Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NATIONAL REVIEW OF RADIATION EQUIPMENT IN OPERATION ACROSS ALL PUBLIC HOSPITALS, COMMUNITY DIAGNOSTIC INSTALLATIONS, DENTAL AND ORTHODONTIC SERVICES AND THE NATIONAL *BREASTCHECK* SCREENING SERVICE 2020

NATIONAL RADIATION PROTECTION OFFICE
HEALTH SERVICE EXECUTIVE
JANUARY 2021

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EXECUTIVE SUMMARY

This report profiles the radiological equipment used in patient care across all public hospitals, community diagnostic installations, dental and orthodontic services and the National *Breastcheck* Screening Service. It presents collated information pertaining to the age profile, scheduled replacement date, quality assurance activity and dose tracking capability for each item of equipment. The implications of the findings are discussed, limitations to the study are identified and recommendations are made to improve diagnostic services nationally.

The review was undertaken in 2020 by the National Radiation Protection Office due to a trend in equipment failure incidents identified on the National Incident Management System, findings from HIQA inspections and because of legal responsibilities imposed on the HSE under the new legislation for radiation protection.

The focus of the review was on equipment used to irradiate patients and the findings are presented hereunder:

Acute Hospital Services

- 29% of units had been in operation for the previous three years, with 26% in operation from four to eight years and 9% in service nine to 11 years. 35% had been in operation for over 11 years and the information was not provided for 1% of units. The oldest unit was reported to have been commissioned in 1988 which indicated that it was operating for 32 years.

  The old units were typically low dose x-ray and C-arm machines however there was an exception. A considerable number of units operated in radiotherapy which is considered a high dose modality and high risk to both patients and staff, were very old.

- Good practice in relation to equipment management is to strategically plan for the eventual end of life of a machine by establishing a nominal replacement date. It was found that 55% of units had an active nominal replacement date, 24% had a replacement date which had expired and 21% did not have an assigned replacement date.

- Failure to maintain an appropriate quality assurance programme is a statutory offence under the new radiation protection legislation. It was found that 79% of units had undergone a quality assurance check in the previous 12 months, with 12% having been tested in the previous 12 to 24 months and 1% tested over 24 months ago. The information was not provided for 8% of units.

- 80% of units were capable of recording the radiation dose delivered to the patient. However, 10% of units, typically old mobile x-ray and C-arm machines, were not capable of performing this function. The information was not provided for 8% of units and deemed not applicable in 2%. Typically, dose tracking software was utilised in high dose procedures.

National Breastcheck Screening Service

- All equipment was considered new or established and all had a nominal replacement date which had not expired.
- All units had been checked and deemed fit for service within the previous six months of the review.
- All units were capable of supporting dose monitoring software and the implementation of a dose tracking system was in progress.

Community Services

It was noted by respondents from several installations that the practice of redeploying decommissioned equipment from one service to another had occurred. In addition, issues were highlighted in relation to the governance of community diagnostic centres where often, the installation fell under the remit of the community service but the technological resources were provided by and managed through the local hospital network.

1) Community diagnostic installations

- Four units were commissioned within the last three years and three were commissioned over 11 years ago.
- All seven units had undergone quality assurance testing within the previous 12 months.
- One unit had an active nominal replacement date, two had an expired replacement date and four did not have an assigned replacement date.
- All units had the capability to record patient dose but it had to be performed manually by the operator.

2) Community dental and orthodontic services

- 44% of units had been in operation for the previous three years, with 21% in operation from four to eight years and 7% in service nine to 11 years. 18% of equipment had been in operation for over 11 years. The information was not provided for 10% of units.
- 69% of units had an active nominal replacement date, 8% had a replacement date which had expired and 23% did not have a proposed replacement date.
- 85% of units had undergone a quality assurance check in the previous 24 months and 9% were tested over 24 months ago. The information was not provided for 6% of units.
- 34% of equipment had the capability of recording dose and 66% did not.

The following recommendations are proposed in the report:

1. Review resources in relation to the provision of radiation protection services nationally to ensure that there is sufficient capacity to meet the demands of the *Slaintecare* programme.
2. Ensure that a strategic replacement plan which considers nominal replacement dates for all units is maintained locally and that this information informs national objectives.
3. Ensure that an expert in radiation protection is consulted on all procurement decisions pertaining to radiation equipment.
4. Review the practice of redeploying radiation equipment which has been decommissioned in one installation for it to be re-activated in another.
5. Consider the implementation of a national, automated dose monitoring process across hospital and community diagnostic installations which is compatible with the existing local radiology information system.

INTRODUCTION

This report profiles the radiological equipment used in patient care across all public hospitals, community diagnostic installations, dental and orthodontic services and the National *Breastcheck* Screening Service (herein known as the *Breastcheck* Group). It presents collated information pertaining to the age profile, scheduled replacement date, quality assurance activity and dose tracking capability for each item of equipment. The implications of the findings are discussed, limitations to the review are identified and recommendations are made to improve diagnostic services nationally.

