors involved, for example:

- The incident classification outlined in the HSE IMF was too generic for radiotherapy and failed to capture the magnitude of risk and required actions associated with radiotherapy incidents.
- The NIMS menu for reporting radiotherapy incidents could lead to misinterpretation when inputting information.

• There was a lack of awareness regarding the need for dual reporting. That is, all incidents must be reported on the NIMS regardless of their clinical significance and the incidents which meet notifiable criteria must also be reported to the relevant regulator.

To understand how all radiotherapy locations managed incidents locally, the NRPO initiated a survey in late 2019 and this is expected be completed in early 2020. In addition, to address the first proposal above, the NRPO adapted the incident guidance template formally developed by the Medical Exposure Radiation Unit to assist locations in identifying and managing incidents in the radiotherapy setting. This template will be submitted to the HSE for consideration in the forthcoming revision of the Incident Management Framework in 2020.

The NRPO radiotherapy incident classification template can be found in Appendix 3.

It is proposed to convene a workshop in 2020 to support incident reporting and management in radiotherapy and compliance with the regulators.

It is anticipated that this initiative will increase the reporting of radiotherapy incidents on the NIMS which should enhance the analysis of trends and the identification of emergent risks. It is important to note however, that such an increase in reports does not indicate that the risks associated with radiotherapy have increased or that treatment is less safe.

3. RADIOLOGICAL EQUIPMENT INVENTORY

The legislation requires the undertaking to maintain a database of radiation equipment, implement an appropriate quality assurance programme and ensure there is a replacement policy in operation for each item of equipment. In addition, the radiation equipment must have the capability of recording the dose delivered to the patient and this information must inform the medical report.

A national review of radiology and radiotherapy equipment was commenced in 2019 by the NRPO, with support from the EPA and is expected to be completed in 2020. This review will result in the generation of a national database of radiation equipment which lists the make, model, dose tracking capability, year of commission, scheduled replacement date and purpose of use. The NRPO will update the information on an annual basis thereafter.

A report detailing the findings from this review will be published by the NRPO when the work is completed.

4. NATIONAL AUDIT OF RADIATION PROTECTION PRACTICES IN CARDIAC CATHETERISATION LABORATORIES

It is known that interventional cardiology procedures often involve the delivery of high doses of radiation to patients. Such procedures can be diagnostic or therapeutic in nature and performed routinely or as an emergency. A report by the EPA published in 2014 https://www.epa.ie/pubs/ reports/radiation/RPII_Radiation_Doses_Irish_ Population_2014.pdf identified that interventional cardiology procedures typically accounted for 1% of all radiation exposures to patients performed in a year yet they were responsible for 20% of the total population exposure to radiation per annum.

The NRPO commissioned the HSE Healthcare Audit Team to undertake an audit of radiation protection practices in cardiac catheterisation laboratories in order to seek assurance that these departments were compliant with SI 256 (2018) and were promoting best practice in relation to radiation safety. This audit is the first of its kind in the speciality of interventional cardiology and commenced in late 2019.

5. COMMUNICATION CAMPAIGN

The aim of the NRPC is to promote good practice in radiation protection across all hospitals and CHOs. Ideally, all stakeholders in radiation protection, referrers and practitioners alike, should be able to access this expert committee and use it as a resource for best practice guidelines; a repository for data on equipment and quality assurance initiatives; a source for information and support when engaging with the various regulators and other national organisations; and as a platform for standardising routine procedures nationally, in the interest of patient and staff safety, through the co-ordinated engagement with local radiation protection committees.

To achieve this ambitious objective, the NRPO is working closely with HSE Digital Communications Division and the Acute Hospital Operations team to include a dedicated webpage for radiation protection on the Acute Hospital website which will include a live portal for the exchange of pertinent information and dissemination of a newsletter to highlight good practice initiatives. In addition, the NRPC minutes of meetings, NRPC reports and NRPO quarterly incident trending updates will be published on the website. Also the aim is to provide additional national trending reports and radiation protection surveys developed by the NRPO, healthcare audit reports relevant to radiation protection and any other relevant radiation safety publications.

It is anticipated that this initiative will be completed in 2020. In the interim, should interested parties require specific information in relation to the NRPC, the work of the NRPO or radiation protection practices in general, they are advised to contact the NRPO directly at radiation.protection@hse.ie

RADIATION PROTECTION PRIORITIES FOR THE NRPC IN 2020

The work of the NRPC builds on previous achievements in radiation protection and will no doubt expand in scope as the use of medical ionising radiation develops over time. With this in mind, the NRPC endeavours to reflect the principles of radiation safety which can be applied universally across all medical specialities in the priorities for 2020.

Focussing on these tenets, as outlined below, will go some way to providing reasonable assurance that medical radiation exposure is maintained at optimum levels and that staff and patient safety are prioritised.