The review was undertaken in 2020 by the National Radiation Protection Office (NRPO) on behalf of the Health Service Executive (HSE). Data collection incorporated NRPO information related to the registration of services with the Health Information and Quality Authority (HIQA) and was informed by data provided by the Environmental Protection Agency (EPA)[1]. In addition, the NRPO liaised with frontline staff who worked with medical ionising radiation in every location to enhance and verify the information collected.

The review was initiated due to a trend in equipment failure incidents identified on the National Incident Management System (NIMS) and because of legal responsibilities imposed on the HSE under the new legislation for radiation protection. Also, inspection reports published by HIQA in 2020 highlighted the operation of equipment in many hospitals that had exceeded the recommended lifespan for use.

Incidents reported on the NIMS

Analysis of the NIMS reports undertaken by the NRPO from 2017 to date indicated a trend of radiation safety incidents associated with equipment failure. Typical incidents reported included, for

[1] HIQA is the regulator for patient radiation protection in relation to medical ionising radiation under Statutory Instrument (SI) 256 (2018). The EPA is the regulator for radiation protection in relation to workers and members of the public under SI 30 (2019). In addition, equipment failure incidents should also be reported to the Health Products Regulatory Authority.

example, equipment not initiating or starting and stopping mid-procedure; diagnostic images being flipped to the alternate side; magnification not working; images being unclear and clinically redundant; issues relating to computer software incompatibility; and unusual noises coming from the equipment when in use. In addition, patient procedures were delayed due to the unavailability of imaging facilities and when a unit ceased working mid-procedure, it was reported that the procedures were either abandoned or proceeded without the benefit of imaging. Indeed, there were reports of equipment starting up without any input from an operator resulting in the inadvertent irradiation of people present in the room.

The consequences of an incident involving radiation equipment ranged from negligible and minor to more severe or catastrophic. It must be noted however that all equipment failure incidents, regardless of impact, represented a risk to the safe delivery of care and required mandatory reporting in accordance with local incident management protocols.

Legal responsibility

Statutory instrument (SI) 256 (2018) requires the HSE, as an undertaking, to maintain a database of radiation equipment and to implement an appropriate quality assurance programme. In addition, the radiation equipment must have the capability of assessing the dose delivered to the patient and this information must inform the examination record. HIQA guidance[2] requires an undertaking to ensure that there is a replacement policy in operation for each item of equipment. The HSE maintains a national inventory of medical devices which includes radiation equipment and it operates a risk based replacement programme. However, it is not known if every radiological unit has been assigned a nominal replacement date locally or if each unit has a device for assessing the dose delivered to the patient and if this device can impart data to the examination record.

Regulation 13 of SI 30 (2019) and regulation 14 of SI 256 (2018) require undertakings to demonstrate that an appropriate quality assurance programme is in operation, with oversight from a Radiation Protection Advisor or Medical Physics Expert and to ensure that the radiation exposure to staff and patients is maintained as low as reasonably possible whilst still achieving the best clinical outcome.

Both HIQA and the EPA have been granted extensive enforcement powers under the new regulations. Therefore, following an inspection by either regulator, where a location is found to be non compliant with legal obligations, the location may be compelled to cease operations which would have serious implications for patients.

HIQA inspections

The HIQA inspection programme commenced in late 2019 and to date many hospitals have been found to operate radiological equipment that HIQA termed *very old*. However, neither the legislation nor relevant HIQA guidance[3] specifies age criteria when considering the replacement of radiological equipment. The inspectors noted that, in most hospitals visited, strict quality assurance programmes

[2] HIQA *Guidance on assessing compliance in ionising radiation 2019* https://www.hiqa.ie/sites/default/files/2019-10/Guidance_assessing-compliance-in-ionising-radiation.pdf

[3] HIQA *Guidance for the criteria on acceptability of medical radiological equipment used in diagnostic radiology, nuclear medicine and radiotherapy 2020* *https://www.hiqa.ie/reports-and-publications/guide/guidance-criteria-acceptability-medical-radiological-equipment-used*

were in operation locally and that the relevant staff in each hospital had assessed the radiation equipment and deemed it safe to use when exposing patients.

At the time of writing this report, HIQA had commenced engagement with community dental and orthodontic practices and the NRPO anticipated that radiation equipment would be a consideration in the forthcoming inspection of these services.

AIM AND OBJECTIVES OF THE REVIEW

The aim of this study was to determine the profile of radiation equipment in operation across all public hospitals, community diagnostic installations, dental and orthodontic services and the *Breastcheck* Group.

The objectives were:

- To inform the HSE medical devices inventory in relation to equipment used to irradiate patients
- To identify the make, model, date of commission, current age and nominal replacement date of each item of equipment
- To confirm the existence and operation of a timely quality assurance programme for each item of equipment
- To determine if each item of equipment could support dose tracking software.

The focus of the review was on equipment used to irradiate patients. It did not encompass diagnostic equipment used in ultrasound or magnetic resonance imaging procedures, or radiological equipment used in medical research.

It was anticipated that the information collected would help to identify the scale of the problem nationally in relation to radiation equipment that was considered very old, clinically obsolescent[4] or incapable of monitoring patient dose.

METHODOLOGY

In 2019, the NRPO collected information on the radiological service provided by public hospitals, community diagnostic installations, dental and orthodontic services and the *Breastcheck* Group in order to inform the inaugural HIQA registration process.

Using this information in 2020, the NRPO engaged with the EPA to ascertain the inventory of equipment held by every location.

The EPA provided the NRPO with the number of units held by each location based on licensing details and the NRPO subsequently issued individual data to each respective location for verification

[4] *Clinical Obsolescence* is the term used by the HSE to signify the decline in clinical usefulness of medical equipment functionality compared with the availability of alternative units that perform the same procedure but better.

purposes. The NRPO also requested that each location confirm if there was a quality assurance programme in operation for each item of equipment and the date of the most recent check; the scheduled replacement date for each item; and confirm if the item of equipment had dose tracking capability or indeed, if it could be modified to incorporate same. An additional comment section was included in the request for information template to give frontline staff operating the equipment the opportunity to voice their opinion or raise any concerns.

The NRPO triangulated the information from HIQA, the EPA and frontline staff to produce an up to date inventory of radiation equipment which listed for each item of equipment in operation, the make, model, date of commission and nominal replacement date, date of last quality assurance check and dose tracking capability.

The data was used to assist the HSE in prioritising radiation protection initiatives for 2021 and to inform the national inventory of medical devices maintained by the HSE.

FINDINGS

This review provided the HSE with a profile of radiological equipment in operation across all acute hospital services, community diagnostic installations, dental and orthodontic services and the *Breastcheck* Group.

The request for information was issued by the NRPO to all hospital Chief Executive Officers or equivalent and all Community Healthcare Organisation (CHO) Chief Officers for completion and return within a specified timeframe. It was also disseminated to relevant frontline staff working in the field of radiation protection which included for example, Medical Physics Experts, Radiographer and Radiation Therapy Service Managers and Principal Dental Surgeons.

Issues were highlighted in relation to the governance of community diagnostic centres where often, the installation fell under the remit of the community service but the technological resources were provided by and managed through the local hospital network. To avoid the potential for confusion, when the information was returned by the local hospital network, the NRPO included it in the findings for the acute hospital services. When the information was returned by the CHO, it informed the findings for the community services.

The collated findings are presented hereunder.

1) Acute Hospital Services

The acute hospital locations which participated in the review comprised of 57 installations which included voluntary hospitals, HSE managed hospitals and several step-down diagnostic facilities where the radiation protection service was associated with and managed by the local hospital network.

Age profile of radiation equipment

In total, 57 installations returned information about 796 radiological units that were routinely used to irradiate patients for medical purposes.

29% of units had been in operation for the previous three years, with 26% in operation from four to eight years and 9% in service nine to 11 years. 35% of equipment used to irradiate patients had been in operation for over 11 years. The information was not provided for 1% of units. The oldest unit was reported to have been commissioned in 1988 which indicated that it was operating for 32 years.

The age profile of the radiation equipment is presented in Table 1 below.

Table 1: Age profile of radiation equipment in the acute hospital services

Age Profile*	Acute Hospital Services
<3 years (new)	29%
4-8 years (established)	26%
9-11 years (old)	9%
Greater than 11 years (very old)	35%
Information not provided	1%

*The age categorisation is adapted from the HSE *Protocol for the prioritising of medical device replacement*

Analysis of the returns suggested that modern units were used in high dose modalities such as computed tomography whereas the very old cohort of equipment was operated in low dose procedures. It was noted that the oldest machines were often portable x-ray and C-arm units.

However, there was an exception to this as a considerable amount of radiotherapy equipment was categorised as very old. Radiotherapy is a high dose modality and therefore considered high risk to both patients and staff in terms of radiation exposure.

Scheduled replacement date

Ensuring that every item of equipment has a nominal replacement date is no longer a statutory requirement under the new radiation protection legislation. However, planning for replacement of units when they reach the end of service is good practice in equipment management and promoted by both the HSE and HIQA.

55% of units had an active nominal replacement date, 24% had a replacement date which had expired and 20% did not have an assigned replacement date. The information was not provided for 1% of units. The nominal replacement date did not apply to units that were held onsite through a leasing agreement.

This information is presented in Table 2 below.

Table 2: Nominal replacement date of equipment in the acute hospital services

Scheduled Replacement Date	Acute Hospital Services
Percentage of units with an active nominal replacement date	55%
Percentage of units with an expired replacement date	24%
Percentage of units without an assigned replacement date	20%
Information not provided	1%

Quality assurance programme

It is a statutory requirement for an undertaking to ensure that medical equipment used to irradiate patients undergoes regular quality assurance testing in order to be fit for purpose and safe to use. This programme of checks must be developed and managed by a Medical Physics Expert and HIQA recommends they are performed at least annually for hospital equipment and biennially for equipment used in dental services. Failure to maintain an appropriate quality assurance programme is an offence under SI 256(2018)(14)(1).