The NRPC and NRPO would like to thank the staff and management in all hospital and community locations for their positive and proactive engagement and their continued support throughout 2019

APPENDICES

- 1. Membership of the National Radiation Protection Committee
- 2. Governance of radiation protection in hospitals and community healthcare organisations
- 3. Radiotherapy incident classification framework

Appendix 1

MEMBERSHIP OF THE NATIONAL RADIATION PROTECTION COMMITTEE NRPC MEMBERS AND THE ESTABLISHMENT THEY REPRESENT

CO-CHAIRS

Dr. Ciaran Browne	National Office, Acute Hospital Operations, HSE
Mr. Jonathon Paul Nolan	National Office, Community Operations, HSE

MEMBERS

Dr. Andrew Bolas	Principal Dental Surgeon, HSE
Ms. Ann Dolan	National Clinical Programmes Radiology, HSE
Ms. Catherine McKenna	Irish Institute of Radiographers and Radiation Therapists
Ms. Deirdre Groarke	Corporate Estates, HSE
Mr. Des Pearson	National Office, Workplace Health and Wellbeing Unit, HSE
Ms. Mandy Lewis	Voluntary Hospitals Association Risk Management Forum (Radiation Safety Advisory Group)
Dr. Mary T. O'Mahony	Consultant Public Health Medicine
Dr. Naomi Lavan	St. Luke's Radiation Oncology Network
Mr. Niall Phelan	Breastcheck, National Screening Service, HSE
Dr. Niall Sheehy	Faculty of Radiology, Royal College of Physicians in Ireland
Ms. Deirdre O'Keeffe	Hospital Groups Chief Executive Officers
Dr. Peter Kavanagh	National Clinical Programme for Radiology, HSE
Mr. Thomas Heary	Diagnostics Medical Physics Expert
Ms. Louise Fahy	Radiotherapy Medical Physics Expert

Appendix 2

APPENDIX 2: GOVERNANCE OF RADIATION PROTECTION

IN HOSPITALS AND COMMUNITY HEALTHCARE ORGANISATIONS

HSE UNDERTAKING REPRESENTATIVE

HSE hospitals & CHOs – Ms. Anne O'Connor, Deputy Director General Voluntary Hospitals – Nominated by individual hospital

NATIONAL RADIATION PROTECTION COMMITTEE

Provide national oversight and assurance Support best practice in radiation protection Engage with regulators and other stakeholders

Work supported by the National Radiation Protection Office Radiation.protection@hse.ie

REGULATORY REQUIREMENTS

DESIGNATED MANAGERS

(SI 256 of 2018) Hospital CEO / General Managers & CHO Chief Officers

The designated manager for radiation protection in every location has operational responsibility for that location and is required to delegate responsibilities for radiation protection to the relevant staff employed in their location.

EPA LICENSEE OR REGISTERED PERSON

(IRR19)

Hospital CEO / General Managers & CHO Chief Officers

EPA authorisations are issued to individual hospitals or CHOs. A senior management contact with legal responsibility for the licence / registration must be designated.



LOCAL RADIATION PROTECTION COMMITTEE

Local governance, oversight and quality assurance Define local scope of practice for referrers and practitioners Support and implement initiatives from the National Radiation Protection Committee

Appendix 3

RADIOTHERAPY INCIDENT CLASSIFICATION FRAMEWORK

IMF CATEGORY	EXAMPLES	IN ADDITION TO THE IMF PROTOCOL, PLEASE ENSURE THE FOLLOWING ACTIONS ARE TAKEN	TIMESCALE
1	Dose or volume variation from prescribed dose above 10%. Radiation dose or medication error causing death, disability or side effects requiring treatment and intervention or hospitalisation. Set up variation that could impact on normal tissue eg. Heart, lungs, eyes, kidneys. Incorrect volume.	 Inform Radiation Therapy Service Manager; Head of Physics Department; Director of Nursing; Treating Radiation Oncologist; Radiation Safety Committee Chair. The Head of Physics shall conduct a preliminary incident investigation. A review of all patients receiving similar treatment protocols shall be undertaken. An emergency meeting of the RSC shall be convened to consider the preliminary incident report and decide what action must be taken. 	Immediate
2	Dose or volume variation from prescribed total dose up to 10% and from fractional dose > 20% Radiation dose or medication error causing side effects that require minor treatment or ongoing monitoring and assessment. Set up variation > 1cm – no critical structures included.	Inform Radiation Therapy Service Manager; Head of Physics Department; Director of Nursing; Treating Radiation Oncologist; Radiation Safety Committee Chair.	Within 24 hours
3	Dose or volume variation from prescribed dose $<5\%$ Near miss or unsafe condition which could potentially cause a treatment error.	Inform Clinical Specialist and /or Senior Radiation Therapist; Radiotherapy Services Manager; Treating Radiation Oncologist.	Within 24 hours.