For the purpose of this review, the timeline for quality assurance testing was applied retrospectively from September 2020.

79% of units had undergone a quality assurance check by a Medical Physics Expert in the previous 12 months, with 12% having been tested in the previous 12 to 24 months and 1% tested over 24 months ago. It was noted that the relevant information was not provided for 8% of units.

The timeframe for quality assurance testing is presented in Table 3 below.

Table 3: Timeframe for quality assurance testing

Timeframe for Quality Assurance Testing	Acute Hospital Service
Testing performed within last 12 months	79%
Testing performed 13 to 24 months ago	12%
Testing performed more than 24 months ago	1%
Information not provided	8%

The evidence demonstrates that 79% of units met the HIQA requirement for a timely quality assurance assessment.

Dose tracking capability

The aims of recording dose information on the medical report are to put into context for the referrer the level of radiation the patient received; to enable cross-site comparison of doses delivered during typical routine procedures; and to facilitate cumulative studies of radiation exposure to the general population from medical procedures.

Analysis of the data confirmed that 80% of units in operation were capable of recording the radiation dose delivered to the patient. However, 10% of units, typically old mobile x-ray and C-arm machines, were not capable of performing this function. The information was not provided for 8% of units and deemed not applicable in 2%.

The data is presented in Table 4 below.

Table 4: Dose tracking capability of the equipment

Dose Tracking Capability	Acute Hospital Service
Percentage of units with dose tracking capability	80%
Percentage of units without dose tracking capability	10%
Percentage of units where no information was provided	8%
Percentage of units where dose tracking was deemed not applicable	2%

For high dose procedures such as interventional cardiology, interventional radiology and computed tomography imaging, respondents confirmed that the hospital had purchased dose tracking software to ensure that patient exposures were monitored and maintained within safe parameters.

It was noted by frontline staff that a dose management system that would be compatible with the NIMIS[5] platform was urgently needed across all modalities to ensure a cost effective approach to dose tracking and to enable the comparison of dose metrics nationally.

2) The *Breastcheck* Group

The *Breastcheck* Group held 52 mammography x-ray units across four locations, namely the Eccles Street Centre, Merrion Centre, Southern Centre and Western Centre.

Of these, 40 units were used for patient exposure and the relevant information pertaining to these units is presented hereunder.

Age profile of equipment and nominal replacement date

All equipment was considered new or established and all had a nominal replacement date which had not expired, as outlined in Table 5 below.

Table 5: Information returned from the *Breastcheck* Group

Year of Commission	Number of Units	Nominal Replacement Date
2014	5	2022
2015	10	2023
2016	14	2024
2017	8	2025
2018	1	2026
2019	2	2028

These findings are indicative of good equipment management practice in accordance with HIQA and HSE guidance.

[5] The National Integrated Medical Imaging System (NIMIS) facilitates the requesting of medical imaging procedures and the storage and viewing of the associated images and reports. It also allows the secure electronic sharing of data between specialists to promote a speedier diagnosis.

Quality assurance programme

The *Breastcheck* Group operated a strict quality assurance programme in accordance with legislative requirements. All units had been checked and deemed fit for service by a Medical Physics Expert within the previous six months of this review.

Dose tracking capability

The Chief Physicist advised the NRPO that for mammography, meaningful dose indicators could not be directly measured. Therefore, the average glandular dose was calculated from individual patient exposure factors and technical characteristics of the x-ray system.

All 40 units held by the *Breastcheck* Group were capable of supporting dose monitoring software and it was confirmed that the implementation of a patient dose tracking system was currently underway across all four locations.

3) Community Diagnostic Installations, Dental and Orthodontic Services

The NRPO engaged with the nine CHO regions which governed the diagnostic, dental and orthodontic services delivered in the community setting.

As noted previously, data related to some community diagnostic installations had been included in the hospital information submitted to the NRPO and was subsequently incorporated into the findings for the acute hospital service. Also, it was noted by respondents from several community installations that the practice of redeploying decommissioned equipment from one service to another had occurred and an example of this finding is presented.

Collated information pertaining to the diagnostic imaging equipment used in the community setting is presented hereunder.

Community diagnostic installations

The CHO areas returned information to the NRPO regarding seven x-ray units held across six primary care locations. The collated findings are presented in Table 6 below.

Table 6: Information returned by CHOs in relation to community diagnostic installations

Information Requested	Information Returned by each CHO
Date of commission of the equipment	Four units were commissioned within the last three years. Three units were commissioned over 11 years ago.
Quality assurance check	All seven units had undergone quality assurance testing within the previous 12 months.
Nominal replacement date	One unit had an active nominal replacement date. Two units had an expired replacement date. Four units did not have an assigned replacement date.
Dose monitoring capability	All seven units had the capability to record patient dose but it had to be performed manually by the operator.

It was noted by one respondent that equipment decommissioned from the acute hospital service had been redeployed for use in a community diagnostic installation. In this instance, the radiation unit was originally commissioned in 2000 in a Model 3 hospital and in 2013 the machine was moved to the community diagnostic service where it is operated today. There was also a second xray unit in operation at the same community installation which was 18 years old. The manufacturers' warranties for both units had expired in 2018 and the NRPO was advised that replacement parts for both units were only available on a "best efforts" basis.

Community dental and orthodontic services

The information provided to the NRPO regarding HSE community dental and orthodontic installations incorporated regional services managed by 21 Principal Dental Surgeons and detailed the operation of 271 radiation units. One Principal Dental Surgeon in CHO 5 failed to return data pertaining to their service.

The NRPO was informed that a number of dental and orthodontic practices availed of the local hospital diagnostic facilities in their CHO area and therefore did not hold radiation equipment onsite.

It was also noted by a number of respondents that the practice of redeploying equipment from one service to another had occurred.

Age profile of the radiation equipment

44% of units had been in operation for the previous three years, with 21% in operation from four to eight years and 7% in service nine to 11 years. 18% of equipment used to treat patients had been in operation for over 11 years. The information was not provided for 10% of units. The oldest unit was reported to have been commissioned in 1989 which indicated that it was operating for 31 years.

The age profile of the radiation equipment is presented in Table 7 below.

Table 7: Age profile of radiation equipment in the community dental and orthodontic services

Age Profile of Equipment	Community Dental and Orthodontic Services
<3 years (new)	44%
4-8 years (established)	21%
9-11 years (old)	7%
>11 years (very old)	18%
No information provided	10%

It is a positive finding that the majority of equipment used to irradiate patients was considered new or established.

Nominal replacement date of equipment

69% of units had an active nominal replacement date, 8% had a replacement date which had expired and 23% did not have a proposed replacement date.

The data is presented in Table 8 below.

Table 8: Nominal replacement date of equipment in the community dental and orthodontic services

Nominal Replacement date	Community Dental and Orthodontic Services
Number of units with an active replacement date	69%
Number of units with an expired replacement date	8%
Number of units without a specified replacement date	23%

The majority of units had an active nominal replacement date which is indicative of good strategic planning to support equipment management processes.

Quality assurance programme

HIQA recommends that quality assurance testing is performed at least annually for diagnostic equipment used in hospital or primary care installations and biennially for radiation equipment used in dental services. As noted previously, failure to maintain an appropriate quality assurance programme is an offence under SI 256(2018)(14)(1).

85% of units had undergone a quality assurance check by a Medical Physics Expert in the previous 24 months and 9% were tested over 24 months ago. The information was not provided for 6% of units.

The timeframe for quality assurance testing is presented in Table 9 below.

Table 9: Timeframe for quality assurance testing

Timeframe for Quality Assurance Testing	Community Dental and Orthodontic Services
Testing performed within last 24 months	85%
Testing performed over 24 months ago	9%
Information not provided	6%

It was noted by respondents that the emergency pandemic measures implemented throughout 2020 had resulted in the intermittent closure of several installations which had a direct impact on the quality assurance schedule.

Dose tracking capability

The NRPO was advised by the National Radiation Protection Committee that dose tracking in dental services is typically not straightforward. Radiation doses are usually recorded for cone beam computed tomography imaging procedures however this is not often the case for routine dental radiographs, the majority of which are intra-oral procedures. The measurement of dose must be made at the receptor for the intra-oral procedure which would in theory be possible with direct

digital receptors. However, these digital receptors were not a requirement under the previous radiation protection legislation and therefore not included in the manufacture of the equipment.

In specialised scenarios, such as orthodontic services, where radiographs may be extra-oral and perhaps digital, it may be possible to monitor cumulative doses delivered to a patient using the image storage software.

This information was evident in the findings presented below where 34% of equipment had the capability of recording dose and 66% did not.

Table 10: Dose tracking capability of the equipment

Dose Tracking Capability	Community Dental and Orthodontic Services
Percentage of units with dose tracking capability	34%
Percentage of units without dose tracking capability	66%

The HIQA inspection programme for radiation installations will incorporate dental and orthodontic services in 2021 and the statutory requirement to record all radiation doses delivered to a patient presents the HSE with a potential difficulty.

DISCUSSION

1) Age profile and nominal replacement date

There is no age criteria listed in radiation protection legislation or HIQA guidance which defines the life span of equipment. However, the manufacturer of the unit will issue a notice to highlight the end of life for a unit, whereby the unit is considered out of date and the availability of replacement parts or technical support will no longer be facilitated. Good practice in relation to equipment management is to strategically plan for this eventuality by establishing a nominal replacement date. The manufacturer's warranty will not be valid beyond the recommended end of life date or in the event that parts not made for that particular unit are used to repair any faults.

When considering the replacement of equipment, it must be noted that the Health Act (2004) Article 5 dictates that the HSE must have regard to the resources available when performing its function and secure the most beneficial, effective and efficient use of those resources. Fiscal resources in healthcare are finite and the HSE adopts a risk based approach to the maintenance and replacement of medical equipment. Indeed, the risk posed to staff and patients by operating old medical equipment is acknowledged on the HSE Corporate Risk Register.

To mitigate the risk in relation to radiation exposure, the HSE *National Service Plan*[6] included a large scale capital project to upgrade and replace radiotherapy equipment. The project was ongoing at the

[6] HSE *National Service Plan 2019* https://www.hse.ie/eng/services/publications/serviceplans/national-service-plan-2019.pdf

time of writing this report and based on the findings in this review, it is a timely initiative. The service plan also noted that there is a minor capital programme to address risk issues with medical equipment and replace individual units at the behest of a location. The analysis of data returned to the NRPO highlighted that equipment typically used in low dose modalities, in particular, x-ray and C-arm machines, was very old and not prioritised for replacement. Commentary from frontline staff supported this proposition.

The HSE *Medical Device Equipment Management Policy* and HSE *Medical Device Equipment Management Best Practice Guidance* provide national guidance on how to manage medical devices, including radiological equipment. They should be read in conjunction with the HSE risk assessment tool, entitled *Protocol for the prioritising of medical device replacement*, which supports hospital management in making an assessment of medical equipment and deciding if, and when, a unit needs to be replaced.

However, whilst HSE guidance is helpful in determining the risks associated with an individual unit and a timeframe for replacement, the ethical considerations of using an old machine to irradiate a patient when it is known that modern, more effective and efficient units are available, must not be ignored. It was evident from the information returned that most locations had some diagnostic imaging machines in operation that were new or established and similar units also operating that were considered very old. This implied that frontline staff faced a difficult dilemma when treating a patient - should they use the unit in exam room 1 which is considerably older than the unit operating in room 2 and is therefore likely to deliver an unnecessarily high dose of radiation to the patient? The NRPO did not receive any feedback from frontline staff in relation to their personal experience of using old equipment to irradiate patients.

The radiation dose delivered during a diagnostic procedure is typically maintained within the safety parameters established over 10 years ago by the HSE in the form of diagnostic reference levels. However, although these reference levels indicate a safe range of exposure for a particular diagnostic procedure, they are broad and perhaps out dated at this stage, considering the advances in imaging equipment and changes in patient demographics. It is known that an aged machine will administer a radiation dose which may be at the higher end of the reference level compared to a new or established unit which delivers a dose at the lower end of the spectrum to achieve the same clinical outcome. (That is, an older unit will need to deliver more radiation compared to a modern machine to achieve the same clarity in a diagnostic image or therapeutic benefit.) This was demonstrated in 2017 with the HSE *National survey on population dose from computed tomography*[7]. The survey found that, since the last computed tomography (CT) survey in 2009, the number of CT procedures undertaken nationally had almost doubled whilst the cumulative radiation dose delivered to the population had been halved. This was attributed, in part, to the use of modern CT imaging equipment and the application of dose tracking software. Thus, although both old and new units may deliver an individual radiation exposure which meets existing HSE safety parameters, the cumulative dose to the population will be unnecessarily higher when using old equipment.

[7] *National survey on population dose from computed tomography* 2017 https://www.hse.ie/eng/about/who/acute-hospitals-division/radiation-protection/meru-national-survey-on-population-dose-from-computed-tomography-2017.pdf

HIQA, as competent authority for patient radiation protection under SI 256 (2018), has the statutory responsibility to create and maintain diagnostic reference levels and a programme to establish same is currently underway. It is imperative that the old equipment in operation across the hospital and community services is capable of complying with the new HIQA safety parameters and any unit found wanting must be replaced.

2) Quality assurance programme

As noted previously, there is no age criteria listed in radiation protection legislation which defines the life span of equipment however, the undertaking is required to demonstrate that a rigorous quality assurance programme is in operation. In particular, SI 256 (2018) Article 14 dictates that the regulator shall:

> (a) *take steps to ensure that the necessary measures are taken by an undertaking to improve inadequate or defective performance of medical radiological equipment in use, and*
>
> (b) *adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service.*

HIQA advise that quality assurance checks should be conducted at least annually on diagnostic and therapeutic medical equipment and biennially for dental radiation equipment. Also, the testing programme must be developed and approved by a Medical Physics Expert (MPE). HIQA inspections of acute hospital services throughout 2020 highlighted the risks to patients in locations where resourcing of the MPE service was considered less than adequate. To address the issues, hospital groups initiated a programme whereby the medical physics service was shared across hospitals within the individual network. This has proven to be successful in addressing some areas of non compliance in relation to radiation protection.

On a positive note, HIQA inspections found that quality assurance testing was prioritised across most sites and evidence from this review would support that finding. The majority of services confirmed that quality assurance checks had been performed within the previous 12 months however, the HSE must not become complacent. Ensuring that equipment is fit for use for both patients and staff is fundamental to providing a safe, effective and efficient radiological service and for this, regular quality assurance checks of all units within the timeframe specified by HIQA are essential.

The sample of incidents listed in Table 10 were reported on the NIMS over the previous 12 months and are presented hereunder to give some context to the risks and practicalities associated with an equipment failure in the medical radiological environment.

Table 10: A sample of NIMS incidents involving the failure of radiation equipment

NIMS record number	Brief summary of the incident
20178212	A stroke alert patient arrived from Resus. After carrying out the first scan (non con brain), the scanner stated that it had overheated and would shut down....
20154103	The scanner in Emergency Department stopped scanning just after starting the cardiac CT scan. Patient had 95ml omnipaque. Patient informed, had to repeat the scan in other scanner...
20003945	Aristos Fx equipment in the general room emitted an exposure by itself without anybody using the equipment or pressing the exposure button. Incident reported to HPRA and EPA by Radiation Safety Officer.
20960389	Water-like substance leaking from equipment from one end of the C-arm machine onto the folder imaging end. Patient was not prepped and draped. Water leak did not make contact with patient.
20962706	Patient attended for Chest X-Ray. PA & lateral views done. When lateral view was completed, the monitor froze and the system required a shut down and restart. Images were not transferred to PACS and were irretrievable. Patient had to be called back ...
20974673	Part of the x-ray failed to appear during an exam. This led to the entire x-ray exam being repeated, doubling the patient exposure. Equipment malfunction.
20978270	Equipment in Room 1 did not store full videofluoroscopy clip for analysis. Patient was exposed to radiation and Speech and Language Therapist had to generate report from memory. Patient informed.
19905272	Patient was finished nuclear medicine scan. I went to move table out from CT scanner and table controls ceased to function. Patient was unable to get off scanner so I had to manually pull table out. Table could not lower so patient had to get off table at a height....
19832201	Repeat of CT scan due to table movement error.
19836912	Scanner breakdown - would not reboot on post routine full shutdown and further problems with table. Delay in obtaining scan for trauma case.
19843068	Maxillary occlusal film taken, would not read in mini-digitizer - film stuck due to equipment fault. Second maxillary occlusal film taken.

3) Dose tracking capability of equipment

There is a statutory requirement to monitor the radiation dose delivered to a patient during an exposure, as noted in the following articles from SI 256(2018):

- Article 13(2) *An undertaking shall ensure that information relating to patient exposure forms part of the report of the medical radiological procedure.*

- Article 14(2) *An undertaking shall implement and maintain .... appropriate programmes of assessment of dose or verification of administered activity.*

Monitoring the dose delivered during a procedure will provide assurance to frontline staff that the unit is operating within defined safety parameters; it will facilitate cross-site comparison of doses delivered for routine imaging procedures; and it will enable the practitioner to record dose information in the medical report. Also, it will allow the practitioner to anticipate potential side effects which may result from a high dose procedure and factor this into the aftercare plan for the patient.

For most radiation equipment, it was confirmed that the dose information could be recorded for a procedure however the function often required manual input from the person operating the unit. Also, the data did not automatically transfer to the examination report. An automated, standardised dose monitoring process which has the capability of recording the exact dose delivered during a procedure and which can import this data directly to the medical report is the optimal solution.

It was confirmed that this automated process is in operation for high dose procedures with the application of dose monitoring software. However, the software is expensive to purchase and often not compatible with old equipment.

The HSE has a duty to demonstrate regulatory compliance and provide assurance to patients that all equipment delivers a safe dose of radiation during every imaging procedure which is maintained as low as reasonably possible whilst still achieving clinical efficacy. Frontline staff noted that this was a challenge in the absence of an automated, universally applied dose monitoring process.

GOING FORWARD

The *Slaintecare*[8] programme aims to transform healthcare in Ireland by shifting the focus of patient care from the acute hospital setting to community services. For this to be achieved, considerable investment is required to ensure that community based diagnostic facilities are safe, modern, fit for purpose and properly resourced.

It was evident from this review that essential radiation protection staff employed in the acute hospital setting were often required to take responsibility for numerous step down facilities and community installations. HIQA inspections highlighted that the radiation protection demands placed

[8] *Committee on the future of healthcare – Slaintecare report 2017*
https://assets.gov.ie/22609/e68786c13e1b4d7daca89b495c506bb8.pdf

on specialist staff in the acute hospital environment were not always met which resulted in issues of non compliance that had a direct impact on patient care. To increase the provision of diagnostic capacity in the community whilst ignoring the existing demand imposed on radiation protection services in the acute hospital setting is not sustainable. Quality assurance of equipment and optimisation[9] of medical radiation exposures is fundamental to the delivery of a safe and efficient radiological service. In implementing the *Slaintecare* priorities, the provision of sufficient, appropriately trained and competent radiation protection staff to support and manage the increased demand on community diagnostic services must be acknowledged and supported.

Good equipment management practices necessitate strategic planning for the replacement of equipment which is no longer manufactured or deemed clinically obsolescent. The HSE guidance on managing medical devices is helpful but the decision to replace a radiation unit is not straightforward. There are ethical considerations when a very old unit is approved for use to irradiate a person, which must be acknowledged. Indeed, this is especially important when a decision is made to redeploy old radiation equipment from one diagnostic installation to another.

It should be noted also that a generic approach to the procurement of radiation equipment is not recommended. Equipment purchased for a particular location must be specific to the clinical needs of that location and give consideration to the specific dose reduction technology required. For example, equipment used in a general hospital or step down facility may not be suitable for a tertiary referral centre with a particular speciality and vice versa. Thus, it is recommended that all national procurement initiatives should include consultation with a relevant expert in the field of radiation protection.

There is a statutory requirement to monitor the radiation dose delivered to a patient during an imaging procedure and an obligation to ensure this value informs the medical report. To meet these requirements, the HSE is currently implementing a solution which will involve modification of the existing NIMIS, or equivalent, platform. However, it is important to note that this resolution will not automatically record the exact radiation dose delivered to an individual patient during a diagnostic or therapeutic procedure. The initiative is not a panacea but merely a pragmatic, interim solution to meet the new legislative requirements. Going forward, it is recommended that the HSE give consideration to the implementation of a national automated dose monitoring solution across all hospital and community diagnostic installations.

LIMITATIONS TO THE REVIEW

- This was a review of radiation equipment used to treat patients and did not incorporate the non radiation diagnostic imaging equipment used in radiology departments which include magnetic resonance imaging scanners and ultrasound machines. Radiation protection principles promote the use of these modalities, where possible, as a safer alternative to irradiating the patient. However, it was evident from the NRPO review of NIMS reports that malfunction in this cohort of non-radiation equipment often resulted in failures in care, such

[9] Optimisation, a principle of radiation protection, is the practice of delivering a radiation dose to a patient which is kept as low as reasonably possible whilst still maintaining clinical efficacy.

as missed cancer diagnoses, delayed surgical procedures or injuries to a patient. A national review of non radiation diagnostic equipment which considers age profile, replacement date and quality assurance testing is advised.

- Some locations returned information pertaining to equipment which was held on site and used for research purposes but not used to irradiate patients. There are inherent risks to staff operating these units and also a statutory requirement to ensure the establishment of an appropriate quality assurance programme. However, this information was not considered in the review.
- A comment section was included in the request for information template issued to all locations in order to provide staff operating the equipment an opportunity to voice their opinion or raise any concerns. Although a limited number of comments were received in relation to the age of equipment and dose monitoring capability, no opinions on how they found using such aged equipment on a daily basis to treat patients were proffered. As a result, the review failed to acknowledge the personal experience of frontline staff operating the equipment.
- There was confusion regarding the governance of some installations where the site was managed by one service and the technological resources were provided by another. As a result, there were instances of dual reporting to the NRPO in relation to some community diagnostic installations. Clarity concerning the roles of all staff pertaining to statutory responsibilities associated with radiation protection is essential for safe practice. However this issue of governance fell outside the scope of the review.

CONCLUSION

It is considered good management practice for the HSE to ensure that all units have a nominal replacement date which is strategically planned for through the operation of a national equipment replacement programme. Equipment that is tested regularly, well maintained and capable of monitoring the radiation dose delivered during an imaging procedure will give some assurance to the HSE that the service being delivered is safe and appropriate and that regulatory requirements are being met.

Safe practice is the priority, regardless of whether the imaging procedure delivers a high or low radiation dose to the patient. The same duty of care applies to the HSE across both acute hospital and community services in relation to radiation protection and the maintenance of equipment.

Providing a national diagnostic and therapeutic medical ionising radiation service that is modern, fit for purpose and above all, safe for both patients and staff, is paramount. The findings from this review will be used to inform HSE radiation protection priorities going forward.

RECOMMENDATIONS

The following recommendations are proposed to promote best practice in relation to radiation protection and the operation of radiological equipment:

1. Review resources in relation to the provision of radiation protection services nationally to ensure that there is sufficient capacity to meet the demands of the *Slaintecare* programme.
2. Ensure that a strategic replacement plan which considers nominal replacement dates for all units is maintained locally and that this information informs national objectives.
3. Ensure that an expert in radiation protection is consulted on all procurement decisions pertaining to radiation equipment.
4. Review the practice of redeploying radiation equipment which has been decommissioned in one installation for it to be re-activated in another.
5. Consider the implementation of a national, automated dose monitoring process across hospital and community diagnostic installations which is compatible with the existing local radiology information system.

The NRPO would like to thank the management and radiation protection staff working in the acute hospital and community services for their support and positive engagement which enabled the NRPO to complete this national review of radiation equipment.